

Oracle Life Sciences Empirica

User Guide and Online Help



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11 Change log

Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Related resources](#)
- [Access to Oracle Support](#)
- [Additional copyright information](#)

Documentation accessibility

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1

Start here

- [About the Oracle Empirica Signal application](#)
Oracle Empirica Signal offers an analysis environment for exploring post-marketing safety data. The product supports pharmacovigilance and risk management activities at pharmaceutical companies and regulatory agencies.
- [Prerequisites and usage notes](#)
The Oracle Empirica Signal application requires Google® Chrome or Microsoft® Edge.
- [Log in to Oracle Empirica Signal](#)
You log in to Oracle Empirica Signal with the user name and password that your site administrator provided.
- [Your Home page is your starting point](#)
The Home page provides an overview of the status of Oracle Empirica tasks and source data. It also provide links to the Oracle Help Center and the ability to customize the page for your login group.
- [Set your user preferences](#)
A user preference is a setting that customizes Oracle Empirica Signal for your user name. Your user preference settings have no effect on any other Oracle Empirica Signal users.
- [Change your password](#)
Each user name has an associated password. You can change your own password at any time. For example, you might want to change it periodically for security reasons.
- [Navigate Oracle Empirica Signal and Topics](#)
The left navigation pane contains actions that are available. The list of actions depends on your permissions and the site options.
- [Enter information](#)
Throughout Oracle Empirica, you enter data and information by entering values in text boxes or selecting values from a list.
- [Drill down through data](#)
On pages and in reports that display a list of cases identified by case ID, you can save the list of cases for future use. The named and saved list of cases is referred to as a case *series*.
- [Work with tables](#)
Throughout Oracle Empirica, data is presented in tables.
- [Exit Oracle Empirica Signal](#)
You should ensure that you exit the Oracle Empirica Signal application before closing your browser.
- [View release notes and other documents](#)
The latest product documentation is available from the Oracle Help Center.

About the Oracle Empirica Signal application

Oracle Empirica Signal offers an analysis environment for exploring post-marketing safety data. The product supports pharmacovigilance and risk management activities at pharmaceutical companies and regulatory agencies.

Oracle Empirica Signal generates statistical scores for combinations of products and events in a product safety database, and detects signals (unexpected associations of products and events).

Set up your data configurations

A user with Manage Configurations permission sets up the data configurations and makes them available for use. A [data configuration](#) identifies and sets up variables from the [source data](#) for use in the Oracle Empirica Signal application. The configuration determines the drug variables (such as generic name or trade name) and the event variables (such as PT) that are available for such activities as data mining or querying. For Cloud environments, Oracle Empirica Signal supports access to the Oracle public safety data library. After enabling the feature, users with Manage Configurations user permission can access the [Subscription Data Releases administration page](#) to view available data releases, review their release notes, and import the releases of their choice into Oracle Empirica Signal.

Extract data to generate signal scores

Once you have created data configurations, you can perform data mining runs. A data mining run extracts data from the source and applies a statistical algorithm to generate signal scores. Oracle Empirica Signal offers different algorithms as options for [data mining runs](#):

- **Multi-item Gamma Poisson Shrinker (MGPS)**—For MGPS data mining runs, you can indicate a variety of parameters, such as the number of ways in which products and events are combined. For example, a run can generate scores for combinations of up to five values, enabling the study of product interactions and medical syndromes. You can specify a database restriction to specify cases to include in a run.
- **Regression-adjusted Gamma Poisson Shrinker (RGPS)**—If R and RGPS are installed, you can include computations of RGPS in a two-dimensional MGPS data mining run that does not include subsets.
- **Information component (IC)**—You can include Information Component as an additional option to an MGPS run.
- **Proportional Reporting Ratios (RRR)**—You can include computations of PRR and ROR in an MGPS run. PRR computation relates to product-event combinations only, in two-dimensional data mining runs. In two-dimensional data mining runs, the application computes the ROR only for product-event combinations.
- **Logistic Regression (LR)**—These data mining runs model how the probability of an event appearing in an adverse event report depends on multiple predictors (both demographic factors and the presence/absence of various products), which can be important for obtaining unbiased results in the presence of polytherapy.

Review the signal scores

Once a run is completed and published for use by other Oracle Empirica Signal users, you can view the resulting signal scores in tabular or graphical format. You can [select criteria](#) to choose results for review and sort the results as needed. You can also choose a variety of options for displaying the table or graph. If a hierarchy is available, representing different levels for product or event terms, you can specify terms at any of these hierarchical levels before reviewing results. For example, you can view the scores for combinations of a particular product and any event in a particular MedDRA System Organ Class (SOC), the highest level in the MedDRA event hierarchy.

If appropriate site options and permissions are set up, you can [drill down](#) from run results to view the list of cases involved. For example, the combination of ProductA and EventB has a high signal score and there are 12 cases with that product-event combination. You can drill

down to view a list of those 12 cases, and then drill down to detailed information about any of those cases.

You can also print tables or graphs of results and download them for use in applications such as Microsoft Excel (.xls, .csv) or Microsoft Word (.docx).

Monitor potential safety signals

[Signal review](#), a feature of the Oracle Empirica Signal and Topics application, is used to view disproportionality analysis statistics for successive updates of safety data, allowing you to monitor alerts and evaluate changes in safety signals over time.

Query data and define and run reports

You can [query](#) the source data based on criteria that you specify. You can save the query results as a [case series](#), which is a list of cases of interest.

In addition to [reports](#) that are delivered with Oracle Empirica Signal, you can construct your own reports by specifying which variables to include as columns and which variables determine report rows. There are two types of reports:

- Regular reports, which are non-interactive and are run against cases in a case series.
- [Interactive reports](#), which are based on a specified query for which you can supply values when running the report.

Note

A special type of interactive report is the [All Cases Summary report](#), which is used for drug profiles.

View drug profiles

[Drug profiles](#) are presentations of statistical and other information about one or more selected drugs. Depending on how the drug profile feature is set up, you can view existing charts or create your own. Drug profiles are made up of charts, which can be either of the following:

- A graph based on the results of a data mining run.
- A graph or table based on a report output.

A drug profile layout is a saved collection of charts, as well as their placement and display options.

Track signals with topics

[Oracle Empirica Topics](#), a feature of the Oracle Empirica Signal application, is used to organize and track tables, graphs, and documents related to particular subject matter. For example, issues identified through various means, such as automated signal detection, literature review, regulatory requests, and so on, can be saved as attachments to a topic.

You can set up topics to follow workflow through different states, such as Initial, Planned, Reviewed, and Closed. You can also assign topics to users and make them visible to [work teams](#).

- [Signal detection methods](#)
What benefits can signal detection methods bring to the pharmacovigilance effort, and what are the costs? How can different methods be compared and assessed? What do data mining statistics do?

- [What is a project?](#)
A project in the Oracle Empirica Signal application is an organizational tool (similar to a folder) that allows you to group certain objects for reference, searching, and retrieval purposes.

Signal detection methods

What benefits can signal detection methods bring to the pharmacovigilance effort, and what are the costs? How can different methods be compared and assessed? What do data mining statistics do?

Note

This information was excerpted from the WebVDME Newsletter, Volume 2, Issue 2 (Autumn 2005). WebVDME is the previous name of the Oracle Empirica Signal application.

The information in this article is intended to help non-statisticians understand similarities and differences between the statistical algorithms that are used for safety data mining. It can also help reframe these concerns into new questions that can make your evaluation and implementation of signal detection methods more effective.

What do data mining statistics do?

Data mining is the process of applying statistical algorithms to a database, resulting in the generation of statistical values or scores. As part of a pharmacovigilance effort, these scores can alert safety evaluators to potential safety issues, including actual safety signals.

At Oracle, we believe that data mining statistics yield information that safety evaluators can use to help prioritize investigations. Whether a pharmacovigilance group uses data mining or not does not change the need for experienced medical professionals to perform careful evaluations to determine causal relationships between drugs and adverse events.

What data mining statistics do is indicate the strength of the association between a drug of interest and an event in the reporting database: the higher the score, the stronger the statistical association.

Statistical association vs. causal relationship

While a strong association (high score) may indicate a causal relationship between the drug and the event, it could also be the result of some other circumstance: some examples include an AE that is an indication for the drug (known as “reverse causality”), or a product-event combination that has been subject to media attention and that has a higher reporting rate than would otherwise occur as a result (often called “publicity effects”). A strong association can also indicate a causal relationship that is already known and labeled.

So, while a high score may serve as an alert to a previously undetected problem, medical knowledge is crucial to the interpretation of data mining results.

Prioritizing with rankings or thresholds

When used with a large database, such as the public FDA AERS data, data mining statistics help users sort through several million potential combinations of drugs and events. Even a hypothetical pharmacovigilance department with an unlimited staff and budget, that could investigate every possible product-event relationship for causality, could use data mining statistics to help them determine which reviews to undertake first.

Using ranking

A straightforward way to prioritize investigations using statistical scores would be to start with the highest score generated and work down through the list to the lowest score. Outside of our hypothetical big-bucks department, practical considerations mean that the number of investigations must be limited: a prioritization approach that ranks scores might result in investigations into the top 10, 250, or 10,000 scores, whatever number is feasible for a group's resources.

Choosing a threshold

Another way to limit the number of investigations is to choose one score as a threshold. Any score that exceeds this predetermined threshold alerts reviewers to a potential signal for investigation. Unlike the cutoff for ranking, the number of scores above the threshold will fluctuate over time. But, like ranking, departments can select a threshold score that makes the best use of their resources while helping prioritize investigations.

Other factors to consider

Regardless of whether ranking or a threshold is used for the scores, some reports are likely to be prioritized ahead of any others: a safety evaluator wouldn't have to wait for a high data mining score to flag just one new report of Torsade de pointes, QT prolongation, Stevens-Johnson syndrome, or a similar sentinel event as a high priority for investigation. Serious events in general are likely to need investigation earlier than less serious events. To meet this need for different prioritization levels, a low threshold could be set for sentinel events, a slightly higher one for other serious events, and a third threshold for all other events.

Problems in nonscientific public safety databases, including the biases that result from under reporting, over reporting, and publicity effects, have been widely discussed. When working with signal scores generated from these databases, a higher threshold (or set of thresholds) might be used than when working with a smaller, more controlled and complete company database.

For departments that use ranking as the prioritization method, the relative reliability of the sequencing or ordering of the scores produced by a method may be a consideration. When a threshold is used, any score above that threshold is examined, while with ranking, the highest scores should reflect the strongest associations.

Other considerations, including company goals, the medical knowledge and safety evaluation experience of individual evaluators, and other tools available for the pharmacovigilance effort, also contribute to the prioritization effort.

What are the data mining statistics?

Some of the data mining statistics that are widely used for signal detection are:

- EBGm – Empirical Bayes Geometric Mean
- IC – Information Component
- PRR – Proportional Reporting Ratio
- ROR – Reporting Odds Ratio

Each of these statistics is the result of a different statistical algorithm. All of the algorithms were designed to uncover the same type of information: a disproportionately high occurrence of reports for an event and drug, when compared to reports for that event in the entire database. As a result, for large sample sizes, the score that each of these statistics produces for any given product-event combination is likely to be similar.

Note

The sample size (N) generally is defined as large if there are 20 or more instances of a product-event combination in the database.

Drugs that are new to the market, or that are prescribed to a small number of patients, may have a small presence in the database. For these drugs, the N may be quite low, which tends to make scores calculated for their product-event combinations low also.

Some data mining algorithms include statistical techniques that compensate for disparate sample sizes in the safety database and the extreme scores that can result.

How does the method cope with statistical uncertainty?

The PRR and ROR statistics do not in themselves indicate a level of certainty or uncertainty due to a small sample size. Rather, each product-event combination is often accompanied by an additional statistic, a chi squared test statistic, and its corresponding p (significance) value. When you assess a PRR or ROR value, you are supposed to suspect the reliability of large values unless the chi squared value is very large (or, equivalently, the p value is very small). However, there is no clear rule for evaluating a large PRR value that has a moderate p value. Similarly, there is no rule for adjusting for the “multiple comparisons” problem, in that you are focusing on the few largest values of PRR or ROR out of millions that may have been computed in a data mining run.

The algorithms that calculate IC and EBGm address both statistical variability due to small N and multiple comparisons by using a technique called “Bayesian shrinkage.” This statistical technique results in a single relative reporting ratio (with confidence limits) that is easier to interpret directly without the added complexity of a separate chi squared or p value. Reporting ratios that are based on small counts (and that are therefore less reliable) are “shrunk” or moved toward the value 1 using an appropriate Bayesian probability formula. The set of EBGm scores across all product-event combinations is more restricted than the set of unshrunk scores, so focusing on more extreme EBGm scores is less likely to lead to overestimates of the true reporting ratios than would searching for the largest values of PRR or ROR. The IC method has a similar advantage.

The Bayesian shrinkage technique primarily affects estimates of product-event reporting ratios based on small counts or small expected counts (that is, when reports mentioning either the drug or the event are quite rare in the database.) Other statistical issues, such as confounding, can cause biased relative reporting ratios even for more frequent product-event combinations.

Can the method adjust for confounding?

When data mining scores are calculated, adjustments can be made for “confounding” variables. Confounding variables occur in any database that is not completely random. In a drug safety database, for example, a drug that is administered only to the elderly, or only to male subjects, or that is new on the market, has the subject’s age group or gender or the report’s receipt year (or all three) as a confounding variable.

The presence of confounding variables in the data can result in high scores for product-event combinations that otherwise would not have a strong statistical association. For example, a drug that is generally prescribed for women over 50, and an event that occurs more frequently for women over 50, may well result in a high score for the combination of that drug and event, based only on the coincidence of the gender and age group involved.

Statistical techniques are available to adjust for confounding variables: for example, a technique called Mantel-Haenszel stratification (used in MGPS) divides the database into groups, one for each value that the variable in question has in the database, and then

recalculates an overall score. When a technique like stratification is used, the result is often a lower score (and investigational priority) for a product-event combination that is affected by a confounding variable, while the effect is minimal on scores for combinations that are not subject to confounding.

Why do statistics for significance matter?

Each of the data mining statistics listed above, IC, EBGM, PRR, and ROR, indicate the strength of the association between a drug and an event. Each one can also have associated scores that indicate the statistical significance (or uncertainty) of the relationship. As mentioned above, for the PRR and ROR statistics, the chi-squared test of statistical significance can be used to calculate a p value. Unfortunately, the chi squared and p values are in different units than are the basic reporting ratio values, making it hard to interpret them all together. The algorithms for EBGM and IC represent statistical uncertainty with confidence limits, which are less likely to be misinterpreted.

Calculations for significance incorporate information about the sample size. The p value indicates the likelihood that such a large reporting ratio could occur by chance alone if the drug and the event are completely unrelated, but does not provide information about what range of reporting ratios are most likely. A confidence interval shows what range of reporting ratios are consistent with the data. A small N results in a wide confidence interval: the larger the N, the narrower the confidence interval.

Using significance scores

A pharmacovigilance group might choose to prioritize investigations based on scores for statistical significance, rather than for association, to avoid following up potential associations that could have arisen merely by chance. However, using a PRR or ROR p value to rank associations may result in excessive focus on drugs and events that are common overall in the database. This may occur because frequently reported drugs and events may have reporting ratios that are only slightly greater than 1, but have very tiny p values. Investigating these product-event combinations can potentially eclipse larger reporting ratios for less-frequently reported drugs or events.

Both the statistical significance and the reporting ratio can contribute to a prioritization system. This is easier to accomplish with confidence limits than with p values. Ranking product-event combinations by their lower confidence limits (for MGPS, by using EB05 rather than EBGM) provides an extra layer of protection against false alarms due to chance fluctuation (beyond that afforded by the Bayesian shrinkage discussed above).

Comparing significance and association scores

Comparing the scores for both types of statistics can also be revealing. This illustration shows two product-event combinations that have identical EB05 scores. The higher EBGM score for the first combination, however, indicates a stronger likelihood of an association than the EBGM score for the second combination. This graph also gives an indication of the relative number of reports in the database for each combination: Combination 1 has fewer reports than Combination 2, since its confidence interval is relatively wide.



Some pharmacovigilance groups may find it effective to prioritize investigations based on both significance and association scores, rather than relying on only one score. For example, a threshold of $EBGM > 2$ AND $EB05 > 1$ could be used. This is roughly equivalent to the common recommendation for PRR, which requires $PRR > 2$ AND $N > 2$ AND $\chi^2 > 4$.

Benefits: automated, objective analysis

Signal detection methods are an independent and automated process for assessing all of the product-event combinations in a safety database, which may contain millions of records. Using these statistics can provide earlier warning than methods that rely on human knowledge, skill, and intuition, and reduce the amount of effort needed to discover signals in safety data.

The value of using a signal detection method is highest when scores alert pharmacovigilance professionals to previously unknown, unexpected, or uncharacteristic events that happen more frequently in combination with one drug than with most all other drugs. These objectively produced alerts can then be evaluated using other pharmacovigilance tools to determine the possibility of a causal relationship.

Costs: false alarms

When a pharmacovigilance group uses data mining scores to prioritize investigation, resources may be spent investigating “false positives,” or high scores that do not, in fact, indicate a relationship or causal relationship.

Conversely, a “false negative” can occur when a low score is calculated for a product-event combination that is, in fact, causally related. Errors of both types can occur with any signal detection method.

If data mining scores are used alone to determine investigational priorities, the group is faced with a conundrum: if you investigate fewer high scores to reduce false positives, you may also increase the number of false negatives. The need for efficiency must be balanced against the cost of missing any true signals.

Fortunately, pharmacovigilance professionals have access to other tools to help make the best choices they can for the situations they need to address. Impact analysis, tracking changes in scores over time, and the “other factors to consider” described above can help a department make the best use of the information that the statistical scores are designed to give them.

Summary: comparing signal detection methods

One way to assess the comparative value of different signal scores is to evaluate the results of different algorithms when used to data mine the same database. When setting up such a test, these questions can act as guidelines for the comparison:

- Is the same minimum sample size used by all of the algorithms?
- Is stratification used for all of the algorithms? What confounding variables were selected?
- Are the scores selected for comparison all scores for statistical association, or are they all scores for statistical significance?
- How many signal scores does each algorithm generate over all?
- Is the same threshold used for all scores?

It may be difficult to know how many true signals there are in the database used for the test. If the number is known, then the number of false positives and false negatives produced by each algorithm can also be compared.

Improving statistical algorithms

With WebVDME 5.0, Oracle introduced a new statistical method for evaluation of database disproportionately ratios: Logistic Regression. This statistical technique is intended to support focused investigations into possible polypharmacy effects. Logistic Regression currently alerts WebVDME users to potential signals in cases where the scores calculated by other algorithms do not adjust for confounding by polypharmacy or cloaking. Oracle is also researching the potential for this statistical technique to serve as a database screening tool.

Data mining bibliography

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What is a project?

A project in the Oracle Empirica Signal application is an organizational tool (similar to a folder) that allows you to group certain objects for reference, searching, and retrieval purposes.

On the Oracle Empirica Signal pages that list objects (such as data mining runs, queries or case series), you can select a project to filter the list to only objects in that project. Projects have no effect on any computations.

When creating an object, you can assign it to an existing project or create a new project. The list of existing projects includes projects for objects that you created or that are published to you. You can also choose not to use projects at all. By default, objects are unassigned.

Note

A project remains available until all objects associated with it have been deleted.

Prerequisites and usage notes

The Oracle Empirica Signal application requires Google® Chrome or Microsoft® Edge.

Configure Google Chrome

Clear the cache in Chrome

1. Open the Chrome browser.
2. From the **Customize and control Google Chrome** menu (⋮) on the far right of the browser header, select **More tools**, then **Clear browsing data**.
3. On the Basic tab, select **Cached images and files**, then click **Clear data**.
4. To close the Chrome browser, click the **Customize and control Google Chrome** menu (⋮) and select **Exit**.

Allow pop-ups within Oracle Empirica Signal

1. Open the Chrome browser.
2. From the Chrome menu on the right of the browser header, select **Settings**.
3. In the left pane, under **Privacy and security**, select the **Site Settings** link.
4. Under **Content**, select the **Pop-ups and redirects** link.
5. Select **Add** and enter the Oracle Empirica Signal URL.
6. Select **Add** and enter [*.]oracle.com.

Note

If Chrome blocks a pop-up window, it displays an icon to the right of the URL address area (🛑). If this happens, you can also allow pop-ups for Oracle Empirica Signal by:

1. Clicking the icon (🛑).
2. Selecting the radio button option to **Always allow pop-ups and redirects from [your Oracle Empirica Signal site]** and [*.]oracle.com.

Configure Microsoft Edge

Clear the cache in Edge

1. Open the Edge browser.
2. From the **Settings and more** menu (⋮) on the far right of the browser header, select **Settings**.
3. From the left pane of the Settings tab, select **Privacy, search, and services**.

4. From the **Clear browsing data** section, click **Choose what to clear**.
5. Select **Cached images and files**, then click **Clear Now**.
6. Close the Settings tab.

Turn off the pop-up blocker

1. Open the Microsoft Edge browser.
2. From the **Settings and more** menu () on the far right of the browser header, select **Settings**.
3. In the left pane, select **Cookies and site permissions**.
4. In the right pane, under **All permissions**, select **Pop-ups and redirects**.
5. In the **Allow** section, select **Add** and enter the Oracle Empirica Signal URL, then click **Add**.
6. Select **Add** and enter [* .]oracle.com, then click **Add**.
7. Close the Settings tab.

Settings that apply to all browsers

The browser's Back button

Because the appearance of many pages presented by the Oracle Empirica Signal application relies on choices made on previous pages, Oracle recommends that you do not use the browser's **Back** button. Choices made on other pages may not be captured appropriately. To make navigation between pages easier, while providing accurate information on each page, **Back** links appear on many application pages. It is preferable to use these **Back** links, and the left navigation pane, to navigate to another page.

Multiple sessions

Do not run more than one session of the application using multiple browser sessions or several tabs in the same browser.

Adobe® Acrobat®

For certain features in Oracle Empirica Signal, you can download to a PDF (Portable Document Format) file. To do so, you must install Adobe Acrobat Reader on your computer. Adobe Acrobat Reader is freely distributed software for viewing and printing PDF files, and is available at www.adobe.com.

You also need Adobe Acrobat Reader to view any PDF files that may be provided as links in this help system.

To view PDF attachments embedded in a topic, you must install Adobe Acrobat. You can download the Acrobat Standard software from www.adobe.com.

A PDF file that you create for a [topic](#) might include links to open ZIP files that are attached to the topic. Security features in Adobe Acrobat Reader might prevent you from opening a ZIP file from within the PDF file. See the Adobe website for instructions on modifying this behavior. If you are using Adobe Acrobat Reader 6.x, you might need to set link options correctly to view certain types of attachments from within a topic PDF file.

ZIP file utility

If you create ZIP archive files when downloading data, you must have a ZIP file compression and extraction utility, such as WinZip, installed on your computer. WinZip is available at www.winzip.com. You must also associate the file extension .zip with the ZIP file utility.

Microsoft Excel

If you plan to download data to Microsoft Excel®, make sure that Excel is installed on your computer.

SAS System Viewer

To view files that you create by downloading data to SAS Version 5 transport files (.xpt files), you need the SAS® System Viewer. The SAS® System Viewer is freely distributed software for viewing and printing .xpt files, and is available at www.sas.com.

Base SAS

To use files that you create by downloading data to SAS data step definition files (.sas files), you need Base SAS®. Base SAS® is a third-party application that you can purchase at www.sas.com.

Built-in reports

To run the [built-in reports](#) delivered with the Oracle Empirica Signal application, you must set up a data stub, as described in AERS(1q03: S) Configuration Installation Instructions (located in the Data_Stub folder on the installation CD).

Log in to Oracle Empirica Signal

You log in to Oracle Empirica Signal with the user name and password that your site administrator provided.

If your site administrator has enabled single sign-on, you can log in to the application using your single sign-on user name and password. When you log in, the application authenticates your user name using a case-insensitive match. For example, **jkelley** and **JKelley** both resolve to the **jkelley** user name.

To log in initially:

1. Open the Google® Chrome or Microsoft® Edge browser.
2. Navigate to the URL provided by your site administrator.
3. Log in using your Oracle Empirica Signal user name or single sign-on user name.

To log in using your Oracle Empirica Signal user name:

1. In the **Username** field, enter the user name provided by your site administrator. The **Username** field is not case sensitive. You can enter your user name in uppercase, lowercase, or mixed case.
2. In the **Password** field, enter your user password. The **Password** field is case sensitive. You must enter your password using the same case (upper, lower, or mixed) that was used when the password was defined. Oracle recommends that you then [change your password](#) immediately.

If a message appears stating that your password is due to expire, click **Click here** to change your password. If you do not change your password, the warning message appears each time you log in, until your password expires and you are forced to change it.

3. Click **Log In** or press **Enter**.

The page you set to display initially when you log in to the Oracle Empirica Signal application in [user preferences](#) appears.

Note

Do not open more than one Oracle Empirica Signal session at the same time.

To log in using your single sign-on user name:

- If you are currently logged in via single sign-on, no Login page appears. You can access Oracle Empirica Signal without re-entering your user name and password.
- If you are not currently logged in via single sign-on, the Single Sign-on Login page appears. Enter your single sign-on user name and password, and then click **Log In**.

Your Home page is your starting point

The Home page provides an overview of the status of Oracle Empirica tasks and source data. It also provide links to the Oracle Help Center and the ability to customize the page for your login group.

Your Home page may have any or all of these four sections:

- **Tasks:** This section contains summary information for tasks assigned to you in either Signal Management or Topics. The section is available if you have either View Topics or View Signal Management permission.
- **Source Data:** This section contains summary information about the recency of both data sources and signal management configurations. The section is available if you have either View Signal Management or View Data Mining Results permission.
- **Help Center:** This section provides links to the Oracle Help center where you can search for information and view videos.
- **Custom home page:** A customized home page section, if configured for your login group by the user administrator.
- [The Tasks section shows signal management and topics tasks assigned to you](#)
The Tasks section includes cards that summarize the signal management and topic tasks assigned to you.
- [The Source Data section summarizes the recency of both data sources and signal management configurations](#)
The Source Data section includes cards that summarize the recency of both data sources and signal management configurations.
- [Configure your Home page](#)
You can configure the sections of the home page and the entries within each section.

The Tasks section shows signal management and topics tasks assigned to you

The Tasks section includes cards that summarize the signal management and topic tasks assigned to you.

There are three different types of task cards. Each card type is represented by a different icon.

- **Alerts**



: There is one alert card for each signal management configuration with Tracked Alerts that has been refreshed at least once. Information includes:

- Signal Management Configuration name.
- Progress bar showing reviewed/total alerts percentage for all product-event combinations. This will have the same numbers as the All carousel item on the Products page.
- If you have been assigned as a reviewer, a progress bar for your assigned alerts (for product-event combinations assigned to you as well as product-event combinations assigned to you for other products) shows completed/total alerts percentage.
- If you don't have any assignments, then the text shown is the number of products with unreviewed alerts.
- Hovering over a progress bar shows the actual number of alerts: n % (x of yy alerts reviewed).

- **My Topics**



:

There is one card for each topic workflow configuration for which either a topic or action has been assigned to you. The cards show:

- The number of open topics assigned to you.
- The topic workflow configuration name.
- The number of open actions assigned to you, including the number of actions that are overdue.

- **Work team Topics**



:

There is one card for each topic workflow configuration and work team that you are a member of, and for which either a topic or action has been assigned to that work team.

- Work team Name.
- The card shows the number of open topics assigned to the work team.
- The topic workflow configuration name .
- The number of open actions assigned to the work team, including the number of actions that are overdue.

Selecting an alert card takes you to Signal Review with the signal management configuration selected.

Selecting a topics card takes you to the Topic Management page with that topic workflow configuration selected. The item selector is set to either My or Workteam depending on whether the card is a My Topics or a Workteam Topics card.

The Source Data section summarizes the recency of both data sources and signal management configurations

The Source Data section includes cards that summarize the recency of both data sources and signal management configurations.

There are three different types of Source Data cards. Each card type is represented by a different icon.

-



Data Source Type:

There is one card for each data source type that is published to you. Multiple data configurations are often from the same data source. Information includes:

- Data source name.
- Most recent load date.
- Either the Period, such as Year and Quarter, or the latest as-of-date for time-stamped configurations.

-



Signal management configuration:

There is one card for each signal management configuration that is visible to you, and that has been refreshed at least once.

- Configuration name.
- Last refresh date.
- Either the Period, such as Year and Quarter, or the latest as-of-date for Signal Management Configurations based on time-stamped data configurations.

-



Multi-enterprise signal configuration:

There is one card for each multi-source signal management configuration that is visible to you, and that has been refreshed at least once.

- Configuration name.
- Last refresh date.
- The Data Source and Period for each of the configurations used in the multi-source configuration.

Selecting a data source card takes you to the Data Mining Runs page with the configuration filter set to the alphabetically first data configuration for that source.

Selecting a signal management configuration card or a multi-enterprise signal configuration card takes you to Signal Review with the signal management configuration selected.

Configure your Home page

You can configure the sections of the home page and the entries within each section.

Select the sections to include

Note

In addition to the sections on the Home page, your user administrator can create and publish a custom HTML home page (stored in the \customhomes subdirectory of the server) and then [apply it to your login group](#) on the Login Group Settings page.

1. Log in to Oracle Empirica and select the **Configure**



icon under your name and then select **Setup Home page sections**.

2. On the Configure Sections page, select the sections to include by moving them from the Available list to the Selected list using the right and left arrows.

Note

You can reorder the Selected list using the up and down arrows to the right of the Selected list.

3. To save the Selected list as a default for your login group's home pages, a user administrator can select the **Use current layout as login group default** checkbox.
4. Select **OK**.

The Home page is reconfigured as necessary to match the Selected list.

Note

A user administrator using the *Use current layout as login group default* should have all the additional privileges of users in their login group, such as *View Signal Management* and be a member of all Topic work teams for their login group. Otherwise, not all items will be available for selection.

Select the entries within the sections

1. For each section, select the Configure Section Content



icon.

2. On the Configure Tasks or Source Data page, select the sections to include by moving them from the Available list to the Selected list. using the right and left arrows.
3. To save the Selected list as a default for your login group's home pages, select the **Use current layout as login group default** checkbox.

The selected and available lists contain all possible tasks/sources visible to you. A selected item may not display a card; for example, if you have no topics or actions assigned to you for a Topics Task card.

4. Select **OK**.

Note

To start over and set the configuration back to the login group default, select the **Reset** checkbox. If you are a user administrator, you can save the configuration as the login group default.

Set your user preferences

A user preference is a setting that customizes Oracle Empirica Signal for your user name. Your user preference settings have no effect on any other Oracle Empirica Signal users.

Note

If you have the permission to create user profiles, you can also set user preferences for a user profile.

1. At the top of the main page, click your user name and select **Preferences**.
2. Modify the user preferences described in the table below.
3. Click **Save**.

General user preferences

The following user preferences apply to all users and take effect immediately unless otherwise noted.

Category	Preference	Description
Preference for dates and times:	Time Zone	From the Time Zone drop-down list, select the time zone to be used for server dates and times that are displayed in Oracle Empirica Signal for your user name. This user preference has no effect on the source safety data (for example, an event date shown in case details) or on the display of As Of dates for timestamped data .
Preferences for logging in:	On login, display this page	From the drop-down list, choose a page to display automatically when you log in to Oracle Empirica Signal. The available options may depend on your user permissions , as well as Oracle Empirica Signal site options set for your organization.

Category	Preference	Description
Preferences for logging in:	Show table scrollbars on left (for certain tables)	Select this check box to display vertical scrollbars on the left side (instead of the right side) of tables of information for tables which support this option. Note: This option may not take effect until the next time you log in.
Preference for Query Wizard:	Show case count by default on preview page	Show the count of cases on the Preview Query page. On the Queries page , select Display Case Count in Query Preview. Computation of the case count can be time-consuming. Display it only when necessary. Note: This preference appears only if appropriate Allow Case Count on Query Preview Page checkbox of site option has been enabled.
Preferences for downloading data:	Default download file type	From the drop-down list, select the file type you use most frequently to download data .
Preference for viewing graphs:	Graph color palette	From the drop-down list, set a default color scheme for the graph key for graphs based on the results of data mining runs (this preference has no effect on graphs based on report data).
Preferences for viewing case details:	Days to retain visited status for case ID link	Specify the number of days that an underlined case ID that you can click to view case details appears in a different color. This preference applies to case IDs for only your user name and to all data associated with configurations within the same database group. The default number of days, which is used if you leave the number of days empty, is 45. If you specify 0 as the number of days, the color of a visited link does not change. This preference affects only data associated with data configurations that are in database groups. See Case ID Links .
Preferences for viewing case details:	Wrap Wide Tables	Check to wrap table displays on the Case Details page. Wrapping tables makes the vertical display longer. Not wrapping tables makes the horizontal display wider and can necessitate scrolling to the right to see all columns in the tables.

Category	Preference	Description
Preferences for viewing case details:	Show Table of Contents	Check to show a table of contents on the Case Details page . The table of contents consists of links that jump to the data displayed on the page.

Preferences for selecting and viewing run results

Note

These preferences are available only to users with the View Data Mining Results permission.

When you set the following user preferences, they take effect immediately.

Preference	Description
Default Run	From the drop-down list, select a data mining run to appear by default in the Run Name field on the Select Criteria page when you go to the Data Mining Results page for the first time in an Oracle Empirica Signal session. You can select any run listed on your Data Mining Runs page. You can also specify <Last Used> or <No Run>.
Display Only Results with score-type Scores Over number	Specify a default minimum score for viewing results of a data mining run for the first time. The score type and value that you specify appear on the Select Criteria page as a default, but you can change them as needed before reviewing results. You can set a default minimum for: • EBGM —Applies to MGPS runs only. • EB05 —Applies to MGPS runs only. • N —Applies to run results for any type of data mining run (however, does not apply to the tables of results for covariates or interactions if they are produced for a logistic regression run). This preference affects only run results that you have never viewed. Once you have viewed a run, the setting that you choose on the Select Criteria page is used for that run until you change it. If you select a statistic other than N, a default of LROR>0 is used for logistic regression run results.
Enable Adverse Event Hierarchy Browser	Check to browse and select terms from the hierarchy for tasks that require you to select event values. For an event variable that is set up in the data configuration to have an associated hierarchy, the Select <hierarchy> Terms link appears for these tasks; for example, Select MedDRA Terms .

Preference	Description
Enable Drug Hierarchy Browser	Check to browse and select terms from the hierarchy for tasks that require you to select drug values. For a drug variable that is set up in the data configuration to have an associated hierarchy, the Select <hierarchy> Terms link appears for these tasks; for example, Select ATC Terms .
Include SQL WHERE Clause for Advanced Results Selection	Check to enable use of a SQL WHERE clause for selecting results criteria . To view all advanced options, click Show Advanced on the Select Criteria page.

Preference for creating runs

Note

These preferences are available only to users with the Create Data Mining Run permission.

When you set the following user preferences, they take effect immediately.

Preference	Description
Minimum Count	Specify a default for the Minimum Count field on the Data Mining Parameters page . You can override this default as needed.
Replace Missing Values with	Specify text to represent missing values for variables in the results of data mining runs that you execute. For example, if you set this preference to ^missing^ the results table shows ^missing^ for any item that has no value in the database. You cannot use spaces or the following characters in your replacement string: * \ " : / ? > < This preference affects only the appearance of run results, and not the source data. When you access source data, as when drilling down from a case series, missing values display as blank. The Job Details page for a run's extraction job (accessible from the Jobs for Run page) shows the value that was in effect for missing data for the run. Note: Other users who view results of a run that you executed will also see the missing value that was set as your user preference at the time you executed the run.
Exclude associations if items are of the same type (all drugs, all events)	Check to include a default for a field on the Data Mining Parameters page when you create a new MGPS data mining run. You can override this default as needed. The recommended setting is checked. Checking this preference improves time and space utilization because fewer results are loaded into the results table.

Preferences for viewing drug profiles

Note

These preferences are available only to users with the View Drug Profiles permission.

When you set the following user preferences, they take effect immediately.

Preference	Description
Drug Profile Configuration	From the drop-down list, select the drug profile configuration. The drug profile configuration determines the source of graphs and reports that you can add as charts to a drug profile layout. You must set this preference to access the Drugs Profiles page. Available drug profile configurations are those that you created or that are published to you. (If you have the Administer Users permission, they also include unpublished configurations created by users in your login group.)
Drug Profile Layout	From the drop-down list, select the drug profile layout, the name of a saved collection of charts, as well as their placement and display options. Layouts are not associated with a particular drug profile configuration. Available layouts are those that you created or that are published to you. (If you have the Administer Users permission, they also include unpublished layouts created by users in your login group.) Use this setting in the following situations: • You have not previously used a drug profile layout on the Drug Profile page. • You delete the layout you were last using and then return to the Drug Profile page without having selected a layout. • You select a drug name on the Signal Review Products page.

Preferences for viewing signals

If your organization uses the [signal review](#) component of Oracle Empirica Signal, there are additional user preferences. If you set the following user preferences, they take effect the next time you log in.

Note

These preferences are available only to users with the View Signal Management permission.

Preference	Description
Signal Management Configuration	From the drop-down list, select a signal configuration. Available signal configurations are those that you created or that are published to you. If you set the preference to --, the signal configuration associated with your login group is used. You can also update this preference directly on the Signal Review page by selecting another Signal Management configuration from the drop-down box at the top of the page.
Allow SQL WHERE Clause on the Signal Review Page	Check to enable the user of a SQL WHERE clause to restrict rows that appear on the Products page, Automatic Assignments page, Product-Event Combinations page, and Event Comments page.

Preferences for working with topics

Note

This preference is available only to users with access to at least one topic workflow configuration. To change the configuration on the Topic Management page, the user must have View Topics permission and more than one topic workflow configuration published to the user's login group.

If you set the following user preference, it takes effect immediately.

Preference	Description
Topic Workflow Configuration	From the drop-down list, select a topic workflow configuration. Available topic workflow configurations are those that you created or that are published to you. This setting overrides the association between your login group and a topic workflow configuration. For example, if your login group is associated with configuration A, but you specify configuration B as the preference, configuration B is in effect the next time you log in. The override is intended to facilitate testing of configurations that you create or edit. Note: You can change your topic workflow configuration selection on the Topic Management and the User Preferences pages. A change from one of these pages updates the selection on the other page. If you set the preference to --, the topic workflow configuration associated with your login group is used. Note: If you select a topic workflow configuration that requires each topic to be visible to one and only one work team, you must also define membership in a work team and assign appropriate work team permissions.

Change your password

Each user name has an associated password. You can change your own password at any time. For example, you might want to change it periodically for security reasons.

A user who has the Administer Users permission can also change your password. For example, if you have forgotten your password, that user can set a new password for you.

If your password is due to expire, a warning message appears when you log in. Click the link in the message and go to step 3, below.

Note

If your authentication method is single sign-on or LDAP, you cannot change your password in Oracle Empirica Signal.

1. At the top of any page, click **Settings**.
2. Click **Change Password**.
3. In the **Old Password** field, enter your current password.
4. In the **New Password** field, enter a new password. Site options determine the required password length and the types of characters allowed (alphabetic, numeric, non-alphanumeric, lowercase, uppercase, and so on). There may be restrictions on the re-use of old passwords.

To log in to Oracle Empirica Signal application, you must enter your exact password in the correct case (upper, lower, or mixed).

5. In the **Confirm Password** field, re-enter your new password.
6. Click **Change Password**.

Oracle Empirica Signal updates your password. The next time you log in, you must use your new password. The password expiration period, if one has been set as a site option, begins for the new password.

Navigate Oracle Empirica Signal and Topics

The left navigation pane contains actions that are available. The list of actions depends on your permissions and the site options.

Buttons	A c t i o n r e q u i r e d
Home	C
	l i c k t o r e t u r n t o y o u r O r a c l e E m p i r i c a S i g n a l

Buttons	A c t i o n r e q u i r e d
	h o m e p a g e .

Buttons

Action required

Signal Review 

Click to display the product and Product - event combination

Buttons

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Topic Management

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Buttons

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Buttons

Action required

Settings 

Click to display settings you can specify or change depicted

Buttons

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Enter information

Throughout Oracle Empirica, you enter data and information by entering values in text boxes or selecting values from a list.

You can also group and save up to 1,000 product or event terms in a [saved list](#) to refer to the list instead of individual items.

- [Enter values in text boxes](#)
Throughout Oracle Empirica Signal, you have the option of selecting or entering values.
- [Select values from a list](#)
One of the ways that the Oracle Empirica Signal application facilitates your work is to provide lists of accepted values for many functions. These values often appear in alphanumeric order in a dialog box and often include an All option as well as individual values.
- [How a saved list can prevent you from selecting values individually](#)
A saved list can contain up to 1,000 drugs or event terms. In activities where you need to specify values for a drug, event, or item variable, you can select a saved list instead of selecting values individually.

Enter values in text boxes

Throughout Oracle Empirica Signal, you have the option of selecting or entering values.

For example, you might specify the value of an Event item variable by doing one of the following:

- [Selecting a MedDRA term](#) using the hierarchy browser.
- [Selecting a value from a list](#) of available values.
- [Selecting a saved list](#) of values.

- Entering a value.

To prevent spelling and capitalization errors, Oracle recommends that you select rather than enter values. However, if you prefer to enter values, do the following:

- Match the spelling and case of the intended values exactly.
- Separate the values using commas.
- To enter a value that contains a comma, enclose the value in double quotation marks, for example, "Diabetes, Type II".
- To enter a value that includes a backslash or double quotation mark, precede the backslash or double quotation mark with a backslash, for example, Cold\\flu or \"Terrible\"headache.

Select values from a list

One of the ways that the Oracle Empirica Signal application facilitates your work is to provide lists of accepted values for many functions. These values often appear in alphanumeric order in a dialog box and often include an All option as well as individual values.

Select a single value

If the dialog box includes a list of available values but no list of selected values, you can select only one value.

- Click a value to highlight it and then click **OK**.

Note

When you highlight a single value, the full value is displayed as pop-up text. This enables you to see the full value in case the displayed value is cut off because of its length.

Select multiple values

1. To select values from a list, click **Select Available Values**
2. To select values, you highlight and move them as follows:
 - If the dialog box includes a list of available values and a list of selected values, you can select multiple values (up to 1,000 values).
 - To highlight a value, click it.
 - To highlight multiple non-contiguous values, hold down the Ctrl key while clicking each value.
 - To highlight multiple contiguous values, click a value, hold down the Shift key, and click another value. Values between and including those values are highlighted.
 - To remove highlighting from a value, hold down the Ctrl key while clicking the selected value.
 - To move values back and forth between the list of all values and the list of selected values, you can double-click a highlighted value or use the arrow keys as follows:

Button	Use To
	Move highlighted values from the list of all values to the list of selected values.
	Move all values from the list of all values to the list of selected values.
	Move highlighted values from the list of selected values to the list of available values.
	Move all values from the list of selected values to the list of available values.

If up and down arrows are available for the list of selected values, you can use them to order the selected values. For example, when specifying breakdown details in a report definition, you can order the selected values as you want them to appear in the report.

3. When you are satisfied with the selected values, click **OK**.

 Note

In some contexts, you can click **Save As List** to [create a saved list](#) of values for future use.

Filter available values

You can filter the available values if the **Show Filter Options** link appears.

1. Click **Show Filter Options**.
2. In the **Filter** field, type a value on which to filter the available values.
3. Specify filtering options:
 - **Case-sensitive** —If checked, the application lists only available values exactly matching the case (upper, lower, or mixed) of your entry in the Filter field.
 - **Show values** —From the drop-down list, select **Starting with Filter** to list available values that start with your entry in the Filter field. Select **Containing Filter** to include any values containing the specified filter in any position. Select **Ending Filter** to list values that end with the entry in the Filter field.

If there are more than 100 possible values in total (regardless of filter options), the following additional options are available:

- **Minimum filter length** —Select the minimum number of characters you must enter in the Filter field before any available values will be listed. (0 indicates no minimum.)
- **Maximum values to show** —Select the maximum number of available values to be listed. If the maximum number is n, the first n matching values found in the list appear.

Note that as you move values to the Selected Values list, more values appear in the Available Values list.

A message informs you if any values have been filtered out of the Available Values list by the Maximum values to show field.

Note

If network performance is not fast, avoid using No Limit. This can be slow when used with Generic_Name, for example, since there are thousands of values.

How a saved list can prevent you from selecting values individually

A saved list can contain up to 1,000 drugs or event terms. In activities where you need to specify values for a drug, event, or item variable, you can select a saved list instead of selecting values individually.

Your available saved lists are ones you have created, or ones you have been given Read or Edit permission. They must also be compatible with the [data configuration](#) of the object with which you are working.

To select a saved list, click the row for the saved list, and then click **OK**.

The Select Saved List page provides the following information about each saved list. See [Field descriptions—Saved List](#) page for more information.

Drill down through data

On pages and in reports that display a list of cases identified by case ID, you can save the list of cases for future use. The named and saved list of cases is referred to as a *case series*.

- [Case ID links](#)
When a case ID appears as a link anywhere in the application, you can click the link to drill down to case details.
- [Drilldown options](#)
You can drill down on the count (N) of cases from tables and graphs to access useful options and further information.
- [Create a case series from drill-down information](#)
On pages and in reports that display a list of cases identified by case ID, you can save the list of cases for future use. The named and saved list of cases is referred to as a *case series*.
- [View a list of cases](#)
You view cases from the Case Series page, the Signal Review page, and the Data Mining Results page.
- [View case details](#)
When a case ID, such as an ISR number, appears as a link anywhere in Oracle Empirica Signal, you can click the link to drill down to case details. This includes information about the case, presented as a set of tables showing source data for the case.

Case ID links

When a case ID appears as a link anywhere in the application, you can click the link to drill down to case details.

Once you have clicked a case ID link, the color of the link changes. This color change:

- Applies to only your user name and across your Oracle Empirica Signal sessions.
- Lasts for the number of days that you have set as your [user preference](#), **Days to retain visited status for case ID links**.
- Applies across all activities within the application.
- Applies to data associated with all [data configurations](#) in the same database group (an attribute of a configuration).

For example, two data mining runs are based on data configurations in the same database group. When viewing results for one run, you drill down to a list of cases and then click the case ID, 1435. The color of case ID 1435 changes, indicating that you have visited the case ID. You log out, log back in, and view a case series that includes case ID 1435 and is based on the second data configuration. Case ID 1435 appears in the changed color, indicating that you have visited it.

Note

- The user preference, **Days to retain visited status for case ID links**, applies to case ID links that you visit after you set the preference.
- The visited status is reset each time you visit a case ID link. For example, suppose that your user preference is set to 5. On Day 2, you click a case ID link. The link visited status is retained for 5 days beginning with Day 2. You visit the case ID link again on Day 3. The link visited status now is retained for 5 days beginning with Day 3. Then you change the user preference to 10. On Day 9, you view a list of cases that includes the case ID. The case ID link is the original color again because 6 days have passed since Day 3. When you click the link, the user preference is reset, so the visited status is retained for 10 days (the new preference setting) from Day 9.
- If you do not want case ID links to change color when they are visited, you can set your user preference to retain the visited status of case IDs to 0 days.
- If the data is associated with a data configuration that is not in a database group, the color of visited case ID links never changes.

To remove the visited status of all your case ID links at any time, click **Settings** and then click **Remove Visited Status of Case ID Links**.

Drilldown options

You can drill down on the count (N) of cases from tables and graphs to access useful options and further information.

The type of data presented during drilldown is from the source database tables, and is determined by the [drilldown map table](#) associated with the data configuration.

- On Oracle Empirica Signal tables, the count (N) of cases is a link that you can click to display a menu with drill-down options.
- In graphs, you can click an element (such as a bar or cell) of the graph to display the menu.

You can select the following options for the cases that make up the count or are represented by the graph element:

Options	Click to
View Cases	View a list of cases.
Create Case Series	Create a case series. For timestamped data , the As Of date of the case series will be that of the object you are viewing.
Transfer to Case Series	Transfer the list of cases to an existing case series.
Download Cases	Download the list of cases.
Download Case Details	Download case details for the cases to an Excel spreadsheet or a Word Rich Text Format File. You can download case details only if the appropriate site option has been set. (When viewing a particular case, you can also download case details for that one case.)
Reports	View a report for the cases. You can run only one report definition at the same time. Report definitions appear only if they are compatible with the data configuration for the object that you are viewing.

Create a case series from drill-down information

On pages and in reports that display a list of cases identified by case ID, you can save the list of cases for future use. The named and saved list of cases is referred to as a *case series*.

You can also [transfer cases](#) to an existing case series.

1. From the left navigation pane, select either of these Oracle Empirica features:

- Signal Review** ().
 On the Products page, display the Product-Event Combination table for a product by selecting one of these methods:
 - From a product's **Row Action menu** (), select **View Product-Event Combinations**.
 The Product-Event Combinations page appears.
 The Product-Event Combinations page appears.
 Pull down the menu for a cell with a boldface value and select **Create Case Series**.
- Data Analysis** () , then select **Data Mining Results**.
 From the **Run name** drop-down list, select the run you want to view, specify [selection criteria](#), and then click **View Results Table**.

Click the drug's **Row Action Menu** () and select **Create Case Series**.

- On the Create Case Series page, in the **Name** field, type a name for the new case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
- In the **Description** field, enter a description of the case series. A default description, which you can modify, might appear.
- To add the case series to a [project](#), click **Add to existing project** and select the project from the drop-down list of projects associated with objects that you created or that are published to you.

5. To create a new project and assign the case series to it, click **Add to a new project named** and type a project name.
6. Click **Create**.

View a list of cases

You view cases from the Case Series page, the Signal Review page, and the Data Mining Results page.

View cases from the Cases Series page

Note

Oracle Empirica Signal retrieves the data that appears on the Cases page from the source data. Therefore, it does not include [custom terms](#) or values created by [data transformation](#).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. Select the case series' **Row Action menu** (), and then select **View Cases**.
The Cases page lists the cases in the case series in a table. The variable representing the case ID is the first column of the table. The data configurations associated with the case series determine the additional columns that appear. For example, if the site option **All Case Comment/Review/Exclusion** is enabled, additional columns indicate whether the case has been reviewed or excluded, and whether comments have been added by a reviewer.
3. Perform additional actions on cases:
 - To [view case details](#), select the **case ID** in the first column.
 - To [add cases manually](#), select the **Manually Enter IDs** link, enter case IDs, separated by lines or commas, in the text box, and then select **Append**.
 - To see the reports that can be run on the case series, select the **Report** link.
 - To [download case details](#) for all cases in the list to an Excel spreadsheet or a Word Rich Text Format File, select the **Download Case Details** link. (When viewing a particular case, you can also download case details for that one case.) Oracle Empirica Signal does not include cases that are marked as excluded and that are hidden at the time of the download.
 - To [save the list of cases as an attachment to a topic](#), select the **Save to Topic** link (available if the Topics feature has been set up). The application does not include cases that are marked as excluded and that are hidden at the time you save the list as an attachment.
 - If any cases have been marked as excluded as part of reviewer input, you can select the **Hide Excluded** link. Excluded cases are not visible on the Cases page. If you select **Show Excluded**, such cases are visible.

View cases from the Data Mining Results page

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Results**.

2. From the **Run name** drop-down list, select the run you want to view. Your **Default Run user preference** determines which run is selected by default.
3. Specify [selection criteria](#), and then click **View Results Table**.
4. Click the drug's **Row Action menu** () and select **View Cases**.
5. Click **Close** or perform any of these additional activities on the cases shown:
 - To see the details of a case, click the [Case Number](#).
 - To [create a case series](#) containing the case IDs, click **Create Case Series**. For [timestamped data](#), the As Of date of the case series is that of the object you were viewing when you drilled down.
 - To [transfer the list of cases](#) to an existing case series, click **Transfer to Case Series**.
 - To [download case details](#) for all cases in the list to an Excel spreadsheet or a Word Rich Text Format File, click **Download Case Details**. You can download case details only if the appropriate site option has been set. (When viewing a particular case, you can also download case details for that one case.)
 - To [view a report](#) for the cases, click **Reports**. Report definitions appear only if they are [compatible](#) with the data configuration for the object that you were viewing.
 - To [save the list of cases as an attachment to a topic](#), click the **Save to Topic** link (available if the Topics feature has been set up).

View cases from the Signal Review page

1. In the left navigation pane, select **Signal Review** () to display the Products page.
2. From the drop-down to the right of the Signal Review page title, select the signal configuration associated with the versioned case series.
3. Select the product's **Row Action menu** (), and then select **View Product-Event Combinations**, or select the product name or total count.
4. Drill down to the actual cases by selecting the case count displayed in one of the associated columns and selecting **View Cases** from the drop-down. For signal management configurations configured to use versioned case series, the cases page contains three annotation-related columns:
 - **Current Version Annotated:** The most recent date that an annotation was added to the current version of the case.
 - **Prior Version Annotated:** The most recent date that an annotation was added to the most recent previous version of the case.
 - **Annotation:** The Annotation text from either the current annotation, if any, or the most recent annotation on a prior case version, if any.

When case data is updated, Oracle Empirica Signal considers it a new version of the case with the corresponding case version date.

5. From the Cases page, you can [view case details](#) and [add annotations to a case](#).

View case details

When a case ID, such as an ISR number, appears as a link anywhere in Oracle Empirica Signal, you can click the link to drill down to case details. This includes information about the case, presented as a set of tables showing source data for the case.

At a minimum, the following information appears:

- Case Information (demographic information).
- Reported Drugs/Vaccines.
- Reported Events/Symptoms.

There might also be additional information about reported outcomes, case report sources, narrative text, and so on. If specified by the [data configuration](#), a description of source data appears below the case details. For example: **Source Data:** AERS data as of 4th quarter 2004 from NTIS Public Release loaded on 2005-04-18.

If you drill down from the Signal Review page and the signal configuration has an associated versioned case series, there is an [additional Annotation section](#) and the Case Version Date is displayed.

Note

Oracle Empirica Signal retrieves the data that appears as case details from the source data. Therefore, [custom terms](#) or values created by [data transformations](#) do not appear.

From Signal Review:

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Select the product, click the **Row Action menu** () icon, and select **View Product-Event Combinations**, or click the product name or total count.
4. In a product-event combination table, click a total of cases in a column that appears in **bold**. The bold denotes that the number is a link that, when clicked, displays a menu.
5. Click **View Cases**.
6. On the Cases page, click a case ID; for example, an ISR number.
The cases page shows the cases associated with the selected product-event combination and contains three annotation-related columns:
 - **Current Version Annotated:** The most recent date that an annotation was added to the current version of the case.
 - **Prior Version Annotated:** The most recent date that an annotation was added to the most recent previous version of the case.
 - **Annotation:** Abbreviated Annotation text.

If an annotation has already been attached, it appears in the Current or Prior column. The annotation type appears in the Annotation column.

7. Perform additional actions in the Case Details window:
 - To print case details, click **Print**
 - To [download case details](#) to an Excel spreadsheet or a Word Rich Text Format File, click **Download**.
 - To [save the case details as an attachment to a topic](#), click **Save to Topic** (available topics feature has been set up).
 - To [work with annotations associated with a selected case](#), click the **Case ID** to open the Case Details page.

From Data Mining Results:

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Results**.
2. From the **Run name** drop-down list, select the run. Your Default Run [user preference](#) determines which run is selected by default.
3. Specify [selection criteria](#), and then click **View Results Table**.
4. Click the **Row Action menu** () or click the link in the **N** column and then click **View Cases**.
5. Click a case ID; for example, an ISR number.
6. Perform additional actions in the Case Details window:
 - To print case details, click **Print**.
 - To [download case details](#) to an Excel spreadsheet or a Word Rich Text Format File, click **Download**.
 - To [save the case details as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).

Work with tables

Throughout Oracle Empirica, data is presented in tables.

- [About tables](#)
Many of the Oracle Empirica Signal pages present information in a tabular format. This topic describes how to work with this tabular information.
- [Arrange table columns and rows](#)
To select, arrange, sort, and filter the columns and rows in the table, use the **Columns** and **Rows** links.
- [Apply filters](#)
For many tables, you can reduce the amount of data displayed to make finding and comparing rows easier by filtering the data.
- [Specify a SQL WHERE clause](#)
At certain places in Oracle Empirica Signal, you can specify a SQL WHERE clause to restrict rows of a table or a report.
- [Download data](#)
When you view a table or case details, you can download the information to various types of files.

- [Print a table](#)
You can print an entire table or only the currently displayed page of a table.
- [Use hierarchy tables](#)
Data configurations defined in older versions of the Oracle Empirica Signal application might have used hierarchy tables instead of an event hierarchy account to set up hierarchies for events.

About tables

Many of the Oracle Empirica Signal pages present information in a tabular format. This topic describes how to work with this tabular information.

If you are using Signal Review, see [Arrange table columns](#).

To work with information in tables, you can use the following options:

To	Click this link	Help topic
Select, arrange, sort, and filter the columns that display in the table.	Columns or Columns and Rows On the Signal Review page, select the header action menu, then select Columns .	Arrange table columns
Print the contents of the table.	Print	Print a table
Download the contents of the table to a variety of file formats.	Download	Download data

Oracle Empirica Signal saves the display choices that you make for a particular table. Your choices remain in effect for that table across Oracle Empirica Signal sessions, until you make different choices.

Navigating between pages

To specify how many rows display at a time, enter a number in the **Rows per Page** field and press **Enter**. In general, you can display up to 999 rows on each page.

On the Signal Review page, to change the number of rows per page, select a different value from the **Rows Per Page** dropdown.

The default number of rows is typically 50, but may vary for different Oracle Empirica Signal pages.

To go to another page, on most pages, do the following:

1. To view the next page, click .
2. To view the previous page, click .
3. To view a specific page, type a number in the **Page** field and press the **Enter**.

To go to another page in Signal Review, do the following:

1. To view the next page, click .
2. To view the previous page, click .

3. To view the first page, click .
4. To view the last page, click .
5. To view a specific page, type a name in the **Page** field and press **Enter**.

Finding text

To find specific text on a page:

- In Chrome, select the Chrome menu, then **Find**.
- In Edge, select the Edge menu, then click **Find on page**.

In all of these browsers, you can press CTRL+F to select Find. For efficiency, you may want to set the Rows per Page to a large number before using the Find feature.

Vertical scrollbars

A site option determines whether vertical scrollbars for tables of information are always on the left side, always on the right side, or determined by the [user preference](#) Show table scrollbars on left side. This option does not apply to the Signal Review Products or Product-Event Combinations pages.

Column descriptions

In some tables, when you hover on a column heading, a description of the column appears:

EBGM	EB05	EB95	RR	E
1.74	1.25	1.25	1.85	20.8
0.863	0.583	1.24	0.865	20.8

Empirical Bayesian Geometric Mean: a more stable estimate than RR

Sorting the table

You can sort a table by up to three columns. The current sort order appears above the table. You can sort a column as follows:

1. To sort a column, click the column header. The column is sorted and an arrow is displayed next to the column name to indicate the sort order. To sort in reverse order, click the column header again.

Note

Numeric and date columns initially sort higher-to-lower numbers or more recent-to-earlier dates. Alphanumeric columns initially sort in order from A to Z, and are not case-sensitive.

2. Click **Columns** or **Columns and Rows** or, on the Signal Review page, click the **Header**

Action menu () , and then click Columns. (See [Arrange table columns](#).)

When you click the column header to sort a column, that column is the primary sort order based on the column type. For example, suppose that the current sort order is Generic_Name, PT, and EBGM (desc):

If you decide to sort by EB05 in descending order, click the header in that column. The sort order becomes:

Dimension: 2 Selection Criteria: Generic_Name(ATC5) + PT Rows Per Page: 5 Page: 1 of 64 ▶
317 rows Sorted by EB05 desc, Generic_Name, PT

	Generic_Name ▲	PT ▲	N	EBGM	EB05 ▼	EB95	RR	E
⋮	Niacin Extended Release	Flushing	1968	78.3	75.5	81.3	78.4	25.1
⋮	Niacin Extended Release	Skin burning sensation	257	51.9	46.8	57.4	52.2	4.93
⋮	Niacin Extended Release	Feeling hot	411	33.5	30.9	36.3	33.6	12.2
⋮	Niacin Extended Release	Generalised erythema	57	30.9	24.7	38.3	31.5	1.81
⋮	Niacin Extended Release	Product lot number issue	14	39.1	24.4	59.9	42.9	0.326

- The most recent sort order you specify becomes the primary sort order.
- Other columns continue to be used for sorting (secondary and third sort orders).
- For most tables, empty columns appear first, if you sort in ascending order, and last, if you sort in descending order.

If you want to clear a sort order or explicitly specify levels of sorting, use the Columns (or Columns & Rows) dialog box. For example, you can change the above sort order as follows:

	Column Name	Sort Order
Column 1:	EB05 ▼	Desc ▼
Column 2:	PT ▼	Asc ▼
Column 3:	Generic_Name ▼	Asc ▼

Dimension: 2 Selection Criteria: Generic_Name(ATC5) + PT Rows Per Page: 5 Page: 1 of 64 ▶
317 rows Sorted by EB05 desc, PT, Generic_Name

	Generic_Name ▲	PT ▲	N	EBGM	EB05 ▼	EB95	RR	E
⋮	Niacin Extended Release	Flushing	1968	78.3	75.5	81.3	78.4	25.1
⋮	Niacin Extended Release	Skin burning sensation	257	51.9	46.8	57.4	52.2	4.93
⋮	Niacin Extended Release	Feeling hot	411	33.5	30.9	36.3	33.6	12.2
⋮	Niacin Extended Release	Generalised erythema	57	30.9	24.7	38.3	31.5	1.81
⋮	Niacin Extended Release	Product lot number issue	14	39.1	24.4	59.9	42.9	0.326

Dimension: 2 Selection Criteria: Generic_Name(ATC5) + PT Rows Per Page: 5 Page: 1 of 64 ▶
317 rows Sorted by Generic_Name, PT, EBGM desc

	Generic_Name ▲	PT ▲	N	EBGM ▼	EB05	EB95	RR	E
⋮	Niacin Extended Release	Abdominal discomfort	49	1.78	1.40	2.23	1.81	27.0
⋮	Niacin Extended Release	Abdominal distension	18	0.863	0.583	1.24	0.865	20.8
⋮	Niacin Extended Release	Abdominal pain	32	0.525	0.391	0.694	0.520	61.5
⋮	Niacin Extended Release	Abdominal pain upper	48	1.26	0.987	1.58	1.27	37.9
⋮	Niacin Extended Release	Abnormal dreams	9	0.925	0.533	1.52	0.936	9.61

Arrange table columns and rows

To select, arrange, sort, and filter the columns and rows in the table, use the **Columns** and **Rows** links.

1. From the **Header Action menu** () for a table or from the links at the top of a page, click **Columns**.
2. Select columns to include in the table from the **Available Columns** list and move them to the **Selected Columns** list using the arrow buttons.

If a table includes a lot of columns or the columns contain long values, the entire table may not fit across your browser window. Scroll to the right to see the rest of the table.

3. To change the order in which columns display in a table, in the **Selected Columns** list, click the column name and:

- Click  to move the column up in the list.
- Click  to move the column down in the list.
- To move multiple columns, hold down the Ctrl key while you click the column names, and then click the up or down arrows.

4. To replace your choices with the Oracle Empirica Signal defaults, click **Reset** in the **Columns** dialog box. For the all tables, except Product-Event Combinations, the table columns and sorting return to the default values. For the Product-Event Combinations table, the Reset button in the Columns dialog resets to whatever was selected when you opened the dialog. To reset a Product-Event Combinations table to the default settings,

from the **Header Action menu** () , click **Reset View to Default**.

5. Specify the sort order.

If you sorted the table by clicking column headers, that sort order appears in the Column Name and Sort Order fields. To specify a sort order:

- a. From the **Column Name** drop-down lists, select a column name for up to three columns.
 - b. From the **Sort Order** drop-down list, select **Asc** (ascending order: A-Z, 1-9) or **Desc** (descending order: Z-A, 9-1).
6. If you are managing columns and you have checked the **Allow SQL Where Clause on the Signal Review page** check box on the [Set User Preferences](#) page, you can [specify a SQL WHERE clause](#) to filter rows on the Products table. For the Product-Event Combinations table, this is only available for scripted signal configurations and added tabs.
 7. For all tables, except the Product-Event Combinations table, if you have the Administer Users permission, you have the option to make the current layout the default for all of the users in your login group. This replaces the default table layout supplied by the application with your current layout for any user who has not yet arranged that table.
 8. Click **OK**.

Oracle Empirica Signal saves your arrangement of columns and rows and uses it as a default for the Products or Product-Event Combinations tables for the selected signal configuration until you change the arrangement.

Note

When you initially display the Products table or Product-Event Combinations table, the columns shown and the sort order within the table reflect the current selections. Any changes you make are retained for that configuration.

Impact of multiple sorts on the Products table

1. Hover over an unsorted column header. A sort arrow appears indicating the initial sort order.
 - Dates and numbers are sorted in descending order.
 - Strings are sorted in ascending order.
 - The sort arrow is displayed for primary, secondary, and tertiary sorted columns.
2. Hover over a sorted column header and it continues to show the current sort direction.
 - The primary arrow is black. Secondary and tertiary arrows are gray.
 - The tooltip for a sort arrow indicates the new sort direction such as "Sort Interaction Descending" or "Sort Interaction Ascending."

Apply filters

For many tables, you can reduce the amount of data displayed to make finding and comparing rows easier by filtering the data.

Oracle Empirica Signal quick filters are labeled drop-down lists that appear above a table. Each drop-down list is dynamically populated with valid values and a - option for *no filter specified*. When you select a value from the drop-down list, the table display includes only those records that match that value (if you specify only one of the quick filter) or to records that match both of the selected values.

Specify a SQL WHERE clause

At certain places in Oracle Empirica Signal, you can specify a SQL WHERE clause to restrict rows of a table or a report.

Note

When specifying a SQL WHERE Clause, you can click **Show Columns** to display the Select Table Columns page listing variables (columns) that you can include in the WHERE clause. To insert a variable into the WHERE clause, click the column name.

When specifying a SQL WHERE clause, do not enter the word WHERE. Oracle Empirica Signal adds WHERE internally to the start of the condition that you enter. For example, to view all results for which EBGM is greater than 5, type EBGM > 5.

To connect conditions, use AND or OR. For example:

- N > 5 AND EBGM > 8
- EBGM > 5 OR EBGMDIF > 6

If you provide a SQL expression with incorrect syntax or unsupported SQL functions, an error message appears at the top of the page when you save the expression. Common errors are a wrong or misspelled column name, and unclosed or mismatched parentheses.

The way in which a variable is stored in the Oracle database determines how you can search for it.

Text variables

If a variable is stored as a text field in the Oracle database, you must enclose the text string in single quotes. Capitalization within the quoted string must match the text string in the database exactly.

To find a value that includes a single quotation mark, or apostrophe, precede the quotation mark or apostrophe with another single quotation mark in the quoted string. For example, to find Bell's palsy for the PT variable, type PT like 'Bell's palsy'.

You can use any valid SQL operators, including the following commonly used operators:

Operator	Meaning	Example
LIKE	matches	SUBSET LIKE 'F'
NOT	is not the condition that follows	SUBSET NOT LIKE 'F'

You can use the % wildcard character in a text string after LIKE; it matches any characters in its position, as follows:

Type of Match	Example
Exact match	ITEM1 LIKE 'Asthma NOS'
Starts with specified string	ITEM1 LIKE 'As%'
Includes specified string	ITEM1 LIKE '%th%'
Ends with specified string	ITEM1 LIKE '%NOS'

Numeric variables

If a variable is stored as a number field in the Oracle database, you can use any valid SQL operators, including the following commonly used operators:

Operator	Meaning	Example
=	is equal to	EBGM = 3
!= or <>	is not equal to	EBGM != 3 EBGM <>3
>	is greater than	EBGM > 98.6
>=	is greater than or equal to	EBGM >= 98.6
<	is less than	EBGM < 8.5
<=	is less than or equal to	EBGM <= 8.5
BETWEEN	is between (includes both 6.5 and 8.0)	EBGM BETWEEN 6.5 AND 8.0

Date variables

If a date variable is stored as a text field in the Oracle database, you can search for it as you would search for any text string.

If a date variable is stored as a date field in the Oracle database, you can use the Oracle function `TO_DATE` to change a text string to an Oracle date. Then you can use the same operators as for numeric variables. For example, if you want to find `RCVD_DATE` dates later than 2019-01-17, you specify:

```
RCVD_DATE > TO_DATE('2019-01-17', 'yyyy-mm-dd', 'NLS_DATE_LANGUAGE = American')
```

If you do not specify a time, the time is considered to be midnight of the specified date.

Column names

To select table columns (variables) to include in the WHERE clause, from the **Header Action**

menu () on the Products or Product-Event Combinations tables, click **Columns**. On the Columns dialog, enter the WHERE clause in the **Where Clause** text box. To copy an existing column into the WHERE clause, click the **Show columns** link.

When using a SQL WHERE clause to select criteria for run results that you are viewing or to filter a source table that you are viewing, avoid referring to the product or event variables or related hierarchy terms. The actual column names in the underlying table are not the same as the labels for fields on the Select Criteria page or as the column headers in the results table. The actual column names are `ITEM1`, `ITEM2`, etc.

Note

The alphabetical order of prefixes defined in the configuration for the drug and event variables determines whether the variables are `ITEM1` or `ITEM2`. For example, if the prefix for the drug variable is D and the prefix for the event variable is E, the drug variable is `ITEM1` because D is first alphabetically.

SQL functions

Oracle Empirica Signal supports the following SQL functions in WHERE clauses:

acos	length	soundex
ascii	lower	sqrt
asciiStr	last_day	substr
asin	ln	tan
atan	log	tanh
atan2	lpad	to_date
BitAnd	ltrim	to_dsinterval1
Ceil	mod	to_multi_byte
Chr	months_between	to_number
Compose	new_time	to_single_byte
concat	next_day	to_timestamp
convert	power	to_timestamp_tz
cos	remainder	translate
cosh	replace	tz_offset
decompose	round	abs
dump	rpadd	to_yminterval

acos	length	soundex
exp	rtrim	add_months
floor	sign	upper
initcap	sin	vsize
from_tz	sinh	to_char
instr	-	-

The following are caveats of the SQL functions:

- Functions with no parameters are permitted (for example, sysdate)
- Functions with optional arguments (for example, to_date) require ALL arguments

Download data

When you view a table or case details, you can download the information to various types of files.

Set a default download file type by modifying your [user preferences](#). When downloading, however, you can override the default by selecting another file type.

Note

For floating-point numbers that are downloaded, the precision of the numbers is accurate to the level of precision in the numbers, as displayed in Oracle Empirica Signal.

1. Make sure you have [arranged table columns](#) as you want them.
2. From the Signal Review page **Header Action menu** () , click **Download**. On other pages, click the appropriate **Download** link.
3. In the **Base filename** field, enter a filename. Do not include an extension. We recommend that you use a filename that identifies the content of the download.
4. Select one of the following file types. For some types of information, only certain file types are available.

File Type	Description
Comma-separated file (.csv)	Text file in which values are separated by a comma. Can be used as input to or output from Microsoft Excel.

Note

Check that leading zeroes have been downloaded to the .csv file. Excel may remove the leading zeroes when you download.

File Type	Description
Tab delimited file (.txt)	Plain text file. Typically, the file extension .txt is associated with a text editor, such as Microsoft Notepad.
Excel spreadsheet (.xlsx)	Spreadsheet file that can be opened by Microsoft Excel. You must have Microsoft Excel installed on your computer. If you try to download a table of more than 1,048,575 rows, a message warns you that this exceeds the capacity of Excel. When you download case details to an Excel spreadsheet, a separate worksheet is used for each of the different types of data shown on the Case Details page. Each worksheet is limited to 1,048,575 rows.
SAS Version 5 transport file (.xpt)	Industry-standard SAS transport file, as defined for SAS Version 5 (XPORT format).
SAS data step definition (.sas)	SAS data step file, which can be used by SAS software to create a native SAS dataset.
Portable Document Format (.pdf)	File that includes formatting and layout information, as well as the data. This option requires the Adobe Acrobat Reader. You can download up to a million rows.
Word document (.docx)	Downloads case details to a Word document formatted so that each case starts on a new page.

Note

If dates are not displayed appropriately in Excel, you might need to change the display format in Excel.

Note

When you are downloading case details, only the Excel spreadsheet (.xlsx) or Word format (.docx) formats are available.

5. In the **Limit to** field, enter the number of rows that you want to download (instead of downloading the entire table). For example, if you specify 1000, only the first 1,000 rows of the table download. Keep in mind that the way in which the table is sorted determines which rows are downloaded. If you do not fill in the Limit to field, all rows of the table download.

The number of rows per page of the displayed table has no effect on downloading. For example, the table includes 100 rows and 25 rows appear per page. If you download the table, all 100 rows download.

Note

When you download case details, we recommend that you do not limit the number of rows. The limit applies to each type of data. For example, if you limit the download to two rows, only the first two drugs and the first two adverse events for the case are downloaded.

6. If you select **Create a Zip archive file for download**, the Oracle Empirica Signal creates a file with the extension .zip to hold the file that contains the downloaded table. You must have a ZIP file compression and extraction utility, such as WinZip, installed on your computer.

The zip file also includes an id.txt file that provides the name of the user who downloaded the table and the date and time of the download.

Note

When you download data from a report, you can also include a report definition file and analysis files. The report definition is an XML representation of the report. The analysis files include an analysis description file and an analysis script file (if defined for the report).

7. Click **OK**.
8. **Open** or **Save** the file.

For large case series, a message appears stating the file is being prepared. You can leave this page and click anywhere in Oracle Empirica Signal while the file is downloading.

Note

When you download data mining results or reports, Oracle Empirica Signal includes notes in the download (to all file types except .xpt and .sas) if they appeared at the time of the download.

Print a table

You can print an entire table or only the currently displayed page of a table.

To print the entire table:

1. Set up the displayed table as you want it to appear when printed. The table prints with the same columns and sort order as the displayed table.
2. Click **Print**.

To print only the data on the currently displayed page of the table:

1. From the browser File menu, select **Print**. (This option is available only if the table appears in a browser window and not a separate dialog box.)
2. Optionally, change the orientation of the paper (Portrait or Landscape) and make other printing choices. If all displayed columns do not print in Landscape mode, you can remove columns from the table before printing it.

3. Select a printer.
4. Click **Print**.

Use hierarchy tables

Data configurations defined in older versions of the Oracle Empirica Signal application might have used hierarchy tables instead of an event hierarchy account to set up hierarchies for events.

The following information is for reference only. See [Drug and event hierarchies](#) for information about the newer method of setting up hierarchies for drugs or events.

When you use hierarchy tables, users must select from a list of event or drug values, instead of using the hierarchy browser. The Select Criteria page and results table use general labels for the hierarchical levels: Level 0, Level 1, and Level 2. If both a hierarchy account and a hierarchy table are specified by the configuration, the hierarchy table takes precedence.

A hierarchy table specifies a hierarchy of terms (such as drugs and events) available for selecting criteria for data mining results before viewing them. A hierarchy table has no effect on the generation of statistical results for a run.

For each configuration variable for which you want to use a hierarchy, there must be a hierarchy table. If there is a hierarchy table specified for one or more variables in a configuration, then a run creator has the option to use the hierarchy or not.

You can create a hierarchy table outside of the Oracle Empirica Signal application using tools that provide access to the Oracle database. The table must be in the Oracle account containing the source database tables. You refer to the table from a configuration variable within the Oracle Empirica Signal application. You can also edit an existing configuration variable to add a hierarchy table to it.

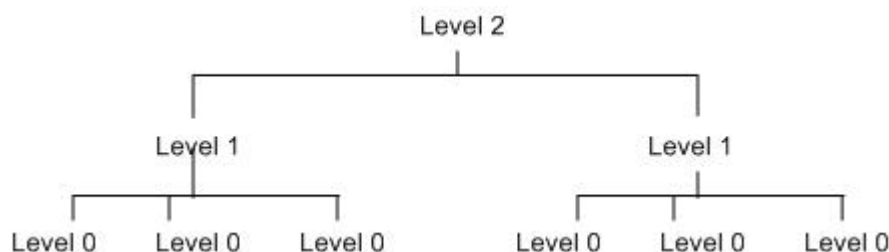
Note

You can also create a hierarchy table while you are editing a configuration variable. In this situation, an empty hierarchy table is created and you must populate it outside of the application.

For the table name, Oracle recommends that you use a name that identifies the table as a hierarchy; for example, DRUG_HIER or EVENT_HIER. A hierarchy table must include the following columns:

- **ITEM_VALUE** —Drug or event name. This is Level 0 of the hierarchy. There must be one value for each unique drug or event name.
- **H1_VALUE** —Middle-level term of the drug or event hierarchy. This is Level 1 of the hierarchy.
- **H2_VALUE** —Top-level term of the drug or event hierarchy. This is Level 2 of the hierarchy. If you are creating a two-level hierarchy, this column can be empty.

There can be zero levels, one level, or two levels in a hierarchy, as in the following example:



Each Level 0 term can have only one Level 1 term associated with it. Each Level 1 term can have only one Level 2 term associated with it.

Note

If a drug is not included in the hierarchy table, it is not available when the results reviewer filters results according to a Level 1 or Level 2 term. For example, all drugs except DrugA are in the hierarchy table and have a Level 2 value of OTC or RX. If the reviewer filters according to the Level 2 terms OTC and RX, DrugA is not in the displayed results. (However, DrugA is still available as a Level 0 term even if it is not in the hierarchy table.) When source data is updated and includes new drugs or events, this situation may occur unless the hierarchy table is updated as well.

You can view hierarchy tables on the [Data sources page](#).

- [How to select hierarchy terms](#)
Adverse events and drugs can be associated with a dictionary, thesaurus, or other standardized terminology that organizes terms into a hierarchical structure.
- [Specify hierarchy versions for timestamped data](#)
If a data configuration supports timestamped data, you must specify a hierarchy version for each time period in the source data.

How to select hierarchy terms

Adverse events and drugs can be associated with a dictionary, thesaurus, or other standardized terminology that organizes terms into a hierarchical structure.

For example, adverse event terms may be associated with a version of the Medical Dictionary for Regulatory Activities (MedDRA¹), and drugs may be associated with the WHO Anatomical Therapeutic Chemical (ATC) classification system. The hierarchical terms and their relationships are stored in a special account, then associated with variables in [data configurations](#).

To select specific drug or event values for a variable, you click the **Select Available Values** link to view and [select values from an alphabetized list](#). If the drug or event variable has an associated hierarchy, another link appears so that you can browse through the hierarchy. For example, you can click **Select MedDRA Terms** to browse for Preferred Terms (PT) in the hierarchy. The variable must be set up in the data configuration and you must check the [user preference](#), **Enable Adverse Event Hierarchy Browser** or **Enable Drug Hierarchy Browser**.

¹ MedDRA® is a registered trademark of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). MedDRA® the Medical Dictionary for Regulatory Activities terminology is the international medical terminology developed under the auspices of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

Note

The name of the hierarchy associated with the variable appears as part of this link. For example, for a drug variable, Select ATC Terms appears. This help system uses Select <hierarchy> Terms as a general reference to this link.

When you click **Select <hierarchy> Terms**, the Hierarchy Browser dialog box opens and enables you to browse the hierarchy and review, search for, and select terms at the appropriate level of the hierarchy.

Help

MedDRA 21.0 Hierarchy
SOC, HLG1, HLT, PT, LLT

+

Infec

+

Neopl

+

Blood

+

Immun

+

Endo

+

Metab

+

Psych

+

Nerv

+

Eye

+

Ear

+

Card

+

Vasc

+

Resp

+

Gastr

+

Hepat

+

Skin

+

Musc

+

Renal

+

Preg

+

Repro

+

Cong

+

Genrl

+

Inv

Available Preferred Term Values
(0 values)

Selected Preferred Term Values
(0 values)

Match:

Search

Save As List

OK

Cancel

Browsing terms

The section on the left of the Hierarchy Browser lists the terms at the highest, most general level of the hierarchy. For example, System Organ Class (SOC) terms appear for the MedDRA hierarchy, and Level 1 terms appear for the ATC hierarchy. To expand the list to show terms at the next level, click the **Plus sign**  icon next to a term. Repeat to expand the list to show terms at all levels through the lowest, most specific level in the hierarchy. Click the **Minus sign**  to collapse sections of the list.

[Help](#)

MedDRA 21.0 Hierarchy
SOC, HLGT, HLT, PT, LLT

Infec

+

Ancillary infectious topics

+

Bacterial infectious disorders

+

Chlamydial infectious disorders

+

Ectoparasitic disorders

+

Ectoparasitic infestations

+

Fungal infectious disorders

+

Helminthic disorders

+

Infections - pathogen unspecified

+

Mycobacterial infectious disorders

+

Mycoplasmal infectious disorders

+

Protozoal infectious disorders

+

Rickettsial infectious disorders

+

Viral infectious disorders

+

Neopl

+

Blood

+

Immun

+

Endo

+

Metab

+

Psych

+

Nerv

+

Eye

+

Ear

Available Preferred Term Values
(0 values)

Selected Preferred Term Values
(0 values)

Match:

Search

Save As List

OK

Cancel

When you hover over terms in this list, an underline appears if you can click on a term to review and, potentially, select terms at the appropriate level of the hierarchy.

Reviewing terms

The Available <level> Values section in the center of the Hierarchy Browser lists terms at the level of the hierarchy that you are browsing. For example, if you are browsing for PTs, the Available <level> Values section lists all of the PTs in the hierarchy below the term you clicked. If you click on a Higher Level Group Term (HLGT), all of the PTs under that HLGT appear for review.

[Help](#)

MedDRA 21.0 Hierarchy
SOC, HLGT, HLT, PT, LLT

Infec

+

Ancillary infectious topics

+

Bacterial infectious disorders

+

Chlamydial infectious disorders

+

Ectoparasitic disorders

+

Ectoparasitic infestations

+

Fungal infectious disorders

+

Helminthic disorders

+

Infections - pathogen unspecified

+

Mycobacterial infectious disorders

+

Mycoplasmal infectious disorders

+

Protozoal infectious disorders

+

Rickettsial infectious disorders

+

Viral infectious disorders

+

Neopl

+

Blood

+

Immun

+

Endo

+

Metab

+

Psych

+

Nerv

+

Eye

+

Ear

Available Preferred Term Values
(513 values)

High Level Group Term "Bacterial infectious disorders"

Abdominal hernia gangrenous

Abscess bacterial

Acid fast bacilli infection

Acinetobacter bacteraemia

Acinetobacter infection

Acrodermatitis chronica atrophicans

Actinomycosis

Actinomycotic abdominal infection

Actinomycotic pulmonary infection

Actinomycotic sepsis

Actinomycotic skin infection

Acute focal bacterial nephritis

Adenopathy syphilitic

Administration site cellulitis

Aeromonas infection

Alcaligenes infection

Alopecia syphilitic

Alpha haemolytic streptococcal infection

Angina gangrenous

Anicteric leptospirosis

Anorectal cellulitis

Selected Preferred Term Values
(0 values)

Match:

Search

Save As List

OK

Cancel

Note

Not every term at every hierarchical level shown on the left can be clicked. For example, if you select MedDRA PTs, you cannot click on a lower level term (LLT) to review or select PTs above that LLT in the hierarchy.

Searching for terms

Another way to find and review terms at the hierarchical level of interest is to enter text in the **Match** field at the bottom of the window and click **Search**. (The Match field is not case sensitive.) The list of Available <level> Values appears on the right and contains all terms that match your text at the appropriate hierarchical level. The hierarchy section on the left also refreshes; only terms at the top-most hierarchical level appear, and each term that has a matching term in its path appears in *italics*.

[Help](#)

MedDRA 21.0 Hierarchy
SOC, HLGT, HLT, PT, LLT

Showing "dislocation" within hierarchy:

- Infec
- Neopl
- Blood
- Immun
- Endo
- Metab
- Psych
- Nerv
- Eye*
- Ear*
- Card
- Vasc
- Resp
- Gastr*
- Hepat
- Skin*
- Musc*
- Renal
- Preg
- Repro
- Cong*
- Genrl
- Inv

Available Preferred Term Values
(13 values)

Results for search of terms matching "dislocation":

- Congenital knee dislocation
- Device dislocation
- Dislocation of sternum
- Dislocation of vertebra
- Joint dislocation
- Joint dislocation pathological
- Joint dislocation postoperative
- Joint dislocation reduction
- Lens dislocation
- Radial head dislocation
- Tendon dislocation
- Tooth dislocation
- Vertebra dislocation reduction

Selected Preferred Term Values
(0 values)

Match:

When you click the **Plus sign**  next to an italicized term, the hierarchy expands all of the levels for that term to show the complete path to the term that matches. Italics appear at every level in the path to assist you in following the path to the matching term or terms. **Boldface** highlights the actual match.

[Help](#)

MedDRA 21.0 Hierarchy
SOC, HLGT, HLT, PT, LLT

Showing paths for "Lens dislocation":

Eye

Anterior eye structural change, deposit and degeneration

Anterior chamber structural change, deposit and degeneration

Cataract conditions

Conjunctival structural change, deposit and degeneration

Corneal structural change, deposit and degeneration

Iris and ciliary body structural change, deposit and degeneration

Lens structural change, deposit and degeneration (excl cataracts)

Acquired lenticonus

Anterior capsule contraction

Aphakia

Aphakia congenital

Fibrin deposition on lens postoperative

Lens dislocation

Anterior dislocation of lens

Available Preferred Term Values
(13 values)

Results for search of terms matching "dislocation":

Congenital knee dislocation

Device dislocation

Dislocation of sternum

Dislocation of vertebra

Joint dislocation

Joint dislocation pathological

Joint dislocation postoperative

Joint dislocation reduction

Lens dislocation

Radial head dislocation

Tendon dislocation

Tooth dislocation

Vertebra dislocation reduction

Match:
dislocation

Search

Save As List

OK

Cancel

Alternatively, you can click a term in the **Available <level> Values** list to expand the hierarchy section to show the primary path for that term. The **Primary Path** icon  indicates the primary path.

[Help](#)

MedDRA 21.0 Hierarchy
SOC, HLGT, HLT, PT, LLT

Showing paths for "Lens dislocation":

Metab

Psych

Nerv

Eye

Anterior eye structural change, deposit and degeneration

Anterior chamber structural change, deposit and degeneration

Cataract conditions

Conjunctival structural change, deposit and degeneration

Corneal structural change, deposit and degeneration

Iris and ciliary body structural change, deposit and degeneration

Lens structural change, deposit and degeneration (excl cataracts)

Acquired lenticonus

Anterior capsule contraction

Aphakia

Aphakia congenital

Fibrin deposition on lens postoperative

Available Preferred Term Values
(13 values)

Results for search of terms matching "dislocation":

Congenital knee dislocation

Device dislocation

Dislocation of sternum

Dislocation of vertebra

Joint dislocation

Joint dislocation pathological

Joint dislocation postoperative

Joint dislocation reduction

Lens dislocation

Radial head dislocation

Tendon dislocation

Tooth dislocation

Vertebra dislocation reduction

Match:
dislocation

Search

Save As List

OK

Cancel

If the term also has a secondary path in the hierarchy, that path also expands and is marked by the **Secondary Path** symbol . You can scroll through the hierarchy to review any alternate paths for the term.

[Help](#)

MedDRA 14.1 Hierarchy
SOC, HLT, HLT, PT, LLT

Showing paths for "Lens dislocation":

- [-] Cong
- [-] Genrl
- [-] Inv
- [-] **Inj&P**
 - [-] Administration site reactions
 - [-] Bone and joint injuries
 - [-] Chemical injury and poisoning
 - [-] **Injuries NEC**
 - [-] Abdominal injuries NEC
 - [-] Cardiovascular injuries
 - [-] Cerebral injuries NEC
 - [-] Chest and lung injuries NEC
 - [-] Cranial nerve injuries
 - [-] Ear injuries NEC
 - [-] **Eye injuries NEC**
 - [-] Aqueous humour leakage
 - [-] Blindness traumatic
 - [-] Cataract traumatic
 - [-] Chorioretinal scar
 - [-] Choroidal detachment
 - [-] Choroidal rupture
 - [-] Commotio retinae

Available Preferred Term Values
(1 value)

Results for search of terms matching "lens dislocation":

- Lens dislocation**

Selected Preferred Term Values
(0 values)

Match:
lens dislocation Search Save As List

OK Cancel

Note

- When you click a term in the Available <level> Values list, its full name appears as pop-up text. This enables you to see the complete value in case the displayed value is cut off because of its length.
- Terms that appear in the hierarchy multiple times appear only once in the Available <level> Values list.
- The terms shown in this dialog box are from the special account that contains hierarchy data. As a result, custom terms do not appear in the hierarchy list, and cannot match entered search values.

Selecting terms

After you review terms in the Available <level> Values list, you can make selections. To select values, you highlight and move them as follows:

- To highlight a value, click it.
- To highlight multiple non-contiguous values, hold down the **Ctrl** key while clicking each value.
- To highlight multiple contiguous values, click a value, hold down the **Shift** key, and click another value. Values between and including those values are highlighted.
- To remove highlighting from a value, hold down the **Ctrl** key while clicking the selected value.

When your selections are complete, click **OK**. The window closes and you return to the task you were performing.

To create a [saved list](#) of terms for future use, click **Save As List**.

Specify hierarchy versions for timestamped data

If a data configuration supports timestamped data, you must specify a hierarchy version for each time period in the source data.

For [timestamped data](#), a time period is a range of dates during which only one hierarchy version was used to code the source data.

Note

In the Cloud, Oracle manages the MedDRA versions for connected Oracle Argus Mart configurations. Submit a service request to update MedDRA in Oracle Argus Cloud Service and the associated Oracle Empirica Signal configurations simultaneously.

In Oracle Empirica Signal, you must specify the version of MedDRA used to code the source data for each time period. For details, see [Specify hierarchy versions for timestamped data](#).

Exit Oracle Empirica Signal

You should ensure that you exit the Oracle Empirica Signal application before closing your browser.

If you close your browser without exiting, your session continues to run for some time before the automated timeout and may retain system resources unnecessarily.

You can exit the Oracle Empirica Signal application, however, while background processing jobs are running. Background processing jobs are not affected by your logout, and continue running after you exit the application.

If you logged in using your single sign-on user name and password, exiting the Oracle Empirica Signal application may log you out of your single sign-on environment, or from Oracle Empirica Signal only, depending on your Oracle Empirica Signal configuration.

1. Click the down arrow next to your user name, visible in the upper right-hand corner of each page. Select **Exit**.

A message appears, indicating that you are logged out of the application.

If you logged in using your single sign-on user name and password and your site administrator specified a custom logout page, that page appears.

2. To log in to Oracle Empirica Signal again, with the same or a different user name, click the link provided on the logout page.

Note

From outside of the Oracle Empirica Signal application, your system administrator can specify the number of minutes before automated session timeout occurs for Oracle Empirica Signal users. The session timeout occurs if you have not performed any action within the time period, regardless of whether or not a job you initiated, such as a data mining run, is running in the background.

View release notes and other documents

The latest product documentation is available from the Oracle Help Center.

To view release notes and other documents maintained on your server, in the left navigation pane, select **Settings** , then s **About**.

The relevant links are at the bottom of the page.

- [Use Help](#)
The Oracle Empirica Signal Online Help system provides information about pages, procedures for performing Oracle Empirica Signal activities, and conceptual and instructional topics.
- [Send feedback](#)
Oracle welcomes your comments, problem reports, suggestions, or requests about the Oracle Empirica Signal application.

Use Help

The Oracle Empirica Signal Online Help system provides information about pages, procedures for performing Oracle Empirica Signal activities, and conceptual and instructional topics.

The Help system is context-sensitive; that is, if you click the **Help** link on an Oracle Empirica Signal page, information about that page appears.

- Help topics include underlined links that you can click to display more information.
 - Help topics remain open until you close them. You can leave the Help open in the background while you are using the application.
1. In the left navigation pane, click the **Help** icon  or click **Help** on an Oracle Empirica Signal page. Help for the page that you are viewing appears in a new browser window.
 2. To view the main help page, click **Show Table of Contents** at the top of the help page. The main help window includes a toolbar with the following buttons:

Button	Description
Table of Contents	Display the table of contents for the Help system. 1. In the table of contents, expand a top-level entry in the table of contents by clicking either its name or the closed book icon  before its name. The icon changes to . 2. Click a topic name to display the topic in the right-hand side of the Help window.
Search	To find help topics containing a particular word or phrase: 1. Click the Search button  on the left. 2. Select Search this book. 3. Type a word or phrase and click the Submit button . 4. Click a listed topic to display it.

Button	Description
Download	Click the Download button () to download a PDF version of the help for offline use and printing.

Send feedback

Oracle welcomes your comments, problem reports, suggestions, or requests about the Oracle Empirica Signal application.

1. In the left navigation pane, click the **Feedback icon** ().
The Life Sciences Support page appears.
2. From the Pharmacovigilance Products section, click the  for either **Empirica Cloud Service** or **Empirica - (on premise)**.
3. Follow the instructions shown to create a Support Request or call the local number for support assistance. You can also call or text the Sales team.

2

Perform a Signal Review

Signal review, a feature of the Oracle Empirica Signal and Topics application, is used to view disproportionality analysis statistics for successive updates of safety data, allowing you to monitor alerts and evaluate changes in safety signals over time.

The Products and Product-Event Combinations pages provide graphical and tabular alert information at all levels. Reviewers can easily assess the review completeness of alerts for all products or specific product groupings.

- [Signal Review basics](#)
Signal Review, a feature in the Oracle Empirica Signal and Topics application, is used to view disproportionality analysis statistics for successive updates of safety data, allowing monitoring of alerts and evaluating of changes in safety signals over time.
- [Step 1: Select a signal configuration](#)
Selecting the configuration you want to apply is the first step in performing a signal review.
- [Step 2: Select a product, group of products, or multiple products to investigate](#)
Selecting the products to investigate is the second step in performing a signal review.
- [Step 3: Review product-event combinations for a product or multiple products](#)
The Product-Event Combinations panel is a set of tables that represent views of the product-event combinations assembled from the current Refresh runs, as well as rows from previous refreshes which have either unreviewed alerts or comments.
- [Step 4: Submit the review](#)
The Submit Review page groups together all the functionality related to completing a review and documenting the disposition of a product-event combination and the alerts raised for that product-event combination.
- [View signal management reports](#)
Predefined Oracle Analytics reports are optional signal management reports that provide greater detail on signal reviews.

Signal Review basics

Signal Review, a feature in the Oracle Empirica Signal and Topics application, is used to view disproportionality analysis statistics for successive updates of safety data, allowing monitoring of alerts and evaluating of changes in safety signals over time.

The user interface for the optional Signal Review component has a modern, hierarchical structure that helps users visualize and prioritize activities. The Products and Product-Event Combinations pages provide graphical and tabular alert information at all levels. Reviewers can easily assess the review completeness of alerts for all products or specific product groupings.

This browser-based user interface provides a rich experience that helps safety reviewers perform periodic surveillance efficiently. The emphasis of this approach is on visual tracking and interaction with alerts, including user-defined alerts.

Additional information is built throughout the user interface. If you hover over most fields, a pop-up shows additional information. *Alerts Reviewed* is a column in the Products table that provides a graphical view of the percentage of tracked alerts that have been reviewed. If you

hover over the value in the *Alerts Reviewed* column for a product, a popup shows the reviewed percentage, the number of alerts that have been reviewed, and the total alerts for the product.

- [Start with the Products and Product-Event Combination pages](#)
The Oracle Empirica Signal Products and Product-Event Combinations pages summarize alert information and track review of alerts for products and product-event combinations in a visually intuitive and interactive manner.
- [Signal Review configurations: interactive, multisource, and scripted](#)
There are three types of signal configurations: interactive, multisource, and scripted.
- [Use the Detail panel as your dashboard](#)
When you select a Products By card or select one or more products in the Products table, the Detail panel on the right updates.
- [Configured alerts: tracked vs. informational](#)
As part of interactive signal management, you can configure alerts. Configured alerts are defined by a user with Manage Signal Configurations permission.
- [Keyboard shortcuts for the Products and Product-Event Combinations tables](#)
Using these keyboard shortcuts can facilitate your work with Signal Review.

Start with the Products and Product-Event Combination pages

The Oracle Empirica Signal Products and Product-Event Combinations pages summarize alert information and track review of alerts for products and product-event combinations in a visually intuitive and interactive manner.

- The [Products page](#) shows a summary of the monitored products and alerts included in the [chosen configuration](#). From the Products page you can [narrow your focus to a single product](#) or expand your focus to include multiple products.
- From the Products page you can drill into the [Product-Event Combinations table](#). You can [filter the product-event combinations panel](#) to a specific System Organ Class by selecting a System Organ Class card. Select a tab to further filter the product-event combinations table.

For the Products and Product-Event Combinations tables, the cards summarize the number of tracked alerts that have been reviewed and the total count of alerts.

Signal Review configurations: interactive, multisource, and scripted

There are three types of signal configurations: interactive, multisource, and scripted.

- **Interactive signal configurations** allow a user, with appropriate permissions, to create, validate, and refresh the configuration in the application. Interactive signal configurations are currently available for proprietary data maintained in and for public safety data from the Adverse Event Reporting System (AERS).
- **Multisource signal configurations** combines the results of multiple underlying signal configurations into a single configuration. A multisource signal configuration extends an existing interactive signal configuration by adding data from one or more secondary signal configurations and enables you to view safety data from multiple data sets side by side in a single configuration.
As an extension of interactive signal configuration, the multisource signal configurations add data from one or more secondary signal configurations, to align all datasets in one view on the Signal Review page. Changes to shared features synchronize between the multisource signal configuration and the lead configuration. Any changes you make in the multisource signal configuration are reflected in the underlying configuration and vice-versa. All independent features remain unchanged.

- **Scripted signal configurations** require modifying most aspects of the signal configuration outside of the application, based on your organization's requirements, and running command-line scripts to perform refreshes. Scripted signal configurations are available for other data sources, including proprietary databases.

To set up and edit the configurations, you must have the Manage Signal Configurations permission. See [Edit a signal configuration](#).

Use the Detail panel as your dashboard

When you select a Products By card or select one or more products in the Products table, the Detail panel on the right updates.

The details shown include:

- **Product Group or Groups Selected:** If you choose a single product, the heading at the top of the Detail panel displays the name of the product group selected. If you select one or more products by [activating Select Rows mode](#) from the Header menu, the heading changes to the number of products selected.
- **Tracked Alerts:** Shows a graph of all tracked alerts and their reviewed and unreviewed counts. Oracle Empirica Signal updates tracked alert counts when product-event combinations are reviewed. When users perform a submit review for a product-event combination, all tracked alerts associated with that product-event combination are considered reviewed. The panel is expanded by default.
- **Informational Alerts:** Shows a graph of non-tracked alerts and their total counts. These alerts do not contribute to the triage progress. The panel is collapsed by default.
- **Open Topics:** Shows how many product-event combinations have been associated with open topics. This section does not appear if the selected signal configuration is not integrated with Topics. The panel is expanded by default.
- **Notes:** Shows the most recently entered product notes. The Notes section appears when a row in the Products table is selected and not when a Products By card or multiple products are selected. The panel is collapsed by default.

If you are in Select Rows mode and have selected one or more products, [to see the notes](#),

from the **Header Action menu** (), select **View Notes**. Notes for all the products selected appear on the View Notes page.

Configured alerts: tracked vs. informational

As part of interactive signal management, you can configure alerts. Configured alerts are defined by a user with Manage Signal Configurations permission.

There are two types of configurable alerts:

- **Tracked:** In Signal Review, tracked alert types are alerts for which product-event combinations require an initial signal review in the current period. After a refresh, tracked alerts have Reviewed/Total counts. Unreviewed alerts from a prior refresh are retained in the next refresh. If you submit a review of a product-event combination with an unreviewed tracked alert, the Reviewed count for that alert goes up.
- **Informational:** In Signal Review, non-tracked alert types are alerts for which product-event combinations do not require review. No tracking is performed; that is, these alerts do not contribute to Reviewed/Total counts. After a refresh, informational alerts only have a Total count. If you submit a review of a product-event combination with an unreviewed informational alert, Reviewed counts are not impacted.

You can base a configurable alert on product review period or on product complexity level. A configurable alert based on complexity level is calculated only when it is “due”; that is, based on each product’s birthdate and the alert periodicity.

Note

Scripted signal managements have built-in alerts, which are not configurable through the user interface and do not provide tracking.

Additional considerations for multisource configurations

In addition to the above criteria, when working with multisource signal configurations, you must set up and plan the [tracked alert type](#) and views.

Tip

Refresh the multisource configuration after setting them up to enable your configured alerts to be calculated.

Keyboard shortcuts for the Products and Product-Event Combinations tables

Using these keyboard shortcuts can facilitate your work with Signal Review.

To interact with the Products and Product-Event Combinations tables:

1. To set focus to the table, press **Tab** or **Shift+Tab**.
2. To navigate up or down rows in the table, press the **Up** or **Down** arrow.
3. To display the row action menu when a row has focus, press **Enter**.
4. To select a menu item, press **Enter**.
5. To dismiss the menu, press **Esc**.

To interact with cells in a row in the table:

1. To restrict focus within a table row, press **F2**.
2. To focus on the next or previous cell, press **Tab** or **Shift+Tab**.
3. To select a link or display a menu in a cell that is in focus, press **Enter**.
4. To turn off navigation within a table row, press **F2** again.

To interact with the table header:

1. To navigate to the table, press **Tab** or **Shift+Tab**.
2. To navigate to the table header, press the **Up** or **Down** arrow.
3. To display the header action menu, press **F2** and **Enter**.
4. To select a menu item, press **Enter**.
5. To dismiss a menu item, press **Esc**. To set focus back to the table header, press **Esc** again.

6. To navigate between header cells, press the **Left** or **Right** arrow.
7. To sort a table column, press **Enter**.

To interact with the select rows mode in the Product-Event Combinations table:

1. To restrict focus within a row, press **F2**.
2. To select or deselect a check box, press **Space**.
3. To exit focus from within a row, press **F2** again.
4. To select or deselect other rows, repeat steps above.

Step 1: Select a signal configuration

Selecting the configuration you want to apply is the first step in performing a signal review.

- [Choose a published configuration](#)
To use Signal Review, you must have access to a signal configuration. The signal configuration defines the behavior and content of the Signal Review page.
- [Why you might have multiple configurations](#)
There are a variety of public and company-specific pharmacovigilance databases that share a common conceptual organization (case reports that contain information on demographics, drugs, and events) but differ in details of field and table naming, presence or absence of specific attributes, and use of specific medical coding dictionaries.

Choose a published configuration

To use Signal Review, you must have access to a signal configuration. The signal configuration defines the behavior and content of the Signal Review page.

1. In the left navigation pane, click the **Signal Review** icon () to display the Products page. You can also get to the Products page by clicking the back arrow (↶) from the Product-Event Combinations page.
2. From the drop-down to the right of the Signal Review page title, choose a [signal configuration](#).

Why you might have multiple configurations

There are a variety of public and company-specific pharmacovigilance databases that share a common conceptual organization (case reports that contain information on demographics, drugs, and events) but differ in details of field and table naming, presence or absence of specific attributes, and use of specific medical coding dictionaries.

These configurations can be set up by expert users who are familiar both with the target database schema and the pharmacovigilance application; medical end-users work with the application-specific variables so defined (end-users do not need to be aware of the target database schema). Multiple configurations can support user access to several different databases; for example, to perform a data mining run—first, on the public data and, then, on in-house data, and also to several different versions of the same database; for example, different chronological snapshots or versions that include or exclude so-called “concomitant” medications.

To insulate both Oracle Empirica Signal and users from superficial variation in the detailed formatting of the target safety database, Oracle Empirica Signal supports multiple database

configurations, each of which defines a mapping between user-visible “variables” and specific database tables and columns, including specification of plausible roles for the variables (for example, a drug name, an event name, an attribute suitable for use in stratification or subsetting, etc.).

When Oracle Empirica Signal is installed, a master configuration table that contains all configurations for all source databases is created in another Oracle account. This master configuration table is populated automatically as configurations are added, copied, or imported. When a configuration is created, a configuration table is created automatically in the same Oracle account as the source data. Multiple configurations (and configuration tables) may exist for an Oracle account.

Step 2: Select a product, group of products, or multiple products to investigate

Selecting the products to investigate is the second step in performing a signal review.

- [Start with the Signal Review Products page](#)
The Signal Review Products page enables you to review comprehensive alert tracking statistics and visualize alerts for all monitored products.
- [Investigate products in the Products table](#)
On the Products table you can view and interact with data for individual and multiple products.
- [Group and filter products](#)
Using the Products By drop-down list and cards, you can group and filter the products included in the Products table.
- [Configure columns for the Products table](#)
On the Edit Signal Configuration page, you can edit the labels and descriptions of the columns on the Products page.
- [Find a product in the Products table](#)
With the Product finder, you can quickly locate a specific product in the Products table.
- [Enter a note about a product](#)
You can enter or edit notes about issues that have been identified and investigated for a product, signals that require further evaluation, or any information you want to associate with a product.
- [Focus on a single product from the Products table](#)
On the Products table, you can interact with individual products by viewing notes, event comments, and sector maps.
- [Focus on multiple products from the Products table](#)
Work in Select Rows mode to interact with multiple products by viewing notes and event comments.

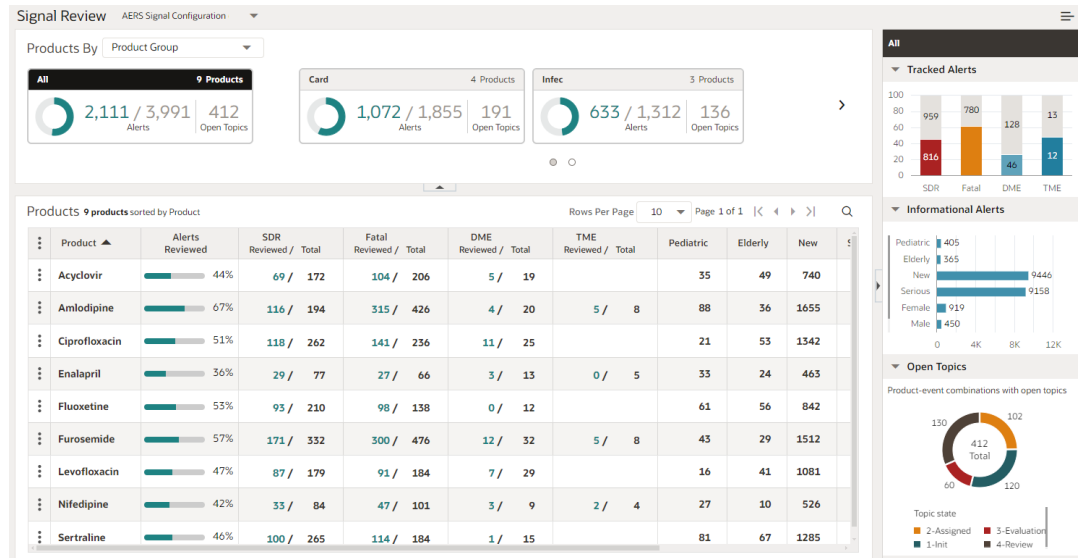
Start with the Signal Review Products page

The Signal Review Products page enables you to review comprehensive alert tracking statistics and visualize alerts for all monitored products.

On the Products page, you can use the Products By panel, Products table, and Detail panel to view and interact with your monitored products.

1. In the left navigation pane, click the **Signal Review** icon () to display the Signal Review Products page.

Figure 2-1 Signal Review Products page



2. From here you can group, filter, and search the products in the following ways:
 - [Group monitored products](#) by selecting one of the five product properties defined for the configuration using the **Products By** drop-down list. When you select a Products By property, the Products By cards update to match your selection.
 - Filter the Products table by selecting a card. This displays the matching products in the Products table and updates the Detail panel on the right to match your card selection.

Note

Oracle Empirica Signal remembers your card selections across sessions for the signal management configuration you are working with.

The Products table lists the products you are monitoring, filtered by your Products By card selection.

- [Search the table for a single product](#). This feature is useful when the Products table contains many entries. You can search for a particular entry in that Products table by selecting Find Product (



).

- [Customize the columns in the Products table](#), from the **Header Action menu** () by selecting **Columns**. You can select columns to include, reorder them, and sort the Products table using up to three different columns.

- [Download the Products table](#), from the **Header Action menu** () by selecting **Download**.
- Limit the table to [one or more product rows](#), from the **Header Action menu** () by selecting **Select Rows**.
- Perform additional actions on an individual product by [choosing an action from the product's Row Action menu](#) ().
- To see details about a product, click a non-linked value in the Products table row.

 Note

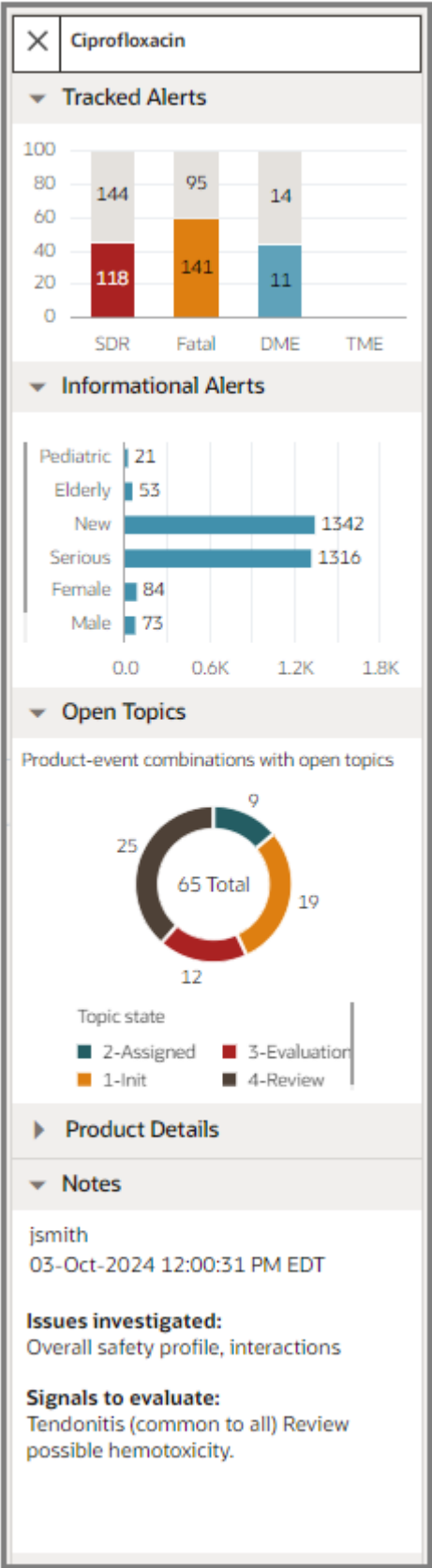
If you click a link in a table row, such as the product name or a total count, the [Product-Event Combinations page](#) displays.

- The Detail panel to the right of the Products table displays the information about your selected product.

 Note

Use the **Close** button, X, to return to the group detail.

Figure 2-2 Signal Review Detail Panel



The panel contains expandable sections appropriate to the selected item and signal configuration:

- The Tracked Alerts and Informational Alerts sections are always available.
- The Open Topics section is available if your signal configuration is integrated with Topics.
- The Product Details and Notes sections are available when you select a product.

You can show (▶) or hide (▼) the sections in the Detail panel.

Use the close button to return to the Group Detail.

Investigate products in the Products table

On the Products table you can view and interact with data for individual and multiple products.

The Products table displays products [grouped and filtered](#) by your selections in the Products By panel.

Figure 2-3 Products table

Products 9 products sorted by Product

Rows Per Page 10 Page 1 of 1

Product	Alerts Reviewed	SDR Reviewed / Total	Fatal Reviewed / Total	DME Reviewed / Total	TME Reviewed / Total	Pediatric	Elderly	New	Serious	Female	Male
Acyclovir	44%	69 / 172	104 / 206	5 / 19		35	49	740	729	67	35
Amlodipine	67%	116 / 194	315 / 426	4 / 20	5 / 8	88	36	1655	1625	124	38
Ciprofloxacin	51%	118 / 262	141 / 236	11 / 25		21	53	1342	1316	84	73
Enalapril	36%	29 / 77	27 / 66	3 / 13	0 / 5	33	24	463	452	56	18
Fluoxetine	53%	93 / 210	98 / 138	0 / 12		61	56	842	786	145	66
Furosemide	57%	171 / 332	300 / 476	12 / 32	5 / 8	43	29	1512	1483	169	46
Levofloxacin	47%	87 / 179	91 / 184	7 / 29		16	41	1081	1063	86	45
Nifedipine	42%	33 / 84	47 / 101	3 / 9	2 / 4	27	10	526	497	61	22
Sertraline	46%	100 / 265	114 / 184	1 / 15		81	67	1285	1207	127	107

Field descriptions—Products table

Field	Description
Summary line	Shows the number of products, the sort order, the number of rows per page, the current page number and total number of pages, and links to navigate between pages. If rows are filtered using the Where Clause in the columns dialog, the summary line displays the text (filtered) to indicate that rows are filtered.
Header row	Contains the Header Action menu and column headers. You can arrange these columns in any order and sort the contents of the columns.

Field	Description
Header Action menu	Provides options that apply to the entire table. • Columns: Select the columns to include in the table and specify the column sort order. • Download: Download the table data. • Select Rows: Select one or more product check boxes to limit the table to those products. While in Select Rows mode, actions apply to all the products selected. • Specify a SQL WHERE clause to filter the data in the table.
Alerts Reviewed	The cells in this column contain a progress gauge with the percent of reviewed tracked alerts associated with the product on that row. Oracle Empirica Signal calculates the percent reviewed from x/y: x = sum of reviewed tracked alerts. y = sum of all tracked alerts.
Alert columns	For tracked alerts, the number of alerts reviewed and the total number of alerts are displayed as Reviewed/Total. For informational alerts, only the total alert count is displayed.
Row for each product	Includes a Row Action menu and alert counts. The Total alert counts are links to further information about that alert, when not in Select Rows mode.
Row Action menu	Includes actions that provide access to product-specific activities.

Products table Row Action menu

The Row Action menu provides access to product-specific activities.

- [View Product-Event Combinations](#): Select this link from the Row Action menu, click a product name, or click a total alert count to investigate product-event combinations for the product.
- [Enter Note](#): Enter or edit a note for a product to indicate:
 - Issues that have been identified and investigated for the product.
 - Signals that require further evaluation.
- [View Notes](#): View notes that have been entered about the product.
- [View Event Comments](#): View comments entered about product-event combinations.
- [View Sector Map for a signal set](#): View a visual representation for a particular product across all System Organ classes (SOCs).

Note

When working with a multisource signal configuration, a menu option may appear for each configuration included in the multisource signal configuration. A prefix matching the secondary configuration label, [defined in the multisource signal configuration](#), identifies the secondary configuration menu option.

If you have the appropriate permissions, the following options also appear in the row action menu, enabling you to manage aspects of products.

- [Manage Targeted Medical Events](#): Maintain a list of adverse events your organization wants to closely monitor for a particular product. You must have the View Signal Management and the Manage Signaling Terms permissions. This applies to interactive and multisource signal configurations only.
- [Manage Listed Events](#): Maintain a list of adverse events listed on the product label. You must have the View Signal Management and the Manage Signaling Terms permissions to manage listed events. This applies to interactive and multisource signal configurations only.
- [Edit](#): Edit monitored product properties. You must have the View Signal Management and the Manage Signaling Terms permissions to perform this task.
- [Rename](#): You can rename monitored products if you have the View Signal Management and the Manage Signaling Terms user permissions. This applies to interactive and multisource signal configurations only.
- [Delete](#): When you delete a product, Oracle Empirica Signal removes it from the Products and Product-Event Combinations tables. Deletion will not succeed if there are notes for the product or comments about a product-event combination that include the product. You must have the Manage Signaling Terms user permission to delete a product.

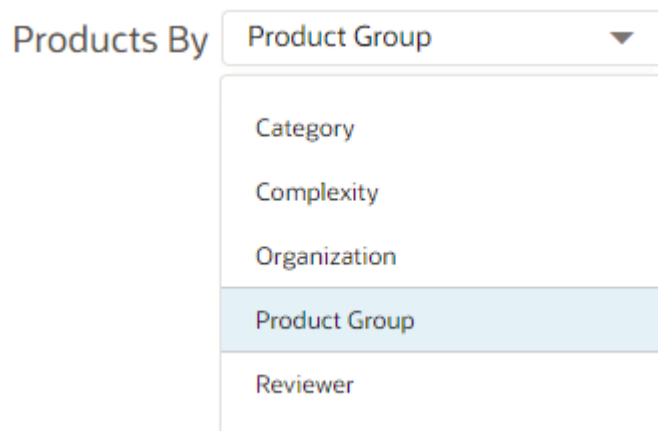
Group and filter products

Using the Products By drop-down list and cards, you can group and filter the products included in the Products table.

Use the Products By drop-down list on the Products page to group products you are tracking.

1. In the left navigation pane, click the **Signal Review** icon (.
2. From the **Products By** drop-down list, select a product property.

Figure 2-4 Products By drop-down list



- **Category**: Customer-definable product field value set when [adding or editing a product to monitor](#). A user with Manage Signal Configuration permission defines the acceptable [product field values](#). Examples include Drug, Vaccine, or Cosmetics, or separation by therapeutic use or chemical class.

- **Complexity:** Customer-definable product field value set when [adding or editing a product to monitor](#). A user with Manage Signal Configuration permission defines the acceptable [product field values](#). Complexity can be used in alert type definitions. Complexity level, periodicity, and birthdate determine if the alert type rule will be part of the data refresh. The default values are High, Medium, and Low. For example, a high-complexity-level product would get scheduled more frequently for review than a product with a lower complexity level.
- **Organization:** Customer-definable product field value set when [adding or editing a product to monitor](#). Your products can, optionally, be assigned to a (sub-)organization in the enterprise. For example, companies might define organizations for branded versus generic drugs, or regional products in an organization located in a separate country.
- **Product Group:** (Default) Customer-definable grouping set when the product was added or edited. Examples include therapeutic areas and cardiovascular products.
- **Reviewer:** Person responsible for reviewing the product-event combinations.

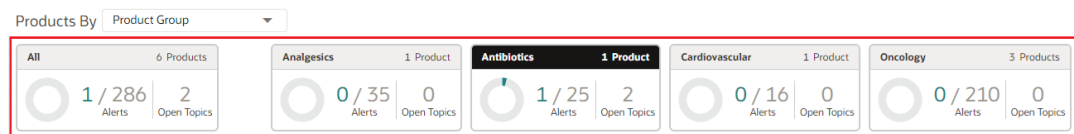
Note

The acceptable [values for customer-definable product fields are defined](#) by a user with Manage Signal Configuration permissions.

Oracle Empirica Signal remembers your Products By selections across sessions for the signal management configuration you are working with.

3. You can further filter the Products table by selecting one of the System Organ Class (SOC) cards displayed below the Products By drop-down.

Figure 2-5 System Organ Class (SOC) cards



The cards shown match your selected grouping. For each grouping, a card aggregates all products in that group and displays elements of the group.

You can move back and forth through the pages of cards by clicking the dots or page numbers below them. You can also scroll the cards using the left and right arrows.

Selecting a card filters the Products table to monitored products contained in that group.

The corresponding products appear in the Products table.

The Detail panel to the right also updates to reflect information relevant to the selection.

4. To remove the filter from the Products table and display all monitored products, select the **All** card.

To learn about the Products table fields and actions, see [Investigate products in the Products table](#).

Configure columns for the Products table

On the Edit Signal Configuration page, you can edit the labels and descriptions of the columns on the Products page.

1. In the left navigation pane, click the **Settings** icon ()
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action menu** () for the signal configuration, and then click **Edit Product Columns**.
4. To the right of a column row, click **Edit**.
5. Fill in the fields.
6. Click **Save**.

Field descriptions—Edit Product columns dialog box

Field	Description
Column name	Name of the column on the Products page.
Column label	Text to appear as the column heading.
Column tooltip	Description of a column. The description appears as a tooltip when you hover over the column label on the Products page.

Find a product in the Products table

With the Product finder, you can quickly locate a specific product in the Products table.

1. On the Product page, in the Products section, select the **Find product** icon (



).

2. In the **Find Product** box, find a product by doing one of the following:

- Click the downarrow (



) to select a product from the list.

- Start entering the product name to make the auto-complete menu appear, with product names that contain the characters you entered. When the product you are searching for appears, select it from the list.
- Enter the name of the product and select **Enter**.

Note

The Find Product list matches the products currently displayed in the Products table, including any [grouping and filtering](#) you have applied.

The Products table locates and selects the chosen product. The Details panel updates to display the product information.

Enter a note about a product

You can enter or edit notes about issues that have been identified and investigated for a product, signals that require further evaluation, or any information you want to associate with a product.

Note

If you work with multisource signal configurations, this is a shared feature. Changes will impact all connected configurations.

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **Enter Note**.
The Enter Product Note page shows the product you selected and the date when a note was last entered or edited. Today's date and current time indicate that this is the first note for this product. There is a text box for each type of note that you can enter.
4. Enter notes in the text boxes.
5. Click **Save**.

You can view the notes from the Row Action menu, Header Action menu, or the Detail panel.

- **From the Row Action menu:**

Select **View Notes**, from a selected product's **Row Action Menu** (.

- **From the Header Action menu:**

Select **View Notes**, from the Header Action menu () while in Select Rows mode.

- **From the Detail panel:**

Expand the Notes Section of the Detail Panel for a selected product row by selecting the down-arrow ()

) to left of the Notes heading.

Focus on a single product from the Products table

On the Products table, you can interact with individual products by viewing notes, event comments, and sector maps.

Note

To [review comprehensive product-event information and statistics](#), select a product and access its Product-Event Combinations page by one of these actions:

- Selecting **View Product-Event Combinations** from the product's **Row Action Menu** ().
- Clicking the product name.
- Clicking a total count in a cell in the Products table.

- [View notes about a product](#)
You can view the notes you entered for a product about issues that have been identified and investigated, signals that require further evaluation, or any additional information you associated with the product.
- [View event comments for a product-event combination](#)
If you added a comment to a product-event combination on the Product-Event Combinations page, you can view it from the product's Row Action menu on the Products page.
- [Use sector maps](#)
A sector map is a visual presentation of data for a particular drug across all System Organ Classes (SOCs).

View notes about a product

You can view the notes you entered for a product about issues that have been identified and investigated, signals that require further evaluation, or any additional information you associated with the product.

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Notes**.

The following information about each note appears on the View Notes page.

Column	Description
Product	Name of the product.
Entered By	Name of the user who entered the note.
Entry Date	The date that the version of the note was entered.
Link	A link to the actual note.

Notes are ordered by their entry date, with the most recent version of the note appearing first in the list.

4. Choose one of the following:
 - To view a note, click the **View Note** link in the last column on the right.
 - To view all notes for the product, click **View All Notes**.
5. Print or download the note.
6. Select **Close**.

View event comments for a product-event combination

If you added a comment to a product-event combination on the Product-Event Combinations page, you can view it from the product's Row Action menu on the Products page.

1. In the navigation pane on the left, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Event Comments**.
4. On the View Event Comments page, from the **View comments** drop-down list, select **All** or **Most Recent**.
5. If [private comments](#) have been enabled, from the **Comment type** drop-down list, select **Private**, **Public**, or **All**.
6. (Optional) To limit comments to a specific date range, enter a **Start date**, an **End date**, or both.
7. Click **Apply**.
8. Choose one of the following links:
 - To show information about the comments, select the **Show Notes** link. The notes appear below the table and Oracle Empirica Signal includes them if you print or download table data.
 - To exclude notes, select the **Hide Notes** link.
 - To save comments to a topic, click the **Save to Topic** link. The comments appear as an attachment to the topic.
 - Print or download the note.
9. To close the View Events Comments page, select **Close**.

Field descriptions—View Event Comments page

Field	Description
Product	Name of the selected product.
Event	Name of an event that is reported in combination with the product.
Created	Date and time the comment was added.
Created by	Name of the user who added the comment.

Field	Description
Filtered	• Yes, if you added the comment when the product-event combination was suppressed. • No, if you added a comment for a product-event combination that was not suppressed. • Empty (blank), for private comments (if the signal configuration has the private comments feature set up).
Comment	Comment for the product-event combination.
Private	Appears if the signal configuration has the private comments feature set up. • Yes, a private comment. • No, a public comment.
Detailed Comment	The optional free text description added with the comment. This column appears only if the Allow Case Comment/Review/Exclusion site option has been set up.

Use sector maps

A sector map is a visual presentation of data for a particular drug across all System Organ Classes (SOCs).

- [View a sector map for a product](#)
A sector map for signal management data is a visual presentation of data for a product across all System Organ Classes (SOCs).
- [Set display options for a sector map](#)
Once you have displayed the sector map, you can customize the display using the options accessible from the Options link provided below the sector map.
- [Zoom in on a sector map](#)
If you zoom in on a particular SOC tile in the sector map, data only for that SOC appears in the zoom window.
- [View sector map statistics](#)
You can view statistics for a specific PT tile.

View a sector map for a product

A sector map for signal management data is a visual presentation of data for a product across all System Organ Classes (SOCs).

- Each System Organ Class (SOC) is represented by a large tile in the sector map.
- Each SOC tile is divided into smaller tiles representing Preferred Terms (PTs).
- The color, size, and ranking of tiles provide a big picture overview of the adverse event profile of a product.
- Data represented in the sector map includes all available data up through the current time period and is for a particular signal set.

When you view a sector map for a product, PTs are ranked in descending order of values of the statistic (EBGM, EB05, Chi-statistic, or PRR) that you choose. A color key indicates relative ranking. You can also list the ranked PTs below the sector map.

1. In the left navigation pane, click the **Signal Review** icon ()
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select a **View Sector Map** option:

Note

If you are working from a [multisource signal configuration](#), options for each configuration included in the multisource signal configuration appear in the menu. You can identify the secondary configurations by the prefix that matches the secondary configuration label [defined in the multisource signal configuration](#).

4. To [set display options for the sector map](#), click **Options** below the sector map.
5. If you point to a PT tile, the MedDRA PT, HLT, HLGT, and SOC appear. The following information for the combination of the product and the term that the tile represents also appears:
 - **N**—Observed number of cases with term.
 - **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate. For more information, see [MGPS computations](#).
 - **EB05**—A value such that there is approximately a 5% probability that the true Relative Ratio lies below it.
 - **PRR**—Proportional Reporting Ratio. For more information, see [PRR computations](#).
 - **Chi-statistic**—Chi-statistic associated with PRR. (If EBGM < 1, the Chi-statistic is expressed as a negative number, indicating that the product-event combination is more rare than expected). The Chi-statistic is the signed square root of Chi-square.
6. To [zoom in](#) on a particular SOC, click anywhere on the SOC tile and select **Zoom** from the menu.
7. If you click a tile for which N is at least 1, a menu appears and you can [drill down](#) to cases that include the PT represented by the tile or view statistics for the tile.
8. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if the **Links** option is checked and the Topics feature has been set up.)
9. To close the Sector Map window, click **Cancel**.

For information about copying or printing a graph, see [Work with results graphs](#). For best results, print the sector map in landscape mode.

Set display options for a sector map

Once you have displayed the sector map, you can customize the display using the options accessible from the Options link provided below the sector map.

1. In the [Sector Map window](#), click **Options** (below the sector map).
2. Change any of the following options:

Column	Description
Color controlled by	Name of the statistic whose values is ranked and is used for coloring the sector map tiles. Possible values are any of the following that are available in the signal management data prepared for your organization: EBGM, EB05, PRR, Chi-statistic (signed).
Term box size controlled by	One of the following options indicating what controls the size of PT tiles: Relative importance of term—Bases the size of PT tiles on an algorithm that determines the relative public health impact of PTs. Using a recent version of AERS data, the public health impact for a PT is computed as: (number of times the PT occurs in serious cases) * (proportion of cases with that PT that are serious or fatal). A higher Public Health Impact score—Corresponds to a larger tile in the sector map. Because size is based on the number of cases of the PT alone (not the number of cases that have the PT and a particular product), the tile size is stable over sector maps for different products. Note For PTs that are new in the MedDRA version associated with the AERS data used to assess public health impact, the tile size cannot be determined. Such PTs are represented as small tiles. All terms have equal size—All PT tiles have the same size.
Display maximum intensity at signal score of	All tiles for which scores are above this value are displayed at the maximum-intensity color, as shown in the color key below the graph.
Use gray-scale instead of colors	Use only shades of gray in the color key to represent score ranking.
Show low scores in green for color graph	Check to show low scores in varying shades of green. Clear to show low signal scores in black.
	Note This setting has no effect if you display the sector map in gray-scale.

Column	Description
Omit rare terms used fewer than __ times in AERS	Number indicating how many times a PT must be in the AERS database (the same one used for Relative importance of term) for that PT to be shown in the sector map.
 Note The notes for a sector map indicate any rare terms that are omitted because of this restriction.	
Group by HLT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLT. If you also group by HLGT, the tiles for PTs are grouped by HLT within each HLGT.
Group by HLGT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLGT.
List __ top scores	Number indicating how many (up to 1000) terms with the top scores are ranked and listed below the sector map. The score is the statistic selected for Color controlled by. If multiple terms have the same score, each term is counted separately. For example, suppose that you enter 20 as the limit. If the 20th row has a score that other terms after that also have, those additional terms are shown as well.
Show top score indexes	If checked, tiles in the sector map are numbered to show their rank, up to the number of scores specified in List __ top scores . For this option to take effect, there must also be a value specified for List __ top scores .
Key	Display a color key below the graph.
Notes	Display information about graph display options below the graph.
Links	Show the following: • Information about what a tile represents when you place the mouse over the tile. • A menu that appears when you click a tile. • A Print link for printing the graph. • A Save to Topic link to save the graph as an attachment to a topic (if the topics feature has been set up). Before copying a graph (for example, with copy and paste functions), you might want to clear this check box so that links are not included in the copy.

3. Click **OK**.

Zoom in on a sector map

If you zoom in on a particular SOC tile in the sector map, data only for that SOC appears in the zoom window.

1. On the [sector map](#), click a SOC tile.
2. From the menu, click **Zoom**.
3. You can perform all the same actions as when [viewing the main sector map](#), except that you cannot zoom in further. Note that the ranking of PTs changes because you are viewing PTs for only one SOC.
4. To close the zoomed-in sector map, click **Cancel**.

View sector map statistics

You can view statistics for a specific PT tile.

1. On the sector map or in the zoom window, click a PT tile.
2. From the menu, click **Statistics**.

A dialog box appears showing the following statistics for the combination of the product and event:

- **N**—Observed number of cases.
 - **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate. For more information, see [MGPS computations](#).
 - **EB05**—A 5% probability value that the true Relative Ratio lies below it.
 - **PRR**—Proportional Reporting Ratio. For more information, see [PRR computations](#). The PRR and Chi-statistic are available only if the data mining run was set up to compute PRR.
 - **Chi-statistic**—Chi-statistic associated with the PRR. (If EBGM < 1, the Chi-statistic is expressed as a negative number, indicating that the product-event combination is more rare than expected). The Chi-statistic is the signed square root of Chi-square.
3. To close the dialog box, click **Close**.

Focus on multiple products from the Products table

Work in Select Rows mode to interact with multiple products by viewing notes and event comments.

- [Select multiple products in Select Rows mode](#)
You can focus on multiple products by accessing Select Rows mode then selecting multiple products from the Products page.
- [View notes about multiple products](#)
You can view all of the notes entered for the selected products on a single View Notes page, from the Header Action menu.
- [View event comments for multiple products](#)
You can view the comments for all selected products from the Header Action menu, if you added comments to product-event combinations on the Product-Event Combinations page.

Select multiple products in Select Rows mode

You can focus on multiple products by accessing Select Rows mode then selecting multiple products from the Products page.

Select Rows mode allows you to apply actions available from the Header Action menu to multiple products at the same time.

1. In the left navigation pane, click the **Signal Review** icon ()
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. At the top of the Products table, click the **Header Action menu** () and select **Select Rows**.
A check box appears to the left of each product in the table.
4. Select the check boxes of the products to include.

Note

[Use the Product finder](#) to locate specific products. You can also select all or clear all selections from Header Action menu.

The Details panel updates to show the number of products selected. The information shown for tracked alerts, informational alerts, and open topics covers all the products selected.

5. From the **Header Action menu** () select the action to perform on all the selected rows.
These include:
 - **Select All:** To include all products.
 - **Clear All:** To clear all selected products and make select different products.
 - **Exit Selection Mode:** To return to focusing on a single product in the Products page.
 - **View Product-Event Combinations:** To [display the Product-Event Combinations page](#) in multi-product selection mode.
 - **View Notes:** To open the View Notes window and [include notes for all of the selected products](#).
 - **View Event Comments:** To open the View Event Comments window and [include event comments for all of the selected products](#).
 - **Download:** To [download the selected product information](#) to various types of files.

View notes about multiple products

You can view all of the notes entered for the selected products on a single View Notes page, from the Header Action menu.

1. On the Products table, with [Select Rows mode activated and multiple products selected](#), click the **Header Action menu** () and select **View Notes**.

The following information about each note appears on the View Notes page.

Column	Description
Product	Name of the product.
Entered By	Name of the user who entered the note.

Column	Description
Entry Date	The date that the version of the note was entered.
Link	A link to the actual note.

Notes are ordered by their entry date, with the most recent version of the note appearing first in the list.

2. Choose one of the following:
 - To view a note, click the **View Note** link in the last column on the right.
 - To view all notes for the products, click **View All Notes**.
3. Print or download the note.
4. Select **Close**.

View event comments for multiple products

You can view the comments for all selected products from the Header Action menu, if you added comments to product-event combinations on the Product-Event Combinations page.

1. In the navigation pane on the left, click the **Signal Review** icon ().
2. On the Products table, with [Select Rows mode activated and multiple products selected](#), click the **Header Action menu** () and select **View Event Comments**.
3. On the View Event Comments page, from the **View comments** drop-down list, select **All** or **Most Recent**.
4. If [private comments](#) have been enabled, from the **Comment type** drop-down list, select **Private**, **Public**, or **All**.
5. (Optional) To limit comments to a specific date range, enter a **Start date**, an **End date**, or both.
6. Click **Apply**.
7. Choose one of the following links:
 - To show information about the comments, select the **Show Notes** link. The notes appear below the table and Oracle Empirica Signal includes them if you print or download table data.
 - To exclude notes, select the **Hide Notes** link.
 - To save comments to a topic, click the **Save to Topic** link. The comments appear as an attachment to the topic.
 - Print or download the note.
8. To close the View Events Comments page, select **Close**.

Field descriptions—View Event Comments page

Field	Description
Product	Name of the selected product.
Event	Name of an event that is reported in combination with the product.

Field	Description
Created	Date and time the comment was added.
Created by	Name of the user who added the comment.
Filtered	• Yes, if you added the comment when the product-event combination was suppressed. • No, if you added a comment for a product-event combination that was not suppressed. • Empty (blank), for private comments (if the signal configuration has the private comments feature set up).
Comment	Comment for the product-event combination.
Private	Appears if the signal configuration has the private comments feature set up. • Yes, a private comment. • No, a public comment.
Detailed Comment	The optional free text description added with the comment. This column appears only if the Allow Case Comment/Review/Exclusion site option has been set up.

Step 3: Review product-event combinations for a product or multiple products

The Product-Event Combinations panel is a set of tables that represent views of the product-event combinations assembled from the current Refresh runs, as well as rows from previous refreshes which have either unreviewed alerts or comments.

You access the Product-Event Combinations page from the [Investigate products in the Products table](#).

- [Start with the Product-Event Combinations page](#)
On the Product-Event Combinations page, you can review comprehensive product-event information and statistics for a single or multiple products.
- [Investigate product-event combinations for a single product or multiple products](#)
The Product-Event Combinations page is a set of tables, accessed after selecting one or more products from the Products page.
- [Review product-event combinations from a multisource configuration](#)
As an extension of interactive signal configuration, multisource signal configurations enable you to perform safety surveillance across multiple data sources.

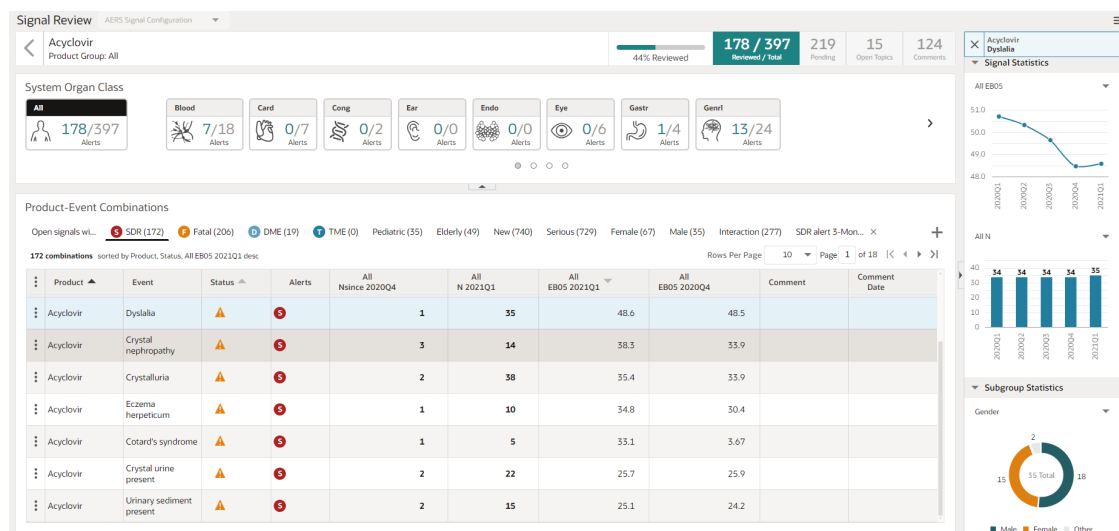
Start with the Product-Event Combinations page

On the Product-Event Combinations page, you can review comprehensive product-event information and statistics for a single or multiple products.

You access the Product-Event Combinations page from the [Products page](#) by selecting one or more products.

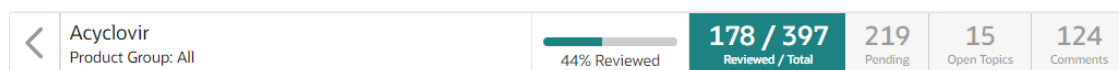
The Product-Event Combinations page appears.

Figure 2-6 Product-Event Combinations page



Product Summary information (across the top): Product statistics appear here with the product name and Products By group, product group, percentage reviewed gauge, count of reviewed/total tracked alerts, the number of pending (unreviewed) alerts, product-event combinations associated with open topics (available if the signal configuration is integrated with Topics), and count of product-event combinations with comments.

Figure 2-7 Product Summary information

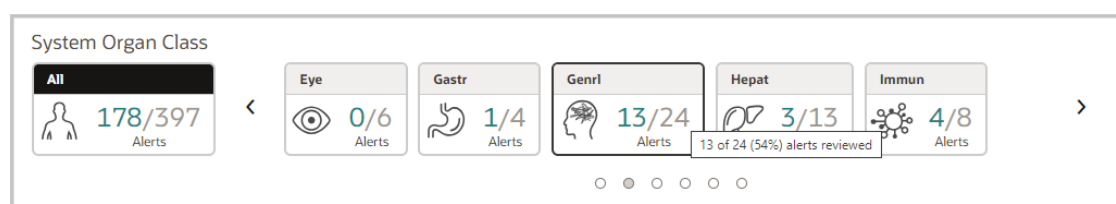


Note

In Select Rows mode with multiple products selected, the summary includes the names of the selected products and the statistics includes the counts for all the selected products.

System Organ Class (SOC) cards: The cards represent the alerts grouped by MedDRA system organ class. The counts represent Reviewed/Total tracked alerts. Selection of a card filters the Product-Event combinations table. If you are in Select Rows mode with multiple products selected, the SOC cards show the sums of alerts across all the products selected.

Figure 2-8 System Organ Class (SOC) cards



Note

If you select an SOC card while in Select Rows mode with multiple product-event combinations selected you will exit Select Rows mode.

Product-Event Combinations panel and tabs: The Product-Event Combinations panel is a set of tables. When investigating a single product, there is a tab above the table for each active alert type. Selecting a tab changes the content of the Product-Event Combinations table. Because alert tabs are based on a particular review for a single product, you won't see alert tabs when you initially access a Product-Event combinations table for multiple products. However, you can [add tabs and views](#) to that table.

Figure 2-9 Product-Event Combinations panel and tabs

Product-Event Combinations

Open signals wi... **S** SDR (172) **F** Fatal (206) **D** DME (19) **T** TME (0) Pediatric (35) Elderly (49) New (740) Serious > +

206 combinations sorted by Fatal N 2021Q1 desc, Fatal Nsince 2020Q4 desc, Status desc Rows Per Page 10 Page 3 of 21 < << >> >

	Product	Event	Status	Alerts	Fatal Nsince 2020Q4	Fatal N 2021Q1	Fatal EB05 2021Q1	All N 2021Q1	Comment	Comment Date
⋮	Acyclovir	Gastrointestinal nonspecific inflammation and dysfunctional conditions (SMQ) [narrow]	✓	F	1	119	1.33	1407	Bring to Meeting	03-Oct-2024 11:23:16 AM EDT
⋮	Acyclovir	Malignancies (SMQ) [narrow]	✓	F	7	116	0.649	303	Of Note	03-Oct-2024 11:44:13 AM EDT
⋮	Acyclovir	Haemodynamic oedema, effusions and fluid overload	✓	F	1	116	1.60	569	Of Note	03-Oct-2024 11:24:56 AM EDT

Each Product-Event Combinations tab is associated with a view or alert type rule. The view or alert type rule determines the columns, rows, and sort order of the tab's table. As you select a tab, a summary line appears below the row of tabs showing the number of combinations, the sort order, the number of rows per page, and the page number. You can add tabs, change pages, and [customize the columns](#).

Columns and cells:

- If the configuration is multisource, there can be columns for the Lead and Secondary configurations.
- The Status column indicates if the product-event combination has been reviewed and if there is a topic for the product-event combination.
- The Alerts column indicates which tracked alerts relate to the product-event combination in the most recent refresh. The icon color and letter were set up when the alert type was created and match the icons in the tabs. In the example above, F stands for Fatal and D for Designated Medical Event.
- Click the **hyperlinked (bold) value in a cell** to display a menu to drill down to case-specific information. Menu items include:
 - [View Cases](#)

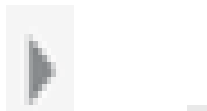
- [Create Case Series](#)
- [Transfer to Case Series](#)
- [Download Cases](#)
- [Download Case Details](#)
- [Reports](#) to view a list of reports about cases and generate a report.

Detail panel: The Detail panel on the right graphically depicts Recent History, Signal Statistics, Subgroup Statistics, and Associated topics for the selected product-event combination. Topics appear only if your configuration is integrated with Oracle Empirica Topics.

Figure 2-10 Detail panel



You can select different variables to graph, such as All EB05, Age Group, or Gender, using the drop-down lists in the Signal Statistics or Subgroup Statistics sections. To perform further actions on the data associated with a bar or donuts slice, click the bar or slice to display the Action menu. You can select **View Cases** or other actions related to case series and reports.



You can show () or hide (▼) the sections in the Detail panel. If you add a comment or change the associated topic information, the panel updates.

The **Detail panel header** displays the Product-Event name and indicates if the event is a Listed, TME, DME, or IME event.

The sections include:

- **Recent History:** Displays the most recent product-event alert and comment information plus up to two other rows of alert and comment information. It also includes a link to the Signal History page.
- **Signal Statistics:** Displays two graphs: a line graph for the chosen statistic and a bar graph for the chosen count. You can update the graph by selecting a different statistic, count, or subgroup. If you are working with a [multisource signal configuration](#), statistics from lead and secondary configurations are available. You can drill down to cases and generate reports from the bars in the bar chart.
- **Subgroup Statistics:** Displays a doughnut chart of case counts for a subgroup, such as a Gender. You can update the graph by selecting a different subgroup. If you are working with a [multisource signal configuration](#), statistics from the lead and secondary configurations are available. You can drill down to cases and generate reports from the sections of the pie chart.
- **Associated Topic:** Displays information about a topic if associated with the product-event combination, including counts of open and overdue actions. Click  to view the topic in the Topic Viewer.

Actions you can perform on the Product-Event Combinations table include:

- [View product-event combinations for a card or tab](#)
Use cards and tabs to choose the specific data to display on the product-event combinations table.
- [Configure columns for the product-event combinations table](#)
Signal summary columns appear on the product-event combinations table. When Signal management is set up for your organization, you can edit the column labels, descriptions, and tooltips for the table.
- [Limit the product-event combinations to a specific alert type](#)
You can limit the Product-Event Combinations table to a specific alert type by clicking a tab above the table.
- [Add a tab to the Product-Event Combinations panel](#)
Use tabs to choose the specific data to display on the product-event combinations table.
- [Create a new view in the Add tab menu](#)
Save your table configurations for easy access.
- [Apply actions to multiple rows with Select Rows mode](#)
Apply actions to multiple Product-Event Combinations table rows simultaneously.
- [Product-event combination statistics](#)
Learn about the statistical scores for product-event combinations.

View product-event combinations for a card or tab

Use cards and tabs to choose the specific data to display on the product-event combinations table.

You can filter the product-event combinations panel to a specific System Organ Class by selecting a System Organ Class card. The Product-Event Combinations tables only include events for the selected System Organ class.

In the product-event combinations panel, select a tab to display a specific product-event combinations table determined by the [tab view](#).

To add tabs to the product-event combinations panel for views [created by](#) or made public to you, click the **Add Tab** (+) icon to the right of the tabs.

Some of the values in the table are links to a menu for [drilling down to case detail and reports](#).

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Select the product, click the **Row Action menu** (⋮) icon, and select **View Product-Event Combinations**, or click the product name or total count.
4. View the product-event combinations for a tab by selecting the **All SOC** card or filter the product-event combination tables by selecting a specific SOC card. For example, to view only product-event combinations for blood and lymphatic symptom disorders, click the Blood card. The Product-Event Combinations panel refreshes to include only the combinations for that SOC.
 - The number of combinations, the sort order, the rows per page, and the number of pages in the table appear under the row of tabs.
 - By default, the table contains Status and Alerts columns. These columns show the review status and alerts associated with the product-event combination.
5. Click a tab to display the product-event combinations for that tab.
 - The default view tab, if available, includes the view's name only.
 - Tracked alert tabs include an alert icon (letter and color as defined by the alert type definition), an alert name and a count.
 - Informational alert tabs include the alert name and a count.
 - Alerts in scripted signal configurations show the alert name only.
 - Added tabs show the view name only.
 - Hover on the tab to show details. If the tab is for a configured alert, then the hover text includes "Alert based on review period or complexity level."
 - The Status column shows whether the product-event combination needs to be reviewed or has been reviewed. If Topics has been integrated with this configuration, the Status column indicates whether a topic has been associated with the combination, by the presence of the () icon.
 - The Alerts column contains an icon for each tracked alert type that was raised in the most recent refresh or any unreviewed tracked alert from a previous refresh.

6. [Drill down on the case details](#) for any product-event combination by clicking the case total in any column and selecting an item from the drop-down menu.
7. [Rearrange the columns](#), [download](#) the table, perform [operations on multiple rows](#) in the table, and save the table as a view from the **Header Action menu** ().

Configure columns for the product-event combinations table

Signal summary columns appear on the product-event combinations table. When Signal management is set up for your organization, you can edit the column labels, descriptions, and tooltips for the table.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action menu** () for the signal configuration, and then click **Edit Product-Event Columns**.
4. Click **Edit** for a column.
5. Edit the fields according to the table below.
For more information, see the field descriptions below.
6. Click **Save**, and then click **Close**.

Field descriptions—Edit Product-Event Columns dialog box

Field	Description
Column name	Name of the column on the Product-Event Combinations page. The name can appear in the tooltip when you hover on the column header if [%COLCODE] is included in the column description.
Column description	Description of a column on the Product-Event Combinations page. The description appears as a tooltip when you hover on the column label.
Column label	Text to appear as the column header on the Product-Event Combinations page.

Limit the product-event combinations to a specific alert type

You can limit the Product-Event Combinations table to a specific alert type by clicking a tab above the table.

Under the tab, the Product-Event Combinations table displays only product-event combinations for that alert type. The columns also reflect the alert type.

Some of the values in the columns are links to a menu for [drilling down to case detail and reports](#).

Add a tab to the Product-Event Combinations panel

Use tabs to choose the specific data to display on the product-event combinations table.

The Product-Event Combinations panel is a set of tables. When investigating a single product, there is a tab above the table for each active alert type. Selecting a tab changes the content of the product-event combinations table.

Each product-event combinations tab is associated with a view or alert type rule. The view or alert type rule determines the columns, rows, and sort order of the tab's table. As you select a tab, a summary line appears below the row of tabs showing the number of combinations, the sort order, the number of rows per page, and the page number.

1. In the left navigation pane, click the **Signal Review** icon ()
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.

All product-event combinations that satisfy the selected SOC filter and meet the condition stated in the selected tab's associated view appear in the Product-Event Combinations panel.
4. To add a tab, click the  sign to the right of the tabs.
5. Choose from a list of tabs.
 - A tab for the selected view is added as the right-most tab.
 - You can hover over the tab to see the associated view's full name and description.
 - Added tabs do not have row counts included. Only tabs defined by tracked alert types display counts.
 - You can click the X at the right of the tab to remove the tab.

The added tabs are retained when returning to the page for any product.

If you add a tab, check [Arrange table columns and rows](#). An asterisk appears to the right of the tab name to indicate that it has changed from the original view. Select **Reset View to Default** in the Header Action menu to restore the tab to the original view.

Create a new view in the Add tab menu

Save your table configurations for easy access.

A signal view specifies the following for the Product-Event Combinations page:

- Which columns are included.
- The sort order of columns.
- The SQL WHERE clause (if any) that applies selection criteria to product-event combination rows.

When you save the view, you can assign it to a category. These categories populate the Add tab menu.

Note

At least one refresh should be run before creating views. You must have at least Manage Signal Views permission to make the view public to your login group. User must have the **Allow SQL Where Clause on the Signal Review page** user preference enabled to modify a view's SQL Where clause.

1. In the left navigation pane, click the **Signal Review** icon ()
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. Use the Add tab menu to add the tab whose view you want to modify or select a tab whose view is similar to the one you want to create.
5. In the **Product-Event Combinations** panel, with the new tab selected, click **Columns** in the **Header Action menu** () , [arrange the columns](#), and sort the columns as you would like them to appear in the view. If available, you can [Specify a SQL WHERE clause](#). Once satisfied with the modification, use the **Save As View** option to either replace the existing view or create a new one. See Step 6.

Note

After changing the SQL Where clause, the tab label is appended with an asterisk and text above the table contains ***(modified)**.

6. From the **Header Action menu** () , click **Save As View**.
 - To replace the existing view, select the **Replace existing view** check box.
 - To create a new view, leave the **Replace existing view** check box unselected.

Note

If you replace a view, the view is available to all users who have access to the original view, and replaces user customization of that view. If you create a new view, it is only available to you until you publish the view.

7. In the **Name for view** field, enter a name for the signal view.

Note

If the signal configuration has the review period feature set up, each view name should include the length of the review period; for example, New Cases (3 months), New Cases (6 months), New Cases (1 year), and so on.

8. In the **Description** text box, enter a description to appear as hover text when the view's tab is added.
9. Assign the view to a category. The category determines the view's location on the Add tab menu.
 - To assign the view to an existing category, click **Add to existing category** and select a category that you created from the drop-down list.
 - To create a new category and assign the view to it, click **Add to a new category named** and enter a category name. The category name must be unique for the signal configuration.

See [Organize signal views](#) for information about ordering categories and ordering views within categories. See [Maintain signal views](#) for information about publishing views.

10. Click **OK**.

Oracle Empirica Signal saves the view and adds it to the list of views available in the Add Tab menu. The view can now be used when adding a tab to the Product-Event Combinations panel.

Apply actions to multiple rows with Select Rows mode

Apply actions to multiple Product-Event Combinations table rows simultaneously.

Select Rows mode allows you to apply actions available from the Header Action menu to multiple rows at the same time.

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. To apply Row Action menu choices to multiple the rows of the Product-Event Combinations table, select the **Header Action** menu () and then select **Select Rows**.
5. Select the check boxes of the rows to include.
6. Select the **Header Action** menu () and select the action to perform on all the selected rows.

Submit Review, Save To Topic, Add Comment, Add Private Comment, Download, Create Case Series, Transfer To Case Series, and Reports are available in the Header Action menu while in Select Rows mode.
7. Perform the tasks to complete the action you selected.
8. To turn off Select Rows mode, from the **Header Action** menu () select **Exit Selection Mode**.

Product-event combination statistics

Learn about the statistical scores for product-event combinations.

If you are working with a [multisource signal configuration](#), columns from the secondary configuration are also available. You can identify the secondary configuration columns in the list by the prefix matching the secondary configuration label [defined in the multisource signal configuration](#).

Field descriptions—Statistical score

The columns available in the Product-Event Combinations table depend on your setup and your specific configuration.

The Product-Event Combinations columns dialog will contain Statistical scores for the each underlining configuration. The lead's statistical scores will be as listed in the table. In addition there will be stat columns for each Secondary interactive signal configurations or SISM. The column names have the SISM label as a prefix. See image below, the SISM has the label VB AM.

The statistical scores that might appear for each product-event combination include the following:

Field	Description
CHISQ	Chi-square.
DRUG_NAME	Common name of product.
DRUG_TERM	Product term.
EB05	The 5 percent confidence interval for the EBGm: A value such that there is approximately a 5% probability that the true Relative Ratio lies below it. The interval from EB05 to EB95 might be considered to be the 90% confidence interval.
EB95	The 95 percent confidence interval for the EBGm: A value such that there is approximately a 5% probability that the true Relative Ratio lies above it. The interval from EB05 to EB95 might be considered to be the 90% confidence interval.
EBGM	Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate, computed as the geometric mean of the posterior distribution of the true Relative Ratio. For more information, see MGPS computations .
ER05	The 5 percent confidence interval for the ERAM: A value such that there is approximately a 5% probability that the true Relative Ratio lies above it. The interval from ER05 to ER95 might be considered to be the 90% confidence interval.
ER95	The 95 percent confidence interval for the ERAM: A value such that there is approximately a 5% probability that the true Relative Ratio lies above it. The interval from ER05 to ER95 might be considered to be the 90% confidence interval.

Field	Description
ERAM	Empirical-Bayes Regression-adjusted Arithmetic Mean. The shrunken observed-to-expected reporting ratio adjusted for covariates and concomitant drugs. For more information, see RGPS computations .
ERAM to EBGM Ratio	Computed as ERAM / EBGM. A high ratio could be an indication that masking by other signals is suppressing non-regression-corrected scores for this PEC.
N	Observed number of cases with the combination of items.
Nsince	Number of new reports (since the date indicated in the header). If a value in this column is underlined, you can click the value to drill down to case information.
PRR	Proportional Reporting Ratio for the combination of a particular product and particular event. For more information, see PRR computations .
PRR_CHISQ	Chi-square of PRR.
PVALUE	P value for chi square statistic for PRR.
RGPS	Regression-Adjusted Gamma Poisson Shrinker. RGPS is a hybrid algorithm, which combines the methodology of Extended Logistic Regression (ELR) and MGPS. For more information, see RGPS computations .
ROR	Reporting Odds Ratio. Computed as: $ROR = (PRR\_A * PRR\_D) / (PRR\_B * PRR\_C)$ With stratification, ROR is computed as a weighted average of the ROR within each stratum. For more information, see ROR computations .
ROR05	Lower 5% confidence limit for ROR.
ROR95	Upper 5% confidence limit for ROR. The interval from ROR05 to ROR95 might be considered to be the 90% confidence interval.
Trnd1	YES/NO flag: EB05 score for the most recent time period is at least 1.5, EBGM score based on all reports increased and current EBGM confidence interval does not overlap the EBGM confidence interval.
Trnd2	YES/NO flag: EB05 score for the most recent time period is at least 1.5, EBGM score based on all reports increased by at least 50%.

Column descriptions—Alert and review information for the product-event combination

Alert and review information for the product-event combination depend on the signal configuration setup and may include the following columns:

Column	Description
Alert	An Alert column appears for each Alert type with the Alert Flag value set as follows: YES - The alert criteria are met in the most recent refresh. P - The alert criteria are not met in the most recent refresh, but unreviewed tracked alerts exist from prior refreshes. null - The alert criteria are not met in the most recent period, and there are no unreviewed tracked alerts from previous refreshes.
Alerts	Tracked alerts triggered for each refresh. Click the alert icon to see detail information for the alert.
Comment	The most recent predefined comment added to the combination.
Comment Date	Date and time when the most recent comment was added.
Detailed Comment	The optional free text description added with the comment. This column appears only if the corresponding site option has been set.
Filter	Yes, if you added the comment when the product-event combination was suppressed. No, if you added a public comment when you were documenting your review, or when you un-suppressed the product-event combination. - Empty (blank), for private comments.
Private Comment	The predefined private comment added to the combination.
Private Comment Date	Date and time when the most recent private comment was added.
Reviewer	Person assigned to review this drug-event combination.
Status	Displays two icons: - An alert status icon, if a tracked alert is associated with this combination. This icon shows whether the alert has been reviewed. - A topic icon, if a topic is associated with this combination. Click to view the topic.

Column descriptions—Topic information for the product-event combination

If signal management is integrated with topics, the table also includes the following columns:

Column	Description
Topic Name	Topic name and ID associated with the product-event combination.
Topic State	Current state of the topic.

Column descriptions—from MedDRA

The table may also include additional columns populated using the MedDRA dictionary associated with the data:

Column	Description
Event Term Change Description	If applicable, description of MedDRA dictionary change affecting this product-event combination.
Event Term Change Flag	Coded value indicating if a MedDRA change (previous to current version) affected this product-event combination.
HLGT	Event High Level Group Term.
HLT	Event High Level Term.
IME	Flag value set to YES if the event is a MedDRA Important Medical Event.
SOC	Abbreviated Event System Organ Class.
SOC Desc	Event System Organ Class.

Column descriptions—other columns

Other additional columns that might appear include the following:

Column	Description
DME	Flag value set to YES for designated medical events.
Event	Name of the event.
Lst	Flag value set to YES for listed drug-event combinations.
Max INTSS	Maximum interaction signal score.
Product	Name of the product.
TME	Flag value set to YES for targeted medical events.

Investigate product-event combinations for a single product or multiple products

The Product-Event Combinations page is a set of tables, accessed after selecting one or more products from the Products page.

Note

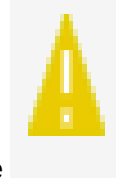
The behavior of actions you take with a single or multiple products on the Product-Event Combinations page is the same. The differences occur depending on whether you use Select Rows mode or not. If you select a single product in Select Rows mode, you have access to the same options as with multiple products.

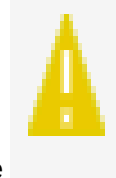
Each tab represents a view of the Product-Event Combinations assembled from the current Refresh runs, as well as rows from previous refreshes which have either comments or unreviewed alerts. By default, for single products, there is a tab for each active alert type. You can add more tabs using the Plus icon on the right. Selecting a tab changes the content of the Product-Event Combinations table.

- The first tab in the Product-Event Combinations table is the product's default view or the signal configuration's default view when either no product view is specified or multiple products are selected.
- Each tab contains the table for that alert type or signal view and reflects the current product and SOC selection. Hover over an alert tab for details about that alert type or view.

If you are working with a multisource signal configuration, keep in mind the [special considerations for multisource signal configurations](#) as you perform the actions below.

- **View product-event combinations for an alert type or view**



Select a product-event combination with the  icon in the **Status** column. The icon denotes that the product-event combination has alerts that haven't been reviewed.



- The  icon denotes that alerts have been reviewed.



- The  icon denotes that topics are associated with the product-event combination.

An alert type tab displays combinations that raised the alerts of this type in the current refresh, as well as unreviewed alerts raised in a previous refresh. The columns reflect the alert type's view. The view shown in an alert tab is based on the alert type's rules and the selected product's review period or complexity level/birthday properties. By default, for each view, the table shows the product, event, status, alerts, statistics, and comments columns.

- **View the detail panel for a product-event combination**

Select a row in the product-event combinations table to display information in the Detail panel.

From the Detail panel, you can review Recent History, Signal Statistics, Subgroup Statistics, and Associated topics for the selected product-event combination.

- **View cases and reports**

Some values in the table are [links to a menu for drilling down to case information and reports](#). Most case counts presented in the table support drilling down for detailed information and open a menu to view or perform operations on the underlying set of cases. Numbers with this capability are displayed in **bold**, and a down-arrow appears when you hover over the field.

- [View Cases](#): Lists cases associated with the count shown in the table. The information shown is customizable through the data configuration. On the View Cases page, if you click the case ID or the value in the ISR column, the Case Details page displays with

the case information. You can select **Next** or **Prior** to move to the next or previous case in the series.

- [Create Case Series](#): On pages and in reports that display a list of cases identified by case ID, you can save the list of cases for future use. The named and saved list of cases is referred to as a case series.
 - [Transfer to Case Series](#): On pages and in reports that display a list of cases, you can transfer cases to an existing case series.
 - [Download Cases](#): When you view a table of cases, you can download the information to various types of files.
 - [Download Case Details](#): When you view case details, you can download the information to various types of files.
 - [Reports](#): This choice displays a list of available reports. To run the report, select a report, click the **Row Action menu** (), and select **Run**.
- **Customize the columns in the Product-Event Combinations table**

Click the **Header Action menu** () and select **Columns**. You can [select columns to include, reorder them, and sort the table](#) using up to three different columns. See [Product-event combination statistics](#).
 - **Download the Product-Event Combinations table**

Click the **Header Action menu** () and select **Download**. You can specify a file name, the format to use, the maximum number of rows, and create a Zip archive file.
 - **Apply Row Action menu choices to multiple rows of the Product-Event Combinations table**

Click the **Header Row menu** () and choose **Select Rows**. Then select the check boxes of the rows to include. Click the **Header Action menu** () and select the action to perform on all the selected rows.
 - **Save your selections as a view that you can reuse**

Click the **Header Action menu** () and select **Save As View**. The saved view is available under the **Add Tab** (). A signal view specifies the following for the Product-Event Combinations page:

 - Which columns are included.
 - The sort order of columns.
 - The SQL WHERE clause (if any) that applies selection criteria to product-event combinations.
 - **Perform additional actions on this product-event combination**

Choose an action from the **Row Action menu** ():

 - [Submit Review](#): Review a product-event combination, add a comment, and associate a topic (optional). If the product-event combination had unreviewed tracked alerts then, upon completion of Submit Review, the tracked alerts are considered reviewed and alert reviewed counts are updated.
 - [Edit Topic](#): If the product-event combination has been reviewed and associated with a topic, edit the associated topic.

- [Add Comment](#): Add a comment visible to all for the product-event combination.
- [Add Private Comment](#): Add a comment visible only to you for the product-event combination.
- [Assign Reviewer](#): Select a reviewer for the specific product-event combination.
- [View Signal History](#): Display a graphic and detailed summary of the statistics associated with the product-event combination.
- [View Similar Combinations](#): View the statistical information for combinations involving the same product and the same HLT, HLGT, or SOC as that of the PT in the original combination.
- [View Interactions](#): Information about an event and product interactions is represented as a nested confidence interval graph of EB05-EB95 confidence intervals and EBGm values for two products and the event.
- [View Age Group Breakdown for a Signal Set \(such as All\)](#): The breakdown of case data by age group or gender for a product-event combination is represented in a bar graph.
- [View Gender Breakdown for a Signal Set \(such as All\)](#): The breakdown of case data by gender for a product-event combination is represented in a bar graph.
- [View the details of a Signal Review alert](#)
You can click an alert icon in the Signal History comments table, or from Submit Review, to see the detailed information that triggered creation of an alert.
- [View product-event interactions](#)
Information about an event and drug interactions is represented as a nested confidence interval graph of EB05-EB95 confidence intervals and EBGm values for two drugs and the event.
- [View signals for similar product-event combinations](#)
You can view the statistical information for combinations involving the same product and the same HLT, HLGT, or SOC as that of the PT in the original combination.
- [View age group breakdown for a product-event combination](#)
The breakdown of case data by age group for a product-event combination is represented in a bar graph.
- [View gender breakdown for a product-event combination](#)
The breakdown of case data by gender for a product-event combination is represented in a bar graph.
- [Assign a reviewer to a product-event combination](#)
You can assign a reviewer to a product-event combination. To assign a reviewer, you must have the Manage Signaling Terms permission.
- [Add a comment](#)
You can add a comment to a product-event combination on the Product-Event Combinations page.
- [Add a comment to multiple combinations](#)
Use the Select Rows option to add comments to multiple product-event combinations.
- [View your signal review history](#)
Oracle Empirica Signal maintains a signal review history that includes the tracked alerts marked as reviewed at the time each comment was submitted as well as statistics about the cases reviewed.

- [Suppress a product-event combination](#)

You can suppress a product-event combination so that it is not included on the Product-Event Combinations page.

View the details of a Signal Review alert

You can click an alert icon in the Signal History comments table, or from Submit Review, to see the detailed information that triggered creation of an alert.

1. In the left navigation pane, click the **Signal Review** icon ().
2. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.
3. Click the product-event combination's **Row Action Menu** () and click **View Signal History** or **Submit Review**.
4. From the Alerts column, click an alert type icon to display details about that specific alert. There is no limit to the number of Alert Details windows you can open.

Details include the date the alert was created, its name and a description, the alert rule it is based on, the complexity level, and the condition that triggered it.

A table displays one row with the information at the time the alert was triggered. The default columns that display are based on the source of the data attached to the alert.

The following links appear at the top of the page and affect the entire page:

- [Columns](#) to select the columns to include in a table, specify the order in which they appear in a table, specify the sort order within columns, and make your layout the default for users in your login group.
 - [Print](#) to print the content of the table.
 - [Download](#) to download the table in a selected format.
5. Click **Close**.

View product-event interactions

Information about an event and drug interactions is represented as a nested confidence interval graph of EB05-EB95 confidence intervals and EBGM values for two drugs and the event.

Data represented in the graph includes all available data up through the current time period. The signals were generated by a particular run that was set up for the purpose of viewing interactions.

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. Click the product-event combination's **Row Action Menu** () and click **View Interactions**.

Note

If you are working with a [multisource signal configuration](#), options for each configuration included in the multisource signal configuration appear in the menu. You can identify the secondary configurations by the prefix that matches the secondary configuration label [defined in the multisource signal configuration](#).

For each combination of two drugs and the event, the graph displays a series of confidence intervals, with the highest dimension shown first. The first confidence interval is for Event+Drug+Drug. The other two confidence intervals are for Event+Drug. You can compare the strength of the interaction between the two drugs and the event with the strength of the interaction between the individual drugs and the event.

In each confidence interval bar, the EB05 value is at the left end, the EBGM value is the dot on the bar, and the EB95 value is at the right end. The count (N) of cases with the combination is also shown at the end of each bar. Bars are colored according to the color key below the graph. To indicate a possible interaction, the confidence interval for the Event+Drug+Drug combination displays in red when the INTSS (Interaction Signal Score) value is greater than a predefined threshold that is set when signal management is configured. For more information about INTSS, see [MGPS computations](#) and [Logistic regression computations](#).

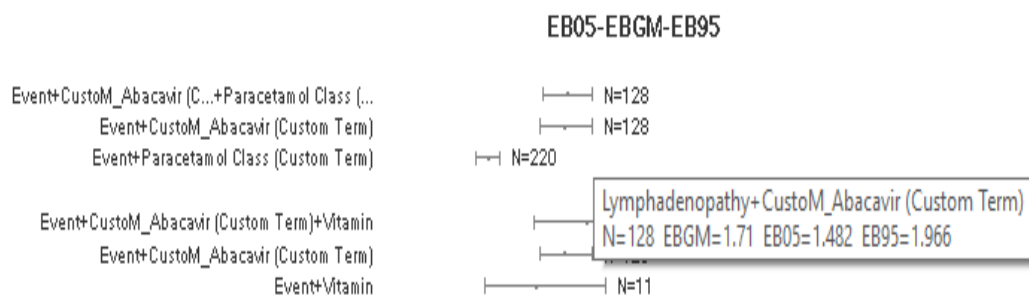
Note that:

- The Event+Drug+Drug combinations are shown in descending order of their INTSS values.
- To conserve space in labeling, the event from the product-event combination is referred to by the label, Event, in the graph.
- Below the graph, there may be additional text provided by a site option.

Note

A message informs you if there are no combinations of the drug and another drug with the event. Depending on how your signal management data was prepared, this option might not be available at all for some product-event combinations or there may be multiple links for different runs.

5. If you point to a confidence interval, the names of the event and the two drugs appear. The following information for the Event+Drug+Drug combination also appears in the sample confidence graph:



- **N**—Observed number of cases with this Event+Drug+Drug combination.
- **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate. For more information, see [MGPS computations](#).

- **EB05**—A value such that there is approximately a 5% probability that the true Relative Ratio lies below it.
 - **EB95**—A value such that there is approximately a 5% probability that the true Relative Ratio lies above it.
 - **INTSS**—Interaction Signal Score. A way of measuring of the strength of a higher-order association above and beyond what would be expected from any of the component pairs of items of different types.
 - **EXCESS2**—A conservative estimate of how many extra cases were observed over what was expected assuming that only a single cross-item interaction is present.
6. To work with the cases represented by an of the coincidence intervals, you can click the bar to see an action menu of options.
 7. To [save the graph as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up). The graph is attached to a PDF file.
 8. Click **Close**.

View signals for similar product-event combinations

You can view the statistical information for combinations involving the same product and the same HLT, HLGT, or SOC as that of the PT in the original combination.

You can also view all combinations for the selected product, the selected product's group or all products. For example, if you are viewing signals for the combination of Ascorbic Acid and Chest Pain, you might also want to view combinations of Ascorbic Acid and any PT that is in the same HLGT as Chest Pain.

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. Click the product-event combination's **Row Action Menu** () and click **View Similar Combinations**.

The product and event you selected for comparison appears above the Similar Combinations table. The columns in the Similar Combinations table are identical to those in the Product-Event Combinations table.

5. To filter the combinations by MedDRA hierarchy level, from the **Show events** within the drop-down list, select a [MedDRA hierarchy level](#).

Note

If an event is a MedDRA SMQ term, you can view the combinations for all PTs in the same SMQ. For multisource configurations, SMQ terms are determined only by the lead signal configuration.

6. (Optional) Perform activities on the list of similar combinations.

The following links appear at the top of the dialog box and affect the entire dialog box:

- [Columns](#)
 - [Print](#)
 - [Download](#)
 - [Save to Topic](#) (if configured)
7. Select from the drop-down filter Show products the **product**, the **product group** or the **all products** option, if you want to organize product-event combinations by the current product only, products within the same product group, or all products.
 8. (Optional) Perform additional activities on a specific combination from the **Row Action** menu () icon.
 - [Submit Review](#)
 - [Add Comment](#) to enter a comment that other users can see.
 - [Edit Topic](#) - **Edit Topic** appears if the combination includes an associated topic that you have permission to edit.
 - [Add Private Comment](#) - **Add Private Comment** appears if private comments are supported in your signal management configuration.
 - [View Signal History](#)
 - [Assign Reviewer](#)
 - [View Interactions](#)
 - [View Age Group Breakdown](#)
 - [View Gender Breakdown](#)

View age group breakdown for a product-event combination

The breakdown of case data by age group for a product-event combination is represented in a bar graph.

Data represented in the graph includes all available data up through the current time period and is for the designated signal set. You cannot view the age group or gender breakdown if there is no value of N.

The x-axis of the bar graph represents the percent of the total number of cases with the product-event combination. The y-axis represents each value of Age Group. For each value of Age Group, there are two bars that are differentiated by the color key below the graph. The bars represent the following:

- **Product**—Cases with the product for the current time period. The total number of cases with the product for the current time period appears in the color key.
- **Product+Event**—Cases with the product-event combination for the current time period. The total number of cases with the product-event combination for the current time period appears in the color key.

If there are no cases including the product-event combination for a particular age group, 0 appears instead of a bar. Cases with NULL values for an age group are represented by a bar for NULL values.

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.

3. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. Click the product-event combination's **Row Action Menu** () and click **View Age Group Breakdown for All**.

If there are multiple signal sets for which you can view a breakdown, the signal set is identified in the link name.

Note

If you are working from a [multisource signal configuration](#), options for each configuration included in the multisource signal configuration appear in the menu. You can identify the secondary configurations by the prefix that matches the secondary configuration label [defined in the multisource signal configuration](#).

5. To [save the graph as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).
6. Click **Cancel**.

View gender breakdown for a product-event combination

The breakdown of case data by gender for a product-event combination is represented in a bar graph.

Data represented in the graph includes all available data up through the current time period and is for the designated signal set. You cannot view the gender breakdown if there is no value of N.

The x-axis of the bar graph represents the percent of the total number of cases with the product-event combination. The y-axis represents each value of Gender. For each value of Gender, there are two bars that are differentiated by the color key below the graph. The bars represent the following:

- **Product**—Cases with the product for the current time period. The total number of cases with the product for the current time period appears in the color key.
- **Product+Event**—Cases with the product-event combination for the current time period. The total number of cases with the product-event combination for the current time period appears in the color key.

If there are no cases including the product-event combination for a particular gender, 0 appears instead of a bar. Cases with NULL values for gender are represented by a bar for NULL values.

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action menu** () and select **View Product-Event Combinations**, or click the product name or total count.

4. Click the product-event combination's **Row Action menu** () and click **View Gender Breakdown for All**.

If there are multiple signal sets for which you can view a gender breakdown, the signal set is identified in the link name.

Note

If you are working from a [multisource signal configuration](#), options for each configuration included in the multisource signal configuration appear in the menu. You can identify the secondary configurations by the prefix that matches the secondary configuration label [defined in the multisource signal configuration](#).

5. To [save the graph as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up). The graph will be attached in a PDF file.
6. Click **Cancel**.

Assign a reviewer to a product-event combination

You can assign a reviewer to a product-event combination. To assign a reviewer, you must have the Manage Signaling Terms permission.

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. Click the product-event combination's **Row Action menu** () and click **Assign Reviewer**.
5. From the **Reviewer** drop-down list, select the reviewer.

You can also select no reviewer (--) to remove an assignment. Available reviewers for assignment are those in login groups to which the signal configuration is published. This assignment does not overlap with the reviewer assignments to products. For example, if User1 is assigned to the product Niacin, you can assign User2 to the combination of the product Niacin and event Flushing.

6. Click **OK**.

You can add the Reviewer column to the Product-Event Combinations table to see reviewer assignments.

Add a comment

You can add a comment to a product-event combination on the Product-Event Combinations page.

All other users can see the comment. If the signal management configuration allows private comments, however, you can add a comment visible to you and superusers only.

Note

If you are working from a [multisource signal configuration](#) any changes you make are also made in all connected configurations.

1. In the left navigation pane, click the **Signal Review** icon ()
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. Select a product-event combination, click that **Row Action Menu** () icon, and select either **Add Comment** or **Add Private Comment**.

Adding a new comment will *not* affect the topic or the topic association with Product-Event Combinations. When you are in the **Select Rows Menu**, there is no need to check the topic association.
5. From the **Comment** drop-down list, select a predefined comment type.
6. In the **Detailed comment** text box, enter a detailed comment (optional). This option is available if the appropriate site option has been set.
7. Click **OK**.

The comment appears for the product-event combination.

Note

Private comments are visible to only you and superusers. However, if the product-event combination becomes part of an attachment in a topic, the private comment becomes visible to anyone who can view that topic attachment.

Add a comment to multiple combinations

Use the Select Rows option to add comments to multiple product-event combinations.

Note

If you are working from a [multisource signal configuration](#) any changes you make are also made in the underlying lead configuration. See [Review product-event combinations from a multisource configuration](#).

1. In the left navigation pane, click the **Signal Review** icon ()
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.

3. Select the product, click the **Row Action menu** (), and select **View Product-Event Combinations**, or click the product name or total count.
4. On the **Product-Event Combinations** page, from the **Header Action menu** (), select **Select Rows**.
5. Select the check box of one or more product-event combinations.
6. To add a comment, from the **Header Action menu** (), click either **Add Comment**, for a public comment, or **Add Private Comment** for a comment visible only to you and superusers.
 - a. Select a comment from the **Comment** drop-down.
 - b. (Optional) Enter a detailed comment.
 - c. Click **OK**.

The comment is added for all of the selected combinations. If a topic was associated, then the attachment contains all of the selected product-event combinations (up to the maximum set by the Site Option, **Max number of rows per table allowed in topic attachments**).

Note

If the product-event combination becomes part of an attachment in a topic, the private comment becomes visible to anyone who can view that topic attachment.

7. To exit multiple selection mode, from the **Header Action menu** (), click **Exit Selection Mode**.

View your signal review history

Oracle Empirica Signal maintains a signal review history that includes the tracked alerts marked as reviewed at the time each comment was submitted as well as statistics about the cases reviewed.

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. Click the product-event combination's **Row Action Menu** () and click **View Signal History**.
5. From the **Signal set** drop-down lists, select the signal set for which you want to view a history, or select **All** to include all data. You can select up to two different signal sets at a time to display graphs for each of them.

Note

If you are working with a [multisource signal configuration](#), signal sets from secondary configurations are identified by a prefix matching the secondary configuration label, defined when creating the multisource signal configuration.

The Signal History includes the following information:

- The name of the product and event (PT) and the HLT, HLGT, and SOC that include the PT.
- A trend graph that shows the EBGM, EB05, and EB95 values over time.
- A histogram that shows the total count of cases with the product-event combination over time.
- Statistical scores for the PT and HLT and SOC, if available. The statistics that are displayed depends on the signal management configuration.
- If Oracle Empirica Signal has been integrated with Oracle Empirica Topics, the title of the Comments table changes to Comments and Topic Associations. The expanded table includes rows related to an associated topic. Additional columns include Topic Association and Topic Name. Topic Association shows whether the association was Created, Removed, or Modified.
- The Alerts column displays an icon for each alert that has been reviewed. The icon abbreviation and color match the [current abbreviation and color for that alert type](#). Alerts from prior refreshes appear on a separate line.

The detailed information about the product-event combination might include multiple signal sets.

6. To save the signal history as an attachment to a topic, next to the **Signal Set** drop-down, click **Save to Topic**.

The signal set graphs and statistics are attached to a PDF file.

7. When you have finished viewing the signal history, click **Close**.

Suppress a product-event combination

You can suppress a product-event combination so that it is not included on the Product-Event Combinations page.

For example, if you determine that a product-event combination has already been reviewed, you might want to suppress that combination.

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. Click the product-event combination's **Row Action Menu** () and select **Submit Review**.

5. From the Comment drop-down list, select one of the comments defined for your signal configuration that has been [configured to support suppressing a product-event combination](#).

If no comment yet exists for the product-event combination, then the Comment drop-down list displays **<Select a comment>**. To clear the existing comment, from the **Comment** drop-down list, select **<Clear Comment>**.

6. To suppress a product-event combination, so that it doesn't appear on the Product-Event Combinations table after the next refresh, click the checkbox.

If the Suppress flag, called FILTER, is set it works only on views that include the FILTER flag. When it has been set and is part of the WHERE clause, it has an immediate effect.

7. (Optional) In the **Detailed comment** text box, enter a detailed comment.
8. (Optional) If signal management is integrated with topics, then you can [associate a topic with a given product-event combination](#).
9. Click **OK**.

Review product-event combinations from a multisource configuration

As an extension of interactive signal configuration, multisource signal configurations enable you to perform safety surveillance across multiple data sources.

When reviewing statistics from a [multisource signal configuration](#), your actions may affect the multisource signal configuration independently or also impact the underlying lead configuration. Any changes that affect the lead also extend to any other [connected configurations](#).

Viewing aggregated data in a multisource signal configuration

When working with a multisource signal configuration, the [Product-Event Combinations table](#) includes aggregated data from all included configurations. You can identify the elements from secondary configurations by the prefix that matches the unique secondary label defined in the multisource signal configuration.

- [Select statistics columns](#) from both the lead and secondary configurations.
- [View interactions](#) for both the lead and secondary configurations.
- [View age group breakdown graphs](#) for both the lead and secondary configurations.
- [View gender breakdown graphs](#) for both the lead and secondary configurations.
- [View signal history](#) from signal sets for both the lead and secondary configurations. The signal history includes the following:
 - Trend graphs (EBGM, EB05, and EB95).
 - Total case count histograms.
 - Statistical scores from signal sets for both the lead and secondary configurations.
 - Comments made on the product-event combination. They are shared with the lead configuration.
 - Alerts reviewed in the multisource configuration.
- [View signals for similar product-event combinations](#) with additional columns and menu items for the secondary configurations available.
- View, select, and interact with data from both the lead and secondary configurations in the Signal Statistics and Subgroup Statistics sections of the [Product-Event Detail panel](#).

Independent data

Although initially populated from the lead configuration, once you start working in the multisource signal configuration, columns, views, and alerts are independent of the lead configuration. Your work is saved to the multisource signal configuration, not to the lead configuration.

Shared data

When working with a multisource signal configuration, the following actions also impact the underlying lead configuration. Any changes that affect the lead also extend to any other [connected configurations](#).

- Topic and Comment information
- Edit Topic
- Add Comment or Private Comment
- Assign Reviewer

Note

If you are working with a multisource signal configuration, be aware that any changes you make to the Reviewers list overwrites the data in all connected configurations. To prevent confusion, you should assign reviewers from either the multisource signal configuration or the lead configuration, but not both. See [Get started with multisource signal configurations](#).

When [assigning a reviewer](#) in the multisource signal configuration, the lead configuration is not updated until the next refresh. Be aware that inconsistencies in the reviewers list may exist until the lead configuration is refreshed.

Step 4: Submit the review

The Submit Review page groups together all the functionality related to completing a review and documenting the disposition of a product-event combination and the alerts raised for that product-event combination.

By submitting your review, you can document the research you did on one or more product-event combinations. If you're working with tracked alerts, submitting the review marks the alert as reviewed and updates the Product-Event Combinations page.

- [Submit a review for a product-event combination](#)
Use the Submit Review option to document the research you did on a product-event combination.
- [Submit a review for multiple combinations](#)
You can submit your review progress for multiple product-event combinations at the same time using the Select Rows option.

Submit a review for a product-event combination

Use the Submit Review option to document the research you did on a product-event combination.

If you have activated tracked alerts for the combination, Oracle Empirica updates tracked alert counts when the product-event combination is reviewed. When you perform a submit review for a product-event combination, all tracked alerts associated with that product-event combination are considered reviewed and the statistics in the Summary section are updated.

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action menu** () and select **View Product-Event Combinations**, or click the product name or total count.

4. Click the product-event combination's **Row Action menu** () icon and select **Submit Review**.

The Submit Review dialog opens.

If there are unreviewed tracked alerts for the selected product-event combination, then the header section of the Submit Review dialog contains the Alerts and Alert Date columns. Click an alert icon to [see details of the alert](#).

5. From the **Comment** drop-down list, select one of the comments defined for your signal configuration. The default is the last public comment made on the product-event combination.

Note

Comments made via Submit Review are considered public comments.

If no comment yet exists for the product-event combination, then the **Comment** drop-down list displays **<Select a comment>**. To clear the existing comment, from the comment drop-down list, select **<Clear Comment>**.

6. (Optional) If the selected comment has been configured to support [suppressing the product-event combination](#), then click the **Suppress the product-event combination** check box so that it doesn't appear on the Product-Event Combinations table after the next refresh.

Note

The Suppress flag is called FILTER and only affects views that include the FILTER flag. When the Suppress flag has been set as part of the WHERE clause, it has an immediate effect.

7. In the **Detailed Comment** text box, enter a detailed comment.
 - Detailed comments are only available if the **Allow Free Text Signal Comments** [site option](#) has been enabled.

- A detailed comment may be required, depending on the [settings for selected comment type](#).

The comment appears in the Detailed Comment column on the Product-Event Combinations table.

8. (Optional) If Signal Management is integrated with Topics:

- You can [associate a topic with a given product-event combination](#).
 - a. On the Submit Review page, for the **Topic Association** field, select **New Topic**.
 - b. Enter the information about the new topic and click **OK**.
Oracle Empirica adds the topic to the product-event combination row and the topic opens in Edit mode. You can [edit this comment](#) from the Topics feature.
- If a topic is already associated, it appears in the **Associated Topic** field. To edit the association or specify another topic, click the **Change** link to display topic association options:
 - **None:** To make no changes.
 - **Existing topic:** To open and edit a topic that has already been added.
 - **New topic:** to add a topic for this product-event combination.

9. Click **OK**.

10. If the topic workflow configuration requires one and only one work team, there is a **Visible to work team** drop-down above the **Topic Template** field that allows you to select a work team from the list, and a **Browse** link to select the work team from a list.

If you added a topic during Submit Review, a folder appears in the Status column. Oracle Empirica Signal also updates the reviewed alert counts for the product in the SOC cards, Product Summary at the top of the page, and the Detail panel.

Note

If you are working with signal configurations connected via [multisource signal configuration](#), some information is shared between the lead configuration and the multisource signal configuration (comments, topics) and other information is independent (alerts). When you submit a review in a connected configuration, the affects on the multisource signal configuration and the lead configuration differ. When you review a product-event combination row of a connected configuration the following takes place:

- The product-event combination row in all connected configurations are updated with the comment and, if applicable, topic information.
- Only the alerts from the selected configuration are marked as reviewed.
 - If you are working in the multisource signal configuration, only alerts in the multisource signal configuration are marked as reviewed.
 - If you are working in the lead configuration, only alerts in the lead configuration are marked as reviewed.
- The product-event combination row and the tables, such as Signal History, in each respective configuration will reflect the changes applied as described above.

Submit a review for multiple combinations

You can submit your review progress for multiple product-event combinations at the same time using the Select Rows option.

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. On the Product-Event Combinations page, from the **Header Action menu** () click **Select Rows**.
5. Select the check box of one or more product-event combinations.
6. From the **Header Action menu** () click **Submit Review**.
7. From the **Comment** drop-down list, select a comment.
8. (Optional) Enter a detailed comment.
Comments made via Submit Review are considered public comments. Oracle Empirica adds the comment to the Product-Event Combinations table, the View Similar Combinations table, and the Signal History table. However, the status of the row in the product-event combinations table is not affected.
9. (Optional) If signal management is integrated with topics, you can [associate a topic with a given product-event combination](#).
10. Click **OK**.
The comment is added for all the selected combinations. If a topic is associated, the attachment contains all of the selected product-event combinations (up to the limit set by the Site Option Max number of rows per table allowed in topic attachments.)
11. To exit multiple selection mode, from the **Header Action menu** () click **Exit Selection Mode**.

View signal management reports

Predefined Oracle Analytics reports are optional signal management reports that provide greater detail on signal reviews.

- [About Oracle Analytics signal management reports](#)
Predefined Oracle Analytics reports provide access to Signal Management data for reporting purposes.
- [Generate a predefined signal management report in Oracle Analytics](#)
You can produce signal management-related Oracle Analytics reports.
- [Filter predefined signal management reports](#)
Filter the data using Shared Analysis Criteria to run the reports you need.

- [Predefined Oracle Analytics signal management reports](#)
Predefined Oracle Analytics reports on signal management data are available from a link in the navigation page if your database administrator and IT administrator installed and configured Oracle Analytics and its components.

About Oracle Analytics signal management reports

Predefined Oracle Analytics reports provide access to Signal Management data for reporting purposes.

They are optional reports that provide detail on signal review information. Your database administrator or IT administrator must install, configure Oracle Analytics and its components first for the reports to be available.

You access the reports in Oracle Analytics from the side navigation pane in Oracle Empirica using the dedicated icon.

[Filter](#) only the fields relevant data using Shared Analysis Criteria.

[Generate](#) the following predefined Oracle Analytics reports are available:

- Alert Counts by Type and Status
- Alert Due Date
- Alert Status
- Dismissed Alerts
- Product Event Details

For more information on the Oracle Analytics reports, see [Predefined Oracle Analytics signal management reports](#).

For more information on installing Oracle Analytics and its components and enabling the signal management reporting feature, see the *Oracle Analytics Configuration Guide for Empirica Reporting*.

Generate a predefined signal management report in Oracle Analytics

You can produce signal management-related Oracle Analytics reports.

A set of predefined signal management reports are built into Oracle Analytics and are accessible from the Analytics Icon within the Oracle Empirica Signal application.

The signal management data is available only for the signal management configurations which your administrator has enabled for Oracle Analytics. However, you only have access to information for signal management configurations published to you. Interactive, multi-source, and scripted signal management configurations are supported.

Note

The **Analytics** icon appears in the navigation pane only when your database administrator and IT administrator have completed the Oracle Analytics reporting setup.

1. In the left navigation pane, select the **Analytics** icon



2. Log in to Oracle Analytics using your username and password or SSO, and select **Sign In**.
3. From the title bar at the top of the page, select **Catalog**.
4. On the Catalog page, open the **Shared** folders, and then open the **Signal Review** folder to list the available reports on the right.
5. Open **Shared Analysis Criteria** to [select the filter settings](#) for the reports and then select **Apply**.
6. Select the tab for one of the predefined reports from the list below and click **Open**:
 - Alert Counts by Type and Status
 - Alert Due Dates
 - Alert Status
 - Dismissed Alerts
 - Product Event Details

For a description and sample of each predefined report, see [Predefined Oracle Analytics signal management reports](#).

Filter predefined signal management reports

Filter the data using Shared Analysis Criteria to run the reports you need.

Before you generate the predefined reports, you must first filter the data in the Shared Analysis Criteria section that corresponds to each report.

If you select a filter that doesn't apply to the report, it will be ignored. You can view each required field for every report on the user interface Shared Analysis Criteria page on the left pane and on the [Predefined Oracle Analytics signal management reports](#).

1. Open **Shared Analysis Criteria** to select the filter settings for the reports:

Filter name	Description
Config Name	The name of the configuration.
Product Group	The group of the product available for that configuration ID.
Product Name	Name of the selected product.
SOC	Displays alerts grouped by MedDRA System Organ Classes (SOCs), based on the existing view in the Product-Event Combinations Page table in Empirica Signal.
Event	Name of an event that is reported in combination with the product, as shown in the Product-Event Combinations Page table in Empirica Signal.
Reviewed	Indicates if the alert was reviewed or not. Two options available Yes and No .
Assigned To	Indicates the user by name the alert is assigned to.
Alert Type	Indicates the standard alert type available for each configured alert. For example, they might be Female, Male, Pediatric, or Elderly.

Filter name	Description
Alert Date	UTC dates using the format MM/DD/YYYY, where you can enter two dates, <firstDate> - <secondDate>, to set up a period of time during which the alert occurred.
Stat Label For Product Event Details	The stat labels available as drop-down options depend on your setup and specific configuration. Indicates the available signal statistics for each product as displayed in the Product-Event Combination page columns and also in the Signal Statistics graphs on the right pane. For more information on their meaning, see Product-event combination statistics .
Config ID Mandatory field	Loads automatically. The stat labels available as drop-down options depend on your setup and specific configuration. Automatically assigned unique identifier of the configuration.

2. Select **Apply**.
3. Navigate to the report tab where the fields apply.

Predefined Oracle Analytics signal management reports

Predefined Oracle Analytics reports on signal management data are available from a link in the navigation page if your database administrator and IT administrator installed and configured Oracle Analytics and its components.

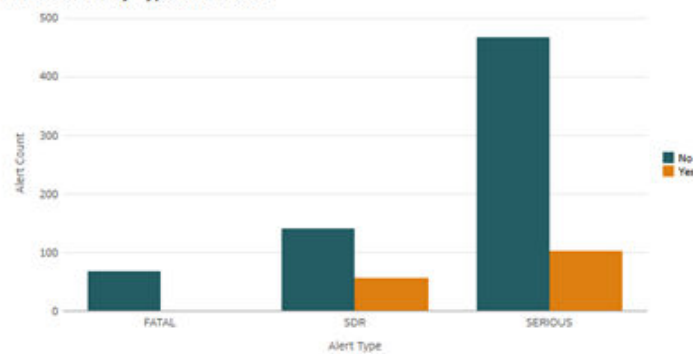
The following sections describe the predefined reports that are available on signal management data.

Alert Counts by Type and Status

Description	Filters for Data Retrieval	Columns
Provides alert counts by type and status information. To the right of the page, a table is sorted in order by alert type and status. To the left of the page, a graph displays counts by alert type, status, and if they are reviewed or not.	• Configuration name • Product Group • Product Name	• Product Name • Reviewed (Yes/No) • Alert Type • Alert Count

Shared Analysis Criteria **Alert Counts by Type and Status** Alert Due Dates Alert Status Dismissed Alerts Product Event Details

Alert Counts by Type and Status



Product Name	Reviewed	Alert Type	Alert Count
6VAX-F	No	SDR	19
		SERIOUS	1
	Yes	SDR	56
		SERIOUS	102
ANTH	No	SDR	15
		SERIOUS	15
MMR	No	FATAL	68
		SDR	75
		SERIOUS	268
VARCEL	No	SDR	32
		SERIOUS	182

Config ID is equal to SELECT "Signal Config"; "Config ID" FROM "Signal Review" where "Signal Config"; "Config Name" = "VAERS Signal Configuration (1)" and Product Name is equal to (All Column Values)

Alert Due Dates

Description

Provides alerts with calculated Days Open, Due Date, and Days Due information.

Days Open starts counting with Alert date until reviewed, then freezes once reviewed.

Due Date is calculated from Alert date and alert characteristics. For example, if the Alert is Complexity Based, the periodicity of the Alert definition for the Alert products complexity level is used.

Days Due is calculated for unreviewed alerts from the due date minus today's date where a negative result means overdue.

Filters for Data Retrieval

- Config Name
- Product Group
- Product Name
- SOC
- Event
- Reviewed
- Assigned to

Columns

- Product Name
- SOC
- Event
- Alert Type
- Assigned To (Names)
- Alert Date
- Complexity
- Review Period
- Reviewed (Yes/No)
- Review Date
- Days Open
- Due Date
- Days Due

Alert Due Dates

Product Name	SOC	Event	Alert Type	Assigned To	Alert Date	Complexity	Review Period	Reviewed	Review Date	Reviewed By	Days Open	Due Date	Days Due
6VAX-F	Card	Bradycardia	SDR, Serious		5/8/2025		1 month	Yes	5/8/2025	Empirica Signal Administrator	0	6/5/2025	
		Cyanosis	SDR		5/8/2025		1 month	No			91	6/5/2025	-61
	Ear	Ear swelling	Serious		5/8/2025		1 month	Yes	5/8/2025	Empirica Signal Administrator	0	6/5/2025	
		Blindness	Serious		5/8/2025		1 month	Yes	5/8/2025	Empirica Signal Administrator	0	6/5/2025	
	Eye	Eye movement disorder	SDR, Serious		5/8/2025		1 month	Yes	5/8/2025	Empirica Signal Administrator	0	6/5/2025	
		Eye lid ptosis	Serious		5/8/2025		1 month	Yes	5/8/2025	Empirica Signal Administrator	0	6/5/2025	
		Oculogyric crisis	SDR		5/8/2025		1 month	No			91	6/5/2025	-61
		Retinal haemorrhage	SDR, Serious		5/8/2025		1 month	Yes	5/8/2025	Empirica Signal Administrator	0	6/5/2025	
	Gastro	Lip swelling	Serious		5/8/2025		1 month	Yes	5/8/2025	Empirica Signal Administrator	0	6/5/2025	
		Vomiting	Serious		5/8/2025		1 month	Yes	5/8/2025	Empirica Signal Administrator	0	6/5/2025	
	Genro	Crying	SDR		5/8/2025		1 month	No			91	6/5/2025	-61
		Developmental delay	SDR		5/8/2025		1 month	No			91	6/5/2025	-61

Alert Status report

Description	Filters for Data Retrieval	Columns
Provides alert review status and detailed review information, such as comments, topic names, etc., per product event combination information.	• Configuration • Product Group • Product Name • SOC • Event • Reviewed • Assigned To	• Product Name • SOC • Event • Alert Type • Alert Date • Assigned To (User names) • Reviewed (Yes/No) • Review Date • Reviewed By • Review Comment (Short) • Topic Name • Topic State

Alert Status Report

Product	SOC	Event	Alert Type	Alert Date	Assigned To	Reviewed	Review Date	Reviewed By	Review Comment	Topic Name	Topic State
δVAX-F	Card	Bradycardia	SDR, Serious	5/6/2025		Yes	5/6/2025	Empirica Signal Administrator	Closed Prior Review		
		Cyanosis	SDR	5/6/2025		No					
	Ear	Ear swelling	Serious	5/6/2025		Yes	5/6/2025	Empirica Signal Administrator	Closed Prior Review		
	Eye	Blindness	Serious	5/6/2025		Yes	5/6/2025	Empirica Signal Administrator	Closed Prior Review		
		Eye movement disorder	SDR, Serious	5/6/2025		Yes	5/6/2025	Empirica Signal Administrator	Closed Prior Review		
		Eyelid ptosis	Serious	5/6/2025		Yes	5/6/2025	Empirica Signal Administrator	Closed Prior Review		
		Oculogyric crisis	SDR	5/6/2025		No					
		Retinal haemorrhage	SDR, Serious	5/6/2025		Yes	5/6/2025	Empirica Signal Administrator	Closed Prior Review		
	Gastr	Lip swelling	Serious	5/6/2025		Yes	5/6/2025	Empirica Signal Administrator	Closed Prior Review		
		Unintentional	Serious	5/6/2025		Yes	5/6/2025	Empirica Signal Administrator	Closed Prior Review		

Dismissed Alerts

Description	Filters for Data Retrieval	Columns
Provides alerts closed without associated topic information.	• Config Name • Product Group • Product Name • SOC • Event • Alert Type • Alert Date	• Product Name • SOC • Event • Alert type • Alert Date • Review Date • Review Comment • Suppressed

Note

If a Product-Event combination was reviewed with an associated topic, and that association is later removed, it will be included in this report.

Dismissed Alerts

Product Name	SOC	Event	Alert Type	Alert Date	Review Date	Reviewed By	Review Comment	Suppressed
δVAX-F	Card	Bradycardia	SDR	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
			Serious	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
	Ear	Ear swelling	Serious	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
			Serious	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
	Eye	Blindness	Serious	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
			SDR	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
		Eye movement disorder	Serious	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
			Serious	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
		Eyelid ptosis	Serious	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
			SDR	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
		Retinal haemorrhage	SDR	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No
			Serious	5/6/2025	5/6/2025	Empirica Signal Administrator	Closed Prior Review	No

Product Event Details

Description	Filters for Data Retrieval	Columns
Provides statistics for selected product-event combinations information.	• Config Name • Product Group • Product Name • SOC • Event • Stat Label for Product Event Details	• Product Name • SOC • Event • Selected Statistics
Customize the report by applying the Product Name and Stat Label for Product Event Details filters.		

Product Event Details

Product Name	SOC	Event	Statistics				
			Adult N 202002	All CHISQ 201905	All CHISQ 201908	All CHISQ 201911	All CHISQ 202001
6VAX-F	Blood	Agranulocytosis	1	32.154	29.053	29.226	29.518
		Anaemia		22.993	24.072	31.186	31.442
		Anisochromia		41.933	41.03	41.246	41.609
		Anisocytosis		1.772	1.717	1.73	1.752
		Autoimmune haemolytic anaemia		34.361	32.466	31.716	31.593
		Autoimmune neutropenia		164.949	153.192	154.023	155.426
		Blood loss anaemia		13.323	13.022	13.094	13.215
		Bone marrow failure		.076	.068	.07	.073
		Coagulopathy		.349	.292	2.327	2.373
		Disseminated intravascular coagulation		.017	.009	.01	.011

3

Use Oracle Empirica Topics

- [Overview of topic management](#)
To manage the process of identifying and investigating product safety issues, including organizing the collection and interpretation of information from different sources over time, you can create topics.
- [About topics, actions, and the calendar](#)
By selecting Topic Management from the left navigation pane, you can organize and track tables, graphs, and documents related to particular subject matter.
- [Display the Topic Management page](#)
A single page provides access to all Oracle Empirica Topics functions.
- [Sections of the Topic Management page](#)
The Topic Management page is your starting point for working with all Oracle Empirica Topics features.
- [Sections of the Topics tab](#)
The Topics tab of the Topic Management page provides information about existing topics. There are three sections.
- [Sections of the Actions tab](#)
The Actions tab of the Topic Management page provides information about existing actions.
- [Sections of the Calendar tab](#)
The Calendar tab of the Topic Management page provides information about actions in an open state that have a Planned Completion Date.
- [Download the Topics or Actions table](#)
You can download the information in the Topics and Actions tables to various types of files.
- [Keyboard shortcuts for the Topics and Actions tables](#)
Use these keyboard shortcuts to facilitate your work with the Topics and Actions tables.
- [Select a topic workflow configuration](#)
To use topic management, you must have access to a topic workflow configuration. The topic workflow configuration defines the behavior and content of the Topic Management page.
- [Choose which items to view on the Topics, Actions, and Calendar tabs](#)
To control the items shown on the Topics, Actions, and Calendar tabs, use these procedures.
- [Work with topics](#)
This section includes procedures for working with topics and topic reports.
- [Work with actions](#)
This section includes procedures for working with actions.
- [Work with the calendar](#)
This section includes procedures for working with open actions.
- [Work with attachments](#)
This section includes procedures for working with attachments.

Overview of topic management

To manage the process of identifying and investigating product safety issues, including organizing the collection and interpretation of information from different sources over time, you can create topics.

What are topics and actions?

A topic in Oracle Empirica Signal is a means to organize and track tables, graphs, and documents related to particular subject matter. You can collect and record issues identified through various means, such as automated signal detection, literature reviews, and regulatory requests as well as your data mining, reporting, and product-event analyses. A topic can help you and the other members of your work team track an issue throughout the process of researching and resolving it. You update the progress of the topic through different stages of work using statuses such as Initial, Reviewed, or Completed. You can monitor topics from creation to completion on the Topics tab and by using reports. You can also download all, or a selected subset, of the information stored with a topic at any time to a PDF file.

For each topic you create, you can choose a template for entering the information (if configured and made visible to a work team) and select the work teams whose members can view or act on the topic.

Within a topic you can create an action. An action is an activity that has been identified as contributing to the understanding or resolution of a topic. Examples of activities that you may track with actions include:

- Research results
- Project meetings or milestones
- Follow-up work

Like topics, actions are given workflow states to track their progress from creation to completion. An action can be assigned to the same user that is currently assigned to the topic or to a different user.

On the Topic Management page you have access to topics and actions that you created and those made visible to a work team of which you are a member.

Use topic workflow configurations to customize Oracle Empirica Topics

The title bar on the Topic Management page contains a topic workflow configuration drop-down list that shows the configurations you have access to and allows you to switch topic workflow configurations. If you have access to only one workflow configuration, Oracle Empirica Signal displays the current configuration without a drop-down list. To use Oracle Empirica Topics, you must have access to a topic workflow configuration. The topic workflow configuration defines the behavior and content of Oracle Empirica Topics.

When you create and edit topics, information is collected using a topic workflow configuration. Although a standard template is provided with Oracle Empirica Topics, it is likely that your organization has customized the topic workflow configuration to meet the specific requirements of your organization. This means that the fields shown on the pages and dialog boxes described in this guide might not exactly match the details in this guide. These customizations include:

- The fields that store information.
- The values that you can supply for each field.
- The workflow states that you can assign.

- The types of attachments you can add: Oracle Empirica Signal objects including run result tables and graphs, reports, and query results, website URLs, text notes, or files.
- The rules for sending automated email notifications triggered when a topic or action is added or modified, a change is made to its workflow state, an action due date is nearing, or the topic is assigned to a different user.

In addition, the fields that are available to store information when topics or actions are in different states, or for different types of attachments, can be set to hidden, visible, editable, or required for each defined field.

All of these attributes are stored in a topic workflow configuration that is managed by an administrator at your organization.

You can design topic workflow configurations to meet the needs of different groups in your organization. For example, a collaborative topic workflow configuration can structure the participation of several members of a work team on every topic, while a separate notebook topic workflow configuration allows individuals working in another part of your organization to track their own issues over time without the participation of other users.

Alternatively, a single topic workflow configuration allows you to work cooperatively with others on projects using topics and also track your own issues by setting up topics that you leave assigned just to yourself. If your organization defines more than one topic workflow configuration, the topics that you enter are based on just one of them. As a result, members of different groups in your organization might work with topics in different ways, supplying different types of information or assigning different workflow states.

If your organization uses the Signal Review feature, you can integrate a topic workflow configuration with a signal management configuration. You can then store and manage topics associated with product-event combinations in the integrated topic workflow configuration. The integrated topic workflow configuration can differ from the one used on the Topic Management page.

Note

When describing topic-related activities, help topics reference the topic workflow configuration supplied with Oracle Empirica Topics.

About topics, actions, and the calendar

By selecting Topic Management from the left navigation pane, you can organize and track tables, graphs, and documents related to particular subject matter.

A topic is a way of organizing information about your work assignments

You can set up topics to follow your workflow through different states, such as Initial, Reviewed, and Closed. You can also make topics visible to work teams and assign them to a user or work team.

Topics organize and track tables, graphs, and documents related to a particular subject matter. You can collect and record issues identified through various means, such as automated signal detection, literature reviews, and regulatory requests.

You access topics through the Topic Management page. You must have the View Topics permission and an administrator must set up Oracle Empirica Topics for your use, including making at least one topic workflow configuration accessible to your login group and, if needed,

making you a member of work team and assigning work team permissions. For information on setting up the topics feature see [Set up Oracle Empirica Topics](#).

Topics can be made visible to work teams. Visibility controls who can see the topic and its actions. Work team permissions control what type of access a work team member has to a topic or action. Topics and actions are assigned to a user or a work team. At the top of the Topic Management page are the **View items for** selectors that control the set of topics you can work with.

When a topic transitions to a new state, if the actions were planned, Oracle Empirica Topics considers whether to activate the actions and move them to the initial state. When actions are moved to the Initial state, any date field values in the action are populated using the current date and the date offset from the action type. Oracle Empirica Topics records the action state change in the Action History and sends email notifications as necessary.

Actions are a way of organizing your work assignments

Within a topic, you can create an action. An action is an activity that has been identified as contributing to the understanding or resolution of a topic. Actions in the Planned state are dormant. These planned actions remain dormant until they are transitioned from the Planned state into the Open state. On the Topic Management page, you have access to topics and actions that you created and those made visible to a work team of which you are a member. You can view them along with other actions in the Topic Actions section of the topic.

Use the calendar to see what you need to do

Use the Calendar tab to view your overdue and upcoming actions. The calendar displays open actions with a planned completion date but with no actual completion date. The tab contains a calendar with one, two, or four months, depending on the space available on the screen, and a detailed list of actions. The actions are filtered by the **View items for** selection (Me, Work Team, or All) and, optionally, by a selected work team or user, action type, or action assignment. There are two views:

- **List view:** The List view provides the list of the available actions. Actions are ordered by Planned Completion Date in ascending order. If more than one action is available on any date, the actions are sorted in alphabetic order.
- **Calendar view:** The Calendar view displays the available actions on a monthly calendar.

Display the Topic Management page

A single page provides access to all Oracle Empirica Topics functions.

1. [Log in to Oracle Empirica Signal](#).
2. In the left navigation pane, click the **Topic Management** icon ()

Sections of the Topic Management page

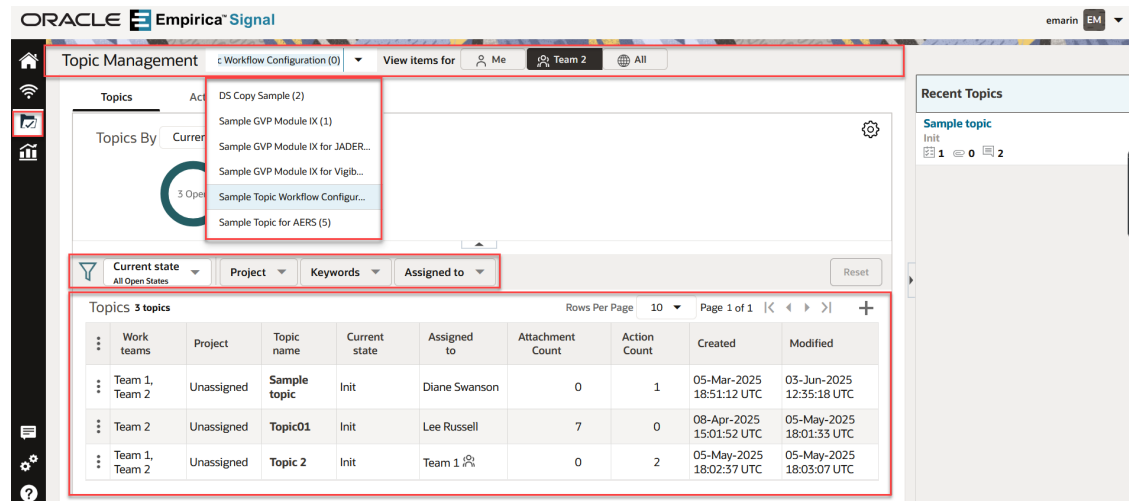
The Topic Management page is your starting point for working with all Oracle Empirica Topics features.

The Topic Management page enables you to filter, sort, and view details on the topics in the database.

Title bar

The Title Bar contains the page title, **Topic Workflow Configuration** drop-down list to switch topic workflow configurations, and the **View items for** selectors.

Figure 3-1 Sections of the Topics Configuration page



Topic Workflow Configuration selector

This drop-down list appears to the right of the page title and includes the topic workflow configurations you have access to. This list is also available on the User Preferences page. If you have access to only one configuration, you will see the configuration name and ID, but no drop-down list.

Note

You can change your topic workflow configuration selection on the Topic Management and the User Preferences pages. A change from one of these pages updates the selection on the other page.

View items for selectors: These selectors control the set of topics you can work with on the Topics, Actions, and Calendar tabs. For a topic and its actions to be available to you on the Topic Management page, they must be visible to a work team that you are a member of or the topic must have been created by you and not visible to any work team. The selectors are:

- **Me:** topics or actions visible to you and assigned to you.
Topics tab includes:
 - Topics assigned to you
 - Topics that contain actions assigned to you
 Actions tab includes:
 - Actions assigned to you
 - Actions from topics assigned to you

- **Work team:** topics and actions visible to you and assigned to the selected work team. If you have access to more than one work team, select from the **Work Team** drop-down list. Topics tab includes topics visible to you and:
 - Topics assigned to selected work team
 - Topics that contain actions assigned to selected work team
 - Topics assigned to any member of the selected work team
 - Topics that contain actions assigned to any member of the selected work team
- Actions tab includes Actions visible to you and:
 - Actions assigned to selected work team
 - Actions from Topics assigned to selected work team
 - Actions assigned to any member of the selected work team
 - Actions from Topics assigned to any member of the selected work team
- **All:** all topics and actions visible to you.

Topics and Actions Tabs

The Topics and Actions tabs contain graphs of topic or action counts by a *filterable* field, table filters, and the Topics or Actions table. Use the [Topics tab](#) to add and maintain topics. Use the [Actions tab](#) to add and maintain actions. Then use the [Calendar tab](#) to manage your assignments by completion date and look at what your team is doing and what actions are overdue and upcoming for you or your team.

The Topics and Actions tabs contain three sections:

- **Graph**
The Graph section graphically displays summary information of topics. Your selection from the **Topics By** or **Actions By** drop-down lists determines the type of graph displayed. If you select anything other than Current State or Action State, a bar chart is displayed. Select Current State or Action State to display a donut graph.

Select a different field from the **Topics By** or **Actions By** drop-down list to view a different graph. Select the menu on any graph bar or donut section to modify the filters on the Filter bar and to apply the filter to the Topics or Actions table below.

Click **Graph Options** (⚙️) to sort the graph by label or count. On the Topics tab, you can choose to include closed topics. On the Actions tab, you can include planned and closed actions.
- **Topics table/Actions table**
The tables contain the set of topics or actions to work with. They are filtered by the **View items for** selector and filters in the Filter bar. The top line of the tables includes a count of the topics or actions. Also included are controls for specifying the number of rows per page, the current page, and arrows to page through the table. If you click the plus sign (+) at the far right of the Topics table, you can add a topic. To the left of the top row of both tables is a **Header Action menu** (⋮) of functions you can apply to the table as a whole.

To the left of each topic or action row is a **Row Action menu** (⋮) of functions you can apply to a specific topic or action.
- **Filter bar**
Above the Topics and Actions tables is the Filter bar. Click the Filter icon. (🔍) to add to or remove filters from the bar. The Current state filter, in the Topics tab, and Action state filter, in the Actions tab, cannot be removed and are always the first filter on the Filter bar.

A drop-down menu appears on the Filter bar for each selection you make from the filter list. Use the drop-down menus to select values for each filter. The results in the table update to reflect your choices.

Note

If you made a **View items for** selection or defined filters on the Filter bar on the Topics and Actions tables, those selections are applied.

Note

Changes made to any sections of the Topics or Actions tabs update both of these tabs. For example, if you view a topic that you select from the Recent Topics list on the Actions tab, then edit the topic and create a new action, these changes appear on the Actions tab. If you modify or delete topics or actions, the Topics, Actions, and Calendar tabs update to reflect any changes. If you view or modify a topic or action, the Recent Topics list updates.

Calendar tab

The [Calendar tab](#) displays a list of actions ordered by planned completion date and a calendar showing upcoming and overdue actions. Only open actions with a Planned Completion Date and without an Actual Completion Date appear on the calendar. The Calendar tab contains a List view and a Calendar view, both showing the actions by Planned Completion Date. The **View items for** selectors, **Me**, **Work Team**, or **All**, may be applied to the calendar. To view actions without planned completion dates, select the Actions tab and sort by Planned Completion Date ascending. This displays the empty values first.

Above the list are drop-down lists for filtering the Calendar tab by assigned user or work team and by the action type. At the top of the list are counts of overdue and upcoming actions.

Detail panel

The Detail panel appears on the right of each tab. It displays a list of recently viewed or edited topics or detailed information about the selected topic or action. You can collapse and expand each section of the panel. If a topic is selected on the Topics tab or an action is selected on the Actions tab, Oracle Empirica Topics displays details for the selected topic or action. The **View items for** selector does not apply to the list of recent topics. When you close the topic or action details, the Recent Topics list displays. You can select any topic in the Recent Topics list to view it. Planned actions are not included.

Sections of the Topics tab

The Topics tab of the Topic Management page provides information about existing topics. There are three sections.

In addition to the Title bar, containing the page title, **Topic Workflow Configuration** selector, and the **View items for** selectors, the three sections of the Topics tab are:

Graph section

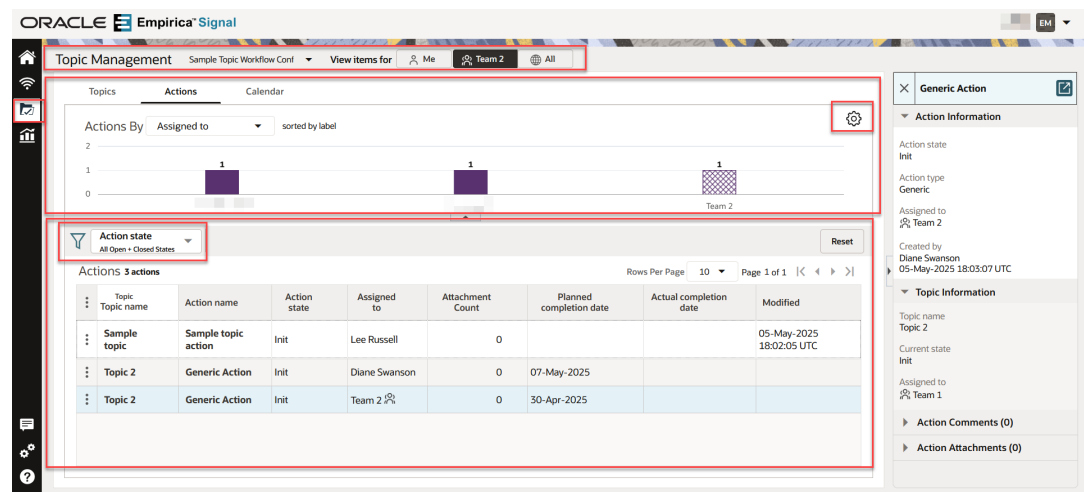
The Graph section on the Topics tab graphically displays summary information of topics. The **Topics By** drop-down list contains a list of filterable fields. The type of field determines if a bar

chart or donut chart is displayed. You may have to scroll horizontally to see all the bars. The donut graph displays when you select **Current State**.

You can perform a number of tasks in the Graph section that impact what you see in the Graph section of the Topics tab.

- Make a selection from the **Topics By** drop-down list to graph the distribution of topics by this field. The graph displays counts (number of topics) for each value of the selected field. Data for which there is no value is displayed as (No Value). There is no impact on the content in the Topics table below.
- For most **Topics By** fields, a solid bar is displayed with a count for each topic with the field value. If the **Topics By** field is **Assigned To** and the value is a work team, the bar is not solid.
- If the **Topics By** selection is **Current State**, the states and number of topics for each state appears in a donut graph whose total area corresponds to 100%. If there are many states, you may want to remove some of the states with larger values to compare the states with smaller values. You can hide or unhide a state in the donut by clicking the state in the legend. If there is only one state, no legend displays.
- Click  to open the Graph Options panel.

Figure 3-2 Sections of the Topics tab



Select a sort option to sort the graph by Label or Count, either in ascending or descending order. Select or deselect the **Closed Topics** check box to include or exclude topics that have been closed. For bar charts, this adds a bar in a lighter color for any closed topics. If there are open and closed topics for the **Topics By** field, then a stacked bar is displayed. Hover over the two sections to see the breakdown of the total shown by closed versus open topics. If you have chosen **Current State** from the **Topics By** drop-down list and selected the **Closed Topics** check box, a second donut chart shows the closed topics. To close the Graph Options panel, click the X. For all other Topics By options, when you select the **Closed Topics** check box, a stacked bar is displayed with any open topics at the bottom and closed topics stacked above in a lighter color. Hover over each section of the bar to see the number of open and closed topics.

- Hide or show the Graph section by clicking the up-arrow or down-arrow that appears at the bottom of the Graphic section, respectively.

- If you click any element in the Graph section, a menu opens with two options:
 - Add to filter:** Add the filter to the Filter bar and filter the Topics table.
 - Replace filter:** Replace current filters on Filter bar with the graph selection and filter the Topics table.

Topics table

The Topics table on the Topics tab includes standard and custom topic fields, as defined by the selected topic workflow configuration, such as Work teams, Project, Topic Name, Current State, Assigned to, Attachment Count, Action Count, Created, and Modified.

Figure 3-3 Topics tab Table section

Work teams	Project	Safety Topic	Current State	Assigned to	Attachment Count	Action Count
DataGenWorkTeam01	DataGenTopicProject	Efficacy of the Otago Exercise Program (OEP) D_GEN	2-Assigned	DataGenWorkTeam01	12	
DataGenWorkTeam01	DataGenTopicProject	A Study for Establishing the Perioperative Sym_GEN	3-Evaluation	DataGenWorkTeam01	0	
DataGenWorkTeam01	DataGenTopicProject	Multi-institutional Prospective Pilot Study of_GEN	6-Closed	DataGen009 User009	6	
DataGenWorkTeam01	DataGenTopicProject	Spontaneous and Evoked Pain in Parkinson's Dis_GEN	6-Closed	DataGen008 User008	8	
DataGenWorkTeam01	DataGenTopicProject	Longterm Ureteral Stenting: Assessment of	6-Closed	DataGen010 User010	4	

- The **View items for** selection and the filters in the Filter bar determine the set of topics shown.
- The **Header Action menu** () provides access to column management and download options, Oracle Analytics Topic reports, and allows you to add a topic to the table.

Note

Topic reports are not available for customers that do not integrate with Oracle Analytics.

- The **Row Action menu** () provides the following options, whose availability depends on your work team and user permissions, and the topic state.
Row Action menu options and permissions

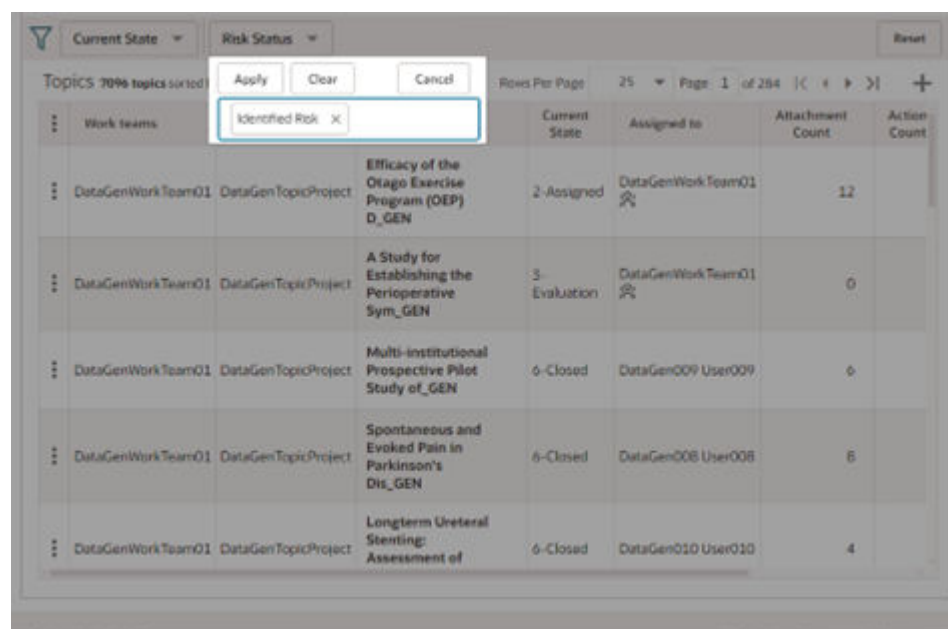
Row Action menu option	Description
View	View the topic.
Edit	Edit the topic.
Delete	Delete the topic.
Reopen	Reopen a closed topic.
Create PDF	Create a Portable Document Format (.pdf) version of the table for downloading.
Create ZIP	Create a compressed .zip file (which contains a .pdf file) version of the table for downloading.

Filter bar

The Filter bar on the Topics tab appears above the Topics table and contains a **Select Filter**

button () for adding custom filters to filter the table below. Available filters are defined in the topic workflow configuration. The **Current State** filter always appears on the Filter bar but you can change the selected state values.

Figure 3-4 Topics tab table filter



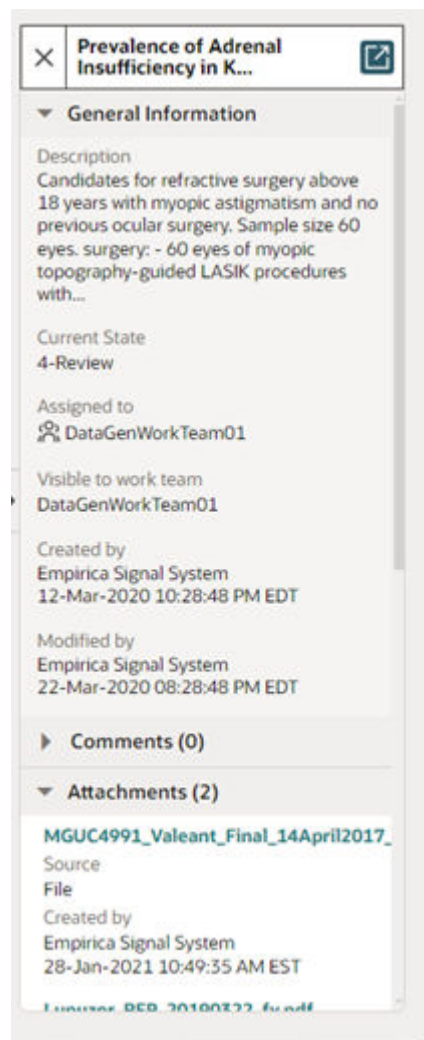
- Click the **Select Filter** button () to add or remove filters. You can add as many filters as you want. After you add the filter, you select values for the filter by clicking the filter.
- Click the **Reset** button to clear the values of the selected filters and set the **Current State** filter to *All Open States*. The filters stay on the Filter bar; however, you can redefine the values for each filter.
- To remove filters from the Filter bar, uncheck the filter from the Select Filter menu.

Detail panel

The Detail panel appears on the right. It displays a list of recently viewed or edited topics and the topic state and the number of actions, attachments, and comments associated with the topic. Planned actions are not included. You can click any topic to view it.

If you click a topic row, the Detail panel updates to become the Topic Detail panel. It contains four sections: General Information, Comments, Attachments, and Actions. You can collapse and expand each section of the panel. To view the topic, click the **View topic** icon (🔗).

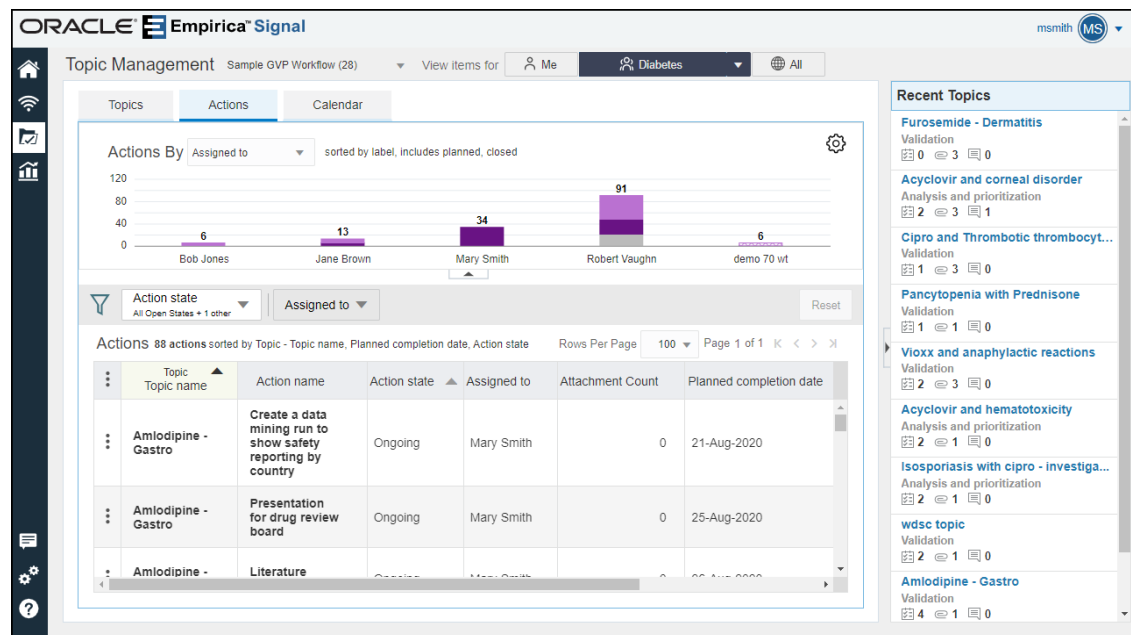
Figure 3-5 Topics Management Detail panel



Sections of the Actions tab

The Actions tab of the Topic Management page provides information about existing actions.

In addition to the Title bar, containing the page title, **Topic Workflow Configuration** selector, and the **View items for** selectors, you can use the Graph and Table section of the Actions tab to filter, sort, and view actions.



Graph section

The Graphic section on the Actions tab graphically displays summary information of actions. The **Actions By** drop-down list contains a list of filterable fields. The type of field determines if a bar chart or donut chart is displayed. You may have to scroll horizontally to see all the bars. A donut chart is a pie chart with a hole in the center that displays the total number of actions. The donut graph displays when you select **Action State**.

You can perform a number of tasks in the Graph section that impact the Graph section of the Actions tab.

- Make a selection from the **Actions By** drop-down list to graph the distribution of actions by this field. The graph displays counts (number of actions) for each value of the selected field. Data points for which there are no value are displayed as (No Value).
- For most **Actions By** fields, a solid bar is displayed with a count for each action with the field value. If the **Actions By** field is *Assigned To* or *Topic Assigned To* and the value is a work team, the bar has a cross-stitched pattern.
- If the **Actions By** selection is **Action State**, the states and number of actions for each state appear in a donut graph whose total area corresponds to 100%. If there are many states, you may want to remove some of the states with larger values to compare the states with smaller values. You can hide a state from the donut by clicking the state in the legend.
- Click to open the Graph Options panel.
- Select a **Sort by** option to sort by label or count, either ascending or descending. Select or deselect the **Planned Actions** check box to include or exclude planned actions. Select the **Closed Actions** check box to include or exclude actions that have been closed. For bar charts, this adds a bar in a lighter color for any closed actions. If either check box is selected for the **Actions By** field, then a stacked bar is displayed. Hover over each bar section to see the breakdown of the total for planned, open, or closed actions. If you have chosen **Action State** from the **Actions By** drop-down list and then select the **Include Planned Actions** or **Include Closed Actions** check box, an additional donut chart appears for each section. Click the **X** to close the Graph Options panel. For all other **Actions By** options, when you select the **Include Closed Actions** check box, a stacked bar is displayed with any open actions at the bottom and closed actions stacked above in a

lighter color. Hover over each section of the bar to see the number of open and closed actions.

- Hide or show the Graph section by clicking the up-arrow or down-arrow that appears at the bottom of the Graph section.
- If you click any item in the Graph section, a menu opens with two options:
 - **Add to filter:** Add the filter to the Filter bar and filter the Actions table.
 - **Replace filter:** Replace current filters on Filter bar with the graph selection and filter the Actions table.

Actions table

The Actions table section on the Actions tab includes standard and custom topic and action fields, as defined by the selected topic workflow configuration, plus Action ID, Action Attachment Count, Created By, Created, Modified By, and Modified.

- The **View items for** selection and the filters in the Filter bar determine the initial set of actions shown.
- The **Header Action menu** () provides access to column management and download options.
- The **Row Action menus** () provide the following options, whose availability depends on your work team.

Row Action menu options and permissions

Row Action menu option	Description
View	View the action.
Edit	Modify the action.
Delete	Delete the action.
Reopen	Reopen a closed action.
Create PDF	Create a Portable Document Format (.pdf) version of the table for downloading.
Create ZIP	Create a compressed .zip file (which contains a .pdf file) version of the table for downloading.

Filter bar

The Filter bar on the Actions tab appears above the Actions table and contains a **Select Filter**

button () for adding custom filters to filter the table below. Available filters are defined in the topic workflow configuration. The **Action State** filter always appears on the Filter bar but you can change the filter values.

- Click the **Select Filter** button () to add or remove filters. You can add as many filters as you want. After you add the filter, you select values for the filter by clicking the filter.
- By default, planned actions are not displayed in the table. Select the **Action State** filter and then select the **Planned** check box to include planned actions in the table. If the **Planned** check box is not displayed in the filter and there are planned actions in the topic, change or reset your filters.

- Click the **Reset** button to clear the values of the selected filters and set the **Action State** filter to *All Open Actions*. The filters stay on the Filter bar; however, you can redefine the values for each filter. To remove filters from the Filter bar, deselect the filter from the **Select Filter** menu.
- Click the **Clear** button and then the Apply button to remove all filter values from this filter.

Detail panel

The Detail panel appears on the right. Initially, it displays a list of recently viewed or edited topics and the topic state and the number of actions, attachments, and comments associated with the topic. You can click any topic name to view it.

If you click in any action row, the Detail panel updates to become the Action Detail panel. It contains four sections: Action Information, Topic Information, Action Comments, and Action Attachments. You can collapse and expand each section of the panel. To view the action, click the **View action** icon (🔍).

Sections of the Calendar tab

The Calendar tab of the Topic Management page provides information about actions in an open state that have a Planned Completion Date.

Using the Calendar tab, you can view actions based on completion date.

The screenshot shows the Oracle Empirica Signal Topic Management page. The 'Calendar' tab is selected. On the left, there's a list of actions with filters for 'Assigned to' (Mary Smith) and 'Action type' (Literature Search). The main area shows a calendar view for October, November, and December 2021, and January 2022. The right panel shows details for a selected action, including 'Action Information', 'Topic Information', 'Action Comments', and 'Action Attachments'.

There is both a List view and Calendar view. You can filter the actions using the **Assigned to** filter and the **Action type** filter. Click Reset to clear both filters. The Calendar tab also contains counts for past due and upcoming actions.

The number of months in the Calendar view depends on the available space on the page and will show one, two, or four months.

List view

The List view contains a single list, sorted in ascending order by Planned Completion date (earliest first). The List view initially scrolls to an area that includes today's date. There are three sections in the List view:

- Overdue actions
- Today's actions
- Upcoming actions (after today)

An action is considered Past Due if the Planned Completion Date is less than today. An action is considered Upcoming if the Planned Completion Date is Today or after Today. If more than one action is available on any date, multiple actions are displayed below the date.

Above the list is a count of the overdue and upcoming actions. You can scroll through the list from beginning to end.

Calendar view

The Calendar view displays up to four months at a time and includes actions in an open state that have a value for Planned Completion Date, but no value for Actual Completion Date. If a date has one action associated with it, there is one circle on the calendar. If a date has more than one action associated with it, the circle has a thick border. Colors in the Calendar view match those in the List view and indicate whether an action is past due (orange), due today (teal), or upcoming (blue).

Above the calendar are buttons for **Previous** (<), **Today**, and **Next** (>). If there are two or more months showing, then, initially, today's month is the second month from the left. If there is only one month showing, then, initially, it is today's month.

Reading from left to right, starting in the upper left, Today's month appears in the second month shown. Use the **Previous** and **Next** buttons to scroll through the calendar month-by-month. Click **Today** to reset the Calendar view to show today's date either in the first or second calendar month. Click a month name link to select a different month and click a year link to select a different year. The available months and years to select or to scroll to are based on the first month with an action and the last month with an action.

Download the Topics or Actions table

You can download the information in the Topics and Actions tables to various types of files.

1. In the left navigation pane, click the **Topic Management** icon (.
2. Select the **Topics** or **Actions** tab.
3. Click the **Header Action menu** () and then click **Download**.
4. In the **Download** popup, type the **Base filename**. Don't include a file extension.
5. Select the format of the file. For more information, see [Download data](#).
6. In the **Limit to** field, enter the maximum number of rows to download.

Note

When downloading to a spreadsheet format, the maximum number of rows is 64K.

7. If you want a Zip archive file of the download, select the **Create a Zip archive file for download** checkbox.
8. Click **OK**.
9. Open or save the downloaded file.

Keyboard shortcuts for the Topics and Actions tables

Use these keyboard shortcuts to facilitate your work with the Topics and Actions tables.

To interact with the Topics and Actions tables:

1. To set focus to the table, press **Tab** or **Shift+Tab**.
2. To navigate up or down rows in the table, press the **Up** or **Down** arrow.
3. To display the row action menu when a row has focus, press **Enter**.
4. To select a menu item, press **Enter**.
5. To dismiss the menu, press **Esc**.

To interact with cells in a row in the table:

1. To restrict focus within a table row, press **F2**.
2. To focus on the next or previous cell, press **Tab** or **Shift+Tab**.
3. To select a link or display a menu in a cell that is in focus, press **Enter**.
4. To turn off navigation within a table row, press **F2** again.

To interact with the table header:

1. To navigate to the table, press **Tab** or **Shift+Tab**.
2. To navigate to the table header, press the **Up** or **Down** arrow.
3. To display the header action menu, press **F2** and **Enter**.
4. To select a menu item, press **Enter**.
5. To dismiss a menu item, press **Esc**. To set focus back to the table header, press **Esc** again.
6. To navigate between header cells, press the **Left** or **Right** arrow.
7. To sort a table column, press **Enter**.

To check the Current State filter on the Topics table:

1. Press **Tab** until keyboard focus is on the filter button.
2. Press **Spacebar**.

Select a topic workflow configuration

To use topic management, you must have access to a topic workflow configuration. The topic workflow configuration defines the behavior and content of the Topic Management page.

When you select Topic Management from the left navigation pane, the Topic Management page appears. Before you select the Topics, Actions, or Calendar tab, select the topic workflow configuration to work with and filter the topics and actions available in the tables and calendar.

Note

You can change your topic workflow configuration selection on the Topic Management and the User Preferences pages. A change from one of these pages updates the selection on the other page.

1. In the left navigation pane, click the **Topic Management** icon (.
2. From the **Topic Workflow Configuration** drop-down in the Title bar, select a different topic workflow configuration if you have access to more than one topic workflow configuration.

Note

You must have View Topics permission for the topic workflow configuration to appear in the Title bar of the Topic Management page. If only one topic workflow is assigned to you, the topic workflow configuration name appears as text and there is no drop-down list.

3. (Optional) Select a **View items for** selector:
 - **Me:** Topics or actions visible to you and assigned to you.
 - **Work team:** Topics and actions visible to you and assigned to the selected work team. If you have access to more than one work team, select from the **Work Team** drop-down list.
 - **All:** All topics and actions visible to you. The Calendar tab is not available if you select **All**.
4. Select the **Topics**, **Actions**, or **Calendar** tab.

Choose which items to view on the Topics, Actions, and Calendar tabs

To control the items shown on the Topics, Actions, and Calendar tabs, use these procedures.

- [Define the set of topics to work with](#)
The **View items for** selectors at the top of the Topics, Actions, and Calendar tabs filter the topics and actions that appear in the Topics and Actions graphs, Topics and Actions tables, and on the calendar.
- [Graph the distribution of topics and actions by a specific field](#)
The Topics By and Actions By drop-down lists that appear in the Graphic section of the Topics and Actions tabs graph the distribution of topics and actions by the selected field.
- [Filter the Topics and Actions tables](#)
Use the **Select Filter** button and the **Filter** buttons on the Filter bar to filter the content of the Topics and Actions tables.
- [Manage the columns on the Topics and Actions tables](#)
You can add and remove columns, reorder columns, and sort columns.

Define the set of topics to work with

The **View items for** selectors at the top of the Topics, Actions, and Calendar tabs filter the topics and actions that appear in the Topics and Actions graphs, Topics and Actions tables, and on the calendar.

View items for selector is intended to show all topics or actions where you or a selected work team might need to act, such as:

- Option **All** displays all items visible to you. For example, items you created and that are assigned to you, or that have been made visible through the **Visible to work team** topic field.
- Options **Me** or **Work team** are restricted to the items displayed based on topic or action assignments as detailed below.

The displayed list uses a broader search taking into account assignments on different levels and for other team members, if you have appropriate access to view them. For a more targeted view of topics or actions specifically assigned to a particular person or team, see [Filter the Topics and Actions tables](#) on the Topics or Actions tables based on the Assigned To field.

1. In the left navigation pane, click the **Topic Management** icon ()
2. (Optional) From the **Topic Workflow Configuration** drop-down list, select a different topic workflow configuration.
3. Select a **View items for** button:
 - **Me** for topics or actions visible to you, and with either the topic or at least one of the included actions assigned to you.
 - **Work team** for topics and actions visible to you, with the topic or at least one of the actions assigned to the selected work team, or any member of that team. If you have access to more than one work team, select from the **Work Team** drop-down list.
 - **All**: for all topics and actions visible to you.
4. Select the **Topics**, **Actions**, or **Calendar** tab.

If you select **All**, the calendar displays a message that it is not available.

Note

When you navigate between the Topics and Actions tabs, Oracle Empirica Signal remembers your most recent topic workflow configuration and the following items for each topic workflow configuration that you select: the **View Items for** selection, the **Topics By** and **Actions By** selection, whether you included closed topics and actions in the graph area, the selected filters and their filter values in the Filter bar, and the **Assigned to** selection in the Calendar tab. These are remembered when you navigate back to the Topics, Actions, or Calendar tab or switch back to a previously selected topic workflow configuration and also remembered the next time that you log in.

Graph the distribution of topics and actions by a specific field

The Topics By and Actions By drop-down lists that appear in the Graphic section of the Topics and Actions tabs graph the distribution of topics and actions by the selected field.

1. [Log in to Oracle Empirica Signal](#).

2. In the left navigation pane, click the **Topic Management** icon ()
3. Select the **Topics** or **Actions** tab.
4. In the Graphic section, change the graph shown by selecting a different field from the **Topics By** or **Actions By** drop-down list.
 - The graph displays counts (number of topics or actions) for each value of the selected field. If the **Topics By** or **Actions By** selection is an **Assigned To** field and the value is a work team, the bar is not solid. Data for which there is no value is displayed as (No Value).
 - If you choose **Current State** or **Action State**, a donut chart shows the states and number of topics for each state in a donut graph whose total area corresponds to 100%. You can remove a state from the donut by clicking the box to the left of it in the legend.
 - Click the Gear icon () to select or deselect the **Planned Actions** check box to include or exclude planned actions. Select or deselect the **Include Closed Topics** or **Include Closed Actions** check box to include or exclude topics or actions that have been closed. For bar charts, this adds a bar in a lighter color for any closed topics or actions. If there are open and closed topics or actions for the **Actions By** field, then a stacked bar is displayed. Hover over the two sections to see the breakdown of the total shown by closed versus open topics or actions. If you have chosen **Action State** or **Topic Current State** from the **Actions By** drop-down list and then select the **Include Closed Topics** or **Include Closed Actions** check box, a second donut chart shows the closed topics or actions.

Note

Changing the graph does not filter the topics in the Topics or Actions tables.

5. Click any element in the Graphic section to open a menu with two options:
 - **Add to filter:** Add the filter to the Filter bar and filter the Topics table.
 - **Replace filter:** Replace current filters on Filter bar with the graphic selection.
6. Hide or show the Graphic section by clicking the up-arrow or down-arrow that appears at the bottom of the Graphic section.

Filter the Topics and Actions tables

Use the **Select Filter** button and the **Filter** buttons on the Filter bar to filter the content of the Topics and Actions tables.

The topics that appear in the Topics and Actions tables are those you can work with and that correspond to your **View items for** selection at the top of the Topic Management page. You can further filter the topics using the **Select Filter** button to apply additional filters to the table.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Topics** or **Actions** tab.
3. To add or remove filter buttons from the Filter bar, click the **Select Filter** button () at the top left of the Filter bar. Check a filter to add it to the bar. Uncheck a filter to remove it from the bar. The filter choices include: Project, Assigned To, plus a set of fields that are configured in the topic workflow configuration to appear as filter fields.

- The **Current state** filter always appears on the Filter bar of the Topics table. The **Action state** filter always appears on the Actions Table. You can't remove these filters, but you can change their values.
- You can add as many filters as you want.
- Each filter impacts the number of topics or actions shown in the table.

Note

If the graph displayed in the Graph section provides a view of the topics or actions you want to work with, you can click an item to open a menu with these choices:

- **Add to filter:** Add the value from the graph to the filter value on the filter bar and filter the Topics or Actions table. If the filter is not already displayed in the Filter bar, it is added to the filter bar.
- **Replace filter:** Clear all the filters and add the value from the graph to the filter value on the filter bar and filter the Topics or Actions table. If the filter is not already displayed in the Filter bar, it is added to the filter bar.

4. To assign the values for a filter, click the filter, select values for the filter, then click **Apply**. Each filter value you add or remove impacts the topics or actions shown in the table. As you modify filter values, the number of topics or actions shown may be changed significantly. To clear the values of a filter, click the **Clear** button to remove all filters so that all actions appear in the table.

There are different types of filters. This means that possible values differ depending on field type associated with the filter. For a filter to be available, administrators must define topic and action fields as *filterable* in the topic workflow configuration. See [Edit a field](#).

- **Current state or Action state:** You can pick all open or closed states or select individual state values. The default setting is all open states. **All Open** or **All Closed** states appear as a toggle that you can turn on and off. When on, all states are included. When off, you can select individual states by selecting their check box. The individual state check boxes vary based on set of states in the current filtered topics or actions. The **All Open** or **All Closed** state toggles always include all open or closed states, even the states that are not currently represented in the topics or actions table. If more than one state is available, **Select All/Deselect All** is available. Clicking this either selects or deselects all the check boxes grouped underneath. For Action state, if there are any planned actions, you can select the planned check box to display them. If the **Planned** check box is not displayed and there are planned actions, you may need to change or reset your filters.
 - **Assigned to:** The values are grouped by work team and user. You can pick multiple work teams and users.
 - **String and integer fields:** Available values depend on how the field is defined in the topic workflow configuration. You can pick multiple values.
 - **Date fields:** From the **Select Filter** button, select the check box for an action or topic field that relates to a date; for example, **Planned Completion Date**. Enter a range of dates in the **From** and **To** text boxes or select the From and To dates by clicking the **Calendar icon**  and selecting a date. Add a single date by making the **To** and **From** dates the same.
5. To clear the values of a filter, click the **Filter** button, then click the **Clear** button and the **Apply** button.

Clear removes any selected values for the filter. The filter remains on the Filter bar. For state filters, **Clear** sets the filter to *All Open States* and *All Closed States*. For the Action state filter, **Clear** also includes the Planned state.

6. To revert to the previous filter values and dismiss the dialog, click **Cancel**.
7. To reset the values of all of the filter buttons back to their defaults, in which no filter values are selected and the **Current State/Action State** filter is set to **All Open States**, click the **Reset** button.

Note

If you log out and then log in again, or change topic workflow configurations, Oracle Empirica Signal remembers your filter selections and the filter values for each topic workflow configuration.

Manage the columns on the Topics and Actions tables

You can add and remove columns, reorder columns, and sort columns.

The Header Action menu () on the Topics and Actions tables has a **Columns** choice. It allows you to add selections from the Available Columns list to the Selected Columns list, add and remove columns, reorder columns, sort columns, and specify the order in which the columns appear in the tables.

1. In the left navigation pane, click the **Topic Management** icon ().
2. Select the **Topics** or **Actions** tab.
3. Click the **Header Action menu** () and then click **Columns**.

Oracle Empirica Topics displays the Columns dialog box. If this is the first time you are working with the columns, the columns that appear in the Selected Columns list are the default columns, shown below. These names will vary if your company has modified the column names.

- Work teams
 - Project
 - Topic - Topic Name
 - Current state
 - Assigned to
 - Attachment Count (includes topic and action attachments)
 - Action Count (includes open and closed actions)
 - Created
 - Modified
4. Select columns to include in the table from the **Available Columns** list and move them to the **Selected Columns** list using the right-arrow buttons. To remove columns, select columns in the **Selected Columns** list and use the left-arrow buttons to move them back to the **Available Columns** list.

When adding columns to the Actions table, both action fields and topic fields appear in the Available Columns list. Action-related fields appear at the top of the list, then topic-related fields, prefixed with *Topic -*.

5. To change the order in which columns display in a table, in the **Selected Columns** list, click the column name and:
 - Click  to move the column up in the list.
 - Click  to move the column down in the list.
6. To move multiple columns, hold down the **Ctrl** key while you click the column names, and then use the up or down arrows or click the first column you want to move and **Shift-click** the last column.

Note

For most tables, rows with empty cells appear first when you sort that column in ascending order, and last if you sort in descending order. Empty columns are always displayed last, regardless of the sort order.

7. If you want to replace your choices with the Oracle Empirica Signal defaults, click **Reset**. The table columns and sorting return to the default values.
8. Specify the sort order:
 - a. From the **Column Name** drop-down lists, select a column name for up to three columns.
 - b. From the **Sort Order** drop-down lists, select **Asc** (ascending order: A-Z, 1-9) or **Desc** (descending order: Z-A, 9-1).
9. Click **OK**.
Oracle Empirica Topics updates the columns on the Topics or Actions table.
If a table includes a lot of columns or the columns contain long values, the entire table may not fit across your browser window. Scroll to the right to see the rest of the table.
10. You can further sort the table by column values by clicking a column header. Depending on the nature of the column, the information appears in ascending or descending order.

Work with topics

This section includes procedures for working with topics and topic reports.

- [View topics](#)
You can view topics you created and topics you have permission to see from your work teams.
- [Filter the Topics table](#)
Use the Select Filter button and modify filter values to filter the content of the Topics table.
- [View a specific topic](#)
You can view general information about a topic and the topic links, comments, attachments, actions, and history associated with the topic.
- [Quickly access topic information](#)
If you click on any row in the Topics table, the Recent Topics panel is replaced with a Detail panel with details about the selected topic.

- [Open a topic from the Recent Topics list](#)
If you click a topic in the Recent Topics list, it opens for viewing.
- [View Topic and Edit Topic pages](#)
From the Topics table, you can view and edit topic information.
- [Edit the general information about a topic](#)
On the Edit Topic page, you can make changes to the general information about a topic.
- [Add or view comments for a topic or action](#)
You can add or view comments for a topic or an action.
- [Add a topic](#)
You can add a topic on the Topic Management page.
- [Associate a topic with a product-event combination](#)
Follow these steps to associate a topic with a product-event combination.
- [Select a topic template](#)
When adding a topic, saving to a topic, or submitting a review, you can select a topic template for your new topic.
- [Make a topic visible to a work team](#)
A work team is a group of users who have an interest in a set of topics. When a topic is made visible to a work team, the members of that team can view the topic and any actions defined for it.
- [Link topics](#)
When you edit a topic, you can add a cross-reference from that topic to another topic by adding a topic link.
- [Remove a link](#)
You can remove a link added to a topic that provides a cross-reference to another topic.
- [Reopen a topic](#)
You can reopen a topic if the topic is in a closed state and your topic workflow configuration includes a transition from that state to another state, such as Assigned or Reopened.
- [Delete a topic](#)
You can delete topics from the Topics table.
- [View the history of a topic](#)
You can view the history of topics you created and topics you have permission to see from your work teams.
- [Viewing topic reports](#)
Predefined Oracle Analytics reports are optional topic reports that provide greater detail on topic information.
- [Create a topic PDF or ZIP file](#)
You can create a PDF or Zip file to document the contents of a topic and include attachments.

View topics

You can view topics you created and topics you have permission to see from your work teams.

1. In the left navigation pane, click the **Topic Management** icon .
2. Select the **Topics** tab to display the Topics table. The fields in the Topics table are described in the [Topics tab: Default field descriptions](#).

The Detail panel appears on the right. It displays a list of recently viewed or edited topics and the topic state and the number of actions, attachments, and comments associated with the topic. Planned actions are not included. You can click any topic title to view it.

If you click in any topic row, the Detail panel updates to become the Topic Detail panel. It contains four sections: General Information, Comments, Attachments, and Actions. You can collapse and expand each section of the panel. To view the topic, click the **View topic** icon ().

3. (Optional) From the **Topic Workflow Configuration** drop-down list, select a different topic workflow configuration.
4. (Optional) Select a **View items for** selector:
 - **Me:** Topics or actions visible to you and assigned to you.
 - **Work team:** Topics and actions visible to you and assigned to the selected work team. If you have access to more than one work team, select from the **Work Team** drop-down list.
 - **All:** All topics and actions visible to you.
5. (Optional) In the Graph section, change the graph shown by selecting a different field from the **Topics By** drop-down list.

 Note

Changing the graph does not filter the topics in the Topics table.

6. In the Filter bar, click the **Select Filter** button to add or remove filters and then modify the filter values to limit the Topics table to those topics you want to work with.
7. Add a topic by clicking the plus sign () above the table at the far right.
8. Click the **Header Action menu** () to perform the following actions on the table as a whole:
 - Add or remove columns, sort columns, and specify the order in which the columns appear in the table.
 - Download the Topics table to various types of files.
 - Produce topic-related Oracle Analytics reports.
 - Add a topic.
9. Click a topic's **Row Action menu** () to perform the following actions on the selected topic:
 - **View:** Display the general information about the selected topic, links to other topics, comments, attachments, actions, and history. You can have up to five view windows open at once. To edit a topic you're viewing, click the **Edit Topic** icon () in the upper-right corner of the View Topic window.
 - **Edit:** [Edit the general information](#) about the selected topic. You can only have one edit window open. If you have already opened a topic for editing and you try to edit another topic, Oracle Empirica Topics asks you to confirm that any unsaved changes on the other topic you started to edit will be discarded.
 - **Delete:** Confirm that you want to [delete the topic](#) and, if so, deletes the topic.

- **Reopen:** [Reopen a topic](#) that is in a closed state.
- **Create PDF:** [Select attachments](#) and actions to include and additional content about the topic. The PDF includes the general information and you can include the topic comments, attachment source details, and general information history.
- **Create ZIP:** [Select attachments](#) and actions to include and additional content about the topic. The PDF includes the general information and you can include the topic comments, attachment source details, and general information history.

Note

Some options are available based on your work team permission and the **Visible to work team** field.

Default field descriptions—Topics tab

The Topic Management page provides information about topics that are visible to a work team of which you are a member. If you have created any topics, those topics also appear.

The table might include these standard columns, and additional columns customized for your organization:

Column	Description
ID	Unique identifying number for the topic.
Work teams	The work team(s), if any, to which this topic is visible.
Project	Project, if any, with which the topic is associated.
Name	Name of topic.
Topic description	Description of the topic.
Current state	The state of the topic in the topic workflow. States are defined by your organization to represent expected workflow stages and are specified in the topic workflow configuration.
Reason for change	Last reason for change, if any, provided for the topic.
Assigned to	User or work team to whom the topic is assigned.
Keywords	Keywords, if any, associated with the topic. This is the column that is searched if you select a keyword at the top of the page.
Resolution	Last resolution, if any, provided for the topic.
Resolution date	Date and time when a resolution was provided for the topic.
Size	Total size of all attachments, including attachments to the topic and to any actions. Also includes attachments that have been deleted from the topic or its actions. (Deleted attachments are retained in the database, although they cannot be accessed from within the application.)
Attachment Count	Total count of attachments to the topic and to any of its actions. (Deleted attachments are not included in this count.)
Action Count	Number of actions associated with the topic, excluding planned actions.
Created	Date and time when the topic was created.
Created By	Name of the user who created the topic.
Modified	Date and time when the topic was last modified.

Column	Description
Modified By	Name of the user who last modified the topic, including modifying links, comments, attachments, or actions.

The table also includes columns for custom fields added by your organization. For information about viewing or downloading tables or changing the way data displays in the table, see [About tables](#).

Filter the Topics table

Use the Select Filter button and modify filter values to filter the content of the Topics table.

The topics in the Topics table are those you can work with and that correspond to your **View items for** selection at the top of the Topic Management page. You can further filter the topics using the Select Filter button to apply additional filters to the table.

1. In the left navigation pane, click the **Topic Management** icon (.
2. Click the **Topics** tab.
3. To add or remove filter buttons from the filter bar, click the **Select Filter** button () at the top left of the Filter bar. Check a filter to add it to the bar. Uncheck a filter to remove it from the bar. The filter choices include: Project, Assigned To, plus a set of fields that are configured in the topic workflow configuration to appear as a filter fields.
4. To assign the values for a filter, click the Filter button. Select the filter value choices and click **Apply**. To cancel your selection, click **Cancel**.

Oracle Empirica Signal applies the filter to the Topics table.

5. To clear a filter, click the Filter button, then click the **Clear** button, and then click the **Apply** button.

View a specific topic

You can view general information about a topic and the topic links, comments, attachments, actions, and history associated with the topic.

1. In the left navigation pane, click the **Topic Management** icon (.
2. Select the **Topics** tab.
3. (Optional) From the **Topic Workflow Configuration** drop-down list select a different topic workflow configuration.
4. (Optional) Select a **View items for** selector:
 - **Me:** Topics or actions visible to you and assigned to you.
 - **Work team:** Topics and actions visible to you and assigned to the selected work team. If you have access to more than one work team, select from the **Work Team** drop-down list.
 - **All:** All topics and actions visible to you. The Calendar tab is not available if you select **All**.
5. (Optional) In the Graph section, change the graph shown by selecting a different field from the **Topics By** drop-down list.

Note

Changing the graph does not filter the topics in the Topics table.

6. In the Filter bar, click the **Select Filter** button to add or remove filter buttons and modify the filter values in the Topics table to those topics you want to work with.

7. Click a topic's **Row Action menu** () and then click **View**.

The general information about the topic appears, along with links to additional information, including:

- **Topic Links:** Related topics linked to this topic.
- **Comments:** Comments added to the topic.
- **Attachments:** Information about items attached to the topic.
- **Actions:** A list of each activity identified for the topic.
- **History:** Changes made to the general information for the topic.

For details, see [View Topic and Edit Topic pages](#).

8. To edit the topic, click the Pencil icon () in the upper-right corner.

Quickly access topic information

If you click on any row in the Topics table, the Recent Topics panel is replaced with a Detail panel with details about the selected topic.

1. In the left navigation pane, click the **Topic Management** icon ().
2. Select the **Topics** tab.
3. Click anywhere in a row on the Topics table.

The Detail panel replaces the Recent Topics panel. The information shown is a summary of the information you would see if you selected the topic's **Row Action menu** () and then clicked **View**.

There are four sections:

- General Information
 - Comments (only available if the Topic Workflow Configuration - allow topic comments property is enabled).
 - Attachments
 - Actions
4. Collapse or expand the sections of the Detail panel by clicking the arrow to the left of the section name. If there are no comments, attachments, or actions, *None* appears below the section name.
 5. To open the topic and see all details, click the arrow to the right of the topic name.
 6. To close the Topics Detail panel and return to the Recent Topics list, click **Close** (to the left of the topic name).

Open a topic from the Recent Topics list

If you click a topic in the Recent Topics list, it opens for viewing.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Select the **Topics**, **Actions**, or **Calendar** tab.
3. On the Recent topics list, click a topic.

The View Topic page opens to the topic's General Information section.

4. To edit the topic, click the Pencil icon () in the upper-right corner.

Note

If you have another topic open for editing, Oracle Empirica Topics warns you that the current Edit Topic window will be replaced with the topic you are opening from Recent Topics.

View Topic and Edit Topic pages

From the Topics table, you can view and edit topic information.

The menu items in a topic's **Row Action** menu () take you to a View Topic or Edit Topic page to view or edit general information about the topic, topic links, comments, attachments, actions, and history.

- Select **Edit** to open the window in Edit mode.
- If you select **View**, then wish to edit the topic, click the **Edit Topic** icon ().

When the page is in Edit mode, you can perform activities based on your permissions and topic workflow configuration.

Menu Item	Description	Available Actions
General Information	Displays the current field values that describe a topic: - The fields are read-only, editable, or required. If a field is required, an asterisk (*) appears next to it. You cannot save the topic until you provide a value for the field. - Each field accepts text, numeric, or date values, or provides a list of values you can select. If a value is not required, you can leave the value empty to indicate no value for the field. Fields may also offer a Select Available Values link so you can select one or more values from a list. - Arrow icons may appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for MedDRA SOC() and MedDRA HLG T () appear, the arrows indicate that you must select a value for the MedDRA SOC field first and then select a value for the MedDRA HLG T field. You cannot select an HLG T value first: the values available for HLG T depend on the SOC you select. - The Visible to work teams field displays a list of work teams whose members can access the topic. In edit mode, once you have entered changes to the General Information, a yellow icon appears in the Topic editor header and General Information tab to indicate you have unsaved changes. - To save changes to the General Information section, click Save. The changes are shown as entries in the History section. Note: The Save button affects only the General Information section of the topic. Do not click Save after you work with other sections of this page. Any changes to other sections are saved to the topic immediately.	None

Menu Item	Description	Available Actions
Topic Links	Displays related topics that are linked to this topic. When the page is in edit mode, you can click Add Topic Link to select a topic and link it to this one. For each linked topic, you can click Remove Link to remove the link or View to view the linked topic. A set of filters appear for the section, determined by the Filter attribute on the Topic fields in the Workflow Configuration. These might include some of the following, plus filters customized for your organization: • Project—Includes projects with the linked topics. • Current state—Includes current topic states of the linked topics. • Assigned to—Includes names of users and work teams assigned to the linked topics.	View Remove Link Columns Print Download
Comments	Displays all comments added to the topic. When in edit mode, you can click Add Comment to add a comment. You cannot modify or remove a comment. Note: This section appears only if your topic workflow configuration allows topic comments.	Add Comment
Attachments	Displays information about items attached to the topic. Your topic workflow configuration determines the types of attachments you can add, such as files, URLs, free-text notes, or Oracle Empirica Signal objects. When in edit mode, you can click Add Topic Attachment to add a file, URL, or note attachment. You can attach Oracle Empirica Signal objects using the Save to Topic link that is displayed on different Oracle Empirica Signal pages.	View View Source Details Comments Edit Delete Columns Print Download
Actions	Displays a list of each activity identified for the topic. Actions may reflect research activities, such as literature searches and scheduled meetings, or any other activity you wish to track for the topic. In edit mode, you can click Add Action to add an action, or click the  to edit the action. When editing an action, you can add attachments or comments to the action.	View Edit Delete Columns Print Download

Menu Item	Description	Available Actions
Planned Actions	Displays a list of each planned activity identified for the topic. If there are no planned actions, this section is not displayed.	View Edit Delete Columns Print Download
History	Displays changes to general information for the topic. A new row is added to the table each time you click Save in the General Information section. Note: The Assigned to column shows work teams and users to which the topic has been assigned.	Columns Print Download

Edit the general information about a topic

On the Edit Topic page, you can make changes to the general information about a topic.

Note

If you have already opened a topic for editing and you try to edit another topic, Oracle Empirica Topics asks you to confirm that any unsaved changes on the previous topic you started to edit will be discarded.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Topics** tab.
3. Click a topic's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic page, select **General Information** from the left menu.
5. Enter values in the fields. See the field descriptions below.

Note

If one or more states included in the **Current state** drop-down list requires approval for transition to another state, you must have **Requires Approval** work team permission to select it. No approval is required to move a topic from Planned to Init.

Depending on your organization's workflow configuration, the following fields appear in this section. Additional fields, customized by your organization, may also appear. Required fields are marked with a red asterisk.

Field descriptions—General Information

Field	Description
Visible to work team(s)	The work team or teams whose members can view or act on the topic. Click Browse to display a descriptive list of work teams. If your topic configuration is visible to only one work team, you can click Browse to select the work team.
Topic Name	Name of the topic.
Topic Description	Description that identifies content of the topic.
Current State	State of the topic in the topic workflow. States are specified in the topic workflow configuration to represent your organization's expected workflow for topics. A topic may require all of its associated actions to be in a final state before you can assign a final state to the topic itself. In this case, a message appears if you try to assign a final state to the topic with actions that are not in a final state.
Assigned to	User or work team to whom the topic is assigned. By default, a topic that you add is assigned to you. Available users and work teams are determined by the Visible to work team selection. • Users: Members of the Visible to work team(s) selection with Edit Topic/Action work team permission. • Work teams: All work teams with the Assign to work team property enabled and at least one active member in the Users list.
Keywords	Free text to filter the topics that appear in a table.

6. Click **Save**.

When a topic is saved and the topic state has changed, Oracle Empirica Topics checks for planned actions that need to move from the Planned to the Initial state. When actions are moved to the Initial state, Oracle Empirica Topics populates any date field values in the action using the current date and the date offset from the action type. Oracle Empirica Topics records the action state change in the Action History and sends any configured email notifications.

 Note

If another user edits a topic at the same time, the first one to save the topic will have their changes saved. The second user will get an error indicating the topic has been changed since the edit session began. In some cases, the General Information section remains visible, allowing the user to print or take a screen shot, so that the information can be re-entered.

7. (Optional) Edit additional information about the topic by selecting a page from the left-hand navigation pane:

Note

The **Save** button affects only the General Information section of the topic. Do not click **Save** after you work with other sections of this page. Any changes to other sections are saved to the topic immediately.

- To display related topics that are linked to this topic, click **Topic Links**.
- To edit public and private comments associated with the topic, click **Comments**.
- To [edit attachments](#) associated with this topic, click **Attachments**.
- To display a list of actions related to this topic, click **Actions**.
- To display a list of planned actions related to this topic, click **Planned Actions**. This section only appears if the Topic contains planned actions.
- To [view the history](#) of this topic, click **History**.

Add or view comments for a topic or action

You can add or view comments for a topic or an action.

Your topic workflow configuration might give you the ability to add comments to all, some, or none of the following:

- A topic as a whole.
- Individual actions.
- [Topic attachments and action attachments](#).

Note

Once you have added a comment, you cannot edit or delete it.

Add comments for a topic or action

1. In the left navigation pane, click the **Topic Management** icon () .
2. Click the tab you wish to work with, either the **Topics** tab or the **Actions** tab.
3. Click the **Row Action menu** () for the item you wish to work with, and then click **Edit**.
4. On the Edit page, select **Comments** from the left menu.
5. Click **Add Comment**.
6. In the text box, enter the comment.
7. Click **Save**.

View comments for a topic or action

1. In the left navigation pane, click the **Topic Management** icon () .
2. Click the tab you wish to work with, either the **Topics** tab or the **Actions** tab.
3. Click the **Row Action menu** () for the item you wish to work with, and then click **View**.

4. On the View page, select **Comments** from the left menu.
Any comments that have been added appear.

Add a topic

You can add a topic on the Topic Management page.

1. In the left navigation pane, click the **Topic Management** icon () .
2. Click the **Topics** tab.
3. Do one of the following:
 - Click the plus sign (+) on the far right side above the table.
 - Click the **Header Action menu** () , and then click **Add Topic**.

The fields that appear on the Add Topic page depend on your topic workflow configuration.

Note

You can add a topic when you [save an attachment to a topic](#) from other pages in the application.

4. In the **Topic template** field, select a topic template that can provide default values for the topic's General Information and Actions, or click **Browse** to select from a detailed table of topic templates.

The topic template field is available only if there are templates that are visible to a work team of which you are a member.

5. In the **Visible to work team** field, [select the work team or teams](#) whose members can view or act on the topic, or click **Browse** to select from a detailed table of work teams.

Available work teams are those for which you have the edit topics/actions permission. Your topic workflow configuration defines whether you must specify a single work team (from the **Visible to work team** drop-down list) or you can select zero, one, or multiple work teams (from the **Visible to work team** list box).

Note

If you do not select any work teams, only you are able to view and act on the topic.

To select multiple work teams in the list box, hold down the **Ctrl** key while clicking each work team. Deselect a work team by holding down the **Ctrl** key while clicking the work team.

6. Specify values for the rest of the fields.
 - Each field may be read-only, editable, or required. If a field is required, an asterisk (*) appears next to it and you cannot save the topic until you provide a value.

Note

When a topic is created during the process of saving another Oracle Empirica Signal object as an attachment, requirements for the initial state are not enforced until the topic is edited.

- Each field accepts text, numeric, or date values, or provides a list of predefined values that you can select. If a value is not required in such a field, you can select leave the value empty to indicate no value for the field. A field that accepts text or numeric values might also offer a **Select Available Values** link so that you can [select one or more values from a list](#).
- Arrow icons might appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for MedDRA SOC  and MedDRA HLGT  appear, the arrows indicate that you must select a value for the MedDRA SOC field first and then select a value for the MedDRA HLGT field. You cannot select an HLGT value first. The values available for HLGT depend on the SOC you select.

The fields listed below are standard fields that might appear on the Topic Management page when you add a topic. Required fields are marked with a red asterisk.

Field descriptions—Standard topic fields

Fields	Description
Visible to work team	The work team or teams whose members can view or act on the topic. Click Browse to display a descriptive list of work teams. If your topic configuration is visible to only one work team, you can click Browse to select the work team.
Topic Name	Name of the topic.
Topic Description	Description that identifies content of the topic.
Current State	The state of the topic in the topic workflow. States are defined by your organization to represent the expected workflow, and are specified in the topic workflow configuration.
Assigned to	User or work team to whom the topic is assigned. By default, a topic that you add is assigned to you. Available users and work teams are determined by the Visible to work team selection. Users: Members of the Visible to work team selection with Edit Topic/Action work team permission. Work teams: All work teams with the Assign to work team property enabled and at least one active member in the Users list.

Additional, custom fields might also be available.

- Optionally, assign the topic to a [project](#).
 - To assign the topic to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the topic to that project, click **Add to a new project named** and enter a project name.
- Click **Save** or, to edit topic links, attachments, etc., click **Save & Edit**.

To cancel this addition, click **Cancel**.

Note

When a topic is saved and the topic state has changed, Oracle Empirica Topics checks for planned actions that need to move from the Planned to the Initial state. When actions are moved to the Initial state, Oracle Empirica Topics populates any date field values in the action using the current date and the date offset from the action type. Oracle Empirica Topics records the action state change in the Action History and sends email notifications as configured.

Associate a topic with a product-event combination

Follow these steps to associate a topic with a product-event combination.

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **View Product-Event Combinations**, or click the product name or total count.
4. Click the product-event combination's **Row Action Menu** () and click **Submit Review**.
5. From the **Comment** drop-down list, select one of the comments defined for your signal configuration.
If no comment yet exists for the product-event combination, then the **Comment** drop-down list displays **<Select a comment>**. To clear the existing comment, from the **Comment** drop-down list, select **<Clear Comment>**.
6. To [suppress a product-event combination](#), select the **Suppress product-event combination** check box.
7. (Optional) In the **Detailed comment** text box, enter a detailed comment.
8. If signal management is integrated with Oracle Empirica Topics, then you can associate a topic with a given product-event combination. If the product-event combination is already associated, click **Change** to modify the association. The topic workflow configuration in use appears above these choices. Select one of the following:
 - **None**—Use this option if you do not want to associate a topic with the product-event combination. This is the default option if no topic has been associated with the product-event combination. If you select this option, comments and detailed comments are still logged but no topic is associated with the product-event combination.
 - **Existing topic**—Use this option to associate an existing topic with the product-event combination. As you type characters, a drop-down list of matching topic names is displayed. You can click **Browse** to select from a list of existing topics. Available topics are those that you can edit, ones you created, or topics that have been made visible to work teams you are in. If you select this option, comments and detailed comments are logged along with a topic association. The product-event combination is saved to the existing topic as an attachment.
 - **New topic**—Use this option to create a new topic and associate it with a product-event combination. If topic templates are available, the new topic can be based on the topic

template that you selected from the Topic template drop-down list. In addition, you can click **Browse** to select from a list of existing topic templates. Available topic templates are those that have been made visible to a work team that you are in.

The comments and detailed comments are logged along with a topic association. The product-event combination is saved to the new topic as an attachment. When you click **OK**, the Edit Topic page is displayed and you can [edit the associated topic](#). This includes adding attachments to the topic as well as viewing source details of attachments, and adding comments to the attachments. When you are finished, click **Save** or **Close**.

9. Click **OK**.

Select a topic template

When adding a topic, saving to a topic, or submitting a review, you can select a topic template for your new topic.

The Select Topic Template dialog box displays information about each template defined for the topic workflow configuration. You can access the Select Topic Template dialog box when [adding a topic](#), [saving to a topic](#), or [submitting a review](#).

Note

If you are working from the Add Topic page and a template has already been selected for the topic, selecting a different topic template resets the fields and content shown on the Add Topic page.

To select a template:

1. Select the row for the template you wish to use.
2. Click **OK**.

You can also double-click the row to select the template.

Make a topic visible to a work team

A work team is a group of users who have an interest in a set of topics. When a topic is made visible to a work team, the members of that team can view the topic and any actions defined for it.

The topic and its individual actions can also be assigned to different members of the work team. Users with appropriate work team permissions can then edit the topic or action in addition to viewing it.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the topic's **Row Action menu** icon () , and then click **Edit**.
3. On the Edit Topic page, select **General Information** from the left menu.
4. Next to the **Visible to work team** field, click **Browse**.

The Browse Work Teams dialog box appears and provides information about each work team for which you have the edit topics/actions permission, in a table that might include these standard columns:

Column	Description
Name	The name of the work team.
Description	Descriptive text about the work team.
Login Group	The name of the login group. Each work team is a subset of a login group.
All Users	Yes, if all users in the login group are members of the work team. No, if users have been individually added to the work team.
Users	The full name and Oracle Empirica Signal username of each member of the work team. Blank, if all users in the login group are members of the work team.
Topic Visibility	Whether or not the topic is visible to the work team.
Topic-Action Assignment	Whether or not topics and actions can be assigned to the work team.
Created By	Name of the user who created the work team.
Created	Date and time when the work team was created.
Modified By	Name of the user who last modified the work team.
Modified	Date and time when the work team was last modified.

The table may also include columns for custom fields added by your organization.

5. If the topic is configured for only one work team, you can select the row for the work team and click **OK**.

Note

Changing work team property settings impacts future adding and editing of topic and actions and topic templates only. For example: A topic is visible to and assigned to a work team. Subsequently, the **Allow topic visibility** and **Allow assignment of topics and actions** properties are unchecked for the work team. You can continue to edit and save the topic. However, once you select a different value for either the **Visible to work team(s)** or **Assigned to** fields, the work team is no longer available.

Link topics

When you edit a topic, you can add a cross-reference from that topic to another topic by adding a topic link.

After you link two topics, information about the link appears on the Topic Links page when you view or edit either of the topics.

Note

Your topic workflow configuration defines whether you can link a topic to any other topic, or only to topics that are currently in a final state such as Closed.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Topics** tab.
3. Click a topic's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic page, select **Topic Links** from the left menu.
5. Click **Add Topic Link**.
6. Optionally, limit the display using the lists that appear above the table. For example, select a [project](#) or enter a keyword to list only topics that match the specified project or keyword.
7. Click the radio button of the row for the topic that you want to select.
8. Click **OK**.

The count of the links is incremented and displayed to the right of the Topic Links item in the menu.

Remove a link

You can remove a link added to a topic that provides a cross-reference to another topic.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Topics** tab.
3. Click a topic's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic page, from the left pane, click **Topic Links**.
5. Click a link's **Row Action menu** () , and then click **Remove Link**.
6. Confirm the deletion by clicking **OK**.

Reopen a topic

You can reopen a topic if the topic is in a closed state and your topic workflow configuration includes a transition from that state to another state, such as Assigned or Reopened.

This option may only be available if you have the work team permission to reopen topics.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Topics** tab.
3. Click the **Row Action menu** () of a topic whose current state is *Closed*, and then click **Reopen**.
4. From the **Current state** drop-down list, select a state. Your topic workflow configuration defines the states that can be assigned to a topic that is in a final state.

5. Click **Save**.

Delete a topic

You can delete topics from the Topics table.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Topics** tab.
3. Click the topic's **Row Action menu** () , and then click **Delete**.
4. Confirm the deletion by clicking **OK**.

Note

Deleted topics cannot be accessed through the application. However, they are not deleted from the database.

View the history of a topic

You can view the history of topics you created and topics you have permission to see from your work teams.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Select the **Topics** tab.
3. Click a topic's **Row Action menu** () and then click **View** or **Edit**.
4. From the left menu, click **History**.

The table displays changes to general information for the topic. A new row is added to the table each time you click **Save** in the General Information section.

Changes that required approval include the Required Approval icon () in the Current State column.

Viewing topic reports

Predefined Oracle Analytics reports are optional topic reports that provide greater detail on topic information.

- [About topic reports](#)
Predefined Oracle Analytics reports provide information on topics and attachments.
- [Generate a predefined topic report in Oracle Analytics](#)
You can produce topic-related Oracle Analytics reports. Several predefined reports are built into Oracle Analytics for Topics and are accessible from the Topics table.
- [Predefined Oracle Analytics topic reports](#)
Predefined Oracle Analytics reports are available from a link on the Topic Management page if your database administrator and IT administrator installed and configured Oracle Analytics and its components.

About topic reports

Predefined Oracle Analytics reports provide information on topics and attachments.

Predefined Oracle Analytics reports are optional topic reports that provide greater detail on topic information. These reports require additional software and are available if your database administrator and IT administrator installed and configured Oracle Analytics and its

components. You access the reports in Oracle Analytics from the **Header Action menu** () on the Topics tab.

You can generate reports on multiple topic workflow configurations in Oracle Analytics Server, with each configuration available in a separate subject area. For on-premise Oracle Empirica Signal users, refer to the *Oracle Analytics Configuration Guide for Empirica Reporting* for instructions on setting up the Add multiple Topic Workflow Configurations option. If you use Oracle Empirica Topics as a cloud customer, please contact your Oracle representative to enable this feature.

The following predefined Oracle Analytics reports are available:

- Action State Timelines
- Actions by Status
- Actions by Topic
- Attachments in Topics
- Topic Counts by Work Team/User
- Topic State Timelines
- Topics by State
- Average Duration in Topic State
- Days in Current Topic State
- Topic Counts by Topic State
- Topic Processing Time

If Oracle Analytics is configured to use the RPD model and the report catalog for the Sample GVP Module IX, then the following predefined report is also available:

- Summary of Safety Signals

For more information on the Oracle Analytics reports, see [Predefined Oracle Analytics Topic Reports](#).

For more information on installing Oracle Analytics and its components and enabling the Oracle Analytics topic reporting feature, see the *Oracle Analytics Configuration Guide for Empirica Reporting*.

Generate a predefined topic report in Oracle Analytics

You can produce topic-related Oracle Analytics reports. Several predefined reports are built into Oracle Analytics for Topics and are accessible from the Topics table.

The Oracle Analytics reports include only the topics that are visible to you when working on the Topic Management page. The reports include the topics that you created and those that are visible to the work teams to which you are assigned.

Note

The **Report** link is available only when your database administrator and IT administrator have completed the Oracle Analytics reporting setup.

1. In the left navigation pane, select the **Analytics** icon



2. Log in to Oracle Analytics using your Oracle Empirica Signal username and password, and select **Sign In**.
3. From the title bar at the top of the page, select **Catalog**.
4. On the Catalog page, from the **Shared Folders** in the Folders section, select **Topics**, and then **Analysis Reports**.
5. To generate a report, from the list of predefined reports in the right pane, select **Open**.
6. If a page displays field values you can customize by selecting values from the drop-down lists, customize the report, and then select **OK**.

Oracle Analytics displays the predefined report.

Predefined Oracle Analytics topic reports

Predefined Oracle Analytics reports are available from a link on the Topic Management page if your database administrator and IT administrator installed and configured Oracle Analytics and its components.

The following sections describe the predefined reports that are available.

Note

Planned actions are excluded from the reports.

Note

Options in drop-down lists appear in case-sensitive alphabetical order.

Action State Timelines

Description	Filters for Data Retrieval	Columns
Provides the total elapsed time in days that each Action spent in a specific state. Computes the elapsed time using the Action Modification Date. If this date is unavailable, computes the time using the Action Creation Date. Sorted in order by Topic ID by Action ID by Action Version ID. Action Version ID is not a visible field.	- Project - Topic name - Action Name	- Project - Topic ID - Topic Name - Action ID - Action Name - Action States

Action State Timelines Sample Report

					Escalated		Init	
					Closed	Init	Closed	Escalated
Project	Topic ID	Topic Name	Action ID	Action Name				
Vaccines	134	Mercury Poisoning	435	Attach Mercury Poisoning info from CDC			2 days	
			436	Attach data mining results			1 day	
					3 days			

Actions by Status

Description	Filters for Data Retrieval	Columns
Provides topic information based on action status. Sorted in order by Action Status by Planned Completion Date by Action Name.	- Action Status - Project - Topic Action Modified Date From/To Note: To ensure that the query retrieves all data for a specific day, you should increase the date in the To field by 1 day. For example, to retrieve topics with Action Modified dates from 02/01/2012-02/04/2012, specify a From date of 02/01/2012 and a To date of 02/05/2012.	- Action Status - Planned Completion Date - Action ID - Action Name - Action Description - Action State - Action Assigned To - Action Created By - Action Created Date - Actual Completion Date - Action Modified By - Action Modified Date - Topic ID - Topic Name - Topic Description - Topic State - Project - Topic Assigned To

Actions by Status Sample Report (partial)

Action Status	Planned Completion Date	Action ID	Action Name	Action Description	Action State	Action Assigned To	Action Created By	Action Created Date
Closed	2/14/2012 12:00:00 AM	435	Attach Mercury Poisoning info from CDC	Visit cdc website and attach their Mercury poisoning info	Closed	Maria Smith	Maria Smith	2/14/2012 4:52:30 AM
	2/15/2012 12:00:00 AM	436	Attach data mining results	Include results from most recent VAERS data.	Closed	Maria Smith	Jane Doe	2/14/2012 5:09:22 AM
No Due Date		450	Contact physicians participating in post-market trial	Reach out to those pediatricians that are investigating in Trial PGE242	Init	Jane Doe	Jane Doe	3/14/2012 5:26:14 PM

Actions by Topic

Description	Filters for Data Retrieval	Columns
Provides topic information based on topic action.	- Project - Topic Name - Topic State - Action State	- Project - Topic ID - Topic Name - Topic Description - Topic Assigned To - Topic Created Date - Topic Modified Date - Topic State - Resolution Date - Search Keywords - Action Name - Action Description - Action State - Action Assigned To - Action Status - Action Type - Action Id - Version No - Planned Completion Date - Actual Completion Date
Sorted in order by Project by Topic Name by Topic Modified Date by Action Name.		

Actions by Topic Sample Report (partial)

Project	Topic ID	Topic Name	Topic Description	Topic Created Date	Topic Modified Date	Topic State	Resolution Date	Search Keywords	Action Name	Action Description	Action State
Vaccines	107	MMR and Autism	Follow up on public perception that MMR and Autism are related	1/27/2012 5:49:58 AM	3/14/2012 5:45:00 PM	Assigned			Contact physicians participating in post-market trial	Reach out to those pediatricians that are investigating in Trial PGE242	Init
	134	Mercury Poisoning	Explore mercury poisoning in childhood vaccines	2/2/2012 7:43:03 AM	2/26/2012 9:55:49 PM	Assigned	2/14/2012 12:00:00 AM		Attach Mercury Poisoning info from CDC	Visit cdc website and attach their Mercury poisoning info	Closed
									Attach data mining results	Include results from most recent VAERS data.	Closed

Attachments in Topics

Description	Filters for Data Retrieval	Columns
Provides topic attachment information. Sorted in order by column from left to right.	- Project - Topic Name - Source - Topic Modified Date From/To Note: If a topic has not yet been modified, the topic Creation Date is used in topic retrieval.	- Project - Topic ID - Topic Name - Source - Topic Attachment Name - Topic Attachment Created By - Topic Attachment Created Date - Topic Attachment Modified By - Topic Attachment Modified Date

Attachments in Topics Sample Report

Project	Topic ID	Topic Name	Source	Topic Attachment Name	Topic Attachment Created By	Topic Attachment Created Date	Topic Attachment Modified By
Vaccines	107	MMR and Autism	Note	Note to self	Jane Doe	3/14/2012 5:45:00 PM	
	134	Mercury Poisoning	Data Mining Results Graph	Poisoning and vaccines	Maria Smith	2/6/2012 3:58:59 AM	
	135	Blood transfusions and infection	Data Mining Results	VAERS results of interest on infection	Maria Smith	2/23/2012 6:25:12 PM	
			Data Mining Results Graph	Confidence Interval graph	Maria Smith	2/23/2012 6:26:11 PM	
				Map Graph for infection in vaers data	Maria Smith	2/23/2012 6:28:08 PM	
			File	Dear Provider letter	Maria Smith	2/23/2012 6:19:37 PM	
			Note	Additional concerns	Maria Smith	2/23/2012 6:20:48 PM	
			URL	Presentation from UK National Blood Service	Maria Smith	2/23/2012 6:18:03 PM	

Topic Counts by Work Team/User

Description	Filters for Data Retrieval	Columns
Provides the number of topics in each state assigned to each user on one or more work teams, and the total number of topics assigned to the work team. There is one table for each work team. Sorted in order by work team user. Note: Topics that are visible to a work team but are not assigned to a member of the work team are not included in the Work Team Total.	Work Team Name	- Topics (count) - Topic State (one column for each) Note: If no topics are in a given state, the Topic State column does not appear.

Topic Counts by Work Team/User Sample Report

Biologics

	Topics	Assigned
User		
Jane Doe	1	1
Maria Smith	1	1
Work Team Total	2	2

Topic State Timelines

Description	Filters for Data Retrieval	Columns
Provides the total elapsed time in days that each topic spent in a specific topic state. Sorted in order by Topic Version ID. Topic Version ID is not a visible field. Note: If the total elapsed time is less than 12 hours, the time period appears as 0 days.	- Project - Topic Name	- Project - Topic ID - Topic Name - Topic Description - Topic State

Topic State Timelines Sample Report

				Assigned	Escalated	Init	
				Closed	Assigned	Assigned	Escalated
Project	Topic ID	Topic Name	Topic Description				
Vaccines	107	MMR and Autism	Follow up on public perception that MMR and Autism are related				2 days
					3 days		
	134	Mercury Poisoning	Explore mercury poisoning in childhood vaccines			0 days	
				12 days			
	135	Blood transfusions and infection				2 days	

Topics by State

Description	Filters for Data Retrieval	Columns
Provides topic information based on topic state. Sorted in order by State by Project by Topic ID.	- Topic State - Project - Topic Modified Date From/To Note: To ensure that the query retrieves all data for a specific day, you should increase the date in the To field by 1 day. For example, to retrieve topics with Topic Modified dates from 02/01/2012-02/04/2012, specify a From date of 02/01/2012 and a To date of 02/05/2012. Note: If a topic has not yet been modified, the topic Creation Date is used in topic retrieval.	- Topic State - Project - Topic ID - Topic Name - Topic Description - Topic Assigned To - Topic Created By - Topic Created Date - Topic Modified By - Topic Modified Date - Resolution - Resolution Date

Topics by State Sample Report

Topic State	Project	Topic ID	Topic Name	Topic Description	Topic Assigned To	Topic Created By	Topic Created Date	Topic Modified By	Topic Modified Date	Resolution
Assigned	Vaccines	107	MMR and Autism	Follow up on public perception that MMR and Autism are related	Jane Doe	Maria Smith	1/27/2012 5:49:58 AM	Jane Doe	3/14/2012 5:45:00 PM	
		134	Mercury Poisoning	Explore mercury poisoning in childhood vaccines	Maria Smith	Jane Doe	2/2/2012 7:43:03 AM	Maria Smith	2/26/2012 9:55:49 PM	There was data available for this topic up
		135	Blood transfusions and infection		Maria Smith	Jane Doe	2/2/2012 7:49:17 AM	Maria Smith	2/23/2012 8:17:11 PM	

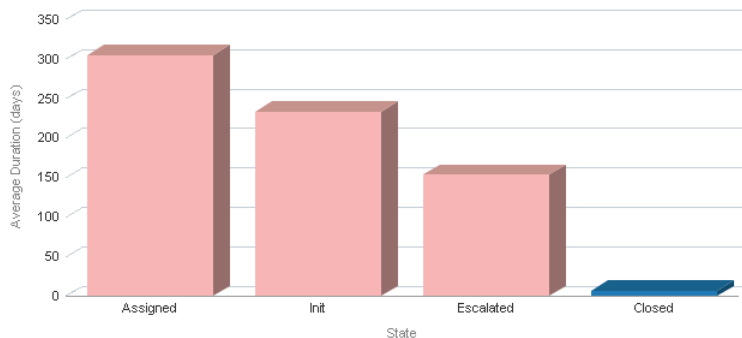
Average Duration in Topic State

Description	Columns	Bar Graph Details
Provides the average length of time a topic has spent in a state. The topic's current state is not considered as part of the report. Sorted by average duration.	- Topic State - Average Duration (days)	- Y-axis label: Average Duration (days) - X- axis label: Topic State - Bar labels: Topic State names from TWC

Average Duration in Topic State Sample Report

Average Duration in Topic State

Average Duration (days)



State	Average Duration (days) ▲▼
Assigned	305.00
Init	234.13
Escalated	153.71
Closed	7.00

Topic Processing Time

Description	Columns
Calculates the duration in days from when a topic is created until the topic moves to the current final state. If Total Processing Time (days) is greater than 100 the cell is shaded light red. Sorted by Total Processing Time (days) .	- Topic Name - Created, Final State - Total Processing Time (days)

Topic Processing Time Sample Report

Topic Processing Time

Topic Name	Created	Final State	Total Processing Time (days) ▲▼
85_Closed_Topic1	2/13/2012 12:00:00 AM	Closed	3503
IAEC	2/1/2012 6:31:02 PM	Closed	13
IEAC	2/1/2012 6:45:13 PM	Closed	13
IAEC time detail	2/1/2012 12:01:00 AM	Closed	1
85_Alt_Proj1_Closed	9/16/2021 1:10:12 AM	Closed	0
85_Closed_Topic2	9/16/2021 1:10:11 AM	Closed	0
85_Closed_Topic3	9/16/2021 1:10:11 AM	Closed	0
85_Closed_Topic4	9/16/2021 1:10:11 AM	Closed	0
STEP 2.2 topic	9/21/2021 5:12:19 PM	Closed	0

Topic Count by Topic State

Description	Columns
Provides the number of topics currently in each state. Sorted by Topic Count.	• Topic State • Topic Count

Topic Count by Topic State Sample Report

Topic Counts by Topic State

Topic Counts by Topic State



Topic State	Topic Count ▲▼
Init	31
Assigned	11
Escalated	10
Closed	9

Days in Current Topic States

Description	Columns
Provides the number of days since a topic transitioned into its current state. The report only includes open topics that are in a non-final state. Sorted by Days in current state.	• Topic Name • Topic State • Days in Current State

Days in Current Topic States Sample Report

Days in Current Topic State

Topic Name	Topic State	Days in Current State ▲▼
ICAE	Escalated	3677
AEAE	Escalated	3573
ICA	Assigned	3552
85_Init_Topic1	Init	3542
IIAAAE	Escalated	3541
85_Alt_Proj1_Assign	Assigned	39
85_Alt_Proj1_Esc	Escalated	39
85_Alt_Proj1_Init	Init	39
85_Asgn_Mod_Topic1	Assigned	39
85_Asgn_Topic1	Assigned	39
85_Asgn_Topic2	Assigned	39
85_Esc_Topic1	Escalated	39
85_Esc_Topic2	Escalated	39
85_Esc_Topic3	Escalated	39

Summary of Safety Signals Report**Note**

This report is available only if Oracle Analytics is configured to use the RPD model and the report catalog for the Sample GVP Module IX.

Ensure the following topic fields are configured properly for the report:

- The topic's Topic name field is populated with a signaling term.
- The topic's Topic description field is populated with a brief summary of the rationale for further evaluation.
- The topic's Product name field is populated with a product name.
If your signal configuration is associated with the GVP Module IX topic workflow configuration and the signal configuration's Topic product field is set to the topic workflow configuration's Product name field, then when you create a new topic using Submit Review the topic's Product name field will be automatically populated.

Description	Filters for Data Retrieval	Columns - Data source
Tabular summary of safety signals ongoing or closed during the reporting interval. Sorted in order by Signal term. Note: The report reflects topic information as of the end of the reporting interval.	- Product name - Reporting interval	- Signal Term - Topic's Topic name field - Date Detected - MMM/YYYY of the Topic's Created Date - Status (Ongoing or Closed) - Topic's Current state field - Date Closed (for closed signals) - MMM/YYYY of the date the topic last transitioned into a final state - Source of Signal - Concatenation of the Origin of signal and Source of topic fields - Reason for Evaluation and Summary of Key Data - Topic's Topic description field - Method of Signal Evaluation (blank column) - Action(s) Taken or Planned - Topic's Recommendation for action field - Resolution - Topic's Justification for confirming or refuting signal field

Summary of Safety Signals Sample Report

Summary of Safety Signals

Signal Term	Date Detected	Status	Date Closed	Source Of Signal	Reason for Evaluation and Summary of Key Data	Method of Signal Evaluation	Action(s) Taken Or Planned	Resolution
Amlodipine - Gastro	Mar/2019	Ongoing		Internal - Statistical analysis	Amlodipine - Gastro Intestinal			
Amlodipine Blood Count Deviations	Sep/2018	Ongoing		Internal - Statistical analysis				
Amlodipine Cardiac Impairment	Sep/2018	Ongoing		Internal - Statistical analysis	Acute heart failure and other server cardiac conditions observed under Amlodipine treatment			
Amlodipine Device Medication Error	Sep/2019	Ongoing		Internal - Statistical analysis	Amlodipine Device Medication Error			
Amlodipine Intentional product misuse	Sep/2019	Ongoing		Internal - Statistical analysis	Amlodipine Intentional product misuse			
Amlodipine and TEN / SJS	Sep/2019	Ongoing		Internal - Statistical analysis	Amlodipine and TEN / SJS			
Amlodipine and deafness	Sep/2019	Closed	Jul/2020	Internal - Statistical analysis	Amlodipine and deafness		Continued monitoring	Insufficient data yet, but continued monitoring recommended

Create a topic PDF or ZIP file

You can create a PDF or Zip file to document the contents of a topic and include attachments.

- [Document the contents of a topic](#)
You can create a PDF or Zip file to document the current contents of a topic. You can include attachments and additional content such as attachment source details, topic comments, attachment comments, action comments, and change logs.
- [Select attachments to include information about a topic in a PDF or ZIP file](#)
When you create a Portable Document Format (.pdf) file or a compressed .zip file (which contains a .pdf file) for a topic, you select the attachments to include.

- [Select content attributes for a topic PDF or ZIP file](#)
When you create a Portable Document Format (.pdf) file or a compressed .zip file (which contains a .pdf file) for a topic, you can select additional content to include. A Change Log includes a Topic History section that provides a summary of the changes made to the Topic General Information.

Document the contents of a topic

You can create a PDF or Zip file to document the current contents of a topic. You can include attachments and additional content such as attachment source details, topic comments, attachment comments, action comments, and change logs.

In the Topic PDF, the topic and action change logs provide a summary of topic and action changes.

- For the Topic change log, each row represents a row in the topic's history table and contains the following columns:
 - Version
 - Current State (or Display name for CURRENT_STATE_ID). If the change in state required approval, the Requires Approval icon (🔒) is replaced with the word approved. For example: Validation (approved, 3).
 - Assigned to (or Display name for ASSIGNED_TO_USER_ID)
 - Modified By
 - Modified
 - Reason for Change
 - Other Changes
The **Other Changes** column appears only in the PDF and summarizes **Visible to work team** and topic field changes from the previous row. This means that the **Other Changes** column is empty in the first row. If there are no changes, the value displayed in the **Other Changes** column is <No other changes>. The column content does not include Assigned to, Current State, and Reason for Change.
- For the Action change log, each row in the change log represents a row in the action's history table. The action change log contains all action history columns.

Select attachments to include information about a topic in a PDF or ZIP file

When you create a Portable Document Format (.pdf) file or a compressed .zip file (which contains a .pdf file) for a topic, you select the attachments to include.

You also [select additional content](#) for the included items. The resulting .pdf file contains a section for information about the topic, followed by additional sections for information about each selected attachment.

Note

To view PDF attachments embedded in a topic, you must install Adobe Acrobat. You can download the Acrobat Standard software from www.adobe.com.

1. In the left navigation pane, click **Topic Management** .
2. Click the **Topics** tab.

3. Click the **Row Action menu** () for the topic, and then click **Create PDF** or **Create ZIP**.

The Select Attachments page appears and lists all topic attachments followed by the action attachments for each action.

Note

If the topic does not have any attachments, or you do not wish to include attachments in the .pdf, click **Next**.

4. From the **Available** list, choose one or more attachments to include in the .pdf file.
 - a. To include all attachments, click .
 - b. To select an attachment, in the **Available** list, click the attachment to highlight it, and then click . The attachment appears in the Selected list. You can also:
 - Highlight multiple non-contiguous attachments. Hold down the **Ctrl** key while clicking each attachment. Click .
 - Highlight multiple contiguous attachments. Click an attachment, hold down the **Shift** key, and click another attachment. Attachments between and including those attachments are highlighted. Click .
 - Remove the highlighting from an attachment. Hold down the **Ctrl** key while clicking the selected attachment.
5. To move attachments back and forth between the list of available attachments and the list of selected attachments, you can double-click a highlighted attachment or use the arrow keys as follows:
6. When you are satisfied with the selected attachments, click **Next**.
The Select Attributes dialog box appears. Continue with [Selecting content attributes for a topic PDF or ZIP file](#).

Select content attributes for a topic PDF or ZIP file

When you create a Portable Document Format (.pdf) file or a compressed .zip file (which contains a .pdf file) for a topic, you can select additional content to include. A Change Log includes a Topic History section that provides a summary of the changes made to the Topic General Information.

1. On the Topics tab of the Topic Management page, select a topic's **Row Action Menu** () and click **Create PDF** or **Create ZIP**.
2. On the **Select Attachments** dialog box, [select the attachments](#) and click **Next**.
The Select Attributes dialog box appears and lists the topic and each attachment that you selected for inclusion. The first row that appears, with Topic - <topic-name> in the Content column, represents the topic as a whole.
3. Choose one of the following:
 - To include information about the source of an attachment, check **Source Details**.

The .pdf file includes Source Details in the section for that attachment with the help text that appears when you hover on the name of the attachment on the Topic page. Additionally, if more information is available for the type of attachment, it appears after the attachment in the PDF file.

- To include source details for every attachment, check the **Source Details** column heading.
4. Choose one of the following:
- To include all comments made about the topic as a whole, or about an attachment, check **Comments**.
The .pdf file includes a section for Topic Comments, or a subsection for the attachment's comments.
 - To include comments for the topic and for all of the attachments, check the **Comments** column heading.
5. Choose one of the following:
- To include a log of changes made to the topic or an attachment, check **Change Log**.
The .pdf file includes a Topic History section that shows the information from the History section of the topic, or an attachment-name Log subsection with changes to the attachment.
 - To include a change log for the topic and for all of the attachments, check the **Change Log** column heading.
6. To specify the order in which attachment information will be presented in the .pdf file, click a row to highlight it, and then use the following buttons:

Button	Use To
	Move the attachment information to the top of the PDF file.
	Move the attachment information up in the PDF file.
	Move the attachment information down in the PDF file.
	Move the attachment information to the bottom of the PDF file.

Note

The section with information about the topic as a whole is always first in the .pdf. You cannot move the Topic - <topic-name> row (top row).

7. For a PDF file, click **Create PDF** or **Create Accessible PDF**. For a ZIP file, click **Create Zip Archive** or **Create Accessible Zip Archive**.

The application creates the .pdf or .zip file. The .pdf file includes links on the first page to navigate to various sections. Files or URL attachments within the .pdf file are linked to from within the PDF file.

Note

Security features in Adobe Acrobat Reader might prevent you from opening a .zip file from within the .pdf file. See the Adobe website for instructions on modifying this behavior.

8. Open or save the PDF or ZIP file.

Note

You can view the generated topic PDF file in a browser. You can also open the PDF file in Adobe Acrobat for full support, including viewing tooltips on images, opening attached files, and for accessibility.

Work with actions

This section includes procedures for working with actions.

- [Work with actions](#)
An action is an activity that has been identified as contributing to the understanding or resolution of a topic.
- [View all actions](#)
You can view all the actions that have been added to the topics you created or topics that have been made visible to a work team of which you are a member.
- [View a topic from the Actions table](#)
You can view a topic from the Actions table.
- [View actions for a topic](#)
You can view actions that have been added to a topic.
- [Add or view comments for an action](#)
You can add comments to an action and view comments associated with an action.
- [View Action and Edit Action pages](#)
From the Actions table, you can view and edit action information.
- [Edit the general information about an action](#)
You can edit the name, description, and any custom fields defined for actions by the topic workflow configuration.
- [Add an action](#)
An action is an activity that has been identified as contributing to the understanding or resolution of a topic.
- [Delete an action](#)
You can delete actions from the Actions table. This option is also only available if you have the Delete Topics/Actions work team permission.
- [View the history of an action](#)
You can view the history of actions you created and actions you have permission to see from your work teams.
- [Reopen an action](#)
You may be able to reopen an action in the Closed state.

Work with actions

An action is an activity that has been identified as contributing to the understanding or resolution of a topic.

Examples of activities that you may track with actions include:

- Performing research such as literature searches.
- Scheduling project meetings or milestones.
- Documenting follow-up work.

Like topics, actions store information in a structured set of fields, and are given workflow states to track their progress from creation to completion. An action can be assigned to the same user that is currently assigned to the topic or to a different user.

After selecting the Actions tab from the Topic Management page, click an action's **Row Action** menu (), then click **View** to view all of the information on the [View Action page](#).

View all actions

You can view all the actions that have been added to the topics you created or topics that have been made visible to a work team of which you are a member.

1. In the left navigation pane, click the **Topic Management** icon ().
2. Select the **Actions** tab to display the Actions graph and table. The fields in the action table are described below.

The Detail panel appears on the right. It displays a list of recently viewed or edited topics and the topic state and the number of actions, attachments, and comments associated with the topic. Planned actions are not included. You can click any topic title to view it.

If you click in any action row, the Detail panel updates to become the Action Detail panel to show a summary for the selected action. It contains four sections: Action Information, Topic Information, Action Comments, and Action Attachments. You can collapse and expand each section of the panel. To view complete information about the action, click the **View action** icon ().

3. (Optional) From the **Topic Workflow Configuration** drop-down list select a different topic workflow configuration.
4. (Optional) Select a **View items for** selector:
 - **Me:** Topics or actions visible to you and assigned to you.
 - **Work team:** Topics and actions visible to you and assigned to the selected work team. If you have access to more than one work team, select from the **Work Team** drop-down list.
 - **All:** All topics and actions visible to you.
5. (Optional) In the Graph section, change the graph shown by selecting a different field from the **Actions By** drop-down list.

Note

Changing the graph does not filter the actions in the Actions table.

6. (Optional) In the Filter bar, click the **Select Filter** button to add or remove filters and limit the Actions table to those actions you want to work with.
7. Click the **Header Action menu** () to perform the following actions on the table as a whole:
 - Add or remove columns, sort columns, and specify the order in which the columns appear in the table.
 - Download the Actions table to various types of files.
8. Click an action's **Row Action menu** () to perform the following actions on the selected action:
 - **View:** Display the general information about the selected action, comments, attachments, and history. You can have up to five view windows open at once.
 - **Edit:** [Edit the general information](#) about the selected action, comments, attachments, and history. You can only have one edit window open. If you have already opened an action for editing, and you try to edit another topic or action, Oracle Empirica Topics asks you to confirm that any unsaved changes on the other action you started to edit will be discarded.
 - **Reopen:** [Reopen an action](#) that is in a closed state.
 - **Delete:** Confirm that you want to [delete the action](#).

Default field descriptions—Actions tab

Column	Description
ID	Unique identifying number for the action.
Action name	Name of the action.
Action description	Description of the action.
Action state	Indicates the state of the action in the workflow. States are specified in the topic workflow configuration to represent the expected workflow.
Action type	Action type for the action.
Assigned to	User or work team to whom the action is assigned.
Start date	Date on which the action was started.
Planned completion date	Due date for performing this action. If a value is defined for this field, then the open action will appear in the Calendar tab.
Actual completion date	Date on which the action was completed.
Attachment Count	Total count of attachments to the action. (Deleted attachments are not included in this count.)
Created By	Name of the user who created the action.
Created	Date and time when the action was created.
Modified By	Name of the user who last modified the action, including adding comments.

Column	Description
Modified	Date and time when the action was last modified.

The table also includes columns for custom fields added by your organization. For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

View a topic from the Actions table

You can view a topic from the Actions table.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Select the **Actions** tab.
3. From the **Topic - Topic Name** column, click a topic name.

The general information for the selected topic appears on the View Topic page.

View actions for a topic

You can view actions that have been added to a topic.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Select the **Actions** tab.
3. Choose one of the following:
 - Click an action's **Row Action menu** () , and then click **View**.
 - From the **Action Name** column, click an **Action Name**.
4. To view all actions for the topic, on the View Action page, click the back arrow (<) in the upper left under the Topic name.

Any actions that have been added to topics appear. The table might include these standard columns:

Column	Description
Topic Name	Name of the topic to which the action is associated.
Action Name	Name of the action.
Action Description	Description of the action.
Action State	Indicates the state of the action in the workflow. States are specified in the topic workflow configuration to represent the expected workflow.
Assigned to	User or work team to whom the action is assigned.
Planned completion date	Due date for performing this action. If a value is defined for this field, then the open action will appear in the Calendar tab.
Actual completion date	Date on which the action was completed.
Attachment Count	Total count of attachments to the action. (Deleted attachments are not included in this count.)

Column	Description
Created By	Name of the user who created the action.
Created	Date and time when the action was created.
Modified By	Name of the user who last modified the action, including adding comments.
Modified	Date and time when the action was last modified.

Add or view comments for an action

You can add comments to an action and view comments associated with an action.

Your topic workflow configuration might give you the ability to add comments to all, some, or none of the following:

- A topic as a whole.
- Individual topic actions.
- Topic attachments and action attachments.

If this feature is available for one or more of these contexts, when you view a topic, action, or attachment, you can also view all of its comments. When editing a topic, action, or attachment, you can both view and add comments.

Note

Once you have added a comment, you cannot edit or delete it.

Add comments for an action

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Actions** tab.
3. Click an action's **Row Action menu** () , and then click **Edit**.
4. On the **Edit Action** page, select **Comments** from the left menu.
5. Click **Add Comment**.
6. In the text box, enter the comment.
7. Click **Save**.

View comments for an action

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Actions** tab.
3. Click an action's **Row Action menu** () , and then click **View**.
4. On the **View Action** page, select **Comments** from the left menu.
Any comments that have been added to the topic appear.

View Action and Edit Action pages

From the Actions table, you can view and edit action information.

The **View** and **Edit** links in an action's **Row Action** menu () take you to a View Action or Edit Action page that includes a left menu to view or edit general information about the action, comments, attachments, and history.

- Select **Edit** to open the window in Edit mode.
- If you select **View**, then wish to edit the action, click the **Edit Topic** icon ().

When the page is in Edit mode, you can perform activities based on your permissions and topic workflow configuration.

Menu Item	Description	Available Actions
General Information	Displays the current field values that describe an action: • The fields are read-only, editable, or required. If a field is required, an asterisk (*) appears next to it and you cannot save the action until you provide a value for the field. • Each field accepts text, numeric, or date values, or provides a list of values you can select. If a value is not required, you can leave the value empty to indicate no value for the field. Fields may also offer a Select Available Values link so you can select one or more values from a list. • In edit mode, once you have entered changes to the General Information, a yellow icon appears in the Topic editor header and General Information tab to indicate you have unsaved changes. • To save changes to the General Information section, click Save. The changes are shown as entries in the History section. Note: The Save button affects only the General Information section of the topic. Do not click Save after you work with other sections of this page. Any changes to other sections are saved to the topic immediately.	None
Comments	Displays all comments added to the action. When in edit mode, you can click Add Comment to add a comment. You cannot modify or remove a comment. Note: This section appears only if your topic workflow configuration allows topic comments.	Add Comment

Menu Item	Description	Available Actions
Attachments	Displays information about items attached to the action. Your topic workflow configuration determines the types of attachments you can add, such as files, URLs, free-text notes, or Oracle Empirica Signal objects. When in edit mode, you can click Add a document-style attachment to add a file, URL, or note attachment.	Add Action Attachment Columns Print Download
History	Displays changes to general information for the action. A new row is added to the table each time you click Save in the General Information section. Note: The Assigned to column shows work teams and users to which the action has been assigned.	Columns Print Download

Edit the general information about an action

You can edit the name, description, and any custom fields defined for actions by the topic workflow configuration.

You can select an action from the Actions table on the Actions tab. You can also edit actions associated with a specific topic from the Topics tab by selecting a topic, displaying the actions associated with the topic, and choosing an action to edit. In either case, you make your edits on the [Edit Action page](#).

1. In the left navigation pane, click the **Topic Management** icon (.
2. Click the **Actions** tab.
3. Click an action's **Row Action menu** () , and then click **Edit**.
4. Update the general information as needed then click **Save**.

Field descriptions—General Information

Required fields are indicated by a red asterisk.

Field	Description
Action state	Indicates the state of the action in the workflow. States are specified in the topic workflow configuration to represent the expected workflow.
Action type	Category of defined action; for example, <i>literature search</i> .
Action name	Name of the action.
Action description	Description of the action.
Keywords	Free text to filter the topics that appear in a table.

Field	Description
Assigned to	User or work team to whom the action is assigned. By default, an action that you add is assigned to you. Available users and work teams are determined by the Visible to work team selection. • Users: Members of the Visible to work team(s) selection with Edit Topic/Action work team permission. • Work teams: All work teams with the Assign to work team property enabled and at least one active member in the Users list.
Start date	The date that the action begins. If you change it and the planned completion date is filled in, the Planned completion date changes to retain the interval between these dates.
Planned completion date	Anticipated completion date for the action. Enter the date in the text box or click the Calendar control  and select a date.
Actual completion date	Actual date that the action was completed. Enter the date in the text box or click the Calendar control  and select a date.

5. (optional) View or edit additional information about the topic action by selecting a tab from the left navigation pane:

Note

The **Save** button affects only the General Information section of the action. Do not click **Save** after you work with other sections of this page. Any changes to other sections are saved immediately.

- To [view or add comments](#) associated with the action, click **Comments**.
- To [view or edit attachments](#) associated with this action, click **Attachments**.
- To [view the history](#) of this action, click **History**.

Add an action

An action is an activity that has been identified as contributing to the understanding or resolution of a topic.

1. In the left navigation pane, click the **Topic Management** icon (.
2. Click the **Topics** tab.
3. Click a topic's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic page, select **Actions** from the left menu.
5. Click the **Add Action** link.
6. Specify values for the fields.

- Each field is display-only, editable, or required. If a field is required, an asterisk (*) appears next to it and you cannot save the action until you provide a value.
- Each field accepts text, numeric, or date values, or provides a drop-down list of predefined values that you can select. If a value is not required in such a field you can leave the field blank to indicate no value for the field.
- Arrow icons may appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for State  and Area Code  appear, the arrows indicate that you must select a value for the State field first and then select a value for the Area Code field. You cannot select an Area Code value first. The values available for Area Code depend on the State you select.

The fields listed below are standard fields that might appear with the same or different field names.

Field	Description
Action type	Choose an action type from the drop-down list. • The Generic action type always appears and, if you select it, it sets the Action state to its initial state and Assigned to field to you. • If you select a different action type, the settings change to match that action; that is, the Assigned to, Start date, and Planned Completion date fields change to match the default values associated with this action type.
Action name	Identifying name for the action (required).
Action description	Description of the action.
Action state	The progress of the action in the workflow. Actions in the Planned state are dormant. These planned actions remain dormant until they are transitioned from the Planned state into the Open state. Action states are defined by your organization to represent expected workflow stages and are specified in the topic workflow configuration.
Activate on topic states	For planned actions, choose: • All States. • Select states, then the Select states link to choose specific topic states that activate the action type. Then click OK.
Assigned to	User or work team to whom the action is assigned. By default, an action that you add is assigned to you. Available users and work teams are determined by the Visible to work team selection. • Users: Members of the Visible to work team selection with Edit Topic/Action work team permission. • Work teams: All work teams with the Assign to work team property enabled and at least one active member in the Users list.
Start date	Date after activation that the action should start.

Field	Description
Planned completion date	Date when the action is expected to be complete. If a value is defined for this field, the open action will appear on the Calendar tab.
Actual completion date	Date when the action was completed.

Additional custom fields might also appear.

7. Click **Save**.

Delete an action

You can delete actions from the Actions table. This option is also only available if you have the Delete Topics/Actions work team permission.

This option's availability is based on your permissions and the topic workflow configuration.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Actions** tab.
3. Click the action's **Row Action menu** () , and then click **Delete**.
4. Confirm the deletion by clicking **OK**.

The action is removed from the table.

Note

Deleted actions cannot be accessed through the application. However, they are not deleted from the database.

View the history of an action

You can view the history of actions you created and actions you have permission to see from your work teams.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Select the **Actions** tab.
3. Click an action's **Row Action menu** () and then click **View** or **Edit**.
4. From the left menu, click **History**.

The table displays changes to general information for the action. A new row is added to the table each time you click **Save** in the action's General Information section.

Reopen an action

You may be able to reopen an action in the Closed state.

This option's availability is based on your permissions and the topic workflow configuration.

1. In the left navigation pane, click the **Topic Management** icon ()

2. Click the **Actions** tab.
3. Click a closed action's **Row Action menu** (), and then click **Reopen**.

Note

The Reopen item appears if action states include a transition following a final action state and your user administrator assigns you the Reopen Topics/Actions permission.

4. From the **Action State** drop-down list, select a state.
5. Click **Save**.

You can view and edit the action as necessary. The action state change is also recorded and you can see the changes if you click **History** on the Edit Action page menu.

Work with the calendar

This section includes procedures for working with open actions.

- [View actions on the calendar](#)
The Calendar tab, selected from the Topic Management page, provides information about open actions that have a value for Planned Completion Date and do not have a value for Actual Completion Date.
- [Pick a date from the Calendar view](#)
Depending on the available space on your browser, the Calendar view displays up to four months at a time, including the month with today's date. If you zoom, resize the window, or expand or collapse the Detail panel, the number of months shown may change.

View actions on the calendar

The Calendar tab, selected from the Topic Management page, provides information about open actions that have a value for Planned Completion Date and do not have a value for Actual Completion Date.

The Calendar tab shows actions as a list and on a monthly calendar, along with total counts for past due and upcoming actions. It is filtered by your selection from the **Assigned to** drop-down list, or you can categorize the actions by action type using the **Action type** drop-down list. If you select the **All** button for the **View Items for** field, the calendar views include actions assigned to all individuals and work teams.

1. In the left navigation pane, click the **Topic Management** icon ().
2. Click the **Calendar** tab.
3. (Optional) From the **Topic Workflow Configuration** drop-down select a different topic workflow configuration.
4. (Optional) Select a **View items for** selector:
 - **Me:** Topics or actions visible to you and assigned to you.
 - **Work team:** Topics and actions visible to you and assigned to the selected work team. If you have access to more than one work team, select from the **Work Team** drop-down list.

- **All:** All topics and actions visible to you.

The overdue and upcoming actions are listed and shown on a month-by-month calendar. Totals appear above the list.

5. To filter the list and calendar by assignee, select a work team or user from the **Assigned to** drop-down list. To filter by action type, select an action type from the **Action type** drop-down list.
6. To clear the **Assigned to** and **Action type** filters, click **Reset**.
The List and Calendar views update accordingly.

Pick a date from the Calendar view

Depending on the available space on your browser, the Calendar view displays up to four months at a time, including the month with today's date. If you zoom, resize the window, or expand or collapse the Detail panel, the number of months shown may change.

At the top of the calendar are **Previous** (<), **Today**, and **Next** (>) buttons. Use the **Previous** and **Next** buttons to scroll the months backwards and forwards one month at a time. Click the **Today** button to display a month with today's date.

1. In the left navigation pane, click the **Topic Management** icon ()
2. Click the **Calendar** tab.
3. Choose from these options:
 - To see today's required work, click today's date on the calendar. The List view scrolls to show actions required for today. The Details pane shows the associated Action Information, Topic Information, Action Comments, and Action Attachments.
 - To see a different day's action list during the current month, click any date with a circle on it.
 - To go to another month by scrolling through the calendar, use the **Previous** and **Next** arrows at the top of the calendar. The calendar scrolls one month at a time.
 - To go to a specific month, click the name of one of the months shown, then select a specific month name.
 - To go to a specific year, click the year of one of the up to four months displayed, then click a year in the list.
Use the **Previous** and **Next** arrows in the year view to display years that are not currently visible. The months and years that you can select are limited by the current open actions in the calendar.

Work with attachments

This section includes procedures for working with attachments.

- [About attachments](#)
Depending on your topic workflow configuration, you can attach one or more types of data to topics and actions.
- [Save Oracle Empirica Signal objects as attachments](#)
You can save tabular, graphical, statistical, and results from your work as attachments to topics and actions.
- [Add other types of attachments](#)
You can save document-style attachments to topics and actions.

- [Work with attachments](#)
You can edit attachment information, add comments, view the source of that attachment and add an attachment count column to the Topics or Actions table.
- [Add or view comments for an attachment](#)
You can add and view comments for a topic or action attachment.

About attachments

Depending on your topic workflow configuration, you can attach one or more types of data to topics and actions.

These include:

- Oracle Empirica Signal objects, such as run results or report output.
- Any type of file, including .docx, .pdf, .pptx, .xlsx, .xml, .xpt, .png, .jpg, and .zip formats.
- The URL of a web page.
- A note.

Save Oracle Empirica Signal objects as attachments

You can save tabular, graphical, statistical, and results from your work as attachments to topics and actions.

- [Oracle Empirica Signal objects types](#)
Oracle Empirica Signal objects include tabular, graphical, statistical, and results. You can save these objects as attachments.
- [Select a topic to save an Oracle Empirica Signal attachment to](#)
When working with Oracle Empirica Signal, you might generate output, such as data mining results, queries, or cases series that you want to save as attachments to specific topics.
- [Save to Topic dialog box](#)
The **Save to Topic** dialog box saves tabular data or graphs as an attachment.
- [Save Oracle Empirica Signal tables and graphs as attachments](#)
You can save the tables and graphs you create while working with Oracle Empirica Signal, such as run results and report output, to topics and actions as attachments.
- [View tabular data as an attachment](#)
Tabular data, such as graphs, can be saved as topic attachments and viewed.

Oracle Empirica Signal objects types

Oracle Empirica Signal objects include tabular, graphical, statistical, and results. You can save these objects as attachments.

You can save the following objects as attachments:

- **Drug Profile**—Collection of charts displayed on the Drug Profile page.
- **Data Mining Results**—Tabular results of a data mining run.
- **Data Mining Results Graph**—Graphical results of a data mining run.
- **Query**—Results of a query.
- **Case Series**—Case series lists.

- **First Level** drill-down—List of cases resulting from drill-down on a count of cases.
- **Cases**—Case details displayed upon drill-down for a particular case.
- **Report Output**—Saved report output or a displayed report for an output that was not saved.
- **Report Graph**—Graph based on a saved report output or on a displayed report for an output that was not saved.

Note

You can save objects to a topic only if you have the [work team permission](#) to add, edit, and delete attachments in open topics/actions.

You can save these additional objects if your organization uses the Signal Management module of Oracle Empirica Signal:

- **Product-Event Combinations**—Combinations selected from the Product-Event Combinations page.
- **Event Comments**—Comments associated with a product on the Products page.
- **Similar Combinations**—Combinations selected from the Similar Combinations page.
- **Interactions Graph**—Interactions graph for a combination on the Product-Event Combinations page.
- **Age Group Breakdown**—Age group breakdown graph for a combination on the Product-Event Combinations page.
- **Gender Breakdown**—Gender breakdown graph for a combination on the Product-Event Combinations page.
- **Sector Map Graph**—Sector map for a product on the Products page.

Note

If you save data from a Signal Management table as an attachment and your signal configuration has the private comments feature set up, all of the Signal Management comments, public and private, are attached to the topic and are visible to all users who can view the topic.

Select a topic to save an Oracle Empirica Signal attachment to

When working with Oracle Empirica Signal, you might generate output, such as data mining results, queries, or cases series that you want to save as attachments to specific topics.

When [saving an attachment to a topic](#), available topics are those that you can edit, which may include those that you created, that are assigned to you, or that have been made visible to a work team that you are in.

Note

You can't add an attachment to a closed topic.

1. On the page in Oracle Empirica Signal where the information to save appears, click the **Save to Topic** link at the top of the page.

When you save tabular data, such as run results, only the first n rows of the displayed tabular data can be saved, where n is determined by a [site option](#). A message is displayed if not all the rows are saved. The number of saved rows and the total number of rows appear as hover help on the attachment name. Click **OK**.

2. On the Save to Topic page, enter the attachment name and optional description.
3. Choose an existing topic or create a new topic:
 - To add the attachment to an existing topic:
 - a. Select **Add to existing topic**.
 - b. In the **Topic name** field, enter the topic name or click **Browse**.
If you browse for the topic, you can filter the Select Topic table using the drop-down lists that appear above the table. (Lists appear above the table if the topic workflow configuration you are using offers this feature.) For example, if you select a [project](#), only topics matching the specified project appear.
 - c. Select the topic you want and click **OK**.
 - d. From the **Action name** list, select an action to associate with the selected topic.
 - e. Click **OK**.
 - To create a new topic and add the attachment to it:
 - a. Select **Create new topic**.
 - b. From the **Visible to work team** drop-down list, select a work team or click the **Browse** link to display a list of work teams. Select a work team and click **OK**.
 - c. From the **Topic template** drop-down list, select a template or click the **Browse** link to display a list of templates. Select a template and click **OK**.
 - d. Enter the topic name and description.
 - e. Choose whether to add the topic to an existing or new project.
 - If you select **Existing**, choose the project from the **Project name** drop-down list.
 - If you select **New**, enter the project name in the **Project name** text box.
 - f. Click **OK**.
 - g. Close the Save to Topic dialog box, or click **Edit** to edit the topic you added the attachment to.

Note

Your administrator may establish a maximum size for the Oracle Empirica Signal tables that you can attach with a [site option](#). If you attempt to save a larger table an error message informs you of the defined limit.

After you add an attachment, you can access it when you view or edit the topic or action to which it is attached. See [Edit an attachment](#).

Note

Changes to, or deletions of, the original object do not affect the attachment. For example, if you save report output as an attachment to a topic and then that report output is deleted, the topic attachment remains unchanged.

If the topic workflow configuration has changed, when you click **OK** on the Save to Topic dialog, Oracle Empirica Signal will warn you that the topic workflow configuration has changed and won't save your changes. Close the dialog and perform your Save to Topic action again.

Save to Topic dialog box

The **Save to Topic** dialog box saves tabular data or graphs as an attachment.

Note

You can save objects to a topic only if you have the [work team permission](#) to add, edit, and delete attachments in open topics/actions.

When you save signal objects to a topic, you either create a new topic with minimal information or add the attachment to an existing topic or one of its actions.

Another user can edit a topic while you are saving an attachment to that topic; however, if the other user closes or deletes the topic during this time, you are prevented from saving the attachment and an error message is displayed.

Field descriptions—Save to Topic dialog box

Field	Description
Topic Workflow Configuration	You can select the topic workflow configuration from the drop-down list.
Attachment name	Name of the attachment.
Attachment description	Description of the attachment.
Add to existing topic	You can select an open topic that is visible to a work team of which you are a member. Or you can select a topic that you created. - You can attach the object to an existing topic. In the Topic name field, type the topic name. or click Browse to select from a list of topics. - To attach the object to an action associated with the topic, from the Action name drop-down list, select an action name or --none--. Planned actions are excluded.

Field	Description
Create new topic	You can attach an object to a new topic. - You might be required to select a Visible to work team value from the drop-down list, based on the definitions for your topic workflow configuration. You can also click Browse to select from a descriptive list of work teams. - If templates exist, from the Topic template drop-down list, optionally select a template or click Browse to choose from a descriptive list of templates. - Type a Topic name and, optionally, a Topic description for the new topic. - Optionally, you can assign the new topic to either an existing or new project.

Save Oracle Empirica Signal tables and graphs as attachments

You can save the tables and graphs you create while working with Oracle Empirica Signal, such as run results and report output, to topics and actions as attachments.

1. On the page where the table or graph appears, click **Save to Topic**.

Note

For a graph on the Data Mining Results page or Report pages, the **Links** check box must be selected for the **Save to Topic** link to appear below the graph.

When you save tabular data, such as run results, only the first **n** rows of the displayed tabular data can be saved, where **n** is determined by a [site option](#). A message is displayed if not all the rows are saved. The number of saved rows and the total number of rows appear as hover help on the attachment name.

Note

On the Product-Event Combinations page, you can select rows, so the first **n** selected rows are saved.

You might want to select different columns before you save. Only the currently displayed columns appear by default when the attachment is viewed. However, the application stores all available columns with the attachment. To customize the columns shown when viewing the attachment within the topic, click **Columns** and select the columns.

2. Enter an attachment name and optional description.
3. Choose to add the attachment to an existing topic or create a new topic.
 - To add the attachment to an existing topic:
 - a. Click the **Add to existing topic** radio button.
 - b. Click the **Browse** link to the right of the Topic name field.

- c. Filter the topics on the Select Topic page by making selections from the drop-down lists above the table.
- d. Select the radio button for the topic.
- e. Click **OK**.
- f. To add the attachment to a specific action associated with the selected topic, from the **Action name** drop-down list, select the action.
- g. Click **OK**.
- To create a new topic and save the attachment to that new topic:
 - a. Click the Create new topic radio button.
 - b. From the **Visible to work team** drop-down list, select a work team or click the **Browse** link to display a list of work teams. Select the radio button of a work team and click **OK**.
 - c. Enter the topic name and description.
 - d. Choose whether to add the topic to an existing or new project.
 - If you select **Existing**, choose the project from the **Project name** drop-down list.
 - If you select **New**, enter the project name in the **Project name** text box.
 - e. Click **OK**.

If you have created a topic, it is assigned to you by default. You can edit the topic as needed.

Note

Your administrator may establish a maximum size for the Oracle Empirica Signal tables that you can attach with a [site option](#). If you attempt to save a larger table an error message informs you of the defined limit.

After you add an attachment, you can access it when you view or edit the topic or action to which it is attached. See [Edit an attachment](#).

Note

Changes to, or deletions of, the original object do not affect the attachment. For example, if you save report output as an attachment to a topic and then that report output is deleted, the topic attachment remains unchanged. If the topic workflow configuration has changed, when you click **OK** on the Save to Topic dialog, Oracle Empirica Signal will warn you that the topic workflow configuration has changed and won't save your changes. Close the dialog and perform your Save to Topic action again.

View tabular data as an attachment

Tabular data, such as graphs, can be saved as topic attachments and viewed.

If a tabular [Signal object](#) was saved as an attachment, the display of that table can be modified.

1. In the left navigation pane, click the **Topic Management** icon ().
2. Click the **Topics** tab or the **Actions** tab.
3. Click the topic's or action's **Row Action menu** () , and then click **View**.
4. On the View Topic or View Action page, select **Attachments** from the left menu.
5. Click **Columns** to show other columns.

By default, only the columns that were displayed in the table when the attachment was saved appears. However, Oracle Empirica Signal stored all available columns with the attachment.
6. If the source of the table is data mining results, reports, report output, or event comments:
 - a. Click **Show Notes** to display the notes.
 - b. Click **Hide Notes** to hide the notes.
7. If the source of the table is a case series, the **Reviewed**, **Excluded**, and **Comments** columns refer to whether, on the **Case Series** page, the case was marked as reviewed or excluded and whether comments were added to the case.

 Note

Modifications to the displayed table are not saved.

Add other types of attachments

You can save document-style attachments to topics and actions.

- [Add an attachment to a topic or action](#)
You can save document-style attachments; that is, files, URLs, or notes, when you edit a topic or action.

Add an attachment to a topic or action

You can save document-style attachments; that is, files, URLs, or notes, when you edit a topic or action.

1. In the left navigation pane, click the **Topic Management** icon ().
2. Click the **Topics** or **Actions** tab.
3. Click the topic's or action's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic or Edit Action page, select **Attachments** from the left menu.
5. Click **Add Topic Attachment** or **Add Action Attachment**.
6. Select the attachment type. One or more of the following standard types might be available:
 - URL
 - File
 - Note

7. Enter values in the remaining fields. If a field is required, an asterisk (*) appears next to it and you cannot save the attachment until you provide a value. The fields that display vary based on the type of attachment selected:
 - For a URL, typically a name and the URL are required, and you can also enter a description. You must enter the protocol (http, https, ftp) when you enter the URL. The application does not add the protocol (such as http://) automatically. Additional fields might also appear.
 - For a file, typically a name and the file name (including its path) are required. Click **Browse** to select the file name and path. You can also enter an attachment description. Additional fields might also appear. Supported file types include, but are not limited to: .docx, .jpg, .pdf, .pptx, .xlsx, .xml, .xpt, and .zip.
 - For a note, typically a name is required. You can also enter a more detailed description. Additional fields might also appear. This option is useful for adding a row that is purely descriptive. For example, you can add a note to describe a set of different documents that you are about to add to the topic or action.
8. Click **OK**.

Note

Your administrator can set a [site option](#) for the maximum size of files that you can attach. If you attempt to save a larger file, an error message informs you of the defined limit.

9. After you add an attachment, you can view or [edit](#) it when you view or edit the topic or action to which it is attached.

Note

Changes to, or deletions of, the original document do not affect the attachment. For example, if you save a document as an attachment to a topic and then that document is edited, the topic attachment remains unchanged.

Work with attachments

You can edit attachment information, add comments, view the source of that attachment and add an attachment count column to the Topics or Actions table.

- [Edit attachment information](#)
You can modify information about topic and action attachments.
- [View source details for an attachment](#)
You can review the source detail information about an attachment.
- [Add an attachment count column to the Topics or Actions table](#)
You can include an Attachment Count column in the Topics and Actions tables to show the total count of attachments.

Edit attachment information

You can modify information about topic and action attachments.

1. In the left navigation pane, click the **Topic Management** icon ().

2. Click the **Topics** or **Actions** tab.
3. Click the topic's or action's **Row Action menu** (), and then click **Edit**.
4. From the left navigation pane, click **Attachments**.
5. Select the attachment's **Row Action menu** (), and then click **Edit**.
6. On the Edit Attachment page, update values as needed. Required fields are indicated by a red asterisk.

You can edit the name, description, and any custom fields defined for attachments by your topic workflow configuration.
7. Click **Save**.

View source details for an attachment

You can review the source detail information about an attachment.

1. In the left navigation pane, click the **Topic Management** icon ().
2. Click the **Topics** or **Actions** tab.
3. Click the topic's or action's **Row Action menu** (), and then click **View**.
4. On the View Topic or View Action page, select **Attachments** from the left menu.
5. Select the attachment's **Row Action menu** (), and then click **View Source Details**.
6. Review the information about the attachment. For an Oracle Empirica Signal object, the page provides information on the attachment's origin. For a document-style attachment, the complete URL or file name appears.
7. Click **Close**.

Add an attachment count column to the Topics or Actions table

You can include an Attachment Count column in the Topics and Actions tables to show the total count of attachments.

1. In the left navigation pane, click the **Topic Management** icon ().
2. Click the **Topics** or **Actions** tab.
3. From the Header Action menu (), and then click **Columns**.
4. On the Columns dialog, move **Attachment Count** from the **Available Columns** list to the **Selected Columns** list.
5. Click **OK**.

When you view or edit a specific topic or action, you can view or edit all of its attachments from the Attachments page available from the left menu. The Topic Attachments page or the Action Attachments page provide information about each attachment in a table that might include these standard columns:

Field descriptions—Attachments

Column	Description
ID	Unique identifying number for the attachment.
Created By	Name of the user who added the attachment.
Created	Date and time when the attachment was saved.
Modified By	Name of the user who last modified the attachment, including adding comments to the attachment.
Modified	Date and time the attachment was last modified.
Source	Type of data saved as an attachment: file, URL, note, or a brief description of the object.
Attachment name	Name of the attachment. Hover help on an attachment name describing the attachment. For tabular data, if only a certain number of rows were saved (as determined by a site option), the number of rows saved and the total number of rows is shown.
Attachment description	Description of the attachment.
URL address	The URL attached to the topic or action. Applies to URL attachments only.
File name	The name of the file attached to the topic or action. Applies to file attachments only.

The table includes columns for custom fields added by your organization. For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

Add or view comments for an attachment

You can add and view comments for a topic or action attachment.

Add comments for an attachment

1. On the left navigation pane, click the **Topic Management** icon (.
2. Click the **Topics** or **Actions** tab.
3. Click a topic's or action's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic or Edit Action page, select **Attachments** from the left menu.
The attachments to the topic or action appear.
5. Select the topic's or action's **Row Action menu** () , and then click **Comments**.
6. On the Comments page, click **Add Comment**.
7. On the Add Comment page, type your comment and click **Save**, then **Close**.
Your comment appears at the bottom of the Comments page.
8. Add another comment or click **Close**.

The attachment shows that you have modified it and the count in the Comments column is increased by one. Click the value in the Count column to view it.

View comments for an attachment

1. On the left navigation pane, click the **Topic Management** icon ()
2. Click the **Topics** or **Actions** tab.
3. Click a topic's or action's **Row Action** menu () , and then click **View**.
4. On the View Topic or View Action page, select **Attachments** from the left menu.
5. Select the attachment's **Row Action** menu () , and then click **Comments**.
Oracle Empirica Signal displays the comments associated with the attachment.
6. Click **Close**.

4

Initiate and monitor data mining runs

- [What is a data mining run?](#)
A data mining run is a three-step process: 1) extraction of data from source data; 2) application of statistical algorithms to the extracted data; and 3) generation of statistical values.
- [View data mining runs](#)
The Data Mining Runs page provides information about existing data mining runs and enables you to define new runs if you have the required permission.
- [Data Mining Runs page](#)
Use the Data Mining Runs page to extract data from source data, apply statistical algorithms to the extracted data, generate statistical values and manage specific data mining runs.
- [Create a Data Mining Run](#)
- [Manage custom terms](#)
- [Define subsets for an MGPS run](#)
- [View source data](#)
- [Manage data mining runs](#)
- [Data mining FAQs](#)
This set of frequently asked questions relates to data mining and its applications in Oracle Empirica.

What is a data mining run?

A data mining run is a three-step process: 1) extraction of data from source data; 2) application of statistical algorithms to the extracted data; and 3) generation of statistical values.

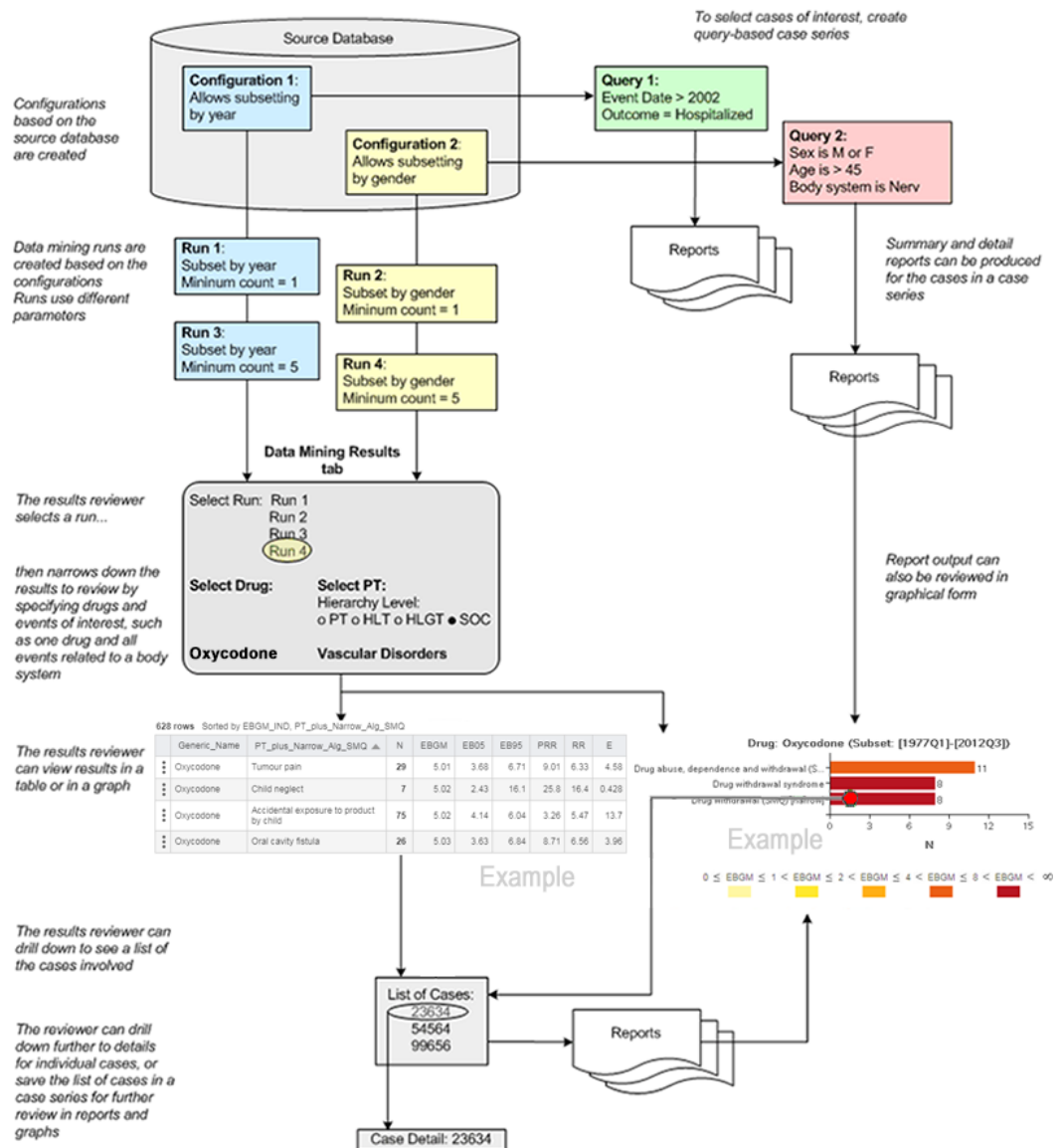
When these statistical values, or scores, exceed a predetermined threshold, they alert reviewers to a potential safety signal. The two primary types of data mining runs are [MGPS runs](#) and [logistic regression runs](#). Within a two-dimensional MGPS run, you can include:

- [Information Component \(IC\) computations](#)
- [Regression-Adjusted GPS Algorithm \(RGPS\) computations](#)
- [Proportional Reporting Ratio \(PRR\) computations](#)
- [Reporting Odds Ratio \(ROR\) computations](#)

Data mining runs are batch jobs that Oracle Empirica Signal submits to a queue for processing. Depending on the number of processors on the Oracle Empirica Signal server, it is possible for several data mining runs to run at the same time. However, Oracle Empirica Signal queues RGPS jobs so that two do not run simultaneously. The run submitter can request that the run be performed immediately, when a processor is available, or at a scheduled date and time. When a user submits a data mining run, the run appears on the Data Mining Runs home page and can be published to other users, even if it has not started running. A user can also cancel, delete, or re-run a data mining run. The data mining runs that appear on the Data

Mining Runs home page and the tasks that you can perform for specific runs depend on your [user permissions](#) and the publication level of runs.

To create a data mining run, you must [select a data configuration](#) that determines the source data on which the run is based. You can base multiple runs on the same configuration. You then specify the type of run and other run parameters. When the run is complete, Oracle Empirica Signal can display the results in tabular or graphical format. When reviewing the results, users with appropriate permissions can [drill down](#) on counts to view case details.



1. Configurations based on the source database are created.
2. To select cases of interest, create query-based case series.
3. Summary and detail reports can be produced for the cases in a case series.
4. Report output can also be reviewed in a graphical form
5. Data mining runs are created based on the configurations. Runs use different parameters.
6. The results reviewer selects a run.

7. Narrow down the results to review by specifying drugs and events of interest, such as one drug and all events related to a body system.
 8. The results reviewer can view the results in a table or in a graph.
 9. The results reviewer can drill down to see a list of the cases involved.
 10. The reviewer can drill down further to details for individual cases in a case series for further review in reports and graphs.
- Configuration 1: Allows subsetting by year
 - Query 1: Event Date > 2002. Outcome = Hospitalized
 - Reports
 1. Run 1: Subset by year. Minimum count = 1
 2. Run 3: Subset by year. Minimum count = 5
 3. Data mining results tab: Select Run: Run 1, Run 1, Run 3, Run 4. Select drug: Oxycodone. Select PT: Hyrarchy Level: PT < HLP, HLGT, SOC. Vascular disorder.
 4. Results show 628 rows sorder by EBGM_IND, PT_plus_Narrow_Alg_SMQ
 5. List of cases. Case detail: 23634
 - Configuration 2: Allows subsetting by gender
 1. Query 2: Sex is M or F. Age is 45. Body system is Nerv.
 2. Reports
 3. Drug: Oxycodone (Subset: [1977Q1]-[20212Q3])
 4. List of cases. Case detail: 23634

View data mining runs

The Data Mining Runs page provides information about existing data mining runs and enables you to define new runs if you have the required permission.

For the selected project and data configuration, the Data Mining Runs home page lists [data mining runs](#) that you created or that are published to you. If you have the Administer Users permission, the page also lists unpublished runs created by any users in your login group.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#) , or select -- to include all configurations.

The selected data mining runs appear.

Data Mining Runs page

Use the Data Mining Runs page to extract data from source data, apply statistical algorithms to the extracted data, generate statistical values and manage specific data mining runs.

What is a data mining run?

A data mining run is a three-step process:

1. Extraction of data from source data.
2. Application of statistical algorithms to the extracted data.
3. Generation of statistical values.

When these statistical values, or scores, exceed a predetermined threshold, they alert reviewers to a potential safety signal.

What can I do on the Data Mining Runs page?

[Create a data mining run](#)

[View the results of a data mining run](#)

[Rename a data mining run](#)

[View details of a data mining run](#)

[View job details of the data mining run](#)

[Cancel or delete a data mining run](#)

[Re-run a data mining run](#)

[Publish a data mining run](#)

[Create a definition file](#)

Create a Data Mining Run

- [Step 1: Select the run type and data configuration](#)
To create a data mining run, you start by selecting the type of run and the data configuration to use.
- [Step 2: \(For timestamped data only\) Select the as-of date](#)
If you are working with timestamped data, select the the as-of date; that is, the date and time for your *snapshot* of the data.
- [Step 3: Select the variables](#)
A variable is a data item in the source data referenced by the configuration that you selected for the data mining run.
- [Step 4 for MGPS runs: Specify data mining parameters](#)
After you have selected item variables for data mining, the Data Mining Parameters page appears.
- [Step 4 for logistic regression runs: Select the events and specify drugs](#)
When defining a logistic regression run, you specify values (that is, responses) for the event variable that you are investigating with the run on the Select Event page. Oracle Empirica Signal computes separate results for each specified event value.
- [Step 5: Define data mining run options](#)
After you specify parameters for a data mining run, the Run Options page appears.
- [Step 6: Name the data mining run](#)
After you define run options you name the data mining run.
- [Step 7: Submit the data mining run](#)
After naming a data mining run that you are creating, you confirm the run parameters and submit the run.
- [Reference](#)

Step 1: Select the run type and data configuration

To create a data mining run, you start by selecting the type of run and the data configuration to use.

After these selections, you specify a series of parameters that tell the application how to restrict or combine data, and which types of statistics to compute. You then submit the run and it is executed in batch mode. When the run is complete, you can view the results in tabular or graphical format.

If you have superuser permissions, you can [create a run definition file](#) to execute MGPS or logistic regression data mining runs from outside of the application. To do so, use the **Create Definition File** link. For more information about executing data mining runs externally, contact Oracle.

Note

If you have exceeded the disk space quota for your username, an error message appears when you attempt to create a run. To proceed, delete one or more of your existing runs or contact your system administrator to increase your quota.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. At the top left of the **Data Mining Runs** home page, click **Create Run**.
3. On the **Create Data Mining Run** page, select the type of run to create:
 - **MGPS data mining run**—The analytical core of Oracle Empirica Signal is a high-performance implementation of the MGPS (Multi-Item Gamma Poisson Shrinker) algorithm. MGPS is based on the metaphor of the market basket problem, in which a database of transactions (adverse event reports) is mined for the occurrence of interesting (unexpectedly frequent) itemsets. For more information about MGPS runs, see [MGPS computations](#).
 - **Logistic regression data mining run**—Logistic regression is a statistical tool for modeling how the probability of a response depends on the presence of multiple predictors, or risk factors. In Oracle Empirica Signal, the predictors are drugs and, optionally, covariates such as report year, gender, or age group, and the responses are adverse events. For more information about logistic regression, see [Logistic regression computations](#).
4. If you selected Logistic regression (LR) data mining run, select the **LR Type**:
 - **Extended**—Use the best alpha computational model.
 - **Standard**—Use 0.5 as the alpha value for every response.
5. From the **Configuration** drop-down, enter a value or click **Browse** to select from a list of data configurations.

Tip

For a logistic regression data mining run, we recommend a data configuration that includes concomitant drugs, such as an AERS S+C configuration. For more information, see [Logistic regression computations](#).

6. To limit the run to cases that meet specified criteria only, check **Define database restriction**.
7. Click **Next**.
 - If you selected a data configuration that supports [timestamped data](#), the Select As Of Date page appears so that you can [specify the As Of date](#).
 - If you selected the Define data base restriction box, follow the steps in [Define a database restriction](#).
 - Then [select variables](#).

Note

Once you have selected a run type and continued to the next page, you cannot change the run type.

Step 2: (For timestamped data only) Select the as-of date

If you are working with timestamped data, select the the as-of date; that is, the date and time for your *snapshot* of the data.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. At the top left of the **Data Mining Runs** home page, click **Create Run**.
3. On the **Create Data Mining Run** page, select the **type of run to create**:
 - [MGPS data mining run](#)
 - [Logistic regression data mining run](#)
4. Click **Next**.
5. On the **Select "As Of" Date** page, choose the latest date and time, as shown. Or, select **Other** to choose a date and time.
 - a. Enter a time in hh:mm:ss am/pm format.
 - b. Click **Next**.
6. Click **Next** to [select the variables](#) to include.

Step 3: Select the variables

A variable is a data item in the source data referenced by the configuration that you selected for the data mining run.

- An MGPS data mining run includes a drug (or vaccine) variable and an event (or symptom) variable.
 - For logistic regression runs, you select the drug (predictor) and event (response) variables. You also have the option to select one or more variables as covariates (additional predictors).
1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
 2. At the top left of the **Data Mining Runs** home page, click **Create Run**.

3. On the **Create Data Mining Run** page, select the **type of run to create** and click **Next**.
4. (For timestamped data) On the **Select "As Of" Date** page, choose the latest date and time or select **Other** to choose a date and time. Then click **Next**.

For an MGPS data mining run:

1. (For timestamped data) On the **Select "As Of" Date** page, choose the latest date and time or select **Other** to choose a date and time. Then click **Next**.
2. On the **Select Variables** page, select at least one **Item Variable** by clicking its name.

✓ **Tip**

To study drug-event combinations, select two or more items that are listed as Drug or Event variables.

3. If you want to use [stratification](#), select one or more **Stratification variables**.
 - You cannot select the same variable as both an item variable and a stratification variable.
 - A warning message appears if there are more than 500 values for all selected stratification variables. Too many stratification values can cause reduced sensitivity in the EBGM and EB05 statistics. To avoid reduced sensitivity, the number of cases divided by the number of unique stratification values should be at least 100. For example, if there are 5,000 cases in the source data, there should not be more than 50 strata values.
4. To define custom terms, follow the steps in [Define custom terms](#).
5. To define subsets, check [Define subsets](#).
6. Click **Next**.

If you didn't choose to define custom terms or subsets, the Data Mining Parameters page appears and you can go on to [Step 4 for MGPS runs: Specify data mining parameters](#).

For a logistic regression data mining run:

1. On the **Select Variables** page, click one variable in the **Event variable** list and one variable in the **Drug variable** list.

✓ **Tip**

To treat combination drugs as if the subject had taken separate drugs, select a variable, such as Single Ingredient, as the drug variable.

2. To include more variables, select them from the **Additional covariates** list.

✓ **Tip**

Typically, a logistic regression run includes one or more additional covariates as predictors. Otherwise, the logistic regression can be subject to confounding due to potentially highly associated covariates being left out. Recommended covariates for an AERS-based configuration include the AgeGroup4, Gender, and Subset_Year variables.

3. (Optional) To set up a custom term for this data mining run, check **Define custom terms**.
4. Click **Next**.

5. If you selected **Define custom terms**, follow the steps in [Define custom terms](#).
6. Click **Next** to go to [Step 4 for logistic regression runs: Select the events and specify drugs](#).

Step 4 for MGPS runs: Specify data mining parameters

After you have selected item variables for data mining, the Data Mining Parameters page appears.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. At the top left of the **Data Mining Runs** home page, click **Create Run**.
3. On the **Create Data Mining Run** page, select the **type of run to create** and click **Next**.
4. (For timestamped data) On the **Select "As Of" Date** page, choose the latest date and time or select **Other** to choose a date and time. Then click **Next**.
5. On the **Select Variables** page, select an item variable and, optionally, stratification variables. Define custom terms and subsets if you wish then click **Next**.
6. Specify the MGPS data mining parameters shown in the table below.
7. Click **Next** to enter the [data mining run options](#).

Parameter descriptions

Field	Description
Specify highest dimension	Maximum number of ways that the item variables you selected are combined during the run. For more information, see Dimensions and patterns. 2—Provide a count for each item variable (one dimension), and generate scores for each item variable+item variable combination (two dimensions). Note If you plan to include RGPS calculations in the run, you must set the dimension to 2. 3—Provide a count for each item variable (one dimension), generate scores for each item variable+item variable combination (two dimensions), and generate scores for each item variable+item variable+item variable combination (three dimensions). Note Three-dimensional runs require very large amounts of space for intermediate storage and to save the final results (potentially hundreds of gigabytes). Use of other data mining parameters, including the minimum count, to reduce the computational effort required for these runs, and restricting results to those results you plan to analyze, is strongly recommended.

Field	Description
Specify minimum count	How many times an item variable combination must occur in the data for the combination to be included in the MGPS computations. For example, if you specify a minimum count of 5, only combinations that occur in at least 5 cases appear. The purpose of the minimum count is to decrease computational time and space requirements. The higher the minimum count, the shorter the computational time. When you specify the minimum count, consider whether or not you are using a subset variable. For example, suppose that the subset categories are report years 2005, 2006, and 2007 and that there are 4 drug-event combinations for DrugA+Rash in 2005, 3 new ones in 2006, and 5 new ones in 2007. If the minimum count is 5, only the 2007 results show any DrugA+Rash combinations. If you are using cumulative subsetting, both 2006 and 2007 show DrugA+Rash combinations. If you specify a minimum count of less than 5, or the run uses cumulative subsetting, a warning message appears. In these situations, the results table takes a very long time to generate and can be very large in size.  Note To supply a default setting for this field, you can set the Minimum Count user preference.
Include drug/event hierarchies' primary paths in run results	Whether to include hierarchy levels in the results. For example, if the data mining run is for drug and Preferred Term (PT) combinations, and the MedDRA Version 12.0 hierarchy is being used, the results include the HLT, HLGT, and SOC representing the PT's primary path in MedDRA Version 12.0, and this will allow you to view results easily for PTs in a higher level of the hierarchy. This option is only available if the data configuration for the run is set up to use a drug or event hierarchy.

Field	Description
Fit separate distributions for the different item type combinations	Whether to take item types into account during MGPS processing. Observed Count (N), Expected Count (E), and Relative Reporting Ratio (RR) values are not affected, but EBGM and other statistical values are affected. The statistical values for each combination are based on the counts and statistical computations of other occurrences of the same type of combination. For example, in computing EBGM values for Drug+Event combinations, only the distribution of RR values for Drug+Event combinations is considered. The distributions of RR values for Drug+Drug or Event+Event combinations are not considered. Note This parameter does not affect the computation of PRR or ROR.
Include calculations for PRR and ROR	Whether to include PRR and ROR computations in the run. If you select this option, the following additional options appear: • Base counts on cases rather than drug-event combinations. • For PRR, include drug of interest in the comparator set. • Apply the Yates correction in computing the value of chi-squared. • Use stratified computation for PRR and ROR. For more information, see PRR computations and ROR computations.
Include calculations for Information Component	Whether to include Information Component computations in the run. For more information, see Information Component computations.
Include calculations for RGPS	Whether to include RGPS computations in the run (available only when the highest dimension is 2, and the run does not include subsets). If you select this option, the Specify minimum count field is set to 1 when RGPS computations are included, and the Restrictions of results will have a default value of N>=1. The following additional option appears: Include Interactions—Whether to include calculations for Drug+Drug interactions using RGPS. If you select this option, set the Specify minimum interaction count field. The default value for the Specify minimum interaction count field is 25. Interaction estimates are calculated for a drug if the number of Drug+Event reports exceeds the specified minimum interaction count. For more information, see RGPS computations.

Field	Description
EBGM >=	Whether to limit the results based on signal scores. For each statistic you select, specify a limit as an integer or floating point number. Combinations for which the signal score is less than the specified limit are not kept in the results. This limit considers all combination types that are included in the results table.
N >=	
EB05 >=	
PRR >=	

 Note

You can also restrict the results using these values on the Specify Criteria page when you are viewing results.

Top <n> combinations based on <score>

Whether to retain results only for the highest scoring combinations. If you select this option, do the following:

1. Specify the number of combinations that you want to include.
2. In the drop-down list select **EBGM** or **EB05**.

Only the top scoring combinations of the statistic you selected are included in the results.

Exclude associations if items are of the same type (all drugs, all events)

Whether to exclude combinations of item variables of the same type in the results, for example, Drug+Drug. Oracle recommends that you select this option.

 Note

To supply a default setting for this field, you can set the Exclude associations if items are of the same type (all drugs, all events) [user preference](#).

Field	Description
Keep only results that include the following values of <item variable>	Restricts the results such that Oracle Empirica Signal retains only results that include certain values for the item variables. To restrict the results, do one of the following: - Use the links to the right of each item variable to select the values that you want to include. Select Available Values—Includes custom terms for the run. Select Saved List—Includes custom terms for the run. Select < hierarchy > Terms—Does not include custom terms for the run. For example, if an item variable uses the MedDRA hierarchy and the Enable adverse event hierarchy browser user preference is enabled, you can select only MedDRA terms. Trade Generic Lookup—For data configurations that include trade name-generic name mapping. You can find the generic name for a drug if you know its trade name, or vice versa. Type the values that you want to include separated by commas. Note To prevent spelling and capitalization errors, Oracle recommends that you select rather than type values. Computations during the run include all item variable values. However, if you restrict the results, only results that include the values that you selected are retained. For example, if you select DrugA, Rash, and Vertigo as values to include, the displayed results include scores for combinations that meet the following criteria: - If there are drugs in the combination, at least one of them is DrugA. - If there are events in the combination, at least one of them is Rash or Vertigo. If you do not restrict the results, results for all values of the item variables are retained.

Step 4 for logistic regression runs: Select the events and specify drugs

When defining a logistic regression run, you specify values (that is, responses) for the event variable that you are investigating with the run on the Select Event page. Oracle Empirica Signal computes separate results for each specified event value.

Oracle Empirica Signal computes values for an event only if it finds a sufficient number of reports. Results are not produced for an event if either of the following situations exists:

- For all drugs explicitly included in the run no reports are found with the event and, in addition, the drugs that do occur in combination with the event most frequently do not meet the specified minimum number of occurrences for inclusion. (For more information on specifying drug values see [Specifying drugs for logistic regression](#).)

- For the covariate variables selected for the run, the number of reports that include the event and each of the possible covariate values averages less than 10. This is determined as follows:
 $10 * \text{the total number of possible values for all covariate variables that occur with this event}$
 $> \text{count of reports for the event.}$

If an event is specified for the run but results are not produced, one of these reasons appears in the [logistic regression log file](#) produced for the run.

If you specify a single event and that event is not found in the data used in the run, the run fails and an error appears on the Jobs for Run page. If you specify multiple events and any one of them is not found, the run fails and a message appears in the error log. You can access the logistic regression log file and the error log from the [Job Detail page](#).

Typically, logistic regression data mining runs do not include every possible drug+event combination. Instead, they are generally used to focus on specific medically related adverse events (response values) and drugs of interest (predictors). For some investigations, you may wish to compute scores for all adverse events in the selected data configuration (after database restrictions are applied).

Note

When selecting events, keep in mind that there is a logistic regression computation for each response value. The more events you select as responses, the longer the LR run takes

- In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
- At the top left of the **Data Mining Runs** home page, click **Create Run**.
- On the **Create Data Mining Run** page, select the **type of run to create** and click **Next**.
- On the **Select "As Of" Date** page, choose the latest date and time or select **Other** to choose a date and time. Then click **Next**.
- On the **Select Variables** page, select an event variable and a drug variable. Include additional covariates and define a custom term if you want, then click **Next**.
- On the **Logistic Regression: Select Events** page, select the **Select all available values** check box to include all of the events in the configuration in your run, type the events in the text box, or select events using the links to the right of the **(Event) HLGT** box.
- Click **Next** to open the Logistic Regression: Select Drugs page, and continue with [specifying drug values](#).
- Read the description of the events you selected and accept or change the values shown for the model.
- Specify the **(Drug) Product Family Name** by typing it in the text box or selecting using the **Select Available Values** and **Select Saved List** links.
- (Optional) Select the **Compute interactions** check box to include drug interactions.
- Click **Next** to define the [run options](#).

Step 5: Define data mining run options

After you specify parameters for a data mining run, the Run Options page appears.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. At the top left of the **Data Mining Runs** home page, click **Create Run**.
3. On the **Create Data Mining Run** page, select the **type of run to create** and click **Next**.
4. On the **Select "As Of" Date** page, choose the latest date and time or select **Other** to choose a date and time. Then click **Next**.
5. Specify the MGPS data mining parameters or logistic regression events and drugs and click **Next**.
6. On the Run Options page, specify when to perform the run:
 - **Run as soon as possible**—Perform the run right away.
 - **Do not run until**—Schedule the run for a future date or time.

✓ **Tip**

Schedule large runs, such as three-dimensional MGPS runs, for after your workday.

7. If you selected **Do not run until**, do the following:
 - Type a date in *mm / dd / yyyy* format, or click the calendar icon () and select a date.
 - Type a time in *hh : mm : ss < am|pm >* format.
8. To receive an email notification when the run is complete, select **Email me when complete** and specify one or more email addresses separated by commas.
 - You receive an email whether the run succeeded or failed.
 - By default, the email address associated with your Oracle Empirica Signal user name appears. To change the address associated with your user name, see your site administrator.
9. To save the intermediate data files that Oracle Empirica Signal produces during the data mining run, select **Save intermediate data files**.

Intermediate data files can include item dictionaries, count files, and so on. The files can be useful for understanding what occurred during the run and for troubleshooting.

📘 **Note**

This option appears only if you have the Save Intermediate files user permission.

If you save intermediate data files, you can view the files on the [Jobs for Run page](#).

10. For a logistic regression run, you can select **Save coefficients** to include the coefficient and standard error values computed for each predictor+response combination in the run in the [logistic regression coefficients log file](#).
11. Click **Next** to continue by [naming the run](#).

Step 6: Name the data mining run

After you define run options you name the data mining run.

1. In the **Run name** field, type the name of the run. The name does not need to be unique, although we recommend that you use a unique name.

Oracle Empirica Signal assigns a unique run ID to each run.

2. (Optional) in the **Description** text box, enter a description of the run. This helps other users to know what results to expect and choose the appropriate run.
3. Choose one of the following:
 - To assign the run to an existing project, select the project from the drop-down list.
 - To add the run to a new project, select **Add to new project named:** and enter a project name.
4. Click **Next** to confirm the run parameters and [submit the run](#).

Step 7: Submit the data mining run

After naming a data mining run that you are creating, you confirm the run parameters and submit the run.

1. On the **Confirm Run Parameters** page, review the parameters chosen for your run to make sure that they are correct. Different parameters display for MGPS runs and logistic regression runs.
2. To change any parameters, click **Back** until you are on the appropriate page and make the necessary changes. Then click **Next** until you are back on the Confirm Run Parameters page.
3. When you are satisfied with the run parameters, click **Submit**.
4. Click **Continue**.

The run status appears on the Data Mining Runs page. To monitor the progress of a run, you can [view jobs for the run](#).

All data mining runs are batch jobs, which continue to run on the Oracle Empirica Signal server even if you log out of the application. The next time you log in to the Oracle Empirica Signal application, you can check on the Data Mining Runs home page to determine if your run has completed. If you selected the **Email me when complete** run option, the application notifies you by email when your run completes.

MGPS run parameters

Field	Description
Type	MGPS.
Name	Name supplied for the run.
Description	Description supplied for the run.
Project	Name of the project to which the run is assigned.
Configuration	Name of the data configuration used for the run.
Configuration description	Description of the data configuration used for the run.
As of date	As Of date for the run, if the run is for timestamped data .

Field	Description
Database restriction	Database restriction , if any, associated with the run.
Item variables	Names of the item variables to be used in the run.
Drug Hierarchy	Name and version of the drug hierarchy used by this run if the data configuration specifies a drug hierarchy.
Event Hierarchy	Name and version of the event hierarchy used by this run if the data configuration specifies an event hierarchy.
Custom terms	Custom terms , if any, specified for the run.
Stratification variables	Stratification variables , if any, to be used for the run.
Subsets	Subset variable , if any, as well as whether the subsets are cumulative, the order of subsets, and the subset labels and values.
Highest dimension	The maximum number of ways in which items are combined. See Specify data mining parameters .
Minimum count	Minimum number of cases in which a combination of items must occur in order for the combination to be included in the run's MGPS computations. See Specify data mining parameters .
Calculate PRR	Whether the run includes PRR computations .
Calculate ROR	Whether the run includes ROR computations .
Base counts on cases	For a run that includes PRR and ROR computations, indicates if counts are based on cases rather than drug-event combinations.
Use "all drugs" comparator	For a run that includes PRR computations, indicates whether the drug of interest are included in the comparator set.
Apply Yates correction	For a run that includes PRR computations, indicates whether the Yates correction is applied.
Stratify PRR and ROR	For a run that includes PRR and ROR computations, indicates whether the PRR or ROR computations are stratified.
Include IC	Whether the run includes Information Component computations .
Include RGPS	Whether the run includes RGPS computations .
Calculate RGPS interactions	Whether the run includes Drug+Drug RGPS interaction scores.
Minimum interaction count	Minimum number of times that a drug must appear in Drug+Event reports for the application to calculate RGPS interaction estimates for the drug.
Fill in hierarchy values	Whether the run option to use hierarchy information was checked.
Limit results to	Limitations, if any, on which results will be kept based on statistical thresholds or specified values of item variables. See Specify data mining parameters .
Exclude single itemtypes	Whether the run excludes combinations of items of the same type. See Specify data mining parameters .
Fit separate distributions	Indicates the run's setting for the advanced parameter to fit separate distributions for the different item type combinations.

Field	Description
Save intermediate files	Whether intermediate processing files for the run are saved. See Define data mining run options .
Source database	Information about the source data (from the source description table).
Scheduled to run	Date and time at which the run is scheduled to be run. See Define data mining run options .

Logistic regression run parameters

Field	Description
Type	LR. For runs completed prior to the installation of Oracle Empirica Signal version 7.1, LR (Legacy) appears.
Name	Name supplied for the run.
Description	Description supplied for the run.
Project	The name of the project to which the run is assigned.
LR type	Indicates the algorithm type selected for the run: standard or extended. See Logistic regression computations . For runs completed prior to the installation of Oracle Empirica Signal version 7.1, an Extended logistic regression field appears instead, with a Yes or No value.
Configuration	Name of the data configuration used for the run.
Configuration description	Description of the configuration used for the run.
As of date	As Of date for the run, if the run is for timestamped data .
Database restriction	Database restriction , if any, associated with the run.
Item variables	Names of the run's selected event and drug variables .
Custom terms	Custom terms , if any, specified for the run.
Covariates	Variables, if any, selected as covariates for the run.
Drug values	Explicitly specified values of the drug variable included in the run, even if they do not meet the minimum number of times a drug must occur in combination with specified events.
Event values	Values of the event variable used in the run.
Minimum count	Minimum number of cases in which a drug must occur in combination with specified events in order to be included in the run (except for drugs specifically selected as Drug values). See Select drugs for logistic regression .
Number of events	Number of event values specified.
Save intermediate files	Indicates whether intermediate processing files for the run are saved. See Define data mining run options .
Run interactions	Indicates whether the run calculates statistics for two predictors (such as Drug+Drug or Drug+Covariate) and a response.
Save coefficients	Indicates whether the lr_coefficients.log file produced for the run include the coefficient and standard deviation values calculated for the run.
Source database	Information about the source data (from the source description table).

Field	Description
Scheduled to run	Date and time at which the run is scheduled to be run. See Define data mining run options .

Reference

- [About MGPS runs](#)
The main statistical scores computed by an MGPS run are EBGM, EB05, EB95, representing the Empirical Bayes Geometric Mean and the 90% confidence interval from 5% to 95%.
- [MGPS computations](#)
The analytical core of the Oracle Empirica Signal application is a high-performance implementation of the MGPS (Multi-Item Gamma Poisson Shrinker) algorithm.
- [MGPS independence model](#)
Prior to Version 5.0 of WebVDME (which was the previous name of the Oracle Empirica Signal application), signal scores for 3D data mining results were computed using the MGPS independence model described here. Starting in WebVDME 5.0, the primary way of computing signal scores for 3D results changed to the MGPS interaction model.
- [Information Component computations](#)
When you specify data mining parameters for an MGPS run, you can include Information Component (IC) computations.
- [RGPS computations](#)
When you specify data mining parameters for a two-dimensional MGPS run without subset variables, you can include Regression-Adjusted Gamma Poisson Shrinker Algorithm (RGPS) computations.
- [Use the PRR calculator](#)
When creating a data mining run, you can specify that Proportional Reporting Ratio (PRR) and Chi-square should be computed and included in the results for each drug-event combination against a specified background database.
- [PRR computations](#)
When specifying data mining parameters for a run, you can perform PRR and ROR computations.
- [Select a case series for PRR computation](#)
PRR computations are made on a case series.
- [ROR computations](#)
When specifying data mining parameters for a run, you can specify that PRR and ROR computations be performed.
- [About logistic regression runs](#)
Logistic regression is a statistical tool for modeling how the probability of a response depends on the presence of multiple predictors, or risk factors.
- [Logistic regression computations](#)
There are two types of logistic regression: standard logistic regression and extended logistic regression.
- [Logistic regression log files](#)
Logistic regression data mining runs produce log files to provide information on run processing. These text files are available for download on the Job Detail page for the LR job in the run.

- [Guidelines for specifying drugs for logistic regression](#)
For a logistic regression run, you define the number of predictor values (that is, how many drugs) to include in computations for each of the events you select for the run.
- [Drug and event hierarchies](#)
A hierarchy determines how adverse event terms and drug terms are organized in the source data. For example, the FOI FDA Adverse Event Reporting System (AERS) database uses the Medical Dictionary for Regulatory Activities (MedDRA) classification system.
- [Timestamped data](#)
Timestamping is a technique for representing multiple versions of the same source data within one database.
- [Specify an As Of date](#)
During some activities, if you select a data configuration that supports timestamped data, the Select 'As Of' Date page appears and you must specify an As Of date and time.
- [Stratification variables](#)
Item values can be associated in an MGPS data mining run because they are associated jointly with other variables, such as gender or age.
- [Dimensions and patterns](#)
On the Select Criteria page, you can specify the dimension and pattern for an MGPS run as criteria for viewing data mining results.
- [View interactions](#)
Each row in the table presents two predictor values, which appear in the columns labeled Item1 and Item2, and a response, which appears in the column labeled for the selected event variable, such as PT.
- [Case scoring algorithm](#)
A case score indicates how well populated a report is for a given product-event combination.
- [Increased frequency algorithm](#)
Reporting proportion (RP) is used as a proxy for exposure adjusted reporting rates and is defined as the number of cases for a product-event combination divided by the total number of cases for the product within the time period.

About MGPS runs

The main statistical scores computed by an MGPS run are EBGM, EB05, EB95, representing the Empirical Bayes Geometric Mean and the 90% confidence interval from 5% to 95%.

The application calculates these scores for each combination of items (such as drugs and events) included in the run. The data configuration that you select determines the items that are available for selection in the run.

Optionally, you can include computations of the following in an MGPS run:

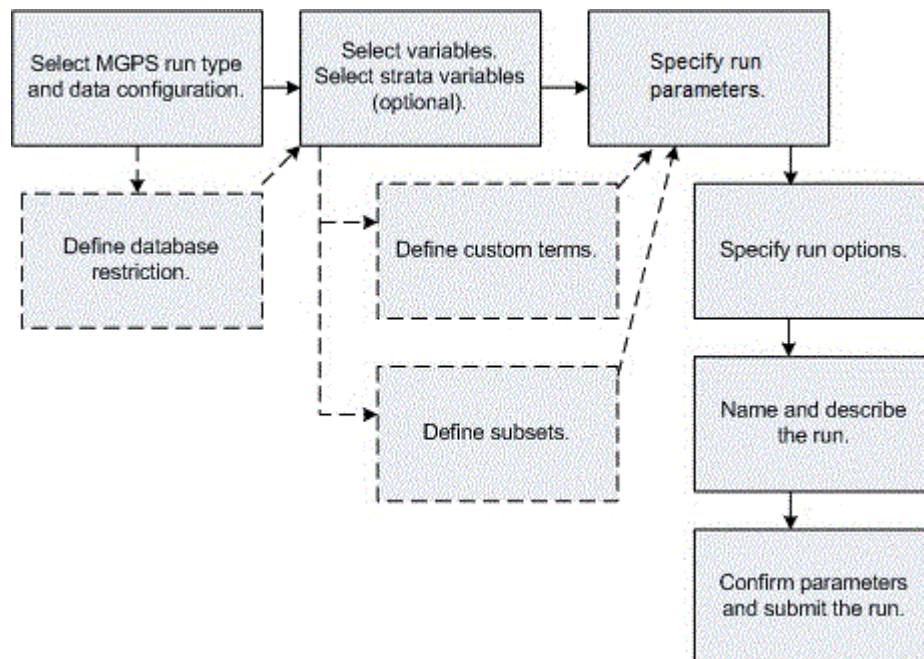
- Information Component (IC)
- Disproportionality estimates and interaction scores using Regression-Adjusted Gamma Poisson Shrinker Algorithm (RGPS)
- Proportional Reporting Ratios (PRR)
- Reporting Odds Ratios (ROR)

When you define an MGPS run, you select the items to combine and for which to generate scores. You typically select a drug (or vaccine) variable and an event (or symptom) variable. You can also select items, such as gender, age group, or report receipt year, for the purposes

of [subsetting](#) or [stratification](#). You can define a [database restriction](#) to limit which cases in source data to include in the run, and [custom terms](#), to select cases meeting specified criteria.

The execution of an MGPS run includes the following steps:

1. Select MGPS run types and data configuration.
 - Define database restriction. (optional)
2. Select variables. Select strata variables (optional).
 - Define custom terms. (optional)
 - Define subsets. (optional)
3. Specify run parameters.
 - Specify run options.
 - Name and describe the run. (optional)
 - Confirm parameters and submit the run. (optional)



As a [data mining parameter](#), you can restrict which results from the run to retain. For example, you can keep only results for drug-event combinations that include certain drugs and certain events. Restricting results does not affect the statistical computations. The application performs the statistical computations first and then keeps only results that meet the restriction.

MGPS computations

The analytical core of the Oracle Empirica Signal application is a high-performance implementation of the MGPS (Multi-Item Gamma Poisson Shrinker) algorithm.

MGPS is based on the metaphor of the market basket problem, in which a database of transactions (adverse event reports) is mined for the occurrence of interesting (unexpectedly frequent) itemsets. For example, these itemsets can represent simple drug-event pairings, or more complex combinations of multiple drugs and events representing interactions and/or syndromes. Interestingness is related to the factor by which the observed frequency of an itemset differs from a nominal baseline frequency.

For each itemset in the database, a Relative Reporting Ratio (RR) is defined as the observed count (N) for that itemset divided by the expected count (E). MGPS allows for the possibility that the database may contain heterogeneous strata with significantly different item frequency distributions occurring in the various strata. To avoid concluding that an itemset is unusually frequent just because the items involved individually all tend to occur more frequently in a particular stratum (Simpson's paradox), MGPS uses the Mantel-Haenszel approach of computing strata-specific expected counts and then summing over the strata to obtain a database-wide value for the expected count.

To improve the estimation of true value for each RR (especially for small counts), the empirical Bayesian approach of MGPS assumes that the many observed values of RR are related in that they can be treated as having arisen from a common super population of unknown, true RR-values. The method assumes that the set of unknown RR values is distributed according to a mixture of two parameterized Gamma Poisson density functions, and the parameters are estimated from a maximum likelihood fit to the data. This process provides a prior distribution for all the RRs, and then the Bayes rule can be used to compute a posterior distribution for each RR. Since this method improves over the simple use of each N/E as the estimate of the corresponding RR, it can be said that the values of N/E borrow strength from each other to improve the reliability of every estimate.

The improved estimates of RR are actually derived from the expectation value of the logarithm of RR under the posterior probability distributions for each true RR.

If you select [subset variables](#) for the run, MGPS computations are performed for each subset. If you select [stratification variables](#) for the run, the MGPS computations are modified to use stratification.

Item variables

When you create an MGPS run, you select item variables. Typically, the item variables represent drugs and events. The counting and estimation that the MGPS computation performs divides the combinations of the selected item types into separate itemsets, based on the combinations possible for the number of dimensions in the run. For the two items D and E in a three-dimensional run, MGPS performs computations on the itemsets DD, DDD, DE, DDE, DEE, EE, and EEE.

Drug-event combination scores

For a combination of drug and event (a two-dimensional or 2D combination), the signal score is the EBGM (Empirical Bayes Geometric Mean) value.

EBGM is defined as the exponential of the expectation value of log (true RR). EBGM has the property that it is nearly identical to N/E when the counts are moderately large, but is shrunk towards the average value of N/E (typically ~1.0) when N/E is unreliable because of stability issues with small counts. The posterior probability distribution also supports the computation of lower and upper 95% confidence limits (EB05, EB95) for EBGM, which is an estimate of the relative reporting ratio.

Interaction scores

Computations for combinations of dimensions greater than 2 focus on measuring and scoring cross-item type combinations, but allow any observed dependence within item types to be fit completely without generating a score. The only exception to this is during the analysis of a homogeneous itemset, such as three events (E1,E2,E3) where all items are of the same type and in which case high EBGM scores do alert reviewers to a potential within-item type association. Thus, for a mixed-type 3D combination like (D1,D2,E1), the values of EBGM, EB05 and so on measure how many times more frequently the pair (D1,D2) occurs with E1 than would be expected if the pair (D1,D2) were independent of E1, without making any

statement about whether the drugs D1 and D2 appear in the same reports more frequently than independence would predict.

The signal score for a 3D combination is the INTSS (Interaction Signal Score) value, which is essentially a way of measuring the strength of a higher-order association above and beyond what would be expected from any of the component pairs of items of different types. INTSS is computed as follows:

$$\text{INTSS} = \text{EB05} / \text{EB95MAX}$$

where:

- EB05 is the conservative estimate score for the 3D combination.
- EB95MAX is the highest EB95 score found for the component pairs of items of different types.

An INTSS of greater than 1 indicates a stronger association than is found for the component pairs of items.

Note

Typically, it would not be concluded that the potential interaction was interesting unless the EB05 score for that DDE combination is large (for example, over 1.5 or 2.0).

To support backward compatibility with versions of the application prior to 5.0, signal scores based on the independence model are still computed for dimensions higher than 2. These values are stored in columns ending in `_IND`. See [MGPS independence model](#).

Custom terms and synthetic values

When estimating shrinkage parameters for EBGM scores, MGPS does not consider the following:

- Custom terms.
- [Excluded synthetic values](#), such as Standardized MedDRA Queries (SMQs), that have been defined for the appropriate [data configuration variable](#).

The raw RR scores for combinations involving custom terms and the excluded synthetic values are shrunk by the Bayesian formula, but they do not participate in the determination of the formula itself.

Note

Users creating a data mining run do not need to take any additional steps to exclude custom terms or already-excluded synthetic values.

MGPS independence model

Prior to Version 5.0 of WebVDME (which was the previous name of the Oracle Empirica Signal application), signal scores for 3D data mining results were computed using the MGPS independence model described here. Starting in WebVDME 5.0, the primary way of computing signal scores for 3D results changed to the MGPS interaction model.

For compatibility with older data mining runs, the application continues to compute scores using the independence model as well.

The MGPS interaction model computes values of INTSS, described in [MGPS computations](#). The independence model computes values of EBGMDIF_IND. The names of columns related to the independence model end in _IND.

The difference between the independence model and the interaction model affects only 3D results. Thus, the values of EBGM and EBGM_IND, which are for 2D results, are the same.

2D results

For a 2D result, it is assumed that the probability of finding items i and j in the same report is the same as the probability of finding i times the probability of finding j:

$$P(i,j) = P(i) \times P(j)$$

For a two-dimensional run that is not stratified, expected counts are computed as follows:

$$E(i,j) = N_{\text{total}} \times P(i,j) = N_{\text{total}} \times P(i) \times P(j)$$

For a two-dimensional run that is stratified, computations are as follows:

$$E(i,j) = \sum E_c(i,j) = \sum N_{\text{total},c} \times P_c(i,j) = \sum N_{\text{total},c} \times P_c(i) \times P_c(j)$$

where the summations occur over the C strata.

The signal score is the EBGM_IND value, which is a more stable estimate than RR; the so-called shrinkage estimate. The EBGM value is computed as the geometric mean of the posterior distribution of the true Relative Ratio.

3D results

For a 3D result, it is assumed that the probability of finding items i, j, and k in the same report is the same as the probability of finding i times the probability of finding j times the probability of finding k:

$$P(i,j,k) = P(i) \times P(j) \times P(k)$$

For a three-dimensional unstratified run, the expected count is computed as follows:

$$E(i,j,k) = N_{\text{total}} \times P(i,j,k) = N_{\text{total}} \times P(i) \times P(j) \times P(k)$$

In the stratified independence model, it is assumed the above equations hold for each stratum. So, if there are C strata:

$$P_c(i,j,k) = P_c(i) \times P_c(j) \times P_c(k)$$

for a given stratum c.

For a three-dimensional stratified analysis, the expected count is computed as follows:

$$E(i,j,k) = \sum E_c(i,j,k) = \sum N_{\text{total},c} \times P_c(i,j,k) = \sum N_{\text{total},c} \times P_c(i) \times P_c(j) \times P_c(k)$$

where the summations occur over the C strata.

The signal score for a 3D combination is the EBGMDIF_IND value, computed as follows:

$$\text{EBGMDIF\_IND} = \text{EBGM\_IND} - \text{E2D\_IND} / \text{E\_IND}$$

where E2D_IND is the expected count based on the all-2-factor log linear model.

Information Component computations

When you specify data mining parameters for an MGPS run, you can include Information Component (IC) computations.

The IC is a measure of disproportionality between the observed and expected number of reports for a drug-event combination. The method was originally introduced at the Uppsala Monitoring Centre (UMC) for use with VigiBase by Norén et. al. [Norén GN, Hopstadius J, Bate A. Shrinkage observed-to-expected ratios for robust and transparent large-scale pattern discovery. Statistical Methods in Medical Research. 2013;22(1):57-69.].

A positive IC indicates that the number of observed reports is greater than the number of expected reports. Similarly, a negative IC indicates that the number of observed reports is less than the number of expected reports.

Oracle Empirica Signal computes IC values only for drug-event combinations. For example, if you create a three-dimensional MGPS run, Oracle Empirica Signal computes IC values for each drug-event combination, and disregards the following:

- Combinations of one drug and two events.
- Combinations of two drugs and one event.
- Combinations of three drugs.
- Combinations of three events.

IC values include the following:

- IC—Information component
- IC025—Lower limit of the 95 percent confidence interval for IC
- IC975—Upper limit of the 95 percent confidence interval for IC

If you selected stratification variables for the run, the expected number of reports (E) is adjusted using the Mantel-Haenszel approach. For more information, see [Stratification variables](#).

If you defined a subset variable for the run, Oracle Empirica Signal computes results for each value of the subset variable with observed cases in the data.

Drug-event combination scores

1. Oracle Empirica Signal determines the observed counts for each drug-event combination as follows:

Event	Drug of interest	All other drugs
Event of interest	a	b
All other events	c	d

- a—Number of reports of the drug of interest and the event of interest.
 - b—Number of reports of the event of interest and not the drug of interest.
 - c—Number of reports of the drug of interest and not the event of interest.
 - d—Number of reports of neither the event or drug of interest.
2. Oracle Empirica Signal computes the expected counts for each drug-event combinations as follows:

Event	Drug of interest	All other drugs
Event of interest	$E(a) = ((a+b)(a+c))/(a+b+c+d)$	$E(b) = ((a+b)(b+d))/(a+b+c+d)$
All other events	$E(c) = ((c+d)(a+c))/(a+b+c+d)$	$E(d) = ((c+d)(b+d))/(a+b+c+d)$

3. Oracle Empirica Signal computes the IC metric for each drug-event combination as follows:

Figure 4-1 Equation 1

$$IC = \log_2 \frac{O + \alpha_1}{E + \alpha_2} \quad \text{with } \alpha_1 = \alpha_2 = 1/2$$

For computation of the 95% confidence interval (denoted as IC025 and IC975), the paper by Norén et. al proposed a simplified approach as follows:

Figure 4-2 Equation 2

$$IC_{025} = IC - 3.3 \cdot (O + \alpha_1)^{-1/2} - 2 \cdot (O + \alpha_1)^{-3/2}$$

$$IC_{975} = IC + 2.4 \cdot (O + \alpha_1)^{-1/2} - 0.5 \cdot (O + \alpha_1)^{-3/2}$$

With the simplified approach, the confidence interval bounds are being estimated slightly too low for small counts, and slightly too high for larger counts of cases (compared to an exact computation based on the gamma posterior distribution). To achieve a higher accuracy beyond the first decimal, Empirica Signal applies an algorithm based on the Wilson-Hilferty transformation [Wilson EB, Hilferty MM. The Distribution of Chi-Square. Proc Natl Acad Sci U S A. 1931 Dec;17(12):684-8.]. Some transformations are needed to the Wilson-Hilferty notation to convert from their chi-squared formulation to use the equivalent Bayesian posterior incomplete gamma quantiles which are used in Empirica Signal, resulting in

Figure 4-3 Equation 3

$$IC_{025} = \log_2 \left(k \cdot \frac{\left(1 - \frac{1}{9 \cdot k} - \frac{1.96}{3 \cdot \sqrt{k}}\right)^3}{E + \alpha_2} \right)$$

$$IC_{975} = \log_2 \left(k \cdot \frac{\left(1 - \frac{1}{9 \cdot k} + \frac{1.96}{3 \cdot \sqrt{k}}\right)^3}{E + \alpha_2} \right) \quad \text{I}$$

with $k = O + \alpha_1$

where O is the observed count, E is the expected count, as detailed above.

RGPS computations

When you specify data mining parameters for a two-dimensional MGPS run without subset variables, you can include Regression-Adjusted Gamma Poisson Shrinker Algorithm (RGPS) computations.

RGPS is a hybrid algorithm, which combines the methodology of Extended Logistic Regression (ELR) and MGPS.

Note

You must install R as described in the Oracle Empirica Signal and Topics Installation Guide to enable RGPS computations.

In general, RGPS differs from MGPS, PRR, and ROR computations in that it adjusts for the effects of polypharmacy and therefore reduces the likelihood of masking biases and "innocent bystander" biases. These biases occur when a drug other than the drug of interest is highly associated with the event of interest.

Masking bias occurs when a highly associated drug other than the drug of interest appears in greater number in reports that do not also include the drug of interest. Masking bias inflates the expected count for a drug-event combination of interest. Consequently, the disproportionality estimate for the drug-event combination of interest is reduced. A lower disproportionality estimate can lead to a missed signal.

"Innocent bystander" bias occurs when a drug with no causal connection to an adverse event is often co-prescribed with a highly associated drug. In this case, both drugs can appear to be associated with the adverse event.

Like MGPS, RGPS calculates a Relative Reporting Ratio (RR) for each itemset in the database. The RR is defined as the observed count (N) for the itemset divided by the expected count (E). However, RGPS computes E using the results of an Extended Logistic Regression (ELR) analysis rather than the Mantel-Haenszel approach.

Note

The Oracle Empirica Signal application allows you to run only one RGPS computation at a time.

Drug-event combination scores

For a combination of a drug and event, the signal score is the ERAM (Empirical-Bayes Regression-adjusted Arithmetic Mean) value. ERAM is the shrunken observed-to-expected reporting ratio adjusted for covariates and concomitant drugs.

The 5 percent (ER05) and 95 percent (ER95) confidence intervals for the ERAM are also calculated.

Drug interaction scores

For an RGPS run, you have the option of including drug-drug interaction computations. Interaction estimates are calculated for drugs where the number of drug-event reports exceeds the specified minimum interaction count.

Use the PRR calculator

When creating a data mining run, you can specify that Proportional Reporting Ratio (PRR) and Chi-square should be computed and included in the results for each drug-event combination against a specified background database.

Before you use the PRR calculator, you must specify three case series (based on the same configuration) to represent a background database, the events of interest, and the drugs of interest. For example, to compute PRR for combinations of analgesics and respiratory ailments in women over age 65, use a case series that includes cases for women over age 65, a case series that includes cases for analgesics, and a case series that includes cases involving respiratory ailments.

1. Click the **Case Series** page.
2. On the Case Series page, [identify or define the three case series](#) to use.
3. Click **PRR Calculator**.
4. From the **Configuration** drop-down list, [select a data configuration](#).
5. For the following types of case series, click **Browse** and [select a case series](#). You must base all three case series on the same configuration.
 - Background Definition Case Series—Defines the customized background for the computations.
 - Event Definition Case Series—Defines the set of events.
 - Drug Definition Case Series—Defines the set of drugs.
6. To define the chi-square calculation method, check or clear **Apply the Yates correction for chi-square**.
7. To define the PRR calculation method, check or clear **Include drug of interest in the comparator set**.
8. Click **Calculate**.

The observed counts and results appear.

- Observed counts of cases with drug-event combinations are represented as a, b, c, and d in a 2x2 table as follows:

Note

When PRR is computed by a data mining run, a, b, c, and d represent counts of drug-event combinations by default. You can select an option to count cases with those combinations instead. However, the PRR calculator always counts cases.

Observed counts of cases with drug-event combinations are represented in the 2x2 table as follows:

Cases	Specific drug	All other drugs
Specific event	a	b
All other events	c	d

- The PRR for the combination of a particular drug and particular event is computed as follows:
 - $PRR = (a / (a + c)) / (b / (b + d))$
- If $b=0$ (and **Include drug of interest in the comparator set** described below is cleared), then the formula is adjusted as follows to avoid the possibility of division by zero:
 - $PRR = ((a+0.5) / ((a+0.5) + (c+0.5))) / ((b+0.5)/((b+0.5) + (d+0.5)))$
- If you checked **Include drug of interest in the comparator set**, the application computes PRR as:
 - $PRR = (a / (a + c)) / ((a + b) / (a + b + c + d))$

For each cell in the 2x2 table, the expected count is computed as follows:

Cases	Specific drug	All other drugs
Specific event	$E(a) = ((a+b)(a+c))/(a+b+c+d)$	$E(b) = ((a+b)(b+d))/(a+b+c+d)$
All other events	$E(c) = ((c+d)(a+c))/(a+b+c+d)$	$E(d) = ((c+d)(b+d))/(a+b+c+d)$

The chi-square of PRR (PRR_CHISQ) for the combination of a particular drug and particular event is computed as follows, where E represents the expected count under the assumption of no relationship between drugs and events:

- $PRR\_CHISQ = ((a-E(a))^2)/E(a) + ((b-E(b))^2)/E(b) + ((c-E(c))^2)/E(c) + ((d-E(d))^2)/E(d)$

If you checked **Apply the Yates correction for chi-square**, PRR_CHISQUARE is computed as follows:

- $PRR\_CHISQ = ([\max(0, |a - E(a)| - 0.5)]^2)/E(a) + ([\max(0, |b - E(b)| - 0.5)]^2)/E(b) + ([\max(0, |c - E(c)| - 0.5)]^2)/E(c) + ([\max(0, |d - E(d)| - 0.5)]^2)/E(d)$

Note

$|a - E(a)| = |b - E(b)| = |c - E(c)| = |d - E(d)|$ for every 2x2 table; this formula can also be expressed as:

$$PRR\_CHISQ = (1/E(a) + 1/E(b) + 1/E(c) + 1/E(d)) [\max(0, |a - E(a)| - 0.5)]^2$$

The P-values for chi-square values are also computed. The P-value is the probability that chi-square would be as large as the value for PRR_CHISQ by chance alone if there were no causal relationship or consistent association between the drug and the event.

Note

If any of E(a), E(b), E(c), or E(d) is zero, the chi-square and P-value cannot be computed and are defined arbitrarily as -1.

- In the table for observed counts, you can click the value of **N** in a column to display a menu. Click **View Cases** to [drill down](#) to cases that have the specified drugs and specified events.

PRR computations

When specifying data mining parameters for a run, you can perform PRR and ROR computations.

For information about ROR, see [ROR computations](#). For information about data mining parameters, see [specifying data mining parameters](#).

The Proportional Reporting Ratio (PRR) computation relates to drug-event combinations, only, in two-dimensional data mining runs. If you specify a dimension of 3 for the run, the application computes PRR only for the 2D pairs; that is, the drug-event combinations, but not the combinations of one drug and two events, two drugs and one event, three drugs, or three events.

Default PRR computations

If you check **Base counts on cases rather than drug-event combinations** but no other PRR options, the application computes PRR as follows. If you select a [subset variable](#) for the run, the application computes PRR separately for each subset.

1. Assume that observed counts of cases with drug-event combinations are named a through d as follows:

Type of event	Specific drug	All other drugs
Specific event	a	b
All other events	c	d

- a is the number of cases with the specific event and the specific drug.
- b is the number of cases with the specific event but not the specific drug.
- c is the number of cases with the specific drug but not the specific event.
- d is the total number of cases with neither the specific event nor the specific drug.

2. The PRR for the combination of a particular drug and particular event is computed as follows:

$$\text{PRR} = (a / (a + c)) / (b / (b + d))$$

If b=0 (and the **Include drug of interest** checkbox is not checked), then the formula is adjusted to avoid the possibility of division by zero:

$$\text{PRR} = ((a+0.5) / ((a+0.5) + (c+0.5))) / ((b+0.5)/((b+0.5) + (d+0.5)))$$

3. For each cell in the table in step 1, the application computes the expected count as follows:

Event	Specific drug	All other drugs
Specific event	$E(a) = ((a+b)(a+c))/(a+b+c+d)$	$E(b) = ((a+b)(b+d))/(a+b+c+d)$
All other events	$E(c) = ((c+d)(a+c))/(a+b+c+d)$	$E(d) = ((c+d)(b+d))/(a+b+c+d)$

4. The application computes the chi-square of PRR (PRR_CHISQ) for the combination of a particular drug and particular event as follows, where E represents the expected count under the assumption of no relationship between drugs and events:

$$\text{PRR\_CHISQ} = ((a-E(a))^2/E(a) + ((b-E(b))^2/E(b) + ((c-E(c))^2/E(c) + ((d-E(d))^2/E(d))$$

The P-values for Chi-square values are also computed. The P-value is the probability that Chi-square would be as large as the value for PRR_CHISQ by chance alone if there were no causal relationship or consistent association between the drug and the event.

Note

If any of E(a), E(b), E(c), or E(d) is zero, the Chi-square and P-value cannot be computed and are defined arbitrarily as -1.

Counts based on drug-event combinations

By default, the PRR computation counts the occurrence of cases. On the Data Mining Parameters page, if you clear **Base counts on cases rather than drug-event combinations**, then a through d represent counts of drug-event combinations. If a case has more than one drug or event, the case supplies several drug-event combinations to the computation. This option is not recommended, especially if data mining results include [custom terms](#) or Standardized MedDRA Queries (SMQs).

If you select [stratification variables](#) for the data mining run, the application checks **Base counts on cases instead of drug-events combinations** automatically and cannot be cleared. The [PRR calculator](#) also always bases counts on cases.

Drug of interest in comparator set

On the Data Mining Parameters page, if you check **For PRR, include drug of interest in the comparator set**, then PRR is computed as:

$$\text{PRR} = (a / (a + c)) / ((a + b) / (a + b + c + d))$$

Yates correction

On the Data Mining Parameters page, if you check **Apply the Yates correction in computing the value of chi-square**, then PRR_CHISQUARE is computed as:

$$\text{PRR\_CHISQ} = ([\max(0, |a - E(a)| - 0.5)]^2 / E(a)) + ([\max(0, |b - E(b)| - 0.5)]^2 / E(b)) + ([\max(0, |c - E(c)| - 0.5)]^2 / E(c)) + ([\max(0, |d - E(d)| - 0.5)]^2 / E(d))$$

Note

$|a - E(a)| = |b - E(b)| = |c - E(c)| = |d - E(d)|$ for every 2x2 table. This formula can also be expressed as:

$$\text{PRR\_CHISQ} = (1/E(a) + 1/E(b) + 1/E(c) + 1/E(d)) [\max(0, |a - E(a)| - 0.5)]^2$$

If you select stratification variables for the data mining run, this option is available only if you do not check **Use stratified computation for PRR and ROR**.

Stratified PRR computation

Even if you select stratification variables for the data mining run, Oracle does not recommend using stratified computation for PRR and ROR. However, on the Data Mining Parameters page you have the option to check **Use stratified computation for PRR and ROR**. The PRR computation is performed as follows.

If there are K strata, then for stratum k (k = 1, 2, ..., K), let a_k , b_k , c_k , d_k be the four cell counts in stratum k, and let

- $M1k = a_k + b_k$
- $M0k = c_k + d_k$

- $N1k = a_k + c_k$
- $N0k = b_k + d_k$
- $T = M0k + M1k = N0k + N1k = a_k + b_k + c_k + d_k$

$$PRR = (\sum K a_k N0k / T_k) / (\sum K b_k N1k / T_k)$$

Note

If the run uses subsetting, only those strata that contain cases for a given subset are used in the PRR computation for that subset.

The Chi-square statistic for stratified PRR is computed as:

$$PRR\_CHISQ = \sum K (a_k - N1k * M1k / T_k)^2 / \sum K ((N0k * N1k * M0k * M1k) / ((T_k - 1) * T^2))$$

Note

For instances where the denominator in the PRR or the chi-square formulas would be zero, the computation adds $0.5/K$ to a_k , b_k , c_k , and d_k , where K is the number of strata.

Select a case series for PRR computation

PRR computations are made on a case series.

1. On the [PRR Calculator page](#), select the configuration that you want to use.
2. Next to a case series field, click **Browse**.

The Select Case Series dialog box appears, listing case series that you have created or that have been published to your login group, and that are based on the selected data configuration.

Note

If you have the Administer Users permission, all published case series based on the selected configuration appear.

The following information is provided for each case series:

Column	Description
Name	Name of the case series.
Description	Description of the case series.
Project	The name of the project to which the case series is assigned.
# Cases	Number of cases in the case series.
Configuration	Configuration used by the case series.
Created By	Name of the user who created the case series.

Column	Description
Created	Date and time when the case series was created.
Modified By	Name of the user who last modified the case series.
Modified	Date and time when the case series was last modified.

- Click the row for the case series that you want to select.
- Click **OK**.

ROR computations

When specifying data mining parameters for a run, you can specify that PRR and ROR computations be performed.

For information about PRR, see [PRR computations](#). For information about data mining parameters, see [specifying data mining parameters](#).

In two-dimensional data mining runs, the application computes the Reporting Odds Ratio (ROR) only for drug-event combinations. If you specify a dimension of 3 for the run, the application computes ROR only for the 2D pairs. This means that the ROR is computed for the drug-event combinations, but not for the combinations of one drug and two events, two drugs and one event, three drugs, or three events.

ROR computations

Note

If you select a [subset variable](#) for the run, the applications computes ROR separately for each subset.

Assume that observed counts of drug-event pairs are named a through d, as follows:

Type of Event	Specific drug	All other drugs
Specific event	a	b
All other events	c	d

- a is the number of cases with the specific event and the specific drug.
- b is the number of cases with the specific event but not the specific drug.
- c is the number of cases with the specific drug but not the specific event.
- d is the total number of cases with neither the specific event nor the specific drug.

The ROR for the combination of a particular drug and particular event is computed as:

Figure 4-4 ROR equation

$$ROR = \frac{ad}{bc}$$

The 90% confidence interval is defined by:

Figure 4-5 ROR and V equations

- $ROR_{05} = e^{Log(ROR) - 1.645\sqrt{V}}$
- $ROR_{95} = e^{Log(ROR) + 1.645\sqrt{V}}$

where:
$$V = \frac{1}{a} + \frac{1}{b} + \frac{1}{c} + \frac{1}{d}$$

In cases where division by zero would arise, 0.5 is added to each of a, b, c and d.

Counts based on drug-event combinations

By default, the ROR computation counts the occurrence of cases. On the Data Mining Parameters page, if you clear **Base counts on cases rather than drug-event combinations**, a through d represents counts of drug-event combinations. If a case has more than one drug or event, the case supplies several drug-event combinations to the computation. Oracle does not recommend this option, especially if data mining results include custom terms or Standardized MedDRA Queries (SMQs).

If you select [stratification variables](#) for the data mining run, the application automatically checks **Base counts on cases instead of drug-events combinations** and cannot be cleared.

Stratified ROR computations

If you select [stratification variables](#) for the data mining run, then on the Data Mining Parameters page you have the option to check Use stratified computation for PRR and ROR. The option, by default, is not enabled and Oracle does not recommend enabling unless under certain circumstances such as a small number of strata and/or of enough cases across strata for the PECs in question. For stratified computation of ROR assume that a, b, c, and d are counts of drug-event pairs for a given stratum.

Figure 4-6 ROR and R, S, T equations

$$ROR = \frac{\sum R}{\sum S}$$

where:

- $R = \frac{ad}{T}$
- $S = \frac{bc}{T}$
- $T = a + b + c + d$
- The sums are taken over all strata.

The 90% confidence interval is defined by:

Figure 4-7 ROR05 and ROR95 equations

- $ROR05 = e^{Log(ROR) - 1.645\sqrt{V}}$
- $ROR95 = e^{Log(ROR) + 1.645\sqrt{V}}$

where:

Figure 4-8 V, P, Q equation

- $V = \frac{\sum PR}{2(\sum R)^2} + \frac{\sum (PS+QR)}{2\sum R \sum S} + \frac{\sum QS}{2(\sum S)^2}$
- $P = \frac{a+d}{T}$
- $Q = \frac{b+c}{T}$

Note

In cases where division by zero would arise, 0.5/K is added to each of a, b, c and d for each stratum, where K is the number of strata.

Reference

Robins J, Greenland S, Breslow N. A General Estimator for the Variance of the Mantel-Haenszel Odds Ratio. *American Journal of Epidemiology* 1986; 124: 719-23.

About logistic regression runs

Logistic regression is a statistical tool for modeling how the probability of a response depends on the presence of multiple predictors, or risk factors.

In the Oracle Empirica Signal application, the predictors are products and, optionally, covariates such as report year, gender, or age group, and the responses are adverse events.

The main statistical scores computed for the predictors and responses in a logistic regression run are LROR, LR05, and LR95, representing the Logistic Regression Odds Ratio and the 90% confidence interval (LR05, LR95). The scores from a logistic regression run, when compared to the results of an MGPS run, can help identify confounding or masking effects.

To create a logistic regression run, you select a data configuration and one drug variable (the predictor) and one event variable (the response) variable to combine for score generation. You can also explicitly specify drug and event values to include in the computation. Because the logistic regression computation assesses the results of polytherapy, selecting configurations that include concomitant as well as suspect products, and drug variables, such as Single

Ingredient, that treat combination products as if the patient had taken separate products, are recommended.

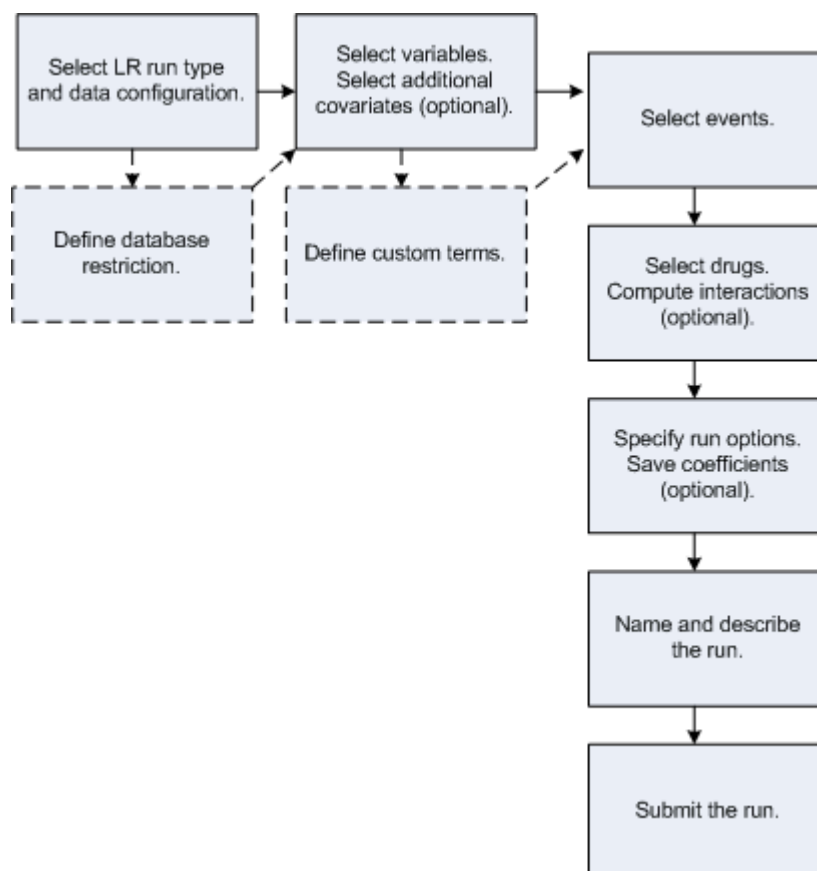
You can also select one or more other variables, such as gender, age group, and report receipt year, as covariates (additional predictor variables) for the computation. Each value of a covariate is used in the logistic regression computation as its own predictor, except for the value with the highest frequency among all reports in the analysis, which is used as the standard to which the other values are compared. For example, if you select Gender as a covariate and Gender has the unique values F, M, and U, with M occurring most frequently, computations are made for the two predictor values GENDER_F and GENDER_U. For the relatively rare situations in which the covariate value that occurs most frequently overall, such as M, does not occur in combination with a certain event, such as Uterine cancer, then the value occurring most frequently with that event is used instead. Logistic regression is then performed with product values and these covariate values as predictors for each response.

For more information about logistic regression computations, see [Logistic regression computations](#).

In addition to [selecting the variables](#) for the run, you also have options to:

- Use either [extended logistic regression](#), which includes the computation of the best alpha value to use for each response, or standard logistic regression, which uses 0.5 as the alpha value for every response.
- Define a [database restriction](#), which limits the cases in the source data that are included in the run.
- Define [custom terms](#), which are pseudo-values.
- Specify [events](#) of interest for the run.
- Explicitly supply [drugs](#) and/or provide the application with guidelines (minimum number of occurrences with the event, total number of drugs to include) for selecting drugs that occur frequently with specified events.
- Include computations for interactions, such as drug+drug+event or drug+covariate+event, for each response.
- Include the computed coefficients and standard errors of the run in the lr_coefficients.log [log file](#).

The execution of a logistic regression run includes the following steps. Dotted lines represent optional steps.



Logistic regression computations

There are two types of logistic regression: standard logistic regression and extended logistic regression.

In standard logistic regression, users select an LR type of Standard on the [Create Data Mining Run](#) page. Extended logistic regression is performed when user select LR type of Extended.

Both models describe the relative weight of the presence of various drugs and other factors in a report in predicting the occurrence of a particular adverse event in the same report, but they provide different methods for **fitting** the model.

- In the standard model, computations always use the same alpha value of 0.5. When the probability of an AE occurring is small, as in the case of a relatively rare AE, the result of the standard computation is an assumption that drug effects are more multiplicative than additive. If this assumption is false, logistic regression is likely to detect associations correctly, but the relative effects of drugs may not be correct. The standard model is equivalent to the logistic regression method found in statistics textbooks.
- The extended logistic regression model allows an extended family of **link** functions that connect the estimated coefficients to the event probabilities. Whereas, the standard model assumes that this link function is the well-known S-shaped logistic curve, the extended model allows other shapes of curves, if another curve in the family fits the data better. The family is parameterized by the scalar alpha, where $0 < \alpha < 1$, and where $\alpha = 0.5$ corresponds to the standard logistic. An interpretation of alpha is that value of the fitted event probability where the curve has a point of inflection, meaning that the curve is linear there and so the effects of multiple predictors are additive in the neighborhood of $P(\text{response event}) = \alpha$. When the extended model option is chosen, the system

estimates the **maximum likelihood** value of alpha and uses that value to form model predictions.

To compare scores calculated by each of these models, you can re-run a logistic regression data mining run that used one of these models and change only its **LR type**, name, and description for the second run.

The alpha value calculated for each response is available for review in the `lr_coefficients.log` file produced by the run.

To review this file:

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Row Action menu** (), for the completed run, select **View Jobs for Run**.
3. On the Jobs for Run page, click the **LR_<number>_0** job, then at the bottom of the Job Detail page click **lr_coefficients.log**.

Logistic Regression

Logistic regression has long been a standard statistical tool for modeling how the probability of an event (the response) depends on multiple predictors. The estimated coefficients can be interpreted as the logarithm of an odds ratio. Especially for medical applications, where so much of statistical analysis consists of analysis of 2 x 2 frequency tables, the odds ratio, the simple ad/bc ratio, where (a, b, c, d) are the familiar counts in the 2 x 2 table examining the association of two values, has become a preferred measure of association. The preference for expressing associations in terms of odds ratios developed because the odds ratio is invariant to the choice of sampling plan of a study.

For example, consider a prospective study in which 1,000 patients are either exposed to a drug or not and then followed for signs of an adverse event such as irregular heartbeat. The data might look like this:

Drug exposure	Irregular	Normal	Total
Drug	a=300	b=700	1000
No Drug	c=100	d=900	1000
Total	400	1600	2000

The risk ratio is $(300/1000)/(100/1000)$, which equals 3.00. The odds ratio is $(300/700)/(100/900)$, which equals 3.86.

The risk ratio and the odds ratio are both large compared to the null hypothesis value of 1 that would be expected if there were no association between drug and irregular heartbeat. In other words, the probability (chance, risk) of irregular heartbeat is 3.00 times greater for patients taking the drug than for those not taking the drug. The odds (in favor) of irregular heartbeat are 3.86 times greater for patients taking the drug. This corresponds to a conversion between probabilities and odds. If a probability is p , the odds are $p/(1-p)$, or if the odds are $X:1$ the probability is $X/(X+1)$. Thus, odds of 3:1 mean that the probability is $3/4 = 0.75$ and vice versa.

Consider now a retrospective study that has determined whether or not all those with irregular heartbeat took the drug, involving the same 400 patients as in the above table, but only 400 other patients with normal heartbeat are sampled instead of 1600. Without bias, the results looks like the following table, in which the Irregular column of the table is unchanged, and the counts in the Normal column have been divided by 4.

Drug exposure	Irregular	Normal	Total
Drug	300	175	475
No Drug	100	225	325
Total	400	400	800

The risk ratio is $(300/475)/(100/325)$, which equals 2.05.

The odds ratio is $(300/175)/(100/225)$, which equals 3.86.

Note that the risk ratio has changed from 3.00 in the first table to 2.05 in the second table, while the odds ratio is unchanged at 3.86 in both tables. The odds ratio as a measure of association is invariant to multiplying either a row or a column of the 2x2 table by a constant. If the risk factor and the adverse event are each rare, then the risk ratio and the odds ratio are almost the same.

Consider the following table, where the Irregular column and the Drug row of the first table above have each been divided by 10 (so that the Irregular-Drug cell is reduced by a factor of $10 \times 10 = 100$).

Drug exposure	Irregular	Normal	Total
Drug	3	70	73
No Drug	10	900	910
Total	13	970	983

The risk ratio is $(3/73)/(10/910)$, which equals 3.74.

The odds ratio is $(3/70)/(10/900)$, which equals 3.86.

Note that the risk ratio is now quite close to the still unchanged odds ratio of 3.86.

In many instances, a relatively small fraction of the population as a whole is exposed to a risk factor for an adverse event, and a relatively small fraction of the population actually suffers the adverse event. In such cases, you can loosely interpret the odds ratio as if it were a multiplier of the probability of the event rather than a multiplier of the odds of the event, since if p is small, $p/(1-p) \sim p$, so probabilities and odds are about the same. In such a case, even though you might have collected data that misestimates the proportion of those suffering the event by some unknown multiplier, and/or your data over- or under-samples those exposed to the risk by some other unknown factor, the odds ratio in your observed table may be a better estimate of the population risk ratio than the risk ratio computed from your 2x2 table, because the odds ratio is robust to bias in the row and column reporting rates. It is possible for a flawed data collection process to cause an excess frequency in just one cell of a table, without a corresponding increase in the other cell of its row or column. In that case, no measure of association from your data table is able to accurately measure the true association in the population.

Estimating odds ratios for multiple risk factors

It is common to collect data retrospectively when patients have been exposed to multiple risk factors. In such cases, you want obtain a measure of association between an adverse event and each of the risk factors, and separate out the associations with each risk factor. This can be a difficult task, especially when there are many risk factors that occur in multiple combinations across patients. No method of analysis is guaranteed to provide a best solution to this problem and, in fact, there may be no best answer, since interactions among the risk

factors can create great ambiguities as to the interpretation of any association measures. However, ignoring such difficulties, the most common approach to this problem is logistic regression, which uses a multifactor analysis to compute a separate odds ratio for each risk factor.

In the ideal application of logistic regression, the odds ratio associated with multiple risk factors is the product of the estimated odds ratios for each of the risk factors being considered. For example, if one risk factor is being over age 65 (odds ratio = 1.5) and another is taking a particular drug (odds ratio = 2.0), then the logistic regression model assumes that the odds of having the adverse event are $(1.5)(2.0) = 3.0$ times as great for those over 65 who take the drug, compared to those under 65 who do not take the drug. The assumption that every risk factor's association with the adverse event can be summarized in a single odds ratio, and that simply multiplying them can describe the associations of multiple risk factors with the adverse event, is usually an oversimplification. Nevertheless, logistic regression has proven to be a very useful tool for summarizing associations among multiple risk factors and an event, and for finding those factors that seem to be consistently associated with the event no matter what other factors are present.

A typical logistic regression analysis produces a prediction equation of the form:

$$\log_e[p/(1-p)] = B_0 + B_1(\text{Factor 1}) + B_2(\text{Factor 2}) + B_3(\text{Factor 3}) + B_4(\text{Factor 4})$$

For example:

$$\log_e[p/(1-p)] = -5.0 + 1.1(\text{Age} > 65) + 0.6(\text{Gender Male}) + 0.3(\text{Drug 1}) + 0.8(\text{Drug 2})$$

where $\log_e[p/(1-p)]$ is the natural log of the odds of observing the adverse event, and the coefficients $B_0, B_1, \dots$ are estimated from the database. The odds ratios for each factor are the exponentials of the coefficients. Therefore, in this example, the over 65 year age group has an odds ratio of $e^{1.1} = 3.00$ for the adverse event, males have an odds ratio of $e^{0.6} = 1.82$, and users of the two drugs have odds ratios of $e^{0.3} = 1.35$ and $e^{0.8} = 2.23$, respectively. The implicit assumption is that the combined odds ratio would be $(3.00)(1.82)(1.35)(2.23) = 16.4$ for males over 65 taking both drugs, compared to females under 65 taking neither drug. However, even when these complex associations are not estimated very exactly, the coefficients and their corresponding odds ratios often are good estimates of the relative overall strength of association of each factor with the adverse event. In this example, the association with age is greater than that of gender or of either drug.

Including potentially highly associated covariates in the computation is important, because otherwise the logistic regression might be subject to confounding due to the left-out covariates. For example, assume that (age > 65) was not in the model and that Drug1 was almost exclusively taken by the elderly in the database. In that situation, the estimated coefficient for Drug1 increases, since Drug1 is, in effect, a partial proxy for being elderly. The result might be an odds ratio for Drug 1 estimated to be 2 or 3 rather than the value 1.35 estimated when the variable (age > 65) is in the model, resulting in an inflated estimate of the association of Drug1 with the adverse event.

Specifying predictors

In general, it is important to include all covariates that might be associated with the adverse event as predictors in the logistic regression equation. For analysis of adverse event databases, Oracle recommends including covariate variables for age groups, gender, and report year, and explicitly including drugs that occur very frequently with the event. Drugs that occur most frequently with the event are, by their very frequency, more likely to be confounded with other drugs of interest in the database, and thereby cause biases if they are left out of the model. The logistic regression user interface makes it easy to enter all drugs in the data that occur more than a set number of times with the response event automatically, up to the defined maximum number of drugs allowed, including the drugs specifically requested.

Covariates must be categorical (stratification) variables having at least $K > 1$ categories, and every category value (K) must have at least one report with the response event present to be included. The covariate category having the most reports across all reports in the analysis is viewed as the standard for the odds ratio of each of the other categories. If there are K categories for a covariate, there will be K-1 coefficients for that covariate, with a corresponding odds ratio for each coefficient. For example, if the categories for the Gender covariate are M, F, and U (for unknown), and if F is the most common gender category, then the output will only have odds ratios for M and for U. The odds ratio for M is the estimated reporting odds ratio comparing M to F, and the odds ratio for U is the estimated reporting odds ratio comparing U to F. Selecting the most common category to be used as the standard is arbitrary, but it allows you to interpret an odds ratio of 1 for a category as meaning that the selected category can be pooled with the most frequent category.

The logistic regression analysis provides a standard error for each coefficient that can be used to produce a confidence interval for each coefficient. The 90% confidence interval (CI) is computed as:

(estimated coefficient) $\pm 1.645 \times$ (standard error of coefficient)

Taking the exponential of the endpoints of the coefficient CI produces a CI for the associated odds ratio. These are then labeled (LR05, LR95) in the logistic regression output tables.

To handle the relatively rare situation in which the most common category of a covariate has no reports with the response event (such as the most common gender category F and the event Prostate cancer), for that response a different category is selected as the most common. The computation does not leave out the gender covariate entirely in these situations as the confounding of gender with drugs taken primarily by one gender would distort the LOR estimates.

Each logistic regression data mining run generates a logistic regression log file ([lr.log](#)), that identifies the most common category found for each covariate. If any events in the run used a different category, the most common category for that event is noted.

Logistic regression models: standard and extended

Logistic regression (without explicit interaction terms) assumes that odds ratios (OR) are multiplicative in the presence of polypharmacy; that is, logistic regression predicts that a drug with $OR=3$ combined with a drug with $OR=4$ produces an $OR=3 \times 4=12$ for the event of interest when both drugs are reported together. This simple relation holds for the OR scale but, for the probability scale, the predicted combined effect of risk factors is more complex. When the probabilities of events are in a middle range of 0.2 to 0.8, the joint effect of two risk factors on probabilities (according to standard logistic regression) is more additive than multiplicative.

For example, if the base rate (probability) for an event is 20%, the rate after applying an OR of 3 is 43%; the rate after applying an OR of 4 is 50%; and the rate after applying an OR of 12 is 75%. Compare these three rates to the original rate both as rate differences and as rate ratios:

Base rate = 0.20	Rate difference	Rate ratio_____
Risk factor with OR=3:	$.43 - .20 = .23$	$.43/.20 = 2.15$
Risk factor with OR=4:	$.50 - .20 = .30$	$.50/.20 = 2.50$
Both factors with OR=12:	$.75 - .20 = .55$	$.75/.20 = 3.75$

Thus, the combination of the two risk factors (if the odds ratios multiply) is more nearly additive than multiplicative on the probability scale, since $.23 + .30 = .53$ is close to $.55$, whereas $2.15 \times 2.50 = 5.38$ is not as close to 3.75.

On the other hand, suppose the base rate were 0.002, which is more in the range of most adverse event probabilities. In this case, applying odds ratios of 3, 4, and 12 results in probabilities of 0.0060, 0.0079, and 0.0234, respectively. Comparing rate differences to rate ratios in the low base rate example:

Base rate = 0.0020	Rate difference	Rate ratio_____
Risk factor with OR=3:	.0060 - .0020 = .0040	.0060/.0020 = 3.00
Risk factor with OR=4:	.0079 - .0020 = .0059	.0079/.0020 = 3.95
Both factors with OR=12:	.0234 - .0020 = .0214	.0234/.0020 = 11.7

In this case, the effect of both factors is more multiplicative than additive on the probability scale, since $.0040 + .0059 = .0099$ is not as close to .0214, whereas $3.00 \times 3.95 = 11.85$ is close to 11.7.

In summary, logistic regression makes the following assumptions: the joint risk of two risk factors is nearly additive on the probability scale if the base rate is relatively large (e.g., about 0.2), but is nearly multiplicative if the base rate is very small (e.g., about 0.002). When modeling spontaneous reports, you are considering relative reporting ratios in a database of reports rather than risk. The question remains, which is more likely to fit spontaneous report ratios better? An additive model or a multiplicative model? Since most individual adverse events occur in a very small proportion of spontaneous reports, applying standard logistic regression fits the data well if the multiplicative model is approximately true.

To allow for the possibility that a nearly additive model for spontaneous report ratios might fit better than a nearly multiplicative model, the Oracle Empirica Signal application provides an alternative model called extended logistic regression. This family of models has a parameter, denoted $\text{Alpha}\alpha$ (alpha), that specifies the region of near-additivity to be centered at an arbitrary base rate. If $\text{Alpha}\alpha = 0.5$, then extended logistic regression reduces to standard logistic regression. If you select the extended option, then the system performs an estimation of the best coefficients for each of many values of $\text{Alpha}\alpha$, and selects the value of $\text{Alpha}\alpha$ that gives the best fit to the observed data.

If the estimated value of $\text{Alpha}\alpha$ is near 0.5, this means that the standard logistic regression fits the data (that is, predicts the presence or absence of the response for individual reports) about as well as the extended logistic model. In practice, if the estimate of $\text{Alpha}\alpha$ is between 0.4 and 0.6, then the odds ratio estimates for individual predictors is close to the corresponding estimates for standard logistic regression. In such a case, for simplicity in explaining your methodology to someone unfamiliar with extended LR, use the standard LR estimates. Another approach to choosing between standard and extended LR is to compare the difference ($\text{Alpha}\alpha - 0.5$) to the standard error of $\text{Alpha}\alpha$. You can compute:

$$(\text{Z-score for Alpha}\alpha) = (\text{Alpha}\alpha - 0.5)/(\text{standard error of Alpha}\alpha)$$

If the Z-score is less than -3 or greater than +3, there is strong statistical evidence that extended LR fits the data better than standard LR.

The estimates of $\text{Alpha}\alpha$ and their standard errors (separate estimates for each response value in the run) can be found in the [Logistic regression coefficients log file](#) (lr_coefficients.log) that is produced for each logistic regression data mining run.

It is difficult to say in advance whether extended LR fits any particular data much better than standard LR. Different response events give different choices. It takes more computation time to find the best fitting $\text{Alpha}\alpha$, so, if you want to get quicker answers for hundreds or thousands of response events, selecting standard LR accomplish that. But, in most situations, the estimation and examination of the values of $\text{Alpha}\alpha$ and its standard errors, using extended LR, are recommended. If the data being used in the LR is voluminous, the standard error of $\text{Alpha}\alpha$ may be very small; perhaps just 0.01 or even smaller. Then, even if $\text{Alpha}\alpha$ is near 0.5,

there may be strong evidence that it is not exactly 0.5. For example, if $\alpha = 0.41$, standard error = 0.005, then the Z-score is 18, but the individual estimated odds ratios do not differ much from those of standard LR.

Two caveats apply to this model selection problem. First, even if one model fits the spontaneous reports better, there is still no guarantee that the resulting estimated odds ratios for each drug are valid estimates of the prospective risk to takers of the drug of an adverse reaction. Second, even in terms of fit to the relative reporting ratios, the better fitting model is not necessarily a perfect guide to which of the many drugs in the regression model are truly significant. If there are 100 drugs in the model, it may be that extended logistic regression fits better than standard logistic regression because it models the polytherapy effects involving 80 of the drugs better, while modeling those involving the other 20 drugs worse. That is, many of the drugs may combine in their effects additively, while others combine multiplicatively (or, in some more complicated combining formula), so that neither model can estimate the effects of every drug reliably. As statisticians often say, "no model is perfect, but many are useful."

The extended model is technically described as a binomial regression with a different link function. Suppose that $z = B_0 + B_1X_1 + B_2X_2 + \dots$ is the linear combination used for prediction, where the B s are coefficients and the X s are predictors. The standard logistic regression defines the probability of event occurrence as $p(z)$, where:

$$p(z) = 1/(1 + \exp(-z))$$

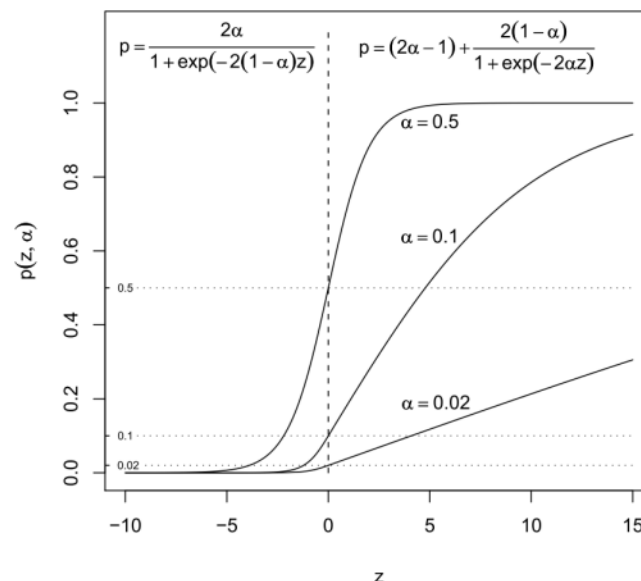
Extended logistic regression uses the formula:

$$p(z, \alpha) = 2\alpha / [1 + \exp(-2(1-\alpha)z)] \quad \text{for } z \leq 0$$

$$p(z, \alpha) = 2\alpha - 1 + 2(1-\alpha)/[1 + \exp(-2\alpha z)] \quad \text{for } z \geq 0$$

Note that $p(z, \alpha)$ reduces to $p(z)$ when $\alpha = 1/2$. Also, $p(z, \alpha)$ and its first two derivatives with respect to z , $p'(z, \alpha)$ and $p''(z, \alpha)$, are each continuous, and, evaluated at $z=0$, for every α , $p(0; \alpha) = \alpha$, $p'(0; \alpha) = \alpha(1-\alpha)$, and $p''(0; \alpha) = 0$.

A two-dimensional plot of the probability distribution function of the extended logistic regression computation follows:



For a predictor X whose standard LR coefficient is B, the odds ratio comparing the probabilities of the event at X = 0 versus X = 1 is $OR = e^B$. In the case of extended logistic regression with estimated link parameter α , the odds ratio is defined as:

$$OR = (1 - p_0) p(z_0 + B, \alpha) / p_0 (1 - p(z_0 + B, \alpha))$$

Where $p_0 = (\# \text{ response events}) / (\# \text{ Reports})$ [proportion of reports with the response event] and z_0 is the solution to the equation $p(z_0 + B, \alpha) = p_0$.

This formula for OR reduces to e^B when $\alpha = 1/2$. The 90% confidence intervals for OR are computed by replacing B in the above formula by $B \pm 1.645 \times \text{standard error}(B)$, analogous to the procedure for standard logistic regression.

Each logistic regression data mining run generates a tab-delimited log file, `lr_coefficients.log`, with the alpha value computed for each response and its standard error. When you [define options](#) for the run, you can check **Save coefficients** to include the coefficient and standard error calculated for each predictor and response in this log.

For more information about logistic regression, see any intermediate-level statistics or biostatistics textbook, such as *Statistical Methods in Epidemiology* by HA Kahn and CT Sempos, Oxford U Press, 1989.

Logistic regression log files

Logistic regression data mining runs produce log files to provide information on run processing. These text files are available for download on the Job Detail page for the LR job in the run.

The `lr.log` file identifies the most frequently occurring value for each covariate variable in the run, such as the value F for the Gender variable. The value that occurs most frequently is determined based on all reports in the analysis. If any of the events in the run were not reported in combination with the most frequently occurring value for a covariate, the application notes the value used in its place for that event.

```

lr.log - Notepad
File Edit Format View Help
Logistic Regression log opened at Mon Jun 08 08:36:53 EDT 2009
Logistic Regression version: 7.1.1.3.2.1

Reading file: GenderIndepVarCaseIndices.xdf
Reading file: Drug namesIndepVarCaseIndices.xdf
Reading file: Adverse event PT termsIndepVarCaseIndices.xdf -- Done: 1 secs.
Processing event 1: 'E_Hepatic Failure'
Following covariate values were excluded from predictors: "Gender_F"
  -- Get cross counts for event at: 0.016 secs.
  -- Select predictors for event at: 0.016 secs.
4 processors are used out of 4
  -- Start LR/interaction computation at: 0.016 secs.
Coefficients file: d:\webvdme\procs\Proc_3905\lr_coefficients.log
Compute LR start time:0 secs.
Constant initialized time:0 secs.
*****
Starting estimation for the event 'E_Hepatic Failure', Num Indep Vars = 91
*****
Extracting and preparing data ...0 secs.
Extracting and preparing data finished time:0.062 secs.
CreateBoolVarFromCaseIndicesVar time:0.062 secs.
EstimateAlphaAndBetas start time:0.062 secs.
Time for overall estimation: 4.312 secs.
EstimateAlphaAndBetas finished time:4.374 secs.
GetRegResultsForOptimalAlpha finished time:4.39 secs.
  
```

The `lr.log` file also provides information on convergence for each response and, if necessary, the reason that an event specified for the run was not included in the computation.

The `lr_coefficients.log` file contains the best alpha value computed for each response in an extended logistic regression data mining run. For standard logistic regression runs, the value 0.5 is always used as the alpha.

When you [define the run options](#) for a logistic regression data mining run, if you check **Save coefficients**, the application includes coefficient and standard error values computed for each predictor and response in the run in this file.

The following example shows the first few rows in an `lr_coefficients.log` file that has been downloaded and opened in Microsoft Excel:

A	B	C	D	E
RO_NUM	Predictor	Response	Coeff	Std Error
N/A	<Alpha>	Hepatic Failure	0.00949967	0.0420202
1	<Intercept>	Hepatic Failure	-1.0337	0.5200001
2	M	Hepatic Failure	0.2783	0.0651565
3	U	Hepatic Failure	0.0270971	0.122427
4	Abacavir	Hepatic Failure	-1.08111	0.540372
5	Acetaminophen	Hepatic Failure	1.35481	0.182878
6	Acyclovir	Hepatic Failure	0.35271	0.472137

Note

The value of B_0 is labeled <Intercept> in the Predictor column, and the value of Alpha value or symbol is labeled <Alpha> in that column. The computed value of Alpha appears in the Coeff column.

For more information on logistic regression, see [Logistic regression computations](#) and the [Job Detail page](#).

Guidelines for specifying drugs for logistic regression

For a logistic regression run, you define the number of predictor values (that is, how many drugs) to include in computations for each of the events you select for the run.

You also define the minimum number of reports in which a selected event must occur in combination with a drug for that drug to be included. Optionally, you can supply a list of drug values to include in the run.

Using these values, the Oracle Empirica Signal application determines what drugs to include for each event in the run, including any explicitly specified drug values and selecting additional drugs that occur in combination with each run event frequently, based on the defined total number of drugs and the minimum number of occurrences.

- If you explicitly specify fewer drug values than the defined total number, the application finds additional drugs in the configuration to make up the difference. The application uses the defined minimum to limit the possible set of drugs to include in the run to those found most frequently in combination with each of the selected run events. For each event, only drugs found in combination at least that number of times are included.
- Each of the drug values that you explicitly supply are included in the run, even if they do not meet the specified minimum for a given run event. (However, the drug+event combination must occur at least once to be included.) If you supply more drug values than the defined total number to include in the run, the Oracle Empirica Signal application orders the drug values alphabetically and includes only the first <total number> from the list.

For example, assume that you specified a single event, Rash, for the logistic regression run. You keep the default, 10, as the minimum number of cases in which the drugs must occur, and you explicitly include DrugD. The following table lists sample drugs in the data configuration, the number of occurrences of Rash, and whether the run computes scores for the drug:

Drug	Number of Cases in which Drug Occurs in Combination with Rash	Whether the run computes scores for the drug
DrugA	11	Yes
DrugB	10	Yes
DrugC	5	No
DrugD	1	Yes
DrugE	0	No

Oracle recommends that you include drugs that occur most frequently with an event, as computational biases can result if they are left out. For more information, see [Logistic regression computations](#).

Drug and event hierarchies

A hierarchy determines how adverse event terms and drug terms are organized in the source data. For example, the FOI FDA Adverse Event Reporting System (AERS) database uses the Medical Dictionary for Regulatory Activities (MedDRA) classification system.

Other databases might use the Coding Symbols for a Thesaurus of Adverse Events (COSTART) or the WHO Anatomical Therapeutic Chemical (ATC) classification systems.

Hierarchy terms are stored in an Oracle database account called the hierarchy account. You associate each variable in a data configuration with a hierarchy level in the hierarchy account. For example, if the source data contains MedDRA terms, you associate each variable in the data configuration with a MedDRA hierarchy level such as PT, HLT, HLG, or SOC in the hierarchy account.

If a data configuration supports timestamped data, you must specify a [hierarchy version](#) for each time period in the source data. A time period is a range of dates during which only one hierarchy version was used.

When you set up hierarchy information, users can:

- Select the **Enable Drug Hierarchy Browser** [user preference](#).
- Select the **Include drug/event hierarchies' primary paths in run results** option in the [Data Mining Parameters](#) page.
- Display a [sector map](#) for data mining results.

Note

You can also set up hierarchy information using [hierarchy tables](#). Hierarchy tables are supported for backward compatibility.

Timestamped data

Timestamping is a technique for representing multiple versions of the same source data within one database.

The [source data](#) must include dates (VALID_START and VALID_END columns) that can be used to determine the period for which each record is valid. This enables the Oracle Empirica Signal application to reconstruct data for different periods of time. As a result, you can base data mining runs, queries, and case series on source data as of a date that you specify. This date is referred to as the As Of date.

In the data mining run, query, or case series, data is used if the following is true:

VALID_START (if present) <= Specified As Of Date < VALID_END (if present)

For example, suppose that the source data includes the following DRUGS table, where an edit occurred for case ID 100:

CASE_ID	DRUG	ROUTE	VALID_START	VALID_END
100	DrugA	IV	01-01-2005	06-01-2005
100	DrugA	ORAL	06-01-2005	No end date

- If a run is performed as of 2/1/2005, the Route for DrugA is IV.
- If a run is performed as of 7/1/2005, the Route for DrugA is ORAL.
- If a run is performed as of 6/1/2005, the Route for DrugA is ORAL.

Specifying an As Of date

On pages where you specify an As Of date, a default date appears. You can change the date to another date that is within the range determined by the [source description table](#) for the data configuration.

Specify an As Of date

During some activities, if you select a data configuration that supports timestamped data, the Select 'As Of' Date page appears and you must specify an As Of date and time.

See [Timestamped data](#) for more information.

1. To specify an As of Date and time, choose one of the following:
 - To use the displayed date, click **Latest Date**.
 - To enter a date in mm/dd/yyyy format, click **Other**.
 - To display a calendar and select a date, click 
2. Enter a time in hh:mm:ss am/pm format.
3. Click **Next**.

Stratification variables

Item values can be associated in an MGPS data mining run because they are associated jointly with other variables, such as gender or age.

To minimize the occurrences of this type of spurious association, use stratification variables in the results of an [MGPS data mining run](#).

For example, Drug X is generally prescribed for women above age 50 and Event Y also occurs more frequently for women above age 50. A data mining run indicates a strong association between Drug X and Event Y, based on the coincidence of the gender and age groups involved. To minimize the occurrence of this type of association, stratify the data mining run by Gender and Age Group. To do this, Gender and Age Group must be available as stratification variables in the configuration.

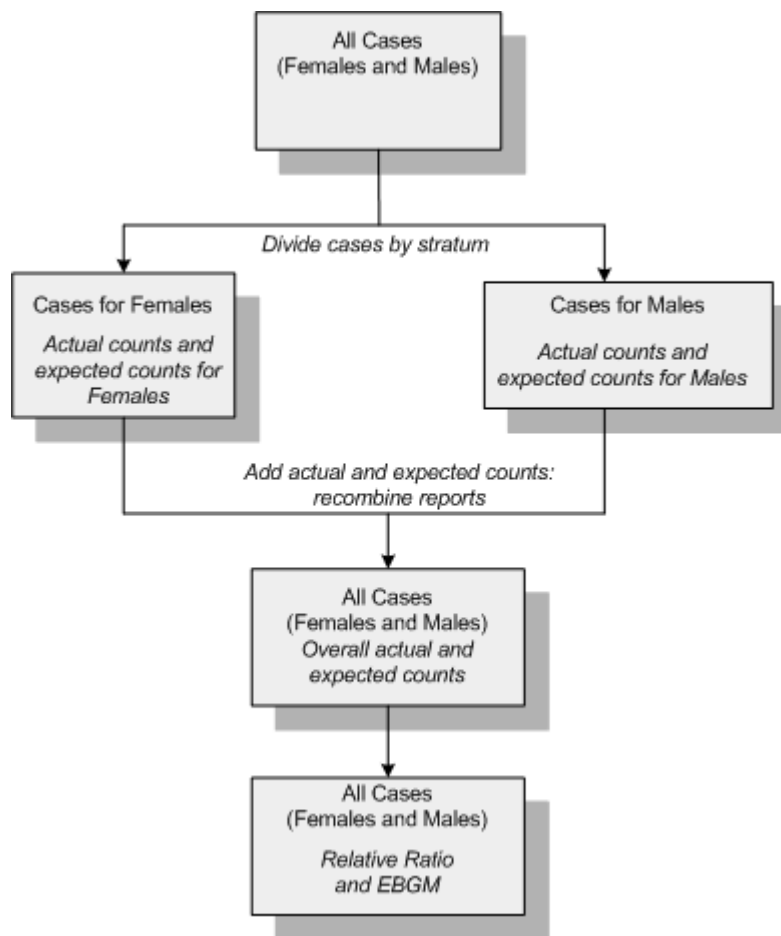
Stratification divides all cases into groups, based on one or more variables, for the computation of expected values (E). The Oracle Empirica Signal application sums these expected values across all of the strata to provide a single expected value for all of the cases in the background. This has the effect of adjusting the expected value (and the other statistics computed with E, including the Relative Reporting Ratio (RR) used in the MGPS computation) for the effects of such covariates as age, gender, and receipt year. In this way, you can perform data mining across the entire background set, yet still be protected from false results that can come from coincidental association with age, gender, and so on. With stratification, there is one set of results (as opposed to the multiple result sets generated by a [subset variable](#)).

Like item variables, stratification variables map to columns in the safety database. You cannot select the same variable as both an item variable and a stratification variable at the same time.

If you select stratification variables for your MGPS data mining run, and also choose to compute [PRR](#) (Proportional Reporting Ratios) and [ROR](#) (Reporting Odds Ratios), you can specify stratification to apply to those computations as well.

Example

The following example shows how reports are divided and then recombined during data mining when you use the stratification variable Gender:



1. From **All Cases (Females and Males)** cases are divided by stratum into:
 - Cases for Females. Actual counts and expected counts for Females.
 - Cases for Males. Actual counts and expected counts for Males.
2. Add actual and expected counts to recombine reports:
 - All Cases (Females and Males). Overall actual and expected counts.
 - All Cases (Females and Males). Relative Ratio and EBGM.

Dimensions and patterns

On the Select Criteria page, you can specify the dimension and pattern for an MGPS run as criteria for viewing data mining results.

To display these controls, click **Show Advanced**.

Dimensions

The dimensions in a run are the number of ways in which items combine to generate scores. When [specifying data mining parameters](#) for MGPS runs, the run creator specifies the highest dimension to compute. The run results include combinations of all dimension combinations, from 1 to the specified highest dimension. For example, a two-dimensional (2D) data mining run performed for drug and event item variables produces scores for the following combinations:

Drug (1D)

Event (1D)

Drug+Drug (2D)

Drug+Event (2D)

Event+Event (2D)

where

Drug and Event represent the names of the item variables used for the data mining run.

Note

One-dimensional results are useful to determine the total count (N) for a drug or event. Other statistics are not generated for 1D results, and you cannot display graphs for 1D results.

A 3D run for the same drug and event item variables produces results for these combinations:

Drug (1D)

Event (1D)

Drug+Drug (2D)

Drug+Event (2D)

Event+Event (2D)

Drug+Drug+Drug (3D)

Drug+Drug+Event (3D)

Drug+Event+Event (3D)

Event+Event+Event (3D)

Note

If you include PRR, RGPS, or ROR computations in an MGPS run, Oracle Empirica Signal produces PRR, RGPS, and ROR scores only for Drug+Event (2D) combinations.

When specifying criteria to view data mining results on the [Select Criteria page](#), you can indicate the number of dimensions to view. You can include 1 dimension up to the highest dimension included in the run. To include all dimensions, select **All**. The default is the highest dimension included in the run. If you change the default number of run dimensions, consider changing the default pattern for the run.

Note

Combinations of two or more dimensions that include only multiple drugs or only multiple events (such as Drug+Drug or Event+Event) are only included in the results table if the run creator specified (on the [Data Mining Parameters page](#)) that results for items of the same type should be kept.

Patterns

You select a pattern to define the item types (such as drugs and events) to appear in the results table or graph. The default pattern depends on the number of dimensions in the run. The following table shows the default pattern for each dimension. Drug and Event represent the names of the item variables used for the data mining run.

Dimensions	Default Pattern
1D	Drug
2D	Drug+Event
3D	Drug+Any Drug+Event

The results table or graph includes results only for the selected pattern. You can change the types of items supplied by the default pattern as needed. The following table describes the options for the pattern fields:

Option	Description
<variable-name>	Lists each item variable used in the data mining run; for example, Generic_Name and PT. (Item variables can also represent other types of data, such as Gender or Age_Group.) For any pattern that includes <variable-name>, you can specify terms for the variable. If you specify terms, the results table displays only those terms and the scores calculated for them; otherwise, the results table displays all values for the <variable-name>.
Any <variable-name>	Lists each of the item variables used in the data mining run with the prefix Any; for example, Any Trade_Name and Any PT. These pattern options allow you to display results for specified terms as though you had supplied an OR between those terms. For example, if you choose the pattern PT+PT and specify the terms Headache and Rash, the results table displays only rows that contain both Headache and Rash. However, if you choose the pattern PT+Any PT, then specify Headache and Rash, the results table displays rows that contain either Headache or Rash.
Any Item	The Any Item option is a wildcard that represents any of the other item variables in the run. You can use Any Item in a pattern for a 3D run that uses the Generic_Name and PT item variables. When you choose the pattern Any Generic_Name+Any Item+PT and specify the term DrugA, the results table displays DrugA+Event+Event combinations and also DrugA+Drug+Event combinations.

View interactions

Each row in the table presents two predictor values, which appear in the columns labeled Item1 and Item2, and a response, which appears in the column labeled for the selected event variable, such as PT.

Note

You can also include columns in the table that indicate the type of variable selected: the P_Item1 and P_Item2 columns contain either D, to indicate the drug variable, or the name of a covariate variable.

The scores appearing for each predictor1+predictor2+response combination include LROR1 (LROR for predictor1+response) and LROR2 (LROR for predictor2+response), which are repeated from the main results table. They reappear in the interactions table as a reminder of the individual predictor disproportionalities with the response.

The table displays the following information:

- **N_TOT**—The total number of times the pair of predictor items appeared together, irrespective of the responses.
- **INT_LOF (lack of fit interaction ratio)**—A Bayesian “shrunk” version of N/E. For example, if INT_LOF = 2, then the response seems to be appearing with this pair of predictor items 2 times as frequently as the standard or extended logistic regression model formula indicates. That is, the model doesn’t “fit” well when these items are both present.
- **INT_REGR**—Compares the standard or extended logistic regression expected adverse event frequency when both items are present to the expected frequency when only the item (of the two) having the larger LROR is present. That is, if INT_REGR = 2, then the regression model predicts that the response is 2 times as likely when both items are present than when just the more associated item is present.
- **INT_TOT = INT_REGR x INT_LOF**—Shows the combined relative effect of having both items present versus having the more associated item present.

Case scoring algorithm

A case score indicates how well populated a report is for a given product-event combination.

For Argus signal management configurations, Oracle Empirica Signal includes a case scoring algorithm. Case scores are computed only if the SM_CASE_SCORE table exists in the database user account referenced by the Argus signal management configuration. For more information, see the *Oracle Argus Mart Data Release Notes*.

Increased frequency algorithm

Reporting proportion (RP) is used as a proxy for exposure adjusted reporting rates and is defined as the number of cases for a product-event combination divided by the total number of cases for the product within the time period.

For [interactive signal configurations](#), Oracle Empirica Signal includes an algorithm to monitor events for increased frequency.

Increased frequency counts are based on the **Data configuration for 2D runs** specified in the [signal configuration](#). Increased frequency is computed for all product-event combinations, and Oracle Empirica Signal sets a **YES** flag for the product-event combinations that have at least three new reports in the most recent 12 months and meet at least one of the following conditions:

- At least a five-fold increase in the RP for the most recent 12 months, compared to the cumulative RP excluding the most recent 12 months.

- At least a two-fold increase in the RP for the most recent 12 months and for the time period of 13 to 24 months ago, both compared to the cumulative RP excluding the most recent 24 months.

The Product-Event Combinations and the Products tables maintain information for increased frequency for three time periods, based on the initial reporting or received date of each case, and follow-up reports are not considered. For example, Argus Signal Management uses the following time periods:

- 1-12 months
- 13-24 months
- 25 or more months

Manage custom terms

- [What are custom terms?](#)
A custom term is a pseudo-value specified in a data mining run for inclusion in cases that meet specified criteria.
- [Define custom terms](#)
When you define a custom term, you create a new query or use an existing query to determine which cases meet the criteria for the term.

What are custom terms?

A custom term is a pseudo-value specified in a data mining run for inclusion in cases that meet specified criteria.

When you perform data mining, Oracle Empirica Signal acts as if the custom term is present for those cases and generates statistics for the custom term. Custom terms are defined and used within the context of data mining runs and do not affect the source data.

You can define multiple custom terms in a data mining run. Oracle Empirica Signal adds the suffix, (Custom Term), to the term that you specify.

A typical use of custom terms is to group together similar terms for products or events as a way to prevent the signal dilution that may occur when similar, but not the same, terms are used in reporting. For example, you can create the custom term, Hepatic Terms, to group the following PTs: Coma hepatic, Hepatic encephalopathy, Hepatic failure, Hepatorenal failure, and Hepatorenal syndrome. The data mining run then computes statistics for Hepatic Terms as if it is a PT in the source data, although the custom term is not added to the source data. The data mining run also computes statistics for the constituent PTs.

When estimating the shrinkage parameters for EBGM scores, MGPS does not consider custom terms. The raw RR scores for combinations involving custom terms are shrunk by the Bayesian formula, but they do not participate in the determination of the formula itself. For more information, see [MGPS computations](#).

Note

For another way of mapping values to a term for use in a data mining run, see [Map text values](#). For information on the differences between these features, see [Custom terms and mapped text values](#).

Custom terms are defined using queries. Reports that match the query condition are considered to have the pseudo value. When defining a new query, you have the option to save it to the Query Library. You can then use it to define custom terms for other data mining runs.

When you re-run a run, the same custom terms are used in the run. However, you cannot switch run types. Thus, if you plan to use a custom term for different run types, make sure that you save the query you define for the custom term for the first run you set up; then you can select that query as the custom term for the other run type(s).

Define custom terms

When you define a custom term, you create a new query or use an existing query to determine which cases meet the criteria for the term.

When defining a new [query](#), you have the option to save it to the Query Library. You can then use it to define custom terms for other data mining runs.

When you re-run a run, Oracle Empirica Signal uses the same custom terms in the run. However, you cannot switch run types. Thus, if you plan to use a custom term for different run types, make sure that you save the query you define for the custom term for the first run you set up. Then you can select that query as the custom term for the other run type(s).

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Data Mining Runs**.
2. Click **Create Run**.
3. Select the [type of run to create](#):
 - MGPS data mining run
 - Logistic regression data mining run
4. Select a [data configuration](#).
5. Click **Next**.
6. Select your variables and check **Define custom terms**. For information about variable selection, see [Select the variables](#).
7. Click **Next**.
8. Click **Create Custom Term**.
9. In the **Name** field, enter the name of the custom term.

If a custom term name includes an invalid character, the application changes it automatically, and a message appears to inform you of the change. Invalid characters are replaced with a pound sign (#). Invalid characters for this field are:

- Control characters
- Non-ASCII characters
- Invalid filename characters: \, /, <, :, >, |, ?, *, ", &, and null.

Note

If you already added a custom term containing an invalid character, first remove it from the [Manage Custom Terms](#) section. Second, on the Products page, delete the custom term containing the invalid character and re-add the term without the character.

10. In the **Item Variable** field, select the variable to which the custom term will be assigned. Available variables are those that you selected as item variables for the MGPS data mining run, or as the Event or Drug variable in a logistic regression data mining run. A variable is not available if it is mapped via a [data transformation](#) or is associated in the data configuration with a hierarchy table (rather than a hierarchy account).
11. Choose one of the following:
 - To create a custom term by defining a new query, click **Create Using Query Wizard**. The [Define Query page](#) appears. You can save the new query to the Query Library so that you can re-use it for other runs.
 - To create a custom term based on an existing query, click **Create from Existing Query**. The [Select Query from Library page](#) appears. Subsequent changes to the query in the library will not affect the custom term.

The screen refreshes and displays the query you created or selected in the Query field. If you click **Edit Query**, the Define Query page appears and you can change query variables, values, and logic.

Note

If you saved the query to the library and then you edit it from this page, your changes are not saved to the library.

12. If the data configuration selected for an MGPS run specifies a [drug or event hierarchy](#), you can select an existing term that has the primary path that you want to associate with the custom term. Next to **Hierarchy Path**, click **Select <hierarchy> Term** to view the [hierarchy](#). If you select a term, the results table includes its hierarchy values for the custom term. If you do not select a term, the results table does not include hierarchy values for the custom term.

The term that you select to indicate the primary path is always a PT (Preferred Term), even if the variable for which you are creating a custom term is a HLT, HLGT, or SOC. The option to specify a hierarchy path applies only to MGPS runs, and has no effect on logistic regression runs.

To remove a previously specified hierarchy path click **Clear Hierarchy Values**. (Before changing a hierarchy path, you should clear the hierarchy path.)

Note

Custom terms do not appear, and are not available for selection, from the hierarchy.

13. When you are satisfied with the custom term, click **OK**.

The new custom term appears on the Define Custom Terms page.

Define subsets for an MGPS run

- [Select a subset variable](#)
To use subsetting in an MGPS data mining, you must select a subset variable.
- [Define subset values](#)
When you have selected a subset variable for an MGPS run, you must specify subsets, with each subset representing one or more values of the subset variable.

- [Define subset labels](#)
If you choose to define subset labels, there must be a label for each subset.
- [Subset variables](#)
When you use a subset variable for an MGPS data mining run, Oracle Empirica Signal divides source data into separate backgrounds, one for each value of the subset variable, and performs a separate run for each of those different backgrounds.

Select a subset variable

To use subsetting in an MGPS data mining, you must select a subset variable.

For more information, see [subsetting](#).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. At the top left of the **Data Mining Runs** home page, click **Create Run**.
3. On the **Create Data Mining Run** page, select the **type of run to create** and click **Next**.
4. On the Select **"As Of" Date** page, choose the latest date and time or select **Other** to choose a date and time. Then click **Next**.
5. On the **Select Variables** page, select at least one **Item** variable by clicking its name, and, optionally, select **Stratification** variables.
6. Select **Define subsets**.
7. Click **Next**.
The Select Subset Variable page appears. If you also checked **Define custom terms** on the Select Variables page, the Select Subset Variable page appears after you add custom terms.
8. From the **Subset variable** list, select the variable to use for subsetting.
You can select only one subset variable, and you cannot select the same variable to be both an item variable and a subset variable in the same data mining run.
9. Click **Next**.
10. Continue with [Define subset values](#).

Define subset values

When you have selected a subset variable for an MGPS run, you must specify subsets, with each subset representing one or more values of the subset variable.

For example, if you use Received Year as the [subset variable](#), you can create one subset for each year except 1998, 1999, and 2000, which you group together into one subset. Oracle Empirica Signal generates a set of data mining results for each subset that you specify.

The source of subset values is either the source database or values that have been defined by [data transformations](#) in the data configuration. For example, if the source database contains report received dates, the creator of a configuration can transform the received dates into years, half-years, or quarter-years.

If a value for the subset variable is missing from the source data, the value of your [user preference](#), **Replace Missing Values with**, appears in place of a value.

Note

When specifying subsets, keep in mind that there is an iteration of MGPS for each subset. The more subsets you specify, the longer the MGPS run takes.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. At the top left of the **Data Mining Runs** home page, click **Create Run**.
3. On the **Create Data Mining Run** page, select the **type of run to create** and click **Next**.
4. On the **Select "As Of" Date** page, choose the latest date and time or select **Other** to choose a date and time. Then click **Next**.
5. On the **Select Variables** page, select at least one item variable by clicking its name, and, optionally, select **Stratification** variables.
6. From the **Available values** list, select the variables for subsetting and use the arrow keys to move values from the **Available values** list to the **Subset values** list:

Button	Use To
	Create a single subset containing all values that are selected in the Available values list, for example, one subset for 1998,1999,2000.
	Create a subset for each of the values that is selected in the Available Values list, for example, a separate subset for each of 2007 and 2008.

7. To include data from all previous subset categories in the results for each subset, select **Subsets will be cumulative**. Typically, a cumulative subset variable represents an ordinal value, such as report year. A non-cumulative subset variable may represent a categorical value, such as age group.
8. If you checked **Subsets will be cumulative**, click one of the following under **Subsets will be ordered**:
 - **As listed** —Generates data mining results for subsets in the order of the subsets.
 - **As reverse of listed** —Generates data mining results for subsets in the reverse of the specified sort order.

The sort order is important for cumulative subsetting. The computations to determine results for each subset include data from all previous subsets. (The sort order also affects the order of columns in map graphs.) For example, the listed order of subsets is:

- 2004
- 2005
- 2006

If you use cumulative subsets (as listed), there are subsets for:

- 2004
- 2004 and 2005 combined
- 2004, 2005, and 2006 combined

If you reverse the listed order, there are subsets for:

- 2006
- 2005 and 2006 combined
- 2004, 2005, and 2006 combined

See [Define subset labels](#) for more examples.

9. Click **Next** and continue with [Define subset labels](#).

Define subset labels

If you choose to define subset labels, there must be a label for each subset.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. At the top left of the **Data Mining Runs** home page, click **Create Run**.
3. On the **Create Data Mining Run** page, select the **type of run to create** and click **Next**.
4. On the **Select "As Of" Date** page, choose the latest date and time or select **Other** to choose a date and time. Then click **Next**.
5. On the **Select Variables** page, select at least one **Item** variable by clicking its name, and, optionally, select **Stratification** variables.
6. Select the variables for subsetting, specify their values, and click **Next**.
7. (Optional) In the **Label** field on the **Define Subset Labels** page, replace the default label with a different label. There must be a label for each subset.

Note

If a label includes an invalid character or space, the application changes it automatically and a message appears to inform you of the change. The application replaces invalid characters with a pound sign (#) and spaces with an underscore (_).

Invalid characters for this field are:

*, \, ", :, /, ?, >, <, &, |, \t, \r, \n, ^, \$, @, and '.

plus any non-ASCII characters.

8. Click **Next** to continue by [defining the data mining parameters](#).

Default labels

When you define subsets, Oracle Empirica Signal assigns default labels. You can change the default labels as needed. For a list of subset values, the default name is:

<first value>.<last value>

Default labels depend on whether the subsets are cumulative and the order of the subsets, the listed order or the reverse orders. The table shows default labels for different types of subsets:

Subsets As Listed on Define Subset Values page	Default Labels for Non-Cumulative Subsets	Default Labels for Cumulative Subsets	Default Labels for Cumulative Subsets in Reverse Order of Listed
1998	1998	1998	2000.2006
1999	1999	1998-1999	1999-2000.2006
2000, 2001, 2002, 2003, 2004, 2005, 2006	2000.2006	1998-2000.2006	1998-2000.2006

Subset variables

When you use a subset variable for an MGPS data mining run, Oracle Empirica Signal divides source data into separate backgrounds, one for each value of the subset variable, and performs a separate run for each of those different backgrounds.

You use subsets to study how the strength of a combination of variables evolved temporally. You can also use subsets to study the strength of variable combinations for age differences, gender differences, and so on. For example, to review separate signal scores for males and for females, you subset the data mining run by gender. Two separate sets of statistics result, one set computed against the background of cases involving males and the other against the background of cases with females.

You can select only one [subset variable](#) for a [MGPS data mining run](#). That variable must have only one value for each case in the database. For example, indication, route, or dose cannot be used directly as subset variables because any case with more than one drug has multiple values for these variables, one for each reported drug. After selecting a subset variable, choose which values of that variable to use for subsetting. The application generates a set of results for each subset.

Note

You cannot select the same variable as both an [item variable](#) and a subset variable.

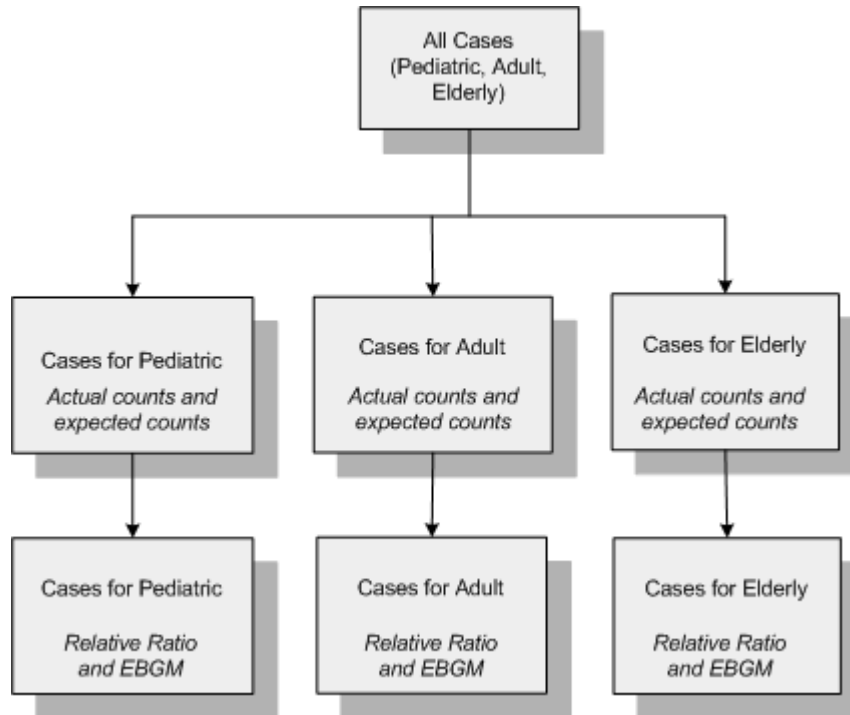
Example

The database contains information on the age of patients reporting adverse reactions. The age has been categorized as Pediatric, Adult, and Elderly, and stored in a variable named AgeGroup. To compare associations of variables for different age categories, you can select AgeGroup as the subset variable (assuming that AgeGroup has been made available as a subset variable by the configuration).

With subsetting, the application computes expected counts, Relative Ratio, and EBGM for each subset separately:

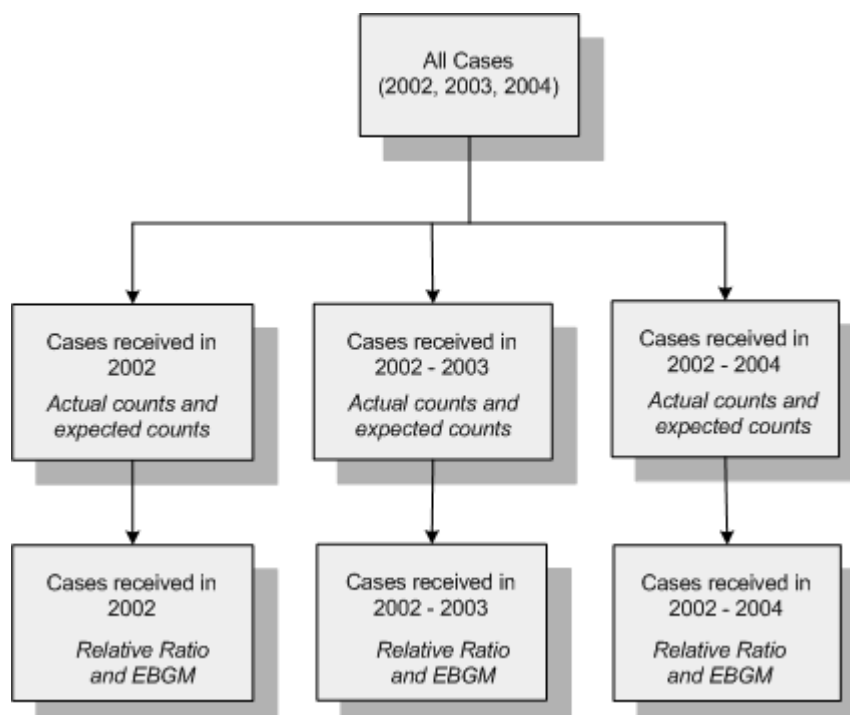
1. All Cases (Pediatric, Adult, Elderly)
2. Cases for Pediatric Actual counts and expected counts
 - Cases for Pediatric Relative Ratio and EBGM
3. Cases for Adult Actual counts and expected counts
 - Cases for Adult Relative Ratio and EBGM
4. Cases for Elderly Actual counts and expected counts

- Cases for Elderly Relative Ratio and EBGM



For a data mining run that uses cumulative subsets, there is one set of results for each subset and the computations to determine results for each subset include data from all previous subsets. A previous subset may or may not be previous chronologically. For more information, see [Define subset values](#). Typically, a variable used for cumulative subsetting represents a time period.

For example, suppose that you use Report Year as the subset variable and the possible report years are 2002 through 2004:



1. All Cases (2002, 2003, 2004)
2. Cases received in 2002 Actual counts and expected counts
 - Cases received in 2002 Relative Ratio and EBGM
3. Cases received in 2002-2003 Actual counts and expected counts
 - Cases received in 2002-2003 Relative Ratio and EBGM
4. Cases received in 2002-2004 Actual counts and expected counts
 - Cases received in 2002-2004 Relative Ratio and EBGM

View source data

- [What is source data?](#)
Typically, product safety data in the original, base tables is cleaned and prepared for useful data mining. The prepared data is stored in an Oracle database and is the source data used by Oracle Empirica Signal.
- [View a data source table](#)
From within Oracle Empirica Signal, you can view the data source tables referenced by the data configuration associated with the currently selected run.
- [Source database tables](#)
Source database tables are the Oracle tables or views that store prepared safety data, which has been cleaned and transformed for data mining.
- [Set viewing options for a data source table](#)
Viewing options allow you to sort rows as needed and choose which columns to include in a data source table.
- [Filter a data source table](#)
When you filter a data source table, you use a SQL WHERE clause to indicate specific characteristics for the data you want to view.

What is source data?

Typically, product safety data in the original, base tables is cleaned and prepared for useful data mining. The prepared data is stored in an Oracle database and is the source data used by Oracle Empirica Signal.

The product safety data to be used in the Oracle Empirica Signal application might include:

- Proprietary data maintained in Oracle Argus Mart.
- Public safety data, such as data from the Adverse Event Reporting System (AERS) or Vaccine Adverse Event Reporting System (VAERS), covered by the Freedom of Information (FOI) Act.
- Subscription data, such as data from Vigibase, the World Health Organization's Adverse Drug Reaction (ADR) database.
- Your company's own safety data.

Each source database resides in a separate Oracle account. In addition to the Oracle tables and views that contain safety data, the source database might include other tables that support the use of source data in the application:

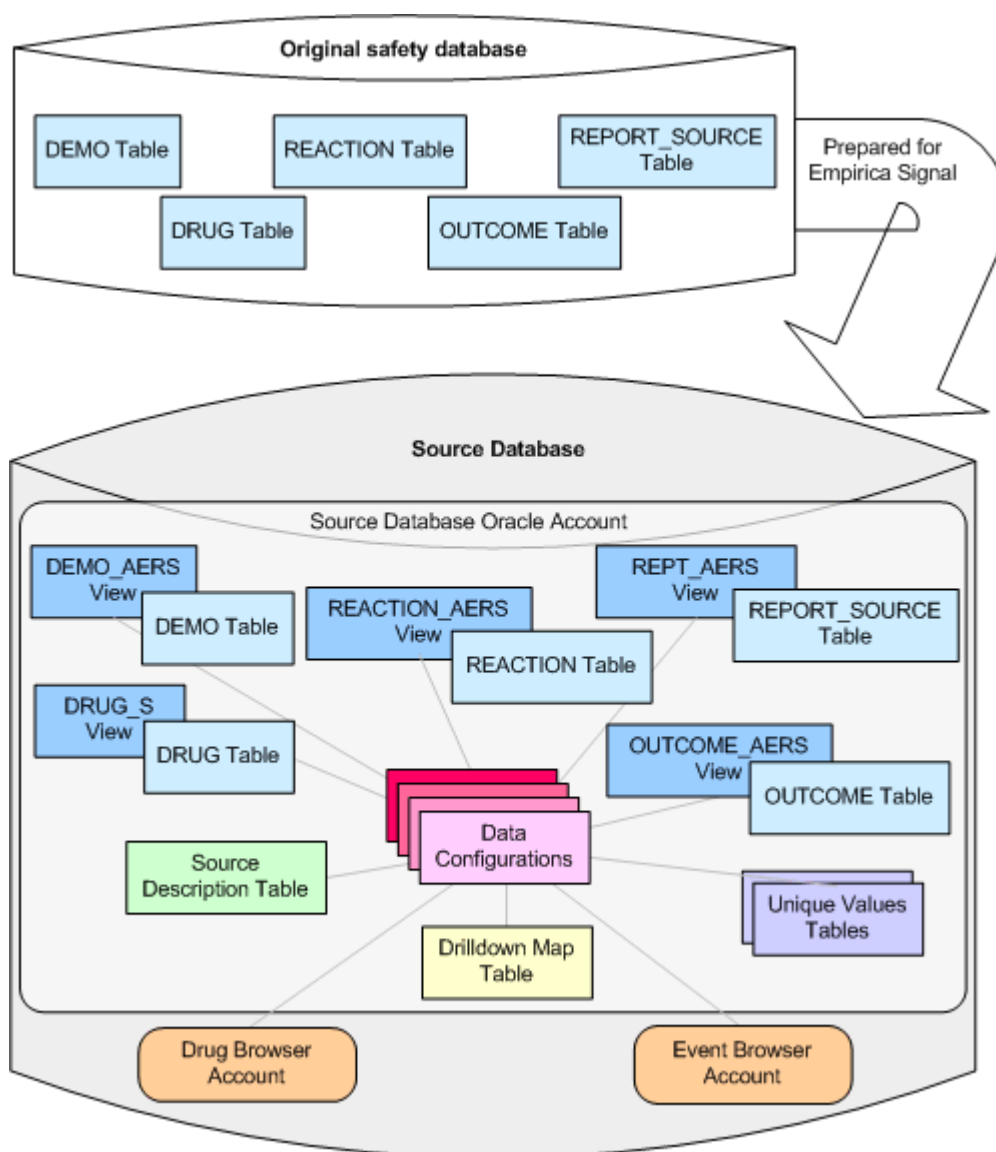
- A [data configuration](#) is a group of variables that correspond to items (database columns) in the source database. There must be at least one data configuration for data mining to be performed. Typically, multiple data configurations are available. For example, there might

be a data configuration for SRS+AERS data and a separate data configuration for AERS data (since 1997).

- A [drilldown map table](#) specifies which data appears when users drill down to case information.
- A [source description table](#) provides a description of the source database, such as its name and when it was loaded.
- [Unique values tables](#) enhance performance by listing unique values for variables.

If dictionaries of hierarchical data from a classification system such as the Medical Dictionary for Regulatory Activities (MedDRA) are used, each version of dictionary data is stored in a separate Oracle account. If hierarchy accounts are defined, users can browse for and select event terms or drug terms [in the hierarchy](#).

The following illustration shows the relationship between the original safety database and the Oracle Empirica Signal source database:



View a data source table

From within Oracle Empirica Signal, you can view the data source tables referenced by the data configuration associated with the currently selected run.

For more information, see [What is source data?](#)

Note

Only a superuser can view data source tables.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. Select the **Row Action** menu icon () for a run, and then click **View Jobs for Run**.
5. In the upper-right corner, click **Sources**.
6. Click the name of the data source table that you want to view.
7. (Optional) Perform actions on the table:
 - To [set viewing options](#), click **Options**.
 - To [filter the data](#) that you want to view to certain specified characteristics, click **Filter**.
 - To [download](#) the data in the table, click **Download** (available if you have the Download Raw Data permission).

Data Source Tables

The following data source tables might be available to view:

Table	Description
Complete Results Table	Complete, raw results table, intended for troubleshooting purposes. For most purposes, the results table available from Data Mining Results is more appropriate. This complete results table might contain more columns than you need to see.
Drug Index Table and Event Index Table	Oracle column indexes for drugs and events.
Master Configuration Table	Oracle Empirica Signal master data configuration table (named DM_CONFIGS), which stores attributes of all data configurations in all the source databases.
Configuration Table	Table containing information about variables in the specific data configuration that was used for the run.
Drilldown Map Table	The drilldown map table , which defines which information (such as case outcomes or narratives) appears when the results reviewer drills down to case details.

Table	Description
Data Source Description Table	Source description table , which defines information (such as the date the data was loaded) about the source database and appears when the results reviewer drills down to view case details and in the Notes section of tables. This table is available only if it was defined for the data configuration.
Source Database Tables Referenced by Configuration	Source database tables referenced by the data configuration; for example, the demographics, drugs, and events tables.
Hierarchy Tables Referenced by Configuration	Available if an older method was used for setting up drug and event hierarchies by providing hierarchy tables for individual variables in a data configuration, and if the run used hierarchy information. For more information, see Drug and event hierarchies .
Unique Values Tables Referenced by Configuration	Unique values tables referenced by the data configuration that was used for the run.
Source Database Tables Referenced by Drilldown Map	Source database tables referenced by the drilldown map table for the data configuration. For example, the drilldown map table might reference a table containing demographics data, making demographics data available as part of the case details.

Source database tables

Source database tables are the Oracle tables or views that store prepared safety data, which has been cleaned and transformed for data mining.

To prepare source database tables, you can use standard Oracle tools or any application that enables you to work with Oracle tables. In preparing the analysis tables, you must:

- Decide how many source database tables or views are needed.
- Ensure that all of the source database tables include an item that links them and can serve as a case identifier in the Oracle Empirica Signal application.
- Ensure that, if the source data is [timestamped](#), the source database tables include dates that can be used as start and end dates for data.
- Ensure that the source database tables include the following:
 - An item or items representing the therapeutic product being studied.
 - An item or items representing the event or symptom being studied.
 - Items that allow stratification during a data mining run.
 - Items that allow subsetting during a data mining run.

Examples of base tables

The base tables are as follows:

DEMO table:

CASE_ID	GENDER	COUNTRY	REPORT_DATE	BIRTH_DATE
123	M	US	12/01/2001	01/16/1954
138	F	France	01/05/2000	07/01/1965
147	M	Japan	09/17/2001	03/11/1942
154	F	US	10/04/1999	09/07/1966

ANTIGENS table:

CASE_ID	VAX_NAME	ANTIGEN	VAX_LOT
123	VAX A	ANTIGEN 1	15HR34
123	VAX A	ANTIGEN 2	15HR34
138	VAX B	ANTIGEN 3	49J3
147	VAX C	ANTIGEN 4	97WEO
147	VAX C	ANTIGEN 2	97WEO
154	VAX D	ANTIGEN 3	D90477F6

SYMPTOMS table:

CASE_ID	SYMPTOM	START	STOP	SEVERITY	NARRATIVE
123	Rash	10/30/01	11/25/01	Moderate	Red weeping rash on left side of neck extending from left back of neck over shoulder to left clavicle.
138	Hearing loss	11/14/00	12/05/00	Severe	Total hearing loss, both ears.
147	Rash	09/01/01	09/03/01	Mild	Red weeping rash on right forearm.
154	Vertigo	09/30/99	10/03/99	Severe	After walking block, patient experienced abrupt feeling of spinning and almost fell down.

Source database tables preparation

Suppose that the following data is needed for data mining:

- All cases originating in the U.S.
- The year that the case report was received.
- Age groups of patients.
- The symptom duration.

To prepare source database tables, you can do the following:

- Create a DEMO_ANALYSIS view on the DEMO table. Rename the CASE_ID to RPT_ID. Exclude case reports that did not originate in the U.S. Derive AGE_GROUP from AGE, which is derived from REPORT_DATE and BIRTH_DATE.
- Create a VACCINES_ANALYSIS view on the ANTIGENS table. Exclude case reports that did not originate in the U.S. Rename the CASE_ID to RPT_ID.
- Create a SYMPTOMS_ANALYSIS view on the SYMPTOMS table. Rename the CASE_ID to RPT_ID. Exclude case reports that did not originate in the U.S. Derive RCVD_YR from CASE_DATE. Derive DUR_DAYS (symptom duration in days) from START and STOP in the SYMPTOMS table.
- Create a DRILLDOWN view including a RPT_ID and any fields from the base tables that the user needs to see upon drilling down to case-level information. Exclude case reports that did not originate in the U.S. (This view is not the same as the drilldown map table.)

Resulting source database tables

The resulting source database tables (or views) might look like this:

DEMO_ANALYSIS view:

RPT_ID	GENDER	RCVD_YEAR	AGE_GROUP
123	M	2001	40-49
154	F	1999	30-39

VACCINES_ANALYSIS view:

RPT_ID	VACCINE	ANTIGEN	LOT_NO
123	VAX A	ANTIGEN 1	15HR34
123	VAX A	ANTIGEN 2	15HR34
154	VAX D	ANTIGEN 3	D90477F6

SYMPTOMS_ANALYSIS view:

RPT_ID	SYMPTOM	DUR_DAYS	SEVERITY
123	Rash	27	Moderate
154	Vertigo	4	Severe

DRILLDOWN view:

RPT_ID	GENDER	VACCINE	SYMPTOM	DUR_DAYS	SEVERITY	AGE_GROUP	NARRATIVE
123	M	VAX A	Rash	27	Moderate	40-49	Red weeping rash on left side of neck extending from left back of neck over shoulder to left clavicle.

RPT_ID	GENDER	VACCINE	SYMPTOM	DUR_DAYS	SEVERITY	AGE_GROUP	NARRATIVE
154	F	VAX D	Vertigo	4	Severe	30-39	After walking a block, patient experienced abrupt feeling of spinning and almost fell down.

Set viewing options for a data source table

Viewing options allow you to sort rows as needed and choose which columns to include in a data source table.

The options apply to the specific [data source table](#) during your current session. When you exit and log back in, Oracle Empirica Signal resets the options to the default settings.

While setting options, click **Clear to reset the options** to the default settings (except for which columns to include).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a data configuration, or select -- to include all configurations.
4. Select the **Row Action menu** icon () for a run, and then click **View Jobs for Run**.
5. In the upper-right corner, click **Sources**.
6. Click the name of the data source table that you want to view.
7. Click **Options**.
8. Specify up to three columns by which to sort the table. You can sort on columns, regardless of whether or not the columns appear in the displayed table. You can also sort by clicking the column headers in the table itself.
 - a. From the **Sort By** drop-down list, select a field to sort by. To sort data in descending order, click the **Descending** check box. Otherwise, results appear in ascending order.
 - b. Within the primary sort, specify up to two additional sort orders by selecting them from the **Then By** drop-down lists. To sort data in descending order, click the **Descending** check box. Otherwise, results appear in ascending order.
9. In the **Rows per page** field, type the number of rows to display per page. (The default is 15.)
10. To show the number of rows and current filter information above the table, check **Show heading**.
11. To show a description of the source database, check **Show notes**. The description comes from the [source description table](#) for the configuration used by the run.
12. To show the SQL WHERE clause that the application used to construct the displayed table, check **Show SQL**.

13. If you want the table to include columns for which no values exist, check **Show empty columns**.
14. From the **Include columns** list, check the columns to include in the table.
15. Click **Save**.

Filter a data source table

When you filter a data source table, you use a SQL WHERE clause to indicate specific characteristics for the data you want to view.

You can access any data that is in the source table. For example, suppose that you are viewing the DEMOG [data source table](#) in the source database, and you want to look at only cases for females. If Gender is stored in the DEMOG table, you can filter by Gender.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. Select the **Row Action menu** icon () for a run, and then click **View Jobs for Run**.
5. In the upper-right corner, click **Sources**.
6. Click the name of the data source table that you want to view.
7. Click **Filter**.
8. In the **SQL WHERE clause** text box, type a SQL WHERE clause. You can refer to any of the columns listed on the [Table Viewing Options page](#), regardless of whether or not you included them in the displayed table.
9. Click **Apply Filter**. To remove the filter, click **Clear**.

Manage data mining runs

- [Rename a data mining run](#)
You can rename a data mining run.
- [View details of a data mining run](#)
You can view details of a data mining run for a specific project or all projects and for a single configuration or all configurations.
- [Arrange the columns on the Data Mining Runs page](#)
Use the Columns option to specify which columns appear and in what order on the Data Mining Runs page.
- [View jobs for a data mining run](#)
The Jobs for Run page presents information about the batch jobs that make up a run and provides access to input and output files for the jobs.
- [View job details for a data mining run](#)
The Job Detail page provides a list of parameters used for a component job in a data mining run, and a list of input and output files produced by the selected job.
- [Define a database restriction](#)
A database restriction is a means of limiting which cases in the source data are included in a data mining run (MGPS or logistic regression) by specifying or selecting a query.

- [Refine a query to create a database restriction or custom term](#)
To refine a query to create a database restriction or custom term, you specify values for variables that are included in the query.
- [Cancel or delete a data mining run](#)
At any point before a data mining run has completed, you can cancel the run.
- [Re-run a data mining run](#)
Once a data mining run has been submitted, it can be re-run as is or with modified parameters.
- [Data configuration and object compatibility](#)
The Oracle Empirica Signal application checks the compatibility of data configurations with other data configurations or other objects.
- [Publish a data mining run](#)
Publication of a data mining run is a way to make it available to other users. By default, the publication level of every newly created object is Private.

Rename a data mining run

You can rename a data mining run.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. Select the **Row Action menu** icon () for a run, and then click **Rename**.
5. In the **Run name** field, enter a new name for the run. The name does not need to be unique, although we recommend that you use a unique name.
6. In the **Description** field, enter a new description. Oracle recommends that you provide an informative description of the run so that users who view run results know which run to use.
7. Choose one of the following:
 - To assign the run to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the run to it, click **Add to a new project named** and enter a project name.
8. Click **OK**.

View details of a data mining run

You can view details of a data mining run for a specific project or all projects and for a single configuration or all configurations.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click Data Mining Runs.
2. (Optional) From the **Project** drop-down list, select a project, or select -- to include all projects.

3. (Optional) From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. Select the **Row Action menu** icon () for a run, and then click **View Run Details**.

Different information appears for MGPS runs and LR runs.

MGPS runs

Field	Description
ID	Automatically assigned, unique numeric identifier of the run.
Type	MGPS.
Name	Name supplied for the run.
Description	Description supplied for the run.
Project	The name of the project to which the run is assigned.
Configuration	Name of the data configuration used for the run.
Configuration description	Description of the configuration used for the run.
As of date	As Of date for the run, if the run is for timestamped data .
Database restriction	Database restriction , if any, associated with the run.
Item variables	Names of the item variables used in the run.
Custom terms	Custom terms , if any, specified for the run.
Stratification variables	Stratification variables , if any, used for the run.
Subsets	Subset variable , if any, as well as whether the subsets are cumulative, the order of subsets (if cumulative), and the subset labels and values.
Drug hierarchy	If the data configuration specifies a drug hierarchy, the name and version of the drug hierarchy used by this run.
Event hierarchy	If the data configuration specifies an event hierarchy, the name and version of the event hierarchy used by this run.
Highest dimension	The maximum number of ways in which items are combined. See Specify data mining parameters .
Minimum count	Minimum number of cases in which a combination of items must occur for the combination to be included in the MGPS computations for the run. See Specify data mining parameters .
Calculate PRR	Whether the run includes PRR computations .
Calculate ROR	Whether the run includes ROR computations .
Base counts on cases	For a run that includes PRR and ROR computations, indicates if counts are based on cases rather than drug-event combinations.
Use "all drugs" comparator	For a run that includes PRR computations, whether or not the comparator set includes the drug of interest.

Field	Description
Apply Yates correction	For a run that includes PRR computations, whether or not the Yates correction is applied.
Stratify PRR and ROR	For a run that includes PRR and ROR computations, whether or not the PRR or ROR computations are stratified.
Include IC	Whether the run includes Information Component computations .
Include RGPS	Whether the run includes RGPS computations .
Calculate RGPS interactions	Whether the run computes Drug+Drug interaction scores using RGPS.
Minimum interaction count	Minimum number of times that a drug must appear in Drug+Event reports for the application to calculate interaction estimates for the drug.
Fill in hierarchy values	Indicates whether the run option to use hierarchy information was checked.
Limit results to	Limitations on which results are kept based on statistical thresholds or specified values of item variables. See Specify data mining parameters .
Exclude single itemtypes	Indicates whether combinations of items of the same type were excluded from run results. See Specify data mining parameters .
Fit separate distributions	Indicates the setting for the advanced parameter to fit separate distributions for the different item type combinations.
Save intermediate files	Whether or not intermediate processing files for the run were saved. See Define data mining run options .
Application	Name and version of the application at the time of the data mining run. For example Empirica Signal 2025.4.1.0.102.
Created by	Name of the user who created the run.
Created on	Date and time at which the run was submitted.
User	Your username (name of the user who is viewing run details).
Source database	Information about the source data (from the source description table).

Logistic regression runs

Field	Description
ID	Automatically assigned, unique numeric identifier of the run.
Type	LR. For runs completed prior to the installation of Oracle Empirica Signal version 7.1, LR (Legacy) appears.
Name	Name supplied for the run.
Description	Description supplied for the run.

Field	Description
Project	The name of the project to which the run is assigned.
LR type	The logistic regression used for the run, either extended or standard .
Configuration	Name of the data configuration used for the run.
Configuration description	Description of the data configuration used for the run.
As of date	If the run is for timestamped data , As Of date for the run.
Database restriction	Database restriction , if any, associated with the run.
Item variables	Names of the selected event and drug variables.
Custom terms	Custom terms , if any, specified for the run.
Covariates	Variables, if any, selected as covariates for the run.
Drug values	Explicitly specified values of the drug variable included in the run, even if they do not meet the minimum number of times a drug must occur in combination with specified events.
Event values	Values of the event variable used in the run.
Minimum count	Minimum number of cases in which a drug must occur in combination with specified events to be included in the run (except for drugs explicitly specified as Drug values). See Guidelines for specifying drugs for logistic regression .
Run interactions	Whether or not the run calculates statistics for two predictors (such as drug+drug or drug+covariate) and a response.
Save coefficients	Whether or not the lr_coefficients.log file produced for the run includes the coefficient and standard deviation values calculated for the run.
Save intermediate files	Whether or not intermediate processing files for the run were saved. See Define data mining run options .
Application	Name and version of the application at the time of the data mining run. For example Empirica Signal 2025.4.1.0.102.
Created by	Name of the user who created the run.
Created on	Date and time at which the run was submitted.
User	Your username (name of the user who is viewing run details).
Source database	Information about the source data (from the source description table).

Arrange the columns on the Data Mining Runs page

Use the Columns option to specify which columns appear and in what order on the Data Mining Runs page.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. In the upper-left corner, click **Columns**.
5. Select columns to include in the table from the **Available Columns** list and move them to the **Selected Columns** list using the arrow buttons.

If a table includes a lot of columns or the columns contain long values, the entire table may not fit across your browser window. Scroll to the right to see the rest of the table.

6. To change the order in which columns display in a table, in the **Selected Columns** list, click the column name and:
 - Click  to move the column up in the list.
 - Click  to move the column down in the list.
7. To move multiple columns, hold down the Ctrl key while you click the column names, and then use the up or down arrows.

Note

For most tables, rows with empty cells appear first when you sort that column in ascending order, and last if you sort in descending order. Empty columns are always displayed last, regardless of the sort order.

8. If you want to replace your choices with the Oracle Empirica Signal defaults, click **Reset**. The table columns and sorting return to the default values.
9. Specify the sort order.
10. If you sorted the table by clicking column headers, that sort order appears in the Column Name and Sort Order fields. Otherwise, the Column Sort Order fields are empty. To specify a sort order:
 - a. From the **Column Name** drop-down lists, select a column name for up to three columns.
 - b. From the **Sort Order** drop-down list, select **Asc** (ascending order: A-Z, 1-9) or **Desc** (descending order: Z-A, 9-1).
11. Click **OK**.

View jobs for a data mining run

The Jobs for Run page presents information about the batch jobs that make up a run and provides access to input and output files for the jobs.

The name and owner of the run appears at the top of the page. If a run is scheduled for future processing, the scheduled date and time appear.

- For runs that are in progress, this page refreshes automatically until the run completes successfully or an error causes a job to fail.

- As the jobs in a run are performed, the Status column indicates Completed or displays the error that caused that job to fail. If any of the jobs in a run fail, the status of the run is Error Occurred.
1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
 2. From the **Project** drop-down list, select a project, or select -- to include all projects.
 3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
 4. Select the **Row Action menu** icon () for a run, and then click **View Jobs for Run**.

The Jobs for Run page provides the following information about each job:

Column	Description
ID	Automatically assigned unique ID of the job. IDs of deleted runs are not re-used.

Column	Description
Name	The name of each job, including a descriptor followed by the number of the run. The jobs included in the run differ for MGPS and LR runs, as follows. An MGPS run includes the following jobs: - extract—Extracts data from the source database. The run ID follows the job name. - mgps—Applies MGPS to the extracted data to produce scores. The run ID and 0 follow the job name. - rgps—For runs that include RGPS computations, applies RGPS to the extracted data to produce scores. The run ID and 0 follow the job name. - Post_Process—Creates unique value tables for the drugs and events that appear in the run results (for use by the results table) and adds column indexes to the output table. There is only one post-process job. The run ID and 0 follow the job name. A logistic regression run includes the following jobs: - LR_extract—Extracts data from the source database. The run ID follows the job name. - LR—Calculates logistic regression scores. The run ID and 0 follow the job name. Click the name of this job to download the log files. These include the tab-delimited lr_coefficients.log file, which contains alpha values computed for every event in an Extended LR run; and, if selected as a run option, the coefficients and standard errors for each predictor+response combination; and the lr.log file, which lists the most common values found for run covariates and summarizes convergence for each response. - LR_Post_Process—Creates unique value tables for the drugs and events that appear in the run results (for use by the results table) and adds column indexes to the output table. There is only one post-process job. The run ID and 0 follow the job name.
Description	The text, Part of Run , followed by the run ID.
Server	The value, Any , appears if the next available listener can perform the job. If multiple listeners are in use and the MGPS or logistic regression run is submitted externally using a run definition file , a listener can be specified to perform each job and the unique ID of the listener appears.
Created	Server date and time when the extraction or base job was created. For a run that is scheduled and may be queued for processing after other runs, the creation of the extraction or base job may be substantially later than the creation date of the run itself.

Column	Description
Start Date	Server date and time when the job was started.
End Date	Server date and time when the job ended.
Runnable	The value remains NO for each job until the preceding job is complete; then the value becomes YES.
Status	The column remains empty until the job has completed or failed. If the job completes successfully, the status is Completed. If the run is canceled when the job is being performed, the status is Canceled. An error message (and red background) appears if the job failed.

Note

Once an extraction completes, there is internal preparation of the extraction for the MGPS or LR job. If you submit two runs, it is possible for the extraction job of the second run to start before the MGPS or LR job of the first run.

- To [view job detail](#), such as the job parameters, and to access input and output files for jobs, click the name of the job.
- To [view source tables](#), click **Sources** (if you are a superuser).

View job details for a data mining run

The Job Detail page provides a list of parameters used for a component job in a data mining run, and a list of input and output files produced by the selected job.

Certain files are always saved and available from this page, while other files are saved and available only if the run creator checked **Save intermediate data files** on the [Run Options page](#).

- An error log file called job_job-id_log-id.log is produced for each extract or LR_extract job. This log contains the date and time that error logging began and messages about any errors that occurred. For LR runs, this log also includes a line for each process in the run.
 - The [lr_coefficients.log file](#) is produced for each LR job. This file contains the computed best alpha value for each response in an extended LR computation, and also includes the coefficient and standard error values computed for each predictor-response combination if the run creator checked **Save coefficients** on the Run Options page.
 - The [lr.log file](#) is produced for each LR job. This file identifies the most common value for each covariate in the run and summarizes convergence for each response.
 - For the mgps job, the datamine.log file shows the version of the MGPS engine that you used. For the LR job in a logistic regression run, the lr.log file shows the version. The version number is helpful to know when communicating with Oracle about issues related to the data mining run.
- In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
 - From the **Project** drop-down list, select a project, or select -- to include all projects.

3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. Select the **Row Action menu** icon () for a run, and then click **View Jobs for Run**.
5. Select the job and click its name.
6. Review the information on the **Job Detail** page.
7. To view the available log files, from the **Job Parameters** section, click the input or output filename.
8. To return to the Jobs for Run page, click **Back**.

Define a database restriction

A database restriction is a means of limiting which cases in the source data are included in a data mining run (MGPS or logistic regression) by specifying or selecting a query.

Data mining statistics are based only on cases that meet the criteria of the query. For example, you can limit a data mining run to only cases that have been reported by health professionals. A data mining run can have only one database restriction.

A database restriction limits cases, not records. For example, if you base a database restriction on a query that finds a particular drug, the application includes each case involving the drug in the run. Because there may be multiple drugs per case; however, the application includes drugs other than the particular drug in the run.

When defining a database restriction, you can create a new [query](#) or use an existing query. When defining a new query, you have the option to save it to the Query Library. You can then use it to define database restrictions for other data mining runs.

When you re-run a run, the application applies the same database restriction. You cannot switch run types. Thus, if you plan to use a particular database restriction for different run types, make sure that you save the query you define for the database restriction for the first run you set up. Then you can select that query as the database restriction for the other run type(s).

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. Select the **Row Action menu** icon () for a run, and then click **View Jobs for Run**.
5. Select the **Define database restriction** check box.
6. Click **Next**.
7. Choose one of the following:
 - To create a database restriction by [defining a new query](#), click **Create Using Query Wizard**. You can save the new query to the Query library so that you can re-use it for other runs.
 - To create a database restriction [based on an existing query](#), click **Create from Existing Query**. Subsequent changes to the query in the library will not affect the database restriction.

Note

If you saved the query to the library and then you edit it from this page, your changes are not saved to the library.

Refine a query to create a database restriction or custom term

To refine a query to create a database restriction or custom term, you specify values for variables that are included in the query.

1. From the **Select Query from Library** page, select the [query](#) and click **Next**.
2. Specify values for query variables.

If all operators in the query are the same; that is, they are all AND, all OR, all INTERSECT, or all UNION, you do not need to specify values for every variable. If you do not specify a value for a variable and you clear Include Null values for the variable, then the application ignores that variable. If any operators differ, you need to specify values for all query variables.

The way in which you specify values depends on the type of variable. For more information, see [Specify query variables](#).

3. To include null (empty) values along with the other values that you specify for a variable, check **Include Null values**. For more information, including how the NOT operator works if you include null values, see [Specify query logic](#).
4. Click **OK**.

Selecting values

- If the Select <hierarchy> Terms link appears for a variable, click it to select terms from the [hierarchy](#). For example, if an event variable is associated with a MedDRA version and your [user preference](#), Enable Adverse Event Hierarchy Browser, is checked, you can click **Select MedDRA Terms**.
- To [select values from a list](#), click **Select Available Values**.
- To refer to a [saved list](#) of terms, click **Select Saved List**. You can specify a saved list that uses the same data configuration as the query.
- To type the terms, review the rules in [Typing values in text boxes](#).

Note

To prevent spelling and capitalization errors, Oracle recommends that you select rather than type values.

- To [look up a drug name](#) for a drug variable, click **Trade/Generic Lookup**. You can find the generic name for a drug (if you only know its trade name) or vice versa. (This link is available if the data configuration's source data included trade name-generic name mapping.)

Matching a text string

If the options Contains, Starts with, Ends with, or Equals appear for a variable, enter a text string and click a radio button to indicate the type of matching. You can also check **Ignore capitalization** to retrieve matching values regardless of upper or lower case.

Specifying ranges

For numeric or date variables, specify a range by entering values in the **From** and **To** fields. Values equal to or greater than the From value and equal to or less than the To value are found. If you leave the From field empty, there is no lower bound. If you leave the To field empty, there is no upper bound.

Enter date values in the format appropriate for your locale or use the calendar icon to select a date. The application uses the Oracle `TO_DATE` function to change the entered date to an Oracle date. For example, if you enter `03/26/2008` in the From field for the `FDA_DATE` variable, in the SQL generated, `FDA_DATE >= to_date('2008-03-26 00:00:00', 'yyyy-mm-dd hh24:mi:ss')`.

If you do not specify a time, the time is considered to be midnight of the specified date.

Note

If a date variable is stored as a text field in the Oracle database, you can search for it as you would search for any text string.

Specifying report IDs

For a variable specified with the type Report ID in the data configuration, you can enter a string of report IDs separated by commas.

Cancel or delete a data mining run

At any point before a data mining run has completed, you can cancel the run.

A canceled run remains on the Data Mining Runs page and can be re-run as is or with modifications. For example, suppose there are several runs in the queue. You need the one that was most recently submitted to run first. You can cancel all runs except the most recently submitted one. Later, you can re-run the canceled runs.

When a run has completed, the run status becomes either Complete or Error Occurred, and you can delete the run. You can also delete a run that has been canceled (the run status is Canceled). Data mining runs can take up a significant amount of server space. Deleting runs that are no longer needed frees up this space for other processes.

Note

To learn more about the error that caused a run to fail, review the information on the [Jobs for Run page](#).

Which runs you can cancel or delete

You can always cancel or delete the data mining runs that you have created, even if your username does not have the Delete Any Run permission.

You can cancel or delete runs created by any users in your login group if you have the Delete Any Run permission.

Cancel a data mining run

The Cancel option is available as soon as the run is submitted. You can cancel a run that is currently running or that is scheduled to run in the future. The status cannot be Completed or Error.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. Select the **Row Action menu** icon () for a run, and then click **Cancel**.
5. Confirm the cancellation by clicking **OK**.

The status of the run changes to Canceled. You can delete or [re-run the run](#).

Delete a data mining run

The Delete option is available only when the run has a status of Completed, Error Occurred, or Canceled. If you want to delete a run that is currently running or is scheduled to run in the future, you must cancel it first. Before deleting a run, make sure that it is not referenced by any [drug profile configurations](#) or [signal configurations](#), because such references are removed.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. Select the **Row Action menu** icon () for a run, and then click **Delete**.
5. Confirm the deletion by clicking **OK**.

Any case series associated with the run are retained, but they no longer have an associated run.

When you delete a run that is associated with an alias, the target status of the alias becomes Broken.

Note

If you want to delete multiple runs at the same time, on the Data Mining Runs page, first choose **Select Rows** from the **Header Action menu** ().

Re-run a data mining run

Once a data mining run has been submitted, it can be re-run as is or with modified parameters.

For example, you need an MGPS run with 5 as the Minimum Count, and another MGPS run with all of the same data mining parameters but with 10 as the Minimum Count. Once you have submitted the first run, instead of creating a new run and supplying all of the same selections again, except for the minimum count, you can re-run and change one parameter.

You can re-run any of the data mining runs that appear on the Data Mining Runs home page, including runs created by other users and runs that are currently running, completed successfully, failed, were canceled, or have not started. You can also re-run runs that are themselves re-runs.

Note

- You cannot change the run type when re-running a run. For example, you cannot change from an MGPS run to a logistic regression run.
- To learn more about the error that caused a run to fail, review the Status column on the [Jobs for Run page](#).
- The re-run option is not available for logistic regression runs created prior to the installation of Oracle Empirica Signal version 7.1, which included significant enhancements to logistic regression computations.

When you re-run a data mining run, Oracle Empirica Signal treats it as an independent run that is not associated with the original run; you are the owner of the new run. The run uses all parameters and options used for the original run (including the [As Of date](#) of the run, if the data configuration supports [timestamped data](#)) unless you explicitly modify them. In addition, the re-run uses the [user preference](#), **Replace Missing Values with**, setting that was in effect for the run creator when the original run was created.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. From the **Project** drop-down list, select a project, or select -- to include all projects.
3. From the **Configuration** drop-down list, select a [data configuration](#), or select -- to include all configurations.
4. Select the **Row Action menu** icon () for a run, and then click **Re-run**.
5. To select a different data configuration, from the **Configuration** drop-down list of [compatible data configurations](#), [select a data configuration](#).
6. To limit the run to only cases meeting specified criteria, check **Add Database Restriction**.
7. Click **Next**.
If you added or modified a database restriction, the [Define Database Restriction](#) page appears. Otherwise, the Run Options page appears.
8. [Modify run options](#) as needed. You can also click **Back** to review all of the selections made for the original run and modify them as needed.

Note

The run uses all of the variables, values, and parameters selected for the original run unless you modify them in the new run. For example, if there was a custom term for the original run, it is used as is unless you modify it. Keep in mind that any changes made to queries on the Queries page have no effect on database restrictions or [custom terms](#) that were part of the original run. During the re-run, you must modify the database restriction or custom term, if needed, including reselecting a query that was modified on the Queries page.

9. Click **Next**.
10. On the **Name Data Mining Run** page, in the **Run name** field, enter a name for the run. The name of the run does not need to be unique, although we recommend that you use a unique name. Oracle Empirica Signal assigns a unique Run ID to each run.

11. In the **Description** field, optionally enter a description. Oracle recommends that you provide an informative description of the run so that users who view run results know which run to use.
12. (Optional) To assign the run to a project, choose one of the following:
 - To assign the run to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the run to it, click **Add to a new project named** and enter a project name.
13. Click **Next**.
14. On the Confirm Run Parameters page, review the parameters chosen for your run to make sure that they are correct. Different parameters display for [MGPS runs](#) and [LR runs](#).
15. If you want to change any parameters, click **Back** until you are on the appropriate page and make the necessary changes. Then click **Next** until you are back on the Confirm Run Parameters page.
16. When you are satisfied with the run parameters, click **Submit**.
17. Click **Continue**.

The run status appears on the Data Mining Runs page. To monitor the progress of a run, you can [view jobs for the run](#).

Data configuration and object compatibility

The Oracle Empirica Signal application checks the compatibility of data configurations with other data configurations or other objects.

For example, when you re-run a data mining run using a different configuration, the application checks that the configuration you specified is compatible with the original configuration used.

Compatibility-checking for various types of objects is as follows.

Data mining runs

Note

Two variables match if they have the same variable name, the same variable type and subtype, and the same settings for use as a subset variable or stratification variable.

When re-running a data mining run, you can select from configurations with variables that match all variables in the original run's configuration. The configurations must also have the same setting for whether the database is timestamped.

Saved lists

Note

Two variables match if they have the same name, selection type, and Oracle data type.

When selecting a saved list, you can select from lists where the variable referenced by the saved list has a matching variable in the configuration associated with the object on which you are working.

Queries and reports

Note

Two variables match if they have the same name (ignoring underscores and spaces), selection type, and Oracle data type.

- When listing reports for a selected case series, the application lists only reports based on configurations with variables that match the variables in the configuration of the selected case series.
- When listing reports for cases that appear when you drill down on a count, the application lists only reports where the variables used by the report match variables in the configuration of the object from which you are drilling down.
- When running a query, you can select from configurations with variables that match all variables referenced by the query.
- When creating a query-based interactive report, you can select from queries where all referenced variables have a matching variable in the report configuration.
- When defining a custom term or database restriction, you can select from queries where all referenced variables have a matching variable in the run configuration.
- When running a query-based interactive report, you can select from configurations with variables that match the union of all variables referenced by the query and all variables referenced by the report.
- When running an All Cases Summary report, you can select from configurations with variables that match all variables referenced by the report.

Case series (not query-based)

Note

Two variables match if they have the same name and selection type.

When transferring cases to a case series, you can select from case series based on configurations with variables that match variables in the configuration of the object from which you are transferring cases.

Deleted data configurations

Note

Two variables match if they have the same name (ignoring underscores and spaces), selection type, and Oracle data type.

When deleting a configuration, you can transfer certain types of objects to another data configuration with variables that match the all variables referenced by the objects.

Publish a data mining run

Publication of a data mining run is a way to make it available to other users. By default, the publication level of every newly created object is Private.

Note

Users without the Administer Users permission can publish only objects they have created. Users with the Administer Users permission can publish objects that they or any users in their login group created.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. Click a data mining run's **Row Action menu** icon () and click **Publish**.
3. To publish to all the users in your login group, click **Publish**.
 - If you are a superuser and the object is not multi-enterprise support-related, you can publish to multiple login groups, including —All—. From the **Publish to Login Groups** list, select one row and hold **Ctrl+ left** click to select more rows.
 - If you publish to —All— and later add a new login group, the object is published automatically to the new login group.
 - If you are a superuser and the object is multi-enterprise support-related, then you can only publish to the Data Mining Run owner's login group.
4. To view details of the selected data mining run, click **View Run Details**.
5. Click **Back**.

Data mining FAQs

This set of frequently asked questions relates to data mining and its applications in Oracle Empirica.

Why data mining?

1. **What is the primary motivation for applying statistical data mining to a medicinal product safety database?**

The Oracle Empirica Signal application acts as a screening device to sort through several million potential drug/event combinations. You can use the application to prioritize tasks and decide what is random noise versus associations that need further investigation. The output is available as new questions are raised.

2. **How might the availability of a safety data mining system affect the way that safety evaluators go about doing their work?**

The data mining feature identifies and investigates potential problems in spontaneous safety data. You can use data mining to identify potential signals, prioritize pharmacovigilance activities, and complete evidence-based reviews.

Interpretation of results

1. **How can you determine that you are seeing more of some AE than expected for a particular drug when you do not know the number of prescriptions filled for that drug (the denominator)?**

The technique of disproportionality analysis, upon which the Oracle Empirica Signal application is based, uses all reports that mention a drug as a surrogate for the exposure.

2. **Does the lack of exposure data make it impossible to differentiate between a relatively safe drug that reports few events and another drug that reports more events?**

The method looks at particular adverse events rather than overall reporting rate. If prescription data is available, then overall reporting rate is worth looking at. In most circumstances, however, the method is less biased than a reporting rate for a particular AE.

3. **Does the fact that you do not know the reporting rate for a drug and/or event (for example, what percentage of true drug-related adverse events are actually reported to FDA) create a problem in obtaining quantitative estimates of product-event association?**

The fact that the reporting rate is unusually high or low for a particular drug does not affect the results as long as the reporting rate for that drug is uniformly high or low across all events. An unusually high or low reporting rate for a particular event does not affect the results as long as the reporting rate for that event is uniformly high or low across all drugs. It is possible that publicity about a particular problem with a drug might cause the report rates for particular product-event combinations to increase without corresponding increases in the overall report rates for the drug or the event. If that happens, the corresponding associations from disproportionality methods, such as MGPS, becomes biased upward.

Counts

1. **Where does the notion of an expected count come from?**

Observed counts for each product-event combination of interest:

Event	Drug of interest	All other drugs
Event of interest	a=N	b
All other events	c	d

Expected counts (E):

Event	Drug of interest	All other drugs
Event of interest	$E(a) = ((a+b)(a+c))/(a+b+c+d)$	$E(b) = ((a+b)(b+d))/(a+b+c+d)$
All other events	$E(c) = ((c+d)(a+c))/(a+b+c+d)$	$E(d) = ((c+d)(b+d))/(a+b+c+d)$

The quantity E(a) is the number of product-event combinations of interest that would be expected if the event of interest appears in reports independently of the drug of interest.

Observed count / Expected count = Relative Reporting Ratio ($N/E = RR$).

Do not confuse the use of RR as an abbreviation for Relative Reporting Ratio in the Oracle Empirica Signal application with the concept of relative risk, which cannot be estimated from spontaneous report frequencies. Relative Reporting Ratio is also different from

reporting rate, which can only be estimated if you know both the number of reported and unreported events. RR in the context of data mining of a spontaneous report database is the ratio of the number of occurrences of the product-event combination of interest to the expected number if the proportion of reports with that event among reports involving that drug were the same as the overall proportion in the database. RR is a disproportionality measure.

2. What does it mean if the expected count is less than 1?

Based on the total number of reports separately for the drug and event, it is expected, statistically, that there would be less than one report of the combination if the drug and event are not associated. The expected count (E) for a product-event combination can be less than 1 when either the number of reports for the drug, or the number of reports for the AE, is small. It is common for E to be less than 1 (sometimes even $E < .001$) for a rarely reported drug combined with a rarely reported event. This causes the ratio N/E to fluctuate wildly when N goes from 0 to 1 or more.

3. How does the EBGM statistic differ from the concept of an observed count (for a product-event combination) divided by an expected count?

EBGM is an improved estimate of the Relative Reporting Ratio (RR). Technically, EBGM is defined as the exponential of expectation value of $\log(RR)$, where, in this case, the probabilities determining expected value are not based on assuming independence of drugs and events, but are based on statistical measures of the dependencies exhibited in the database overall and for each product-event combination. (In Bayesian terminology, this is called the posterior distribution.) EBGM has the property that it is nearly identical to N/E when the counts are moderately large, but it shrinks towards the average value of N/E (typically ~ 1.0) when N/E is unreliable, because of instability issues with small counts.

The posterior probability distribution also supports the calculation of lower and upper 95% confidence limits (EB05, EB95) for the relative reporting ratio.

EB05 and EB95

1. Explain the meaning of EB05 and EB95.

The Oracle Empirica Signal application distinguishes between the observed value of $RR = N/E$ and the true value of the Relative Reporting Ratio that would be observed if a much larger database (so large that sampling error would be negligible) were to be drawn from the same conceptual population of reports. This unknown quantity, sometimes abbreviated as true RR or true N/E , can be bounded probabilistically:

EB05 is a value such that there is about a 5% probability that the true value of N/E lies below it.

EB95 is a value such that there is about a 5% probability that the true value of N/E lies above it.

The interval from EB05 to EB95 is the 90% confidence interval. The confidence interval is a way to describe the uncertainty in an estimate due to small sample size (the larger the number of reports, the narrower the confidence interval). EB05 and EB95 describe the probability distribution for the correct answer. For example, an EB05 of 3 means that there is a 95% chance that the true Relative Reporting Ratio is at least 3.

2. What is the relationship of other safety data mining report statistics, such as the Proportional Reporting Ratio, the Reporting Odds Ratio, and the Information Component, to EBGM (EB05, EB95)?

These different disproportionality statistics all get at basically the same things, and the values for each in any given situation are likely to be similar, provided the sample size is large.

MGPS allows the use of stratification for elimination of some confounding effects, so it will typically provide lower and more realistic scores if there is a confounding variable involved, such as age or gender, compared to a statistic that does not involve stratification. (Randomized trials are the only way of being sure there is no confounding in a dataset.)

You can specify whether or not you want to calculate Proportional Reporting Ratios (PRR) and Reporting Odds Ratios (ROR) for a data mining run. Further, for a data mining run that is stratified, the PRR and ROR calculations can also be computed using stratification.

3. When we apply data mining to evaluate the significance of many different product-event combinations, are we making a multiple comparison? Does this cause problems?

Multiple comparisons refers to searching out the largest association (such as the largest value of N/E among a large number of product-event pairs) in a database and then evaluating it statistically as if that product-event pair had been the focus of the study before looking at the data. Bayesian shrinkage estimates shrink (modify the estimate of N/E towards 1 based on a theoretically sound statistical method) and the raw values of N/E so that all values of EB05 have the same 95% chance of being no larger than the true RR (Relative Reporting Ratio), even if you search out the largest value of EB05 in the output table.

Threshold EB05

1. If MGPS yields a ranked list of associations according to the EBGM signal score, what threshold should be used for determining that an association is an alert that warrants further investigation?

There is no absolute threshold. An alert is an indication that there may be a signal. Where to put the cut-off point demanding further investigation is a business decision that is based, among other considerations, on the nature of the data, seriousness of the AE, available resources, and other signal discovery mechanisms.

2. Why has the threshold EB05 > 2 been recommended?

Although the threshold EB05 > 1 might meet a typical definition of statistical significance, there are many biases in spontaneous report data and costs to following up each alert. Therefore, Oracle suggests you use a somewhat higher threshold. The value 2 is a round number that is often reasonable for relatively rare AEs. (For a rare AE, a doubling of the number of reports may not be a large absolute increase.)

For further discussion, see:

Szarfman A, Machado SG, O'Neill RT. *Use of screening algorithms and computer systems to efficiently signal higher-than-expected combinations of drugs and events in the US FDA's spontaneous reports database*. Drug Saf. 2002;25(6):381-92.

3. If there is a product-event combination with an EB05 greater than my chosen threshold (for example, EB05>2), what can I say with certainty about the relationship between the drug and the event? Are they definitely related? Are they causally related?

This value suggests only that there is a statistical association between this drug and event. The association may indicate a causal relationship or a reverse causal relationship; that is, the AE is an indication for the drug. It may indicate a relationship that is already labeled, or it may indicate a relationship that is not clinically significant for other reasons. The most frequent explanation is that there is a third variable common to both the drug and the event, often related to the drug's indication (confounding by indication).

You should conduct further investigation, including reading the label, doing a literature review, or, at the very least, expert evaluation of the individual medical records leading to

the series of reports, to determine whether they seem causally related. Additional studies, such as clinical trials or case control studies, may be warranted in some cases.

False positives and negatives

1. What is meant by alerts potentially being false positives?

A false positive occurs when any signaling system, such as the EBGM or EB05 value, exceeds a pre-set threshold (such as $EB05 > 2$), while, in reality, the drug is either not related to the event or is related, but not causally.

2. What is meant by alerts potentially being false negatives?

A false negative occurs when any signaling system, such as the EBGM or EB05 value, did not exceed a pre-set threshold (such as $EB05 > 2$), while, in reality, the drug is causally related to the event.

3. How do I set up an alerting system that gives hardly any false positives and hardly any false negatives. Is this possible?

No. While the chances of finding false positives or false negatives can be reduced, you cannot eliminate them. It is possible to decrease the chances of finding false positives or false negatives by improving the current statistical algorithms with the addition of extra information, such as stratification, or by improving the data collection itself. Otherwise, any decrease in false positives is automatically accompanied by an increase in false negatives, and vice versa.

There are two possible reasons for a false positive: there actually is no correlation between the drug and event, or there is a correlation, but it is not causal. The first can be dealt with to some degree statistically (although there will always be unresolved uncertainty for small sample sizes). The second is not a statistical issue, and can only be dealt with through medical knowledge.

Similarly, a false negative can be due to a small sample or be the result of masking from another signal. Given a hypothesis based on medical knowledge you can reduce the masking. Oracle is experimenting with techniques for providing clues about when such masking may be occurring.

A third reason for either a false positive or a false negative is that you are using the wrong threshold.

Signaling sensitivity

1. What is meant by the sensitivity and specificity of signaling systems?

Sensitivity is defined as the percentage of truly causal associations that are identified by the alerting system. Low sensitivity means a high number of false negatives. For example, in a database with counts for 10,000 product-event pairs where 1,000 of the pairs have a truly causal relationship, if MGPS identifies 700 out of the 1,000 true associations, the sensitivity of MGPS is $700/1000$ or 70%. This calculation assumes that the true status of every product-event pair is known. You have to have a gold standard.

Specificity indicates the percentage of noncausal (including nonexistent) associations for which the system does not show an alert. Low specificity means a high false positive rate. If MGPS declares that 3,000 of the 99,000 non-causal pairs are associated, that is a $96,000/99,000 = 97\%$ specificity rate or a 3% false-positive rate. Again, this calculation assumes that you know the actual negatives.

Because there is no gold standard in most pharmacovigilance situations, you cannot usually estimate the values of sensitivity and specificity very well. Sometimes, the gold standard is whether a reaction is on the label. This is problematical. It is a difficult and

subjective task to transform the language on a label into an accurate and complete list of MedDRA terms. The label itself may be wrong or incomplete.

2. If EB05 is large, does that mean that you can be 95% sure that there is a true signal?

No, you can only be 95% sure that an association this large will hold up as the database becomes larger and larger. When $EB05 > 2$, almost all the false positives are due to noncausal associations that are reliably likely to continue as more data is collected, such as events being related to indications for the drugs, or publicity effects. A large EB05 rules out mere statistical fluctuation, but not other spurious causes of the association. Thus, medical knowledge is very important for interpretation of data mining results.

3. If my threshold for signaling is $EB05 > 2$, is a product-event combination with an $EB05 < 2$ definitely not a signal?

The application distinguishes between an alert that occurs when a data mining statistic exceeds a predetermined threshold and a signal that might be declared upon review of all relevant information. Since there can easily be strong evidence of causality from other information in the absence of a data mining alert, $EB05 < 2$ would not rule out the possibility of a signal. Considering the data mining results, you would require $EB95 < 1$, rather than $EB05 < 2$, to say that there is strong statistical evidence against a positive association between the drug and the event. Remember, all of the values of true RR that lie within the interval $(EB05, EB95)$ are reasonably compatible with the observed data.

4. Are there any guidelines regarding the smallest N (for a product-event combination) for which you can get a meaningful signal score?

It is not necessary to take the sample size into account. The methodology does that. In practice, however, the built-in conservatism of the MGPS methodology, and the choice of threshold, prevents $EB05 > 2$ when analyzing adverse event data unless N is at least 3. This suggests that reducing the threshold to $EB05 > 1$ might be advised as part of screening for very serious adverse events, if you want to be warned whenever the first two reports show up significantly earlier than expected for a new drug.

Working with new drugs and small sample sizes

1. If a drug is new and only has a handful of reports (e.g., 50) overall in the database, can useful data mining signals be obtained?

Yes, the EB05 statistic takes the sample size into account.

2. What about the case of an event term for which there is a small number of reports (<100) overall?

Yes, the EB05 statistic takes the sample size into account.

Stratification and subsets

1. What is the difference between stratification and subsetting?

Stratification is a way of normalizing data to eliminate confounding by some variable or variables. You generally stratify by age group, gender, and receipt year. The Oracle Empirica Signal application calculates the expected count separately for each stratum, then sums those counts and uses this total expected count for the RR and EBGM calculations. This process can be used, for example, to deal with confounding due to a drug being administered only to the elderly or only to males, or to the drug being new on the market. This process is often called adjustment for confounding variables in the epidemiology literature. Other possible confounding variables are not generally available in AERS data.

Subsetting is a way of repeating the entire data mining analysis using different subsets of the database. Subsets are typically used to study how the strength of a product-event

association evolved over time, but can also be used to compare strength of associations for different age or gender subsets. For each subset, the application calculates the observed count and expected count, then uses those values to calculate a separate RR and EBGM value for each subset. Different subsets of the reports can be overlapping or non-overlapping, depending on how the subset run parameters are specified.

2. Is it meaningful to compare signal scores across subsets (e.g., signal scores for males versus signal scores for females)?

Yes. Non-overlapping confidence intervals can alert you to the possibility of a gender difference in response to the drug.

Cross-drug comparisons

1. Under what circumstances might it be meaningful to compare signal scores across different drugs?

Non-overlapping confidence intervals can alert you to the possibility of a difference between the safety profiles of the drugs. Alternately, if the confidence intervals overlap a lot, the signal scores can help corroborate evidence that there is no difference.

2. What are the advantages and disadvantages of including concomitant medications (as well as suspect drugs) in the data mining analysis?

An advantage of including concomitant medications is that you can eliminate the bias from physicians who pre-determined the suspect drugs. Each drug will be weighted equally. In addition, including both concomitant and suspect drugs provides a larger background case set for each drug and may reveal associations unsuspected by the reporter.

A disadvantage is that potentially valuable judgments from physicians regarding which drug(s) is/are suspect are not taken into account.

More research is needed to understand whether it is advantageous to include concomitant drugs in an MGPS analysis. Because logistic regression analysis is specifically designed to assess the results of polytherapy, Oracle advises always using a data configuration that includes concomitant drugs in logistic regressions.

3. What are the advantages and disadvantages of fully breaking apart combination drugs into their component ingredients for purposes of data mining?

An advantage is that the number of unique drugs in the database becomes much smaller, and the counts of each unique ingredient are higher. It is also easier to implement drug classification.

A disadvantage is that ingredients are equally weighted no matter whether they were part of combination drugs or not.

Combining reports in a single data mining analysis

1. Is it acceptable to combine foreign and domestic reports in a single data mining run?

Yes. For example, although there is only a small proportion of foreign reports (12%) in the FOI FDA AERS+SRS data, WHO data contains approximately 50% cases reported in the US and 50% with foreign sources. It is possible to specify that report source (US/non-US) be used as an additional stratification variable, which may help protect from biases due to differential reporting rates in US and non-US reports.

2. Is it acceptable to combine health professional and consumer reports in a single data mining analysis?

It can be interesting to compare the two to see whether there is a significant difference. It is not clear that consumer reports are more likely to give false positives or negatives than

health professional reports, given that the application examines disproportional reporting as opposed to absolute numbers.

Subsetting by the report source or occupation code of the reporter allows comparison of values calculated for reports by consumers to those reported by health care professionals. Also, you can use stratification on these variables to eliminate the possibility of confounding based on report source.

3. Is it acceptable to combine serious and non-serious adverse events in a single data mining analysis? What if some drugs have non-serious reports entered into the database and others you are interested in, for purposes of comparing signal scores, do not?

Yes. Although databases such as AERS contain mostly serious events, including large numbers of non-serious events probably improves the performance of the system. Some analyses have shown that the ratios of non-serious event reports are a reasonable surrogate for the exposure ratios. If, for some reason, non-serious reports have been suppressed to a much greater degree for some drugs than for others, the result would be to bias comparisons of alerting scores across the two sets of drugs.

Data issues

1. What is the meaning of a drug showing a positive alerting score with a particular event sometimes being confounded by polytherapy?

If a drug is typically co-prescribed with another drug that causes a particular event, then the first drug is statistically associated with the event as well.

2. What is the impact of cloaking, where a very strong association with one drug masks your ability to see a moderately strong association with another drug?

If a drug has a very strong association with a given event, this may mean that it accounts for a relatively large proportion of the reports for that event in the database. This would tend to raise the expected value for this event for all drugs and, thus, mask the signal (lower observed / expected) for another drug.

3. If a potential signal of interest may be spread across multiple MedDRA Primary Terms (different reporters may choose to use slightly different terminology to describe essentially the same effect), will this reduce the ability to see the signal of interest?

Yes, this is possible, although significant associations for several of the possible PTs are a good indication of something real. If you suspect that this spreading is happening, then it is possible in the Oracle Empirica Signal application to map the suspect PTs into a new pseudo PT, called a custom term, to look at the combined score. Alternatively, data mining analysis can be based on MedDRA HLT or HLGT, rather than PT.

4. MGPS essentially compares the safety profile (relative frequency of different AEs) of each drug against a background comparator of all drugs. Would it be better to choose a more narrowly defined background? For example, to understand the profile of Cerivastatin, why not limit the background to all other statins?

Given that noise is a surrogate for exposure, the bigger the denominator, the better. Oracle performed an experiment to look into this; the results showed more noise with smaller databases. To compare a drug against others in its class to see differences, look at the EB05 scores for each of the drugs run against the entire background. Looking at a drug against its own class also means that it is unlikely that you would find a previously unknown class effect.

5. Are data mining results skewed by publicity effects?

This can occur, and it is one of the possible causes to consider when doing case evaluation of the potential signals.

Comparing EBGM values

1. **When comparing different EBGM values, if a given drug D has an EBGM signal score of 4.0 for event E1 and 8.0 for event E2, is it correct to say that the risk of E2 appears to be twice as high?**

No. At most, you could say (if the confidence interval was very narrow) that the drug had 4 times as many reports for E1 as expected and 8 times as many reports for E2 as expected. To estimate risks you have to know about reporting rates and exposure rates, neither of which are estimable from spontaneous reporting data alone.

2. **What about comparing EBGM values across two drugs? Suppose, for event E, drug D1 has an EBGM score of 10 and drug D2 has an EBGM score of 20. Is the risk of the event twice as high with drug D2 as with drug D1?**

Confidence intervals can be used for comparisons, provided they do not overlap. In this example, the interpretation is that the association between D2 and the event is twice as high as the association between D1 and the event. But associations can differ for reasons unrelated to causation.

3. **What do EBGM scores < 1 signify?**

A score of EBGM < 1 indicates that the product-event combination is occurring less frequently than expected statistically. If EBGM were < 1 and N were high, this might indicate a possible therapeutic effect.

5

Retrieve and review data mining results

- [About data mining run results](#)
Each data mining run produces a set of results that you can review in tabular or graphical format.
- [Load the run and select variables](#)
To view data mining results, you specify criteria such as the drugs and events to include in the table or graph of results on the Select Criteria page.
- [Look up drug names](#)
Oracle Empirica Signal provides an easy way for you to find the generic drug name associated with a trade name that you provide, or the trade name associated with the generic name that you provide.
- [View results tables](#)
- [View results graphs](#)

About data mining run results

Each data mining run produces a set of results that you can review in tabular or graphical format.

[Data mining run](#) results are the scores that indicate the strength of the association between the variables, such as drug and event, included in the run.

You view results on the Data Mining Results page after selecting results criteria (for example, drugs or events of interest). You can view the results of runs that you have created or that are published to you. If you have the Administer Users permission, you can also view the results of any run, published or unpublished, created by any user in your login group.

When reviewing results, you can [drill down](#) on counts to view case details if you have appropriate permissions.

Load the run and select variables

To view data mining results, you specify criteria such as the drugs and events to include in the table or graph of results on the Select Criteria page.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Results**.
2. On the **Select Criteria** page, choose the run from the **Run name** drop-down list. Your **Default Run** [user preference](#) determines which run is selected by default.
 - To view all available runs, click **Browse**.
 - To see the details of the run, click **View Run Details**, examine the details, then click **Close**.
3. Depending on the run you load, the available variables will differ. To specify item variable values, use one or more of the following options:

- If a variable has an associated hierarchy of terms and your [user preference](#) enables use of the hierarchy, you can click **Select <hierarchy-name> Terms** and [select terms from the hierarchy](#). Custom terms used in the run are not in the hierarchy.
- If the run option to store the primary paths of terms in run results was used, you can search for terms at various levels of the hierarchy. Click the radio button for the level at which you want to search. If you select terms at a higher level than the level of the term used in the run, you see results only for terms that have that higher level in their primary path.
- To [select values from a list](#), click **Select Available Values**. The available values include custom terms used in the run.
- To use a [saved list](#) of terms, click **Select Saved List**. A saved list can include custom terms.
- To type the terms, review the rules in [Typing values in text boxes](#).
- To [look up a drug name](#), click **Trade/Generic Lookup**. You can find the generic name for a drug (if you only know its trade name) or vice versa. (This link is available only if the mapping of trade/generic names has been defined as part of preparing source data.)

Note

To prevent spelling and capitalization errors, we recommend that you select rather than type values. Drugs or events that have a missing (null) value in the source data have the value of the [user preference](#), **Replace missing value with**, that was in effect for the user who created the run. (Your own user preference does not affect run results generated by another user.)

4. To include only scores that exceed a minimum threshold value, use the **Limit to** field to select a statistic and supply that minimum number. For a description of the statistics that you can use to limit results, see [Data mining results for MGPS runs](#) or [Data mining results for logistic regression runs](#).

For example, to review only MGPS run results with an EB05 score greater than 2, select EB05 and supply 2. Oracle Empirica Signal uses the setting as the default (for results that you have not yet viewed) until you change it.

- If you provide a limit for an MGPS run and then view a graph, the application applies the limit to the highest dimension in the graph only. For a sector map graph, the limit is ignored.
 - When you view one-dimensional run results for an MGPS run, the application ignores this limit unless you specify a limit for the N statistic.
 - This limit does not apply to sector map graphs or to the tables of covariate and interaction results for a logistic regression run.
 - To supply defaults for this statistic and value the first time you look at results for a run, you can set the [user preference](#), **Display Only Results with <score-type> Scores Over <number>**. If you select a statistic other than N, a default of LROR > 0 is used for logistic regression runs.
5. To select additional criteria, click **Show Advanced**. This link is available if additional fields can be used to limit the results to display. (If you do not generally use these fields you can click **Hide Advanced**.)
 - a. For an **MGPS run In the Dimension** field, select a [dimension](#) to limit the results that appear. You can select 1, up to the highest dimension included in the run, or All to

display results for all of the dimensions included in the run. By default, the dimension is the highest dimension that was selected when the data mining run was created. You can change the dimension to less than the default. The number of Pattern fields that appear depends on the number in the Dimension field.

- b. The **Subset** field appears if the run used [subsetting](#) and at least two subset categories were specified for the run. Select the subset for which you want to view results, or select All to display results for all subsets.
 - c. In the **Pattern** fields, specify a pattern such as Drug+Event. See [Dimensions and patterns](#).
 - d. If your [user preference](#), **Include SQL WHERE Clause for Advanced Results Selection**, is checked, you can [specify a SQL WHERE clause](#) to restrict which run results you view. You can reference any of the columns that can be displayed in the results table, regardless of whether they are currently included in the display. To view the complete list of columns, click the Columns link above the results table. The SQL WHERE clause entered here is ignored if you view a table of covariates or interactions for a logistic regression run, or when you view a sector map graph.
6. If you want to remove your selections from the fields on this page, click **Clear All**.
 7. Click **View Results Table** to view a results table or click **Choose Graph** to [choose a graph type](#) to display. To view a graph, you must specify at least one drug or one event. For MGPS runs, you can view results graphically for two-, or three- dimensional drug-event combinations.

Note

When you view results for a logistic regression run, all criteria defined on this page are used to select the combinations that appear in the results table. However, only the drug and event values specified, if any, are used to define the results that appear in the Covariates Table and Interactions Table.

Look up drug names

Oracle Empirica Signal provides an easy way for you to find the generic drug name associated with a trade name that you provide, or the trade name associated with the generic name that you provide.

This feature is available only if the mapping of trade and generic names has been defined as part of preparing source data for use in the application.

1. In the left navigation pane, hover on the **Data Analysis** icon , then click **Data Mining Results**.
2. On the **Select Criteria** page, click **Trade/Generic Lookup**.
3. In the **Search String** field, type a drug name. You can use the % sign as a wildcard character to match zero or more characters in that position. This field is not case-sensitive; for example, if you enter F%IC ACID, both Folinic acid and Folic acid match even though they use mixed case.
4. Click **Search**.

The first 100 drug names (in either the GENERIC_NAME or TRADE_NAME column) that start with, end with, or include the text string are listed.

5. To sort the results by generic or trade name, click the column name.

6. To dismiss the dialog box, click **Cancel**.

View results tables

- [View a data mining results table](#)
The results of the statistical computations performed for each combination identified during the data mining run are shown in columns of the Data Mining Results table.
- [Data mining results for MGPS runs](#)
The following sections describe the results of MGPS runs.
- [Data mining results for logistic regression runs](#)
The following columns are available for inclusion in the results table for a logistic regression run.
- [Find and select a data mining run](#)
You can use various run characteristics to easily locate a run.
- [Precision of displayed values in data mining results](#)
This topic covers the precision with which various computed numeric columns in the data mining results table appear.
- [Create a case series from a results table](#)
You can create a case series from a results table.

View a data mining results table

The results of the statistical computations performed for each combination identified during the data mining run are shown in columns of the Data Mining Results table.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Results**.
2. On the **Select Criteria** page, choose the run from the **Run name** drop-down list. Your **Default Run** [user preference](#) determines which run is selected by default.
 - To view all available runs, click **Browse**.
 - To see the details of the run, click **View Run Details**, examine the details, then click **Close**.
3. Specify the selection criteria by completing steps 3 through 5 on [Load the run and select variables](#).
4. Click **View Results Table**.

One row appears in the table for each combination identified during data mining.

The results of the statistical computations performed for the combination are shown in columns of the table. The data displayed differs for [MGPS runs](#) and [logistic regression runs](#).

5. Perform additional activities on the results table.
 - To display a description of the column, rest the cursor on any column heading.
 - To drill down to a listing of cases for a row, either click the **Header Action** menu () or click the link in the **N** column and then click **View Cases**.
 - To change your selection criteria and view a different set of results, click **Select Criteria**. Follow steps 3 through 5 described in [Load the run and select variables](#).

- To view a graphical representation of the results, click **Choose Graph** and [choose a graph type](#). You can view data mining run results graphically for logistic regression runs and for two- or three-dimensional drug-event combinations in MGPS runs.
- To [create a case series](#) containing all cases for which there are rows in the displayed table, click **Add to Case Series**. This option is available when the results table contains 20 or fewer rows.
- To show information about the data mining run, click **Show Notes**. The notes appear below the results table, and are included if you print or download table data. Click **Hide Notes** to remove the notes.
- To view scores calculated for covariate(s) (if defined for a logistic regression run), click **View Covariates**. A table of covariate results appears in a separate window. See [Data mining results for logistic regression runs](#).

Note

Only the drug and event values specified as data mining results criteria are used to define the results that appear in the Covariates Table. Other criteria, such as a Limit to value, do not apply to this table.

- To view interaction scores, click **View Interactions**. A table of interaction scores appears in a separate window. Interaction scores are calculated for logistic regression runs, or MGPS runs that include RGPS computations, if you enabled interaction computations when you created the runs. See [Data mining results for logistic regression runs](#) or [Data mining results for MGPS runs](#).

Note

Only the drug and event values specified as data mining results criteria are used to define the results that appear in the Interactions Table. Other criteria, such as a Limit to value, do not apply to this table.

- To [save the results as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).
- To print the table, click **Print**, view the print preview, specify the print options and setting, then click **Print**.
- To [download the table](#), click **Download**, specify the download parameters, and click **OK**.

Data mining results for MGPS runs

The following sections describe the results of MGPS runs.

Note

Hover over a column heading to display a description of the column.

Results table

Column	Description
<variable-name>	Each variable on which data mining was performed. Typically, there is a drug variable and an event variable. If the run used drug or event hierarchies, Oracle Empirica Signal adds a column for each hierarchy level above the term for which data mining was performed to the results table. The primary path in the hierarchy is represented in these columns. For example, if the event variable is PT, the results include HLT, HLGT, and SOC columns showing the primary path of the PT. When you display results for more than two dimensions, the application identifies columns for variables of the same type by adding a numeric suffix to the column name. For example, when you display results for the pattern D+E+E, you see: PT1 HLT1 HLGT1 SOC1 PT2 HLT2 HLGT2 SOC2

Note

For runs with three dimensions, these columns cannot be used to sort the results table. The actual column names in the underlying table are not the same as the labels for fields on the Select Criteria page or as column headers in the results table. The actual column names are ITEM1, ITEM2, and so on.

DIM

Dimension. The number of items combined.

Column	Description
E	The expected number of cases with the combination. For a 2-dimensional (2D) run, computed as: $(\text{Observed \# cases with ITEM1} / \text{Total \# cases}) \times (\text{Observed \# cases with ITEM2} / \text{Total \# cases}) \times \text{Total \# cases}$ For a stratified MGPS run, calculated as total of expected values for all the strata, where the expected number of cases for each stratum is computed as: $(\text{Observed \# cases with ITEM1 for stratum} / \text{Total \# cases for stratum}) \times (\text{Observed \# cases with ITEM2 for stratum} / \text{Total \# cases for stratum}) \times \text{Total \# cases for stratum}$ Overall Expected = Total of Expected values for all strata When $E < .001$, displays in scientific notation. For a 3-dimensional (3D) MGPS run, the calculations include ITEM3. For 3D runs, the calculation of E depends on the mix of item types in the set of items. If the set of items includes at least two different types and also includes at least two items of the same type (such as D+D+E), then E is the result of MGPS interaction calculations. In this model, E incorporates observed within-item-type associations, and uses only the assumption of cross-item-type independence in the computation of E.
EB05	There is approximately a 5% probability that the true Relative Ratio lies below this value.
EB95	There is approximately a 5% probability that the true Relative Ratio lies above this value. The interval from EB05 to EB95 is the 90% confidence interval.
EBGM	Empirical Bayesian Geometric Mean. A more stable estimate than RR. This so-called shrinkage estimate is computed as the geometric mean of the posterior distribution of the true Relative Ratio.
EBMAX	Applies to runs with more than 2 dimensions. For each 3D itemset, EBMAX is the largest 2D EBGM among all included cross-item-type 2D combinations. If the itemset is homogeneous, so that there are no included cross-item-type combinations, EBMAX is the largest EBGM among all the included 2D combinations. The 2D combination for which EBGM = EBMAX is specified by the columns MAXITEM1 and MAXITEM2.
ERAM	For runs that include RGPS computations , the Empirical-Bayes Regression-adjusted Arithmetic Mean. This estimate is computed as the shrunken observed-to-expected reporting ratio adjusted for covariates and concomitant drugs.

Column	Description
ER05	There is approximately a 5% probability that the ERAM lies below this value. The interval from ER05 to ER95 is the 90% confidence interval.
ER95	There is approximately a 5% probability that the ERAM lies above this value. The interval from ER05 to ER95 is the 90% confidence interval.
EXCESS	A conservative estimate of how many extra cases were observed above what was expected. Computed as: $(EB05 - 1) \times E$
EXCESS2	Applies only to runs with more than 2 dimensions. A conservative estimate of how many extra cases were observed over what was expected assuming that only a single cross-item interaction is present. Computed as: $E \times EB95MAX \times (INTSS - 1) = E \times (EB05 - EB95MAX)$ where EB95MAX is the largest 2D EB95 among all included cross-item-type combinations.
F	Applies only to runs created by Oracle, with the advanced parameter, Do comparative analysis , selected.
IC	For runs that include Information Component computations , the IC value: $IC = \log 2 ((O + \alpha_1) / (E + \alpha_2))$ where: $\alpha_1 = \alpha_2 = 1/2$ - O is the observed count. - E is the expected count.
IC025	There is approximately a 2.5% probability that the IC lies below this value. The interval from IC025 to IC975 is the 95% confidence interval.
IC975	There is approximately a 2.5% probability that the IC lies above this value. The interval from IC025 to IC975 is the 95% confidence interval.
ID	Identifies the unique row number assigned as Oracle loads data from the run's output files.
INTSS	Interaction Signal Score. Applies only to 3D runs. Essentially, this is a way of measuring of the strength of a higher-order association above and beyond what would be expected from any of the component pairs of items of different types. Computed as: $EB05 / EB95MAX$ where EB95MAX is the largest 2D EB95 among component pairs of items of different types.

Column	Description
JOB_ID	The identifier assigned by the listener to the sub-job in the run.
MAXITEM1	First item determining the 2D combination for which EBGM = EBMAX.
MAXITEM1P	Prefix, if any, assigned to the variable MAXITEM1.
MAXITEM2	Second item determining the 2D combination for which EBGM = EBMAX.
MAXITEM2P	Prefix, if any, assigned to the variable MAXITEM2.
N	Observed number of cases with the combination of items. You can click the value of N to display a menu from which you can drill down to view or download case information or run reports. (The same options are available when you click the Row  for the row.)
P_ <variable-name>	Prefix, if any, assigned to the variable in the data configuration on which the run is based. The alphabetical ordering of prefixes determines which of the underlying ITEM column names is used for each of the item variables in the results table. For example, if the prefix for the drug variable is D and the prefix for the event variable is E, values for the drug variable appear in the ITEM1 column and values for the event variable in the ITEM2 column.
P_VALUE	For runs that include the calculation of PRR, the probability that chi-square is as large as or larger than the value in the PRR_CHISQ column by chance alone if there is no causal relationship or consistent association between the drug and the event. Small values display in scientific notation.
PRR	For runs that include the calculation of PRR, the Proportional Reporting Ratio for the combination of a particular drug and particular event.
PRR_A	For runs that include the calculation of PRR, the observed count for the combination of a particular drug and particular event. This can be the number of combinations or number of cases, depending on the PRR options used in the run.
PRR_B	For runs that include the calculation of PRR, the observed count for the combination of a particular event and all other drugs. This can be the number of combinations or number of cases, depending on the PRR options used in the run.
PRR_C	For runs that include the calculation of PRR, the observed count for the combination of a particular drug and all other events. This can be the number of combinations or number of cases, depending on the PRR options used in the run.
PRR_D	For runs that include the calculation of PRR, the observed count for the combination of all other drugs and all other events. This can be the number of combinations or number of cases, depending on the PRR options used in the run.

Column	Description
PRR_CHISQ	For runs that include the calculation of PRR, the chi-square of PRR. For more information, see PRR computations .
Q	Intermediate computation in the calculation of EBGM. Defined as the posterior probability that the combination is in component 1 of the mixture prior distribution estimated by the Empirical Bayes algorithm.
ROR05	For runs that include the calculation of ROR, the lower 5% confidence limit for ROR.
ROR95	For runs that include the calculation of ROR, the upper 5% confidence limit for ROR. The interval from ROR05 to ROR95 is the 90% confidence interval.
ROR	For runs that include the calculation of ROR, the Reporting Odds Ratio. Computed as: $\text{ROR} = (\text{PRR\_A} * \text{PRR\_D}) / (\text{PRR\_B} * \text{PRR\_C})$ With stratification, ROR is computed as a weighted average of the ROR within each stratum. For more information, see ROR computations .
ROW_NUM	Identifies the row number assigned in one of the output files. The value in this column may not be unique in the results table for a given run.
RR	Relative Ratio. (The same as N/E.) Observed number of cases with the combination divided by the expected number of cases with the combination. This is a sampling estimate of the true Relative Ratio (that would be observed if the database were much larger, but drawn from the same conceptual population of reports) for the particular combination of drug and event. RR is computed as: $\frac{\text{Observed \# cases with ITEM1+ITEM2 pair}}{\text{Expected \# cases with ITEM1+ITEM2 pair}}$ For a stratified MGPS run, RR is computed as: $\frac{\text{Observed \# cases with ITEM1+ITEM2 pair for all strata}}{\text{Final Expected \# cases with ITEM1+ITEM2 pair}}$ For a 3D MGPS run, the computations include ITEM3.
SUBSET	If an MGPS run includes a <i>subset variable</i> to categorize (subset) results, displays the label for the subset that applies to each combination.

Data in the following columns (ending in _IND) are computed using the [MGPS independence model](#) and are provided to support runs completed in versions of the Oracle Empirica Signal application prior to version 5.0:

Column	Description
E_IND	The expected number of cases with the combination, as calculated by the MGPS independence model. Computed as: $(\text{Observed \# cases with ITEM1} / \text{Total \# cases}) \times (\text{Observed \# cases with ITEM2} / \text{Total \# cases}) \times \text{Total \# cases}$ For a stratified MGPS run, calculated as total of expected values for all the strata, where the expected number of cases for each stratum is computed as: $(\text{Observed \# cases with ITEM1 for stratum} / \text{Total \# cases for stratum}) \times (\text{Observed \# cases with ITEM2 for stratum} / \text{Total \# cases for stratum}) \times \text{Total \# cases for stratum}$ Overall Expected = Total of Expected values for all strata When E_IND < .001, displays in scientific notation. For a 3D MGPS run, the calculations include ITEM3.
E2D_DIV_E_IND	Ratio computed as: E2D_IND/E_IND
E2D_DIV_F_IND	Ratio computed as: E2D_IND/F
E2D_IND	The expected count based on the all-2-factor log linear model.
EB05_IND	A value such that there is approximately a 5% probability that the true Relative Ratio lies below it, where Relative Ratio is defined by the MGPS independence model.
EB95_IND	A value such that there is approximately a 5% probability that the true Relative Ratio lies above it, where Relative Ratio is defined by the MGPS independence model. The interval from EB05_IND to EB95_IND may be considered to be the 90% confidence interval.
EBGM_IND	Empirical Bayesian Geometric Mean, as computed by the MGPS independence model. A more stable estimate than RR; the so-called shrinkage estimate.
EBGMDIF_IND	Applies to 3D runs. Essentially, this is a way of measuring of the strength of a higher-order association above and beyond what would be expected from previously computed component two-factor associations. Computed by the MGPS independence model as: $\text{EBGM\_IND} - \text{E2D\_IND} / \text{E\_IND}$
EXCESS_IND	A conservative estimate of how many extra cases were observed above what was expected. Computed by the MGPS independence model as: $(\text{EB05\_IND} - 1) \times \text{E\_IND}$

Column	Description
EXCESS2_IND	Applies to 3D runs. An estimate of how many extra cases were observed over what was expected using the all-2-factor model. Computed by the MGPS independence model as: $(EBGM\_IND \times E\_IND) E2D\_IND$ where E2D_IND is the expected count based on the all-2-factor log linear model.
RR_IND	Relative Ratio computed by the MGPS independence model. (The same as N/E_IND.) Observed number of cases with the combination divided by the expected number of cases with the combination. This may be viewed as a sampling estimate of the true value of observed/expected for the particular combination of drug and event. RR is computed as: $\frac{\text{Observed \# cases with ITEM+-ITEM2 pair}}{\text{Expected \# cases with ITEM1+ITEM2 pair}}$ For a stratified MGPS run, RR is computed as: $\frac{\text{Observed \# cases with ITEM1+ITEM2 pair for all strata}}{\text{Final Expected \# cases with ITEM1-ITEM2 pair}}$ For a 3D MGPS run, the computations include ITEM3.

Interactions table

Note

Interaction estimates are calculated for a pair of drugs only if for both drugs the number of drug+event reports exceeds the minimum interaction count for the run.

Only drugs and events that you select as [criteria](#) appear in the table of interaction results.

To include only interaction scores that exceed a minimum threshold in the table:

1. In the View Interactions pop-up window, click **Columns and Rows**.
2. In the **Limit to** field, select a statistic and type a minimum value for the statistic.

By default, this limit is set to $N12 > 0.0$.

Note

To include reports in which Item1 and Item2 did *not* occur with the Event, you can set the limit to a negative number such as -1.0.

If you enable the **Include SQL WHERE Clause for Advanced Results Selection** user preference, you can [specify a SQL WHERE clause](#) to limit the results.

Column	Description
Item1	Value of the first predictor in the interaction, for example, Influenza Vaccine.
Item2	Value of the second predictor in the interaction, for example, Anthrax Vaccine.
Event	Response associated with the interaction, for example, Back Pain.
ERAM1	RGPS logistic regression odds ratio for Item1. This value is an exponential function of the logistic regression coefficient.
ERAM2	RGPS logistic regression odds ratio for Item1. This value is an exponential function of the logistic regression coefficient.
NREPORTS12	Observed number of cases reporting Item1 and Item2.
N12	Observed number of cases reporting Item1, Item2, and Event.
E12	Expected value of N12 under the null hypothesis that both Item1 and Item2 have no relative ratio reporting effect. This value is adjusted for covariates and concomitant drugs using the RGPS prediction formula. When $E < .001$, the value displays in scientific notation.
INTRR	Ratio of observed (N12) to expected (E12) reports adjusted for the larger of the disproportionality scores for Item1 and Item2: $N12/(E12 * \max(ERAM1, ERAM2))$
INTEB	Signal score that indicates the strength of the interaction between Item1 and Item2. This value is a shrunken INTRR value.
INT05	Lower 5% confidence limit for INTEB.
INT95	Upper 95% confidence limit for INTEB.

Data mining results for logistic regression runs

The following columns are available for inclusion in the results table for a logistic regression run.

By default, a limited set of columns is included in each of these tables. To include more columns in the results table, click **Columns** above the table and, optionally, check **Show All Columns**.

Note

Hover over a column heading to display a description of the column.

Results Table

The following columns are available for inclusion in the results table for a logistic regression run. For information on the columns available for an MGPS run, see [Data mining results for MGPS runs](#) or [Logistic regression computations](#).

Column	Description
<predictor variable>	Logistic regression runs include a drug variable (the predictor) and an event variable (the response). The results table includes a column with the name of each variable selected for the run; for example, Single Ingredient and PT.
<response variable>	Logistic regression runs can also include covariate variables as predictors. If the run includes covariates, click View Covariates to review results for each covariate-event pair.
N	Observed number of cases with the combination of items. You can click the value of N to display a menu from which you can drill down to view or download case information or run reports.
 Note On the Covariates table, the value of N is not hyperlinked.	
E	The expected number of cases with the combination, computed as: $\frac{(\text{Observed \# cases with predictor} / \text{Total \# cases}) \times (\text{Observed \# cases with response} / \text{Total \# cases})}{\text{Total \# cases}}$ When $E < .001$, displays in scientific notation.
RR	Relative Ratio. Observed number of cases with the combination divided by the expected number of cases with the combination. (The same as N/E.) This is a sampling estimate of the true Relative Ratio (that would be observed if the database were much larger, but drawn from the same conceptual population of reports) for the particular combination of predictor and response and ignoring the LR adjustments for covariates and other drugs.
LROR	Logistic Regression Odds Ratio. Estimated odds ratio relating occurrence of response to occurrence of predictor, adjusting for other predictors.
LR05	Lower 5% confidence limit for the logistic regression odds ratio.
LR95	Upper 95% confidence limit for the logistic regression odds ratio.
	The interval from LR05 to LR95 is the 90% confidence interval.
JOB_ID	The identifier assigned by the listener to the sub-job in the run.
ID	Identifies the unique row number assigned as Oracle loads data from the run's output files.

Column	Description
ROW_NUM	Identifies the row number assigned in one of the run's output files. The value in this column does not have to be unique in the results table for a given run.

Covariates Table

For logistic regression runs that include computations for covariates, such as gender, age group, or report receipt year, you can view a results table for each covariate-event combination. The rows in this table reflect the scores calculated for each event and each possible value for the covariates of the run, with the exception of the value that occurs most frequently. (The value that occurs most frequently for each covariate is used as the standard for the odds ratio calculated for each of the other values.) For example, if you use Seriousness as a covariate and Seriousness has the unique values YES and NO, with NO occurring most frequently, this table only includes rows for YES in combination with each event.

Note

Only the event values specified as [results criteria](#) apply to the table of covariate results.

In addition to the columns shown in the results table, the following additional columns are available in the table of covariate results:

Column	Description
P_ITEM	The name of the selected covariate variable, such as Gender or Seriousness.
ITEM	The value of the covariate, such as M, F, or U for a covariate of Gender, or YES or NO for a covariate of Seriousness.

Interactions Table

For logistic regression runs that include the computation of interactions, you can view a results table of scores calculated for each predictor+predictor+response (drug+drug+event, drug+covariate+event, or covariate+covariate+event).

Only the drug(s) and event(s) that you selected as [criteria](#) are included in the table of interaction results. To include only scores that exceed a minimum threshold value in this table, click the Columns and Rows link above the table and use the Limit to field to select a statistic and supply that minimum number. By default, this limit is set to N > 0.0: to include rows in this table for reports in which the Item1 value and Item2 value did *not* occur with the event value, you must change this limit to a negative number such as N > -1.0.

If your [user preference](#), **Include SQL WHERE Clause for Advanced Results Selection**, is checked, you can also specify a SQL WHERE clause. For example, to view only rows that have a certain drug name as a value for either the first or second predictor, enter a SQL WHERE clause of ITEM1='<drug name>' OR ITEM2='<drug name>'.

The following columns are available in the table of interaction results:

Column	Description
P_ITEM1	For the value that appears in the ITEM1 column, either provides the name of the covariate variable or the configuration prefix for drug (D).
ITEM1	The value of the first predictor in the interaction. This value can be a covariate (if the run included one or more covariates) or a drug.
P_ITEM2	For the value that appears in the ITEM2 column, provides the configuration prefix for drug (D) or the name of the covariate variable.
ITEM2	The value of the second predictor in the interaction. This value can be a drug or a covariate (if the run included multiple covariates).
<response variable name>	Event (response) variable selected for the run, such as PT.
N	Observed number of cases with the combination of all three values (ITEM1, ITEM2, response). You can click the value of N to display a menu from which you can drill down to view or download case information or run reports.
N_TOT	Observed number of cases in the data that have both ITEM1 and ITEM2. To specify a SQL WHERE clause that includes this column, use the underlying column name of INTSS.
E	The predicted value of N based on LR without interactions: the sum, over all N_TOT reports that have both ITEM1 and ITEM2, of the predicted probability of the response using the LR prediction formula. When $E < .001$, the value displays in scientific notation.
INT_LOF	Empirical Bayes shrinkage estimate of additional interaction due to lack of fit to the LR model, based on the ratio N/E. To specify a SQL WHERE clause that includes this column, use the underlying column name of EXCESS2.
INT_REGR	Predicted ratio of probability of the response given both ITEMS, divided by probability given worst ITEM, if LR model is correct. To specify a SQL WHERE clause that includes this column, use the underlying column name of EXCESS.
INT_TOT	Total interaction, computed as $INT\_REGR * INT\_LOF$. To specify a SQL WHERE clause that includes this column, use the underlying column name of LROR.
INT05	Lower 5% confidence limit for INT_TOT. To specify a SQL WHERE clause that includes this column, use the underlying column name of LR05.
INT95	Upper 95% confidence limit for INT_TOT. To specify a SQL WHERE clause that includes this column, use the underlying column name of LR95.
LROR1	Logistic regression odds ratio relating the response event to ITEM1. To specify a SQL WHERE clause that includes this column, use the underlying column name of PRR_A.

Column	Description
LROR2	Logistic regression odds ratio relating the response event to ITEM2. To specify a SQL WHERE clause that includes this column, use the underlying column name of PRR_B.
JOB_ID	The identifier assigned by the listener to the sub-job in the run.
ID	Identifies the unique row number assigned as Oracle loads data from the output files of the run.
ROW_NUM	Identifies the row number assigned in one of the output files of the run. The value in this column may not be unique in the results table for a given run.

Find and select a data mining run

You can use various run characteristics to easily locate a run.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Results**.
2. On the **Select Criteria** page, choose the run from the **Run name** drop-down list. Your **Default Run** [user preference](#) determines which run is selected by default.
3. On the **Select Criteria** page, click **Browse**.
4. From the drop-down lists in the **1. Choose Characteristics** section, specify the characteristics of the runs to select. Select -- to include all runs.

Run Characteristic	Description
Database Group	Database group containing the data configuration that was used for the run.
Data As Of	Run As Of date. If blank, the run is not for timestamped data and has no As Of date.
Event Variable	Event variable used by the run.
Drug Variable	Drug variable used by the run.
Concomitant Drugs	Select Exclude for runs based on a data configuration that is set up to exclude concomitant drugs. Select Include for runs based on a data configuration that is set up to include concomitant drugs, such as an AERS (S + C) configuration.
Dimension	For an MGPS run, the highest dimension specified for the run when the run was created. For an LR run, select 2 for runs that did not compute interactions and 3 for runs that did compute interactions.
DB Restriction	If a database restriction was used for the run, select Yes. If no database restriction was used for the run, select No.
Subset Variable	Subset variable used for the MGPS run. A run can have only one subset variable. If blank, no subset variable was used for the run.

Run Characteristic	Description
Subset Type	If cumulative subsetting was used for the MGPS run, select Cumulative. If non-cumulative (discrete) subsetting was used for the run, select Non-cumulative. If no subsetting was used for the run, the drop-down list is blank.
Strata Variables	Stratification variable used for the MGPS run. The same run can have multiple stratification variables. If blank, no stratification variable was used for the run.
Min Count	For an MGPS run, the minimum count specified for the run. For an LR run, the minimum number of times a drug must occur in combination with a specified event to be included in the run.
Configuration	Name of the data configuration used for the run.
Project	Name of the project for which the run was created.
Run Type	MGPS for an MGPS run; LR for a logistic regression run.

For example, to work with an MGPS run that uses Gender for stratification, choose MGPS as the run type and Gender as the stratification variable. Only runs that have both those characteristics appear in the table.

Note

If there are no existing runs with a certain characteristic, you cannot choose that characteristic. For example, if there are no logistic regression runs, LR is not available for Run Type.

5. In the **2. Select Run** section:

- To [view a description of a run](#), click the **Header Action menu** (), and then click **View Run Details**.

- To choose a run, click the **Header Action menu** (), and then click **Select**.

6. Click **Reset** if you want to reset all criteria to -- (All).

- #### 7. To change the way columns display in this table, or for information on finding text, printing, or downloading, see [About tables](#).

Precision of displayed values in data mining results

This topic covers the precision with which various computed numeric columns in the data mining results table appear.

There are three types of computed numeric columns to consider: relative reporting ratio measures, expected values, and probability values.

Note

The full precision of numeric values is present in the underlying database.

Relative reporting ratio measures

- Numeric values with an absolute value > 10 have one digit to the right of the decimal point.
- Numeric values between 1 and 10 have two digits to the right of the decimal point.
- Numeric values less than 1 appear as 0.xxx with three digits after the decimal.
- Scientific notation is not used.
- MGPS columns of this type: EB05, EB95, EBGM, ER05, ER95, ERAM, INTSS, PRR, ROR05, ROR95, ROR, RR, EBMAX, RR_IND, EB05_IND, EB95_IND, EBGM_IND, EBGMDF_IND, E2D_DIV_E_IND, E2D_DIV_F_IND.
- Logistic regression columns of this type: RR, LROR, LR05, LR95 in the tables for Results and Covariates, INT_REGR, INT_LOF, INT_TOT, INT05, INT95 in the Interactions table

Expected values

- Numeric values with an absolute value > 10 have one digit to the right of the decimal point.
- Numeric values between 1 and 10 have two digits to the right of the decimal point.
- Numeric values between .01 and 1 appear as 0.xxx with three digits after the decimal.
- Numeric values less than .01 are expressed as scientific notation with four significant figures.
- Columns of this type: E, F, EXCESS, EXCESS2, PRR_CHISQ, E_IND, EXCESS_IND, EXCESS2_IND, E2D_IND.

Probability values

- Numeric values between .001 and 1 are displayed as 0.xxxx with four digits after the decimal.
- Numeric values less than .001 are expressed as scientific notation with four significant figures.
- (In the event that a value is 1 or greater, it will display with two digits to the right of the decimal point.)
- Columns of this type: P_VALUE, Q.

Create a case series from a results table

You can create a case series from a results table.

If a results table has 20 or fewer rows, you can create a new case series containing the case IDs of cases represented. You can also add the case IDs to an existing case series that was created from results of the same data mining run.

If you create a case series from the results of a data mining run for [timestamped data](#), the case series has the same As Of date as the data mining run.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Results**.

2. On the **Select Criteria** page, choose the run from the **Run name** drop-down list. The default run you specified in your [user preference](#) determines which run is selected by default.
 - To view all available runs, click **Browse**.
 - To see the details of the run, click **View Run Details**, examine the details, then click **Close**.
3. Specify the selection criteria by completing steps 3 through 5 on [Load the run and select variables](#).
4. Click **View Results Table**.
5. On the [Results Table page](#), click **Add to Case Series**.
 - If there are more than 20 rows in the results table, an error message appears. Click **Continue** and change your selection criteria to restrict results to 20 or fewer rows.
 - If there are existing case series created from results of the same data mining run, the Add Cases from Selected Results page appears.
6. Choose one of the following:
 - Click **Select** for a case series. The cases are added to the selected case series.
 - If there are no existing case series created from result of the same run, you click **New Case Series**, and the Create Case Series page appears.
7. In the **Name** field, type a name for the case series. The name does not need to be unique, although we recommend that you use a unique name.

The name of the run appears by default in the **Description** field as the description of the case series. Edit the description as necessary.
8. Choose one of the following:
 - To add the case series to an existing project, click **Add to existing project** and select the project from the drop-down list.
 - To add the case series to a new project, click **Add to new project named** and type the name of the project.
9. Click **Create**.

View results graphs

- [View a data mining graph](#)
You can review a drug and its associations with other items (drugs or events). You can also review an event and its associations with other items (drugs or events).
- [Work with results graphs](#)
A number of options are available for reviewing a drug or an event and their associations with other items.
- [Set graph cutpoints and palette choices](#)
The graph cutpoints define the ranges of values associated with different colors in the graph. The graph palette is the spectrum of colors used for graphs based on the results of data mining runs (including charts on the Drug Profile page) during your current session.
- [Graphs for 2D results](#)
- [Graphs for 3D results](#)

View a data mining graph

You can review a drug and its associations with other items (drugs or events). You can also review an event and its associations with other items (drugs or events).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Results**.
2. On the **Select Criteria** page, choose the run from the **Run name** drop-down list. Your **Default Run** [user preference](#) determines which run is selected by default.
 - To view all available runs, click **Browse**.
 - To see the details of the run, click **View Run Details**, examine the details, then click **Close**.
3. Specify the selection criteria by completing steps 3 through 5 on [Load the run and select variables](#).

Specify at least one drug term or one event term. For graphs to be available, you can specify no more than 200 drug terms or 200 event terms.

- The limit of 200 is based on terms that are actually in the results.
 - The limit of 200 is the number of terms remaining after applying restrictions on the Select Criteria page. For example, if you specify 300 PTs and $EBGM > 5$, and there are fewer than 200 drug-event combinations for which $EBGM > 5$, graphs are available.
 - You can display a sector map only if you specify no more than 5 drugs (that are actually in the results). The limit of 5 applies regardless of restrictions on the Select Criteria page.
 - For MGPS runs, if you select the terms at a higher level in the hierarchy than the level at which data mining was performed (for example, you specify an HLG and data mining was performed on PTs), typically the run includes more than 200 PTs.
4. Click **Choose Graph**.
 5. From the **Associations selected for graphing**, select the graph to generate:
 - **Review a drug and its associations with other items (drugs or events)**—These graphs focus on a particular drug or drugs that you specified on the Select Criteria page. For example, suppose that you are interested in all the events associated with DrugA. You select DrugA on the Select Criteria page and then choose a graph to review results for the events associated with DrugA.
 - **Review an event and its associations with other items (drugs or events)**—These graphs focus on a particular event or events that you specified on the Select Criteria page. For example, suppose that you are interested in all the drugs associated with Event1. You select Event1 on the Select Criteria page and then choose a graph to review results for the drugs associated with Event1.

Note

If you are viewing results of a three-dimensional run and you specify 2 as the dimension (on the [Select Criteria page](#)), you can view graphs for the two-dimensional combinations in the results.

6. If you want to [modify the graph key](#) (for all graphs), click **Set Graph Cutpoint and Palette Choices**, make your choices, and click **Save** to return to the Choose Graph page.
7. Choose a graph type and click its link.
8. Specify graph display options and click **Display**. For information about setting display options, see the descriptions of each graph:
 - [Graphs for 2D results](#)
 - [Graphs for 3D results](#)
 - [Bar graphs](#)
 - [Confidence interval graphs](#)
 - [Nested confidence interval graphs](#)
 - [Discrete map graphs](#)
 - [Cumulative map graphs](#)
 - [Hierarchy graphs](#)
 - [Overlap graphs](#)
 - [Sector maps](#)

The graphs appear on the right side of the page or in a popup window.

Work with results graphs

A number of options are available for reviewing a drug or an event and their associations with other items.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Results**.
2. On the **Select Criteria** page, choose the run. Your **Default Run** [user preference](#) determines which run is selected by default.
3. To view all available runs, click **Browse**.
4. To see the details of the run, click **View Run Details**, examine the details, then click **Close**.
5. Specify the selection criteria by completing steps 3 through 5 on [Load the run and select variables](#).
6. Click **Choose Graph**.
7. From the **Associations selected for graphing**, select the graph to generate and select options from the list below.

Option	Check to
Popup	Display each graph in an individual window. If you have popup blocking software installed on your PC, it may prevent these windows from opening. You may want to disable your popup blocking software.
Key	Display a color key below the graph to show which value each graph element (such as a bar or region of the graph) represents. You can modify the graph key as needed.

Option	Check to
Notes	Display notes about the graph.
Links	Show the following: • For some graphs, information about what a graph component (such as a bar, cell, or region) represents, or statistics for the component, that appears when you point to that component. • A menu that allows you to drill down when you click a graph component. • Print link. • Save to Topic link (if Topics has been configured to offer this feature). • For some graphs, links to download graph data.

8. Click **Display**.

Set graph cutpoints and palette choices

The graph cutpoints define the ranges of values associated with different colors in the graph. The graph palette is the spectrum of colors used for graphs based on the results of data mining runs (including charts on the Drug Profile page) during your current session.

You can set a default palette as your [user preference](#), **Graph color palette**.

① Note

Neither cutpoints nor color settings have any effect on the sector map graph, graphs that are based on report data, or graphs on the Oracle Empirica Signal Review Products and Product-Event Combination pages.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Results**.
2. On the **Select Criteria** page, choose the run. Your **Default Run** [user preference](#) determines which run is selected by default.
 - To view all available runs, click **Browse**.
 - To see the details of the run, click **View Run Details**, examine the details, then click **Close**.
3. Specify the selection criteria by completing steps 3 through 5 on [Load the run and select variables](#).
4. Click **Choose Graph**.
5. Click **Set Graph Cutpoint and Palette Choices**.
6. To change the cutpoints or minimum/maximum limits for a particular score range, enter an integer or floating point number in each of the range fields for a score. For example enter -5, 0, 1, 5, 8, 97, and 3,043 in:
 - **EBGM**
 - **ERAM**
 - **PRR**

- **INTSS**

If you are unsure about the meaning of a score, see [Data mining results for MGPS runs](#) or [Data mining results for logistic regression runs](#).

7. To change the color palette, click one of the following radio buttons:

- **Bright**
- **Pastel**
- **Autumn**
- **Gray**

Your choices result in ranges with corresponding color gradations, as in the following example that uses the Autumn palette:

8. Click **Save**.

Changes to the cutpoints and palette take effect immediately and apply to all graphs for your current session. The next time you log in, the cutpoints are reset to defaults and the palette is reset according to your user preference **Graph color palette**.

Graphs for 2D results

- [Graphs for 2D results](#)
For two-dimensional results (for example, Drug+Event), the graph types are described in the following table. The graph types are available for MGPS runs. Some are available for logistic regression runs.
- [View a bar graph](#)
In addition to the restrictions you specified on the Select Criteria page, you can include additional restrictions and display options.
- [Bar graphs](#)
Bar graphs provide a straightforward way to display the items most closely associated with a specified drug or event, showing the strength of association by plotting each computed statistical score as the length of a horizontal bar.
- [View a confidence interval graph](#)
Confidence interval graphs are similar to bar graphs but also include a confidence interval or error bar superimposed on each bar to show the 5% and 95% confidence limits.
- [Confidence interval graphs](#)
A confidence interval graph is available for two-dimensional MGPS results and logistic regression results.
- [View a discrete map graph](#)
Discrete map graphs provide a way to compare strength of associations between specified drugs and events across multiple discrete (non-cumulative) subsets.
- [Discrete map graphs](#)
Discrete map graphs are available for two-dimensional MGPS results of data mining runs that use non-cumulative subsets.
- [View a cumulative map graph](#)
Cumulative map graphs provide a way to compare strength of associations between specific drugs and events across multiple subsets, which are typically based on a continuous variable, such as Year.
- [Cumulative map graphs](#)

- [View a sector map](#)
A sector map for data mining results is a visual presentation of data for a particular drug across all System Organ Classes (SOCs).
- [Sector maps](#)
Sector maps are available for two-dimensional results of MGPS data mining runs.

Graphs for 2D results

For two-dimensional results (for example, Drug+Event), the graph types are described in the following table. The graph types are available for MGPS runs. Some are available for logistic regression runs.

Graph	Description
Bar graph	Available for MGPS and logistic regression run results. A horizontal bar graph with one bar for each combination. Use this graph type to plot EBGM, PRR, ROR, ERAM, and LROR scores.

 **Note**

If the run includes subsetting, the graph label includes (for a Single Subset).

- If looking for link name EBGM, use run type MGPS.
- If looking for link name PRR, use run type MGPS with PRR.
- If looking for link name ROR, use run type MGPS with ROR
- If looking for link name ERAM, use run type MGPS with RGPS.
- If looking for link name LROR, use run type Logistic regression.

Graph	Description
Confidence interval bar graph	Available for MGPS and logistic regression run results. A horizontal bar graph with one bar for each combination, showing confidence intervals based on the EB05-EBGM-EB95, ROR05-ROR-ROR95, ER05-ERAM-ER95, or LR05-LROR-LR95 values. Suitable for studying scores and related confidence intervals. Note If the run includes subsetting, the graph label includes (for a Single Subset). • If looking for link name EB05-EBGM-EB95, use run type MGPS. • If looking for link name ROR05-ROR-ROR95, use run type MGPS with ROR. • If looking for link name ER05-ERAM-ER95, use run type MGPS with RGPS. • If looking for link name LR05-LROR-LR95, use run type Logistic regression.
Discrete map graph	Available for results of MGPS runs that use discrete (non-cumulative) subsets. A map graph (discrete) displays a colored grid showing combinations of items (drugs or events) with a drug or event, where each column of the grid reflects the data in a different subset. The subsets were defined as non-cumulative (discrete) in the data mining run. This graph is suitable for comparing strength of association between different subsets. For example, to compare scores for the individual years of 1998, 1999, and 2000, or for the genders Female, Male, and Unknown. Link name: Map Graph showing Multiple Discrete Subsets.
Cumulative map graph	Available for results of MGPS run results that use cumulative subsets. A map graph (cumulative) displays a colored grid showing combinations of items (drugs or events) with a drug or event, where each column of the grid reflects the data in a subset. The subsets were defined as cumulative in the data mining run. This graph is suitable for studying the change in association strength over time. For example, to observe scores for 1998, 1998 through 1999, and 1998 through 2000. Link name: Map Graph showing Cumulative Subsets.

Graph	Description
Sector map graph	Available for MGPS runs that include PT as an item variable and for which you have selected drugs to view results. A sector map graph for data mining results is a visual presentation of data for a particular drug across all System Organ Classes (SOCs). Sector map graphs are available if you select up to five drugs on the Specify Criteria page. The application ignores event selections for the sector map graph. Link name: Sector Map for Specified Drugs(s) and All Events.

Note

If the run includes subsetting, the link name includes (for a Single Subset).

View a bar graph

In addition to the restrictions you specified on the Select Criteria page, you can include additional restrictions and display options.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. Open the [Select Criteria page](#) using one of the following methods:
 - Click the **Header Action menu** () for the run, and then click **View Results**.
 - Hover on the **Data Analysis** icon () , in the left navigation pane then click **Data Mining Results**.

The [Select Criteria page](#) appears

3. From the **Run name** drop-down list, select the run you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one drug or event.
5. Click **Choose Graph**.
6. Select a bar graph.
7. On the Bar Graph page, specify restrictions. These are applied in addition to any restrictions that you specified on the [Select Criteria page](#):

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most ____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.

Restriction	Description
<score> at least	Display only combinations with a score (EBGM, ERAM, PRR, ROR, or LROR) of at least the specified number.
<score> at least	Display only combinations with a lower confidence limit (EB05, ER05, ROR05, LR05) of at least the specified number.
Subset	Available only if you selected All on the Select Criteria page. The available subsets are all those selected during run creation. Bar graphs show data for only one subset. To view data for all subsets in a single graph, click View as a Map Graph Showing Discrete Subsets or View as a Map Graph Showing Cumulative Subsets below the graph.

8. Specify the following display options:

Display Option	Description
Bar length controlled by:	Indicate whether you want bars to show in descending order by: - N (observed count). - The score (EBGM, ERAM, LROR, PRR, or ROR). - The lower confidence interval score (EB05, ER05, LR05, ROR05).
Bar color controlled by:	Indicate whether bar color should be controlled by: - EBGM, ERAM, LROR, PRR, or ROR, as defined by the graph key. - EB05, ER05, LR05, or ROR05, as defined by the graph key. - A single color for all graph bars.
Order by bar length	Check to show the bars of the graph in descending order based on bar length.
Order by item	Check to show the bars of the graph in alphabetical order.

9. Click **Display**.

[The bar graph appears.](#)

10. You can point to a bar of the graph to display statistics for the combination represented by the bar.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
- To [display the cases underlying the bar](#), click **View Cases** to drill down to a list of cases for the bar.
 - To [create a case series](#) from the cases comprising the bar, click **Create Case Series**.
 - To [transfer to a different case series](#), click **Transfer to Case Series**.
 - To [download the cases](#) from the bar, click **Download Cases**.
 - To [download case details](#) of the bar, click **Download Case Details**.

- f. To [run a report](#) about the bar, click **Reports**.
- g. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Work with results graphs](#) for information about links below the graph.

Bar graphs

Bar graphs provide a straightforward way to display the items most closely associated with a specified drug or event, showing the strength of association by plotting each computed statistical score as the length of a horizontal bar.

[Bar graphs](#) are available for two-dimensional results of MGPS data mining runs or logistic regression runs. You can choose a bar graph to display the following scores:

- EBGM, EB05, or N for an MGPS data mining run.
- ERAM, ER05, or N if computed for an MGPS data mining run.
- PRR, if computed for an MGPS data mining run.
- ROR, ROR05, or N, if computed for an MGPS data mining run.
- LROR, LR05, or N for a logistic regression run.

The graph key indicates the statistical ranges that determine the bar colors. On the Choose Graph page, you can [modify the graph key](#) (specifically, the cutpoints and colors).

If the Notes check box is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.

View a confidence interval graph

Confidence interval graphs are similar to bar graphs but also include a confidence interval or error bar superimposed on each bar to show the 5% and 95% confidence limits.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. Perform one of the following:
 - Click the **Header Action menu** () for the run, and then click **View Results**.
 - Hover on the **Data Analysis** icon () , in the left navigation pane then click **Data Mining Results**.

The [Select Criteria page](#) appears.

3. From the **Run name** drop-down list, select the two-dimensional MGPS or Logistic Regression run to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one drug or event.
5. Click **Choose Graph**.
6. Select a confidence interval graph.

7. On the Confidence Interval Graph page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#):

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most ____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
<score> at least	Display only combinations with a score (EBGM, ERAM, PRR, ROR, or LROR) of at least the specified number.
<score> at least	Display only combinations with a lower confidence limit (EB05, ER05, ROR05, LR05) of at least the specified number.
Subset	Available only if you selected All on the Select Criteria page. The available subsets are all those selected during run creation. Bar graphs show data for only one subset. To view data for all subsets in a single graph, click View as a Map Graph Showing Discrete Subsets or View as a Map Graph Showing Cumulative Subsets below the graph.

8. Specify the following display options:

Display Option	Description
Bar color controlled by:	Check to specify how to control bar color: - EBGM, ERAM, LROR, or ROR, as defined by the graph key. - EB05, ER05, LR05, or ROR05, as defined by the graph key. - A different color for each bar in the graph. - A single color for all graph bars.
Order by bar length	Check to show the bars of the graph in descending order based on bar length.
Order by item	Check to show the bars of the graph in alphabetical order.
Show N at end of confidence interval	Display the value of N at the end of each confidence interval bar.

9. Click **Display**.

[The confidence interval graph appears.](#)

10. You can point to a bar of the graph to display statistics for the combination represented by the bar.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
- To [display the cases underlying the bar](#), click **View Cases** to drill down to a list of cases for the bar.
 - To [create a case series](#) from the cases comprising the bar, click **Create Case Series**.

- c. To [transfer to a different case series](#), click **Transfer to Case Series**.
- d. To [download the cases](#) from the bar, click **Download Cases**.
- e. To [download case details](#) of the bar, click **Download Case Details**.
- f. To [run a report](#) about the bar, click **Reports**.
- g. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Work with results graphs](#) for information about links below the graph.

Confidence interval graphs

A confidence interval graph is available for two-dimensional MGPS results and logistic regression results.

You can choose a [confidence interval graph](#) to display the following scores:

- EB05-EBGM-EB95 for an MGPS data mining run.
- ER05-ERAM-ER95 for RGPS computations, if computed in an MGPS data mining run.
- ROR05-ROR-ROR95 for Reporting Odds Ratio computations, if computed in an MGPS data mining run.
- LR05-LROR-LR95 for a logistic regression run.

The graph key shows the statistical ranges that determine the bar colors. You can [modify the graph key](#) (specifically, the cutpoints and colors) on the Choose Graph page.

If the Notes check box is selected when you display the graph, a Notes section appears, and provides information on the selection criteria and display options used for the graph.

View a discrete map graph

Discrete map graphs provide a way to compare strength of associations between specified drugs and events across multiple discrete (non-cumulative) subsets.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. Perform one of the following:
 - Click the **Header Action menu** () for the run, and then click **View Results**.
 - Hover on the **Data Analysis** icon () , in the left navigation page then click **Data Mining Results**.

The [Select Criteria page](#) appears.

3. From the **Run name** drop-down list, select the two-dimensional MGPS run that uses non-cumulative subsets that you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one drug or event.
5. Click **Choose Graph**.
6. Select a discrete map graph.

7. On the **Discrete Map Graph** page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#):

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most ____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
EBGM at least	Display only combinations with an EBGM score of at least the specified number.
EB05 at least	Display only combinations with an EB05 score of at least the specified number.

8. Specify the following display options:

Display Option	Description
Select by and show value of	In each cell of the grid, display the numeric value of N (observed), EBGM, or EB05. Cells with no occurrences are empty.
Color by	Indicates whether the cell color should be controlled by: - EBGM, according to the graph cutpoints and palette. - EB05, according to the graph cutpoints and palette. - No color.
Order by high value in any subset	Depending on your selection for Select by and show value of , orders the combinations in the graph in descending order of N, EBGM, or EB05 across all subsets. For example, if the graph contains values of EBGM and has at most six combinations, order by the high value in any subset. The application orders combinations in descending order of EBGM according to the table that follows this table.
Order by item	Sort combinations in the graph in ascending order of item name across all subsets.

The following table shows how the application orders combinations in descending order of EBGM.

Combination	Subset1	Subset2	Subset3
DrugA-EventA	EBGM=2.0	EBGM=3.8	EBGM=1.4
DrugA-EventB	EBGM=3.1	EBGM=1.1	NA
DrugA-EventC	EBGM=1.5	EBGM=2.6	EBGM=2.8
DrugA-EventD	EBGM=2.7	NA	EBGM=2.4
DrugA-EventE	EBGM=0.5	EBGM=2.5	EBGM=0.8

Combination	Subset1	Subset2	Subset3
DrugA-EventF	NA	EBGM=1.1	EBGM=2.1

9. Click **Display**.

[The discrete map graph appears.](#)

10. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the cell to see the full terms.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
 - a. To [display the cases underlying the bar](#), click **View Cases** to drill down to a list of cases for the bar.
 - b. To [create a case series](#) from the cases comprising the bar, click **Create Case Series**.
 - c. To [transfer to a different case series](#), click **Transfer to Case Series**.
 - d. To [download the cases](#) from the bar, click **Download Cases**.
 - e. To [download case details](#) of the bar, click **Download Case Details**.
 - f. To [run a report](#) about the bar, click **Reports**.
 - g. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Work with results graphs](#) for information about links below the graph.

Discrete map graphs

Discrete map graphs are available for two-dimensional MGPS results of data mining runs that use non-cumulative subsets.

See [Subset variables](#) for more information.

Note

Map graphs show data for multiple subsets. To view data for only a specified subset, click **View as a Bar Graph Showing a Single Subset** or **View as a Single-Subset Bar Graph with Confidence Intervals**.

The graph key indicates the statistical ranges that determine the cell colors. You can [modify the graph key](#) (specifically, the cutpoints and colors) on the Choose Graph page.

If the Notes check box is selected when you display the graph, a Notes section provides information on the selection criteria and display options used for the graph.

View a cumulative map graph

Cumulative map graphs provide a way to compare strength of associations between specific drugs and events across multiple subsets, which are typically based on a continuous variable, such as Year.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.

2. Perform one of the following:

- Click the **Header Action menu** () for the run, and then click **View Results**.
- Hover on the **Data Analysis** icon (), in the left navigation pane then click **Data Mining Results**.

The [Select Criteria page](#) appears.

- From the **Run name** drop-down list, select the two-dimensional MGPS runs with cumulative subsets run that you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
- Type at least one drug or event.
- Click **Choose Graph**.
- Select a cumulative map graph.
- On the **Map Graph (Cumulative)** page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#):

Restriction	Description
N at least ____	Display only combinations with an observed count (N) of at least the specified number.
EBGM at least ____	Display only combinations with an EBGM score of at least the specified number.
EB05 at least ____	Display only combinations with an EB05 value of at least the specified number.
At most ____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.

8. Specify the following display options:

Display Option	Description
Show value of	In each cell of the grid, display the numeric value of N (observed), EBGM, or EB05. You can also select Leave blank to display a grid without labels. Cells with no occurrences are empty.
Color by	Check to specify how to color graph cells: - EBGM, according to the graph cutpoints and palette. - EB05, according to the graph cutpoints and palette. - No color.
Order by first occurrence of	Indicates how to order drug-event combinations in the graph, based on descending order of N, EBGM, or EB05 values. The application applies this ordering to combinations for the first subset. If the maximum number of combinations is not reached, the application applies the ordering to combinations for the second subset, and so on, until the maximum number of combinations is reached. (The maximum number of combinations is determined by the At most __ associations option.) For example, the graph shows values of EBGM and has at most six combinations. You order by the first occurrence of EBGM > 2. The combinations in descending order of EBGM are illustrated in the table that follows this table.

Application orders combinations in descending order of EBGM

Combination	Subset1	Subset2	Subset3
DrugA-EventA	EBGM=2.0	EBGM=3.8	EBGM=1.4
DrugA-EventB	EBGM=3.1	EBGM=1.1	NA
DrugA-EventC	EBGM=1.5	EBGM=2.6	EBGM=2.8
DrugA-EventD	EBGM=2.7	NA	EBGM=2.4
DrugA-EventE	EBGM=0.5	EBGM=2.5	EBGM=0.8
DrugA-EventF	NA	EBGM=1.1	EBGM=2.1

9. Click **Display**.

[The cumulative map graph appears.](#)

10. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the cell to see the full terms.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
 - a. To [display the cases underlying the bar](#), click **View Cases** to drill down to a list of cases for the bar.
 - b. To [create a case series](#) from the cases comprising the bar, click **Create Case Series**.
 - c. To [transfer to a different case series](#), click **Transfer to Case Series**.
 - d. To [download the cases](#) from the bar, click **Download Cases**.
 - e. To [download case details](#) of the bar, click **Download Case Details**.
 - f. To [run a report](#) about the bar, click **Reports**.
 - g. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Work with results graphs](#) for information about links below the graph.

Cumulative map graphs

[Cumulative map graphs](#) are available for two-dimensional MGPS results of data mining runs that use cumulative subsets.

For more information on subset variables, see [Subset variables](#).

① Note

Map graphs show data for multiple subsets, starting with the first subset for which results exist. To view data for a specific subset, click **View as a Bar Graph Showing a Single Subset** or **View as a Single-Subset Bar Graph with Confidence Intervals**.

The graph key shows the statistical ranges that determine the cell colors. You can [modify the graph key](#) (specifically, the cutpoints and colors) on the Choose Graph page.

If the Notes check box is selected when you display the graph, a Notes section provides information on the selection criteria and display options used for the graph.

View a sector map

A sector map for data mining results is a visual presentation of data for a particular drug across all System Organ Classes (SOCs).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. Open the [Select Criteria page](#) using one of the following methods:
 - Click the **Header Action menu** () for the run, and then click **View Results**.
 - Hover on the **Data Analysis** icon () , in the left navigation pane then click **Data Mining Results**.

The [Select Criteria page](#) appears.

3. From the **Run name** drop-down list, select the two-dimensional MGPS run you want to view. (Your [user preference](#), **Default run** determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [Find and select a data mining run](#).
4. Type at least one, but no more than five, drug names.
5. Click **Choose Graph**.
6. Select a sector map graph.
7. On the Sector Map page, specify the following display options:

Column	Description
Subset	Available only if you selected All on the Select Criteria page . The available subsets are all those selected during run creation.
Color controlled by	Name of the statistic whose values will be ranked and used for coloring the sector map tiles. Available values are those computed by the data mining run and include EBGM, EB05, ERAM, ER05, Chi-statistic (signed), and PRR.

Column	Description
Term box size controlled by	The factor that controls the size of PT tiles: • Relative importance of term —Bases the size of PT tiles on an algorithm that determines the relative public health impact of PTs. Using a recent version of the data, the application computes the public health impact for a PT as: (number of times the PT occurs in serious cases) * (proportion of cases with that PT that are serious-or-fatal). A higher Public Health Impact score corresponds to a larger tile in the sector map. Because size is based on the number of cases of the PT alone (not the number of cases that have the PT and a particular drug), the tile size is stable over sector maps for different drugs. Note For PTs that are new in the MedDRA version associated with the data used to assess public health impact, the application cannot determine the tile size. The application represents these PTs as small tiles.
Display maximum intensity at signal score of ____	• All terms have equal size —All PT tiles have the same size. Displays all tiles for which scores are above this value at the maximum-intensity color, as shown in the color key below the graph.
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.
Show low scores in green for color graph	Check to show low scores in varying shades of green. Clear to show low scores in black. Note This setting has no effect if you display the sector map in gray-scale.
Omit rare terms used fewer than ____ times in AERS	Number indicating how many times a PT must be in the database (the same one used for Relative importance of term) for that PT to be shown in the sector map. Note The notes for a sector map indicate any rare terms that are omitted because of this restriction.

Column	Description
Group by HLT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLT. If you also group by HLGT, the tiles for PTs are grouped by HLT within each HLGT.
Group by HLGT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLGT.
List __ top scores	Number indicating how many (up to 1000) terms with the top scores are ranked and listed below the sector map. The score is the statistic selected for Color controlled by. If multiple terms have the same score, the application counts each term separately. For example, you enter 20 as the limit. If the 20th row has a score that other terms after that also have, the application shows those additional terms as well.
Show top score indexes	If checked, the application numbers tiles in the sector map to show their rank, up to the number of scores specified in List __ top scores. For this option to take effect, there must also be a value specified for List __ top scores.

8. Click **Display**.

[The sector map appears.](#)

9. If you point to a PT tile, the MedDRA PT, HLT, HLGT, and SOC appear. The following information for the combination of the drug and the term that the tile represents also appears:
- **N**—Observed number of cases with drug-event combination.
 - **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate.
 - **EB05**—A 5% probability value that the true Relative Ratio lies below it.

Note

The ERAM and ER05 are available only if the data mining run was set up to compute RGPS.

- **PRR**—Proportional Reporting Ratio. For more information, see [PRR computations](#).
- **Chi-statistic**—Chi-statistic associated with PRR. (If EBGM < 1, the Chi-statistic is expressed as a negative number, indicating that the drug-event combination is more rare than expected). The Chi-statistic is the signed square root of Chi-square.

Note

The PRR and Chi-statistic are available only if the data mining run was set up to compute PRR.

10. To [zoom in](#) on a particular SOC, click anywhere on the SOC tile and select **Zoom** from the menu.

11. If you click a tile for which N is at least 1, you can then [drill down](#) to a list of cases for the tile or [view statistics](#) for the tile.
12. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Work with results graphs](#) for information about links below the graph. For best results, print the sector map graph in landscape mode.

Sector maps

Sector maps are available for two-dimensional results of MGPS data mining runs.

A large tile represents each System Organ Class (SOC) in the sector map. Smaller tiles within each SOC tile represent Preferred Terms (PTs). The application ranks PTs in descending order of values of the statistic (EBGM, EB05, Chi-statistic, or PRR) that you choose. A color key indicates relative ranking. You can also list the ranked PTs below the sector map.

Note

The primary path of a PT determines where it appears in the sector map. If a PT is not in the event hierarchy associated with the configuration, it appears in a SOC tile named Unknown.

The list of ranked PTs below the sector map includes the following information:

Field	Description
Rank	Ranking of the term (combined with the drug) according to values of the statistic you have configured the sector map to use (via the Color controlled by option).
SOC	SOC containing the term.
Term (PT)	Specific PT.
EBGM, EB05, Chi-statistic, or PRR	Value of the statistic you have configured the sector map to use (via the Color controlled by option).

If **Notes** is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.

Graphs for 3D results

- [Graphs for 3D results](#)
For three-dimensional results (for example, Drug+Drug+Event), the available graph types are described in the following table. These graph types are available for MGPS runs only.
- [View a hierarchy graph](#)
Hierarchy graphs highlight situations in which there are interaction effects (such as drug interactions or event syndromes), where the score for an interaction or syndrome is not predicted by the scores of its components.
- [Hierarchy graphs](#)
Hierarchy graphs are available for three-dimensional results of MGPS data mining runs.

- [View an overlap graph](#)
Overlap graphs highlight situations in which there are interaction effects (such as drug interactions or event syndromes), where the score for an interaction or syndrome is not predicted simply by the scores of its components.
- [Overlap graphs](#)
An overlap graph is available for three- dimensional results of MGPS data mining runs.
- [View a nested confidence interval graph](#)
To help you investigate possible drug interactions or multi-event syndromes, the nested confidence interval graph displays sets of confidence intervals.
- [Nested confidence interval graphs](#)
In each nested confidence interval graph set, the first confidence interval is for the 3D combination for the specified pattern (such as Drug+Drug+Event). Subsequent confidence intervals in the set are for the 2D combinations (such as Drug+Event.)

Graphs for 3D results

For three-dimensional results (for example, Drug+Drug+Event), the available graph types are described in the following table. These graph types are available for MGPS runs only.

Graph	Description
Hierarchy graph	Columns of colored cells, where the rows represent 2-way and 3-way combinations. This graph is suitable for studying multiple-item combinations such as drug interactions or syndromes. The hierarchy graph uses INTSS values. The independence model hierarchy graph, which uses EBGMDIF_IND values, is for compatibility with releases prior to WebVDME 5.0. Link name: Hierarchy Graph showing Interaction . . .
Overlap graph	A table of colored cells, where the rows represent 2-way and 3-way combinations. Same content as hierarchy graph, but formatted differently. The overlap graph uses INTSS values. The independence model overlap graph, which uses EBGMDIF_IND values, is for compatibility with releases prior to WebVDME 5.0. Link name: Overlap Graph showing Interaction . . .
Nested confidence interval graph	Sets of confidence intervals. In each set, the first confidence interval is for the 3D combination for the specified pattern. Subsequent confidence intervals in the set are for 2D combinations. Uses INTSS values. Link name: Nested Confidence Interval Graph showing Interaction . . .

View a hierarchy graph

Hierarchy graphs highlight situations in which there are interaction effects (such as drug interactions or event syndromes), where the score for an interaction or syndrome is not predicted by the scores of its components.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. Perform one of the following:
 - Click the **Header Action** menu () for the run, and then click **View Results**.
 - Hover on the **Data Analysis** icon () , in the left navigation pane then click **Data Mining Results**.

The [Select Criteria page](#) appears.

3. From the **Run name** drop-down list, select the three-dimensional run you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one drug or event.
5. Click **Choose Graph**.
6. Select a hierarchy graph.
7. On the Hierarchy Graph page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#).

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most ____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Subset	Available only if you selected All on the Select Criteria page. The available subsets are all those selected during run creation.

8. Specify the following display options:

Display Option	Description
Show value of	Select N or EBGM/INTSS as the statistic to show in cells. You can also leave cells blank. For 3D run results, the EBGM score applies to the two-way combinations, which appear in the cells in the left column. The INTSS score applies to the three-way combinations, which appear in the right column.

Note

If the data mining run results do not include items of the same type (an option during run creation), statistics do not appear for items of the same type (such as a drug+drug or event+event combination).

Display Option	Description
Color by	Check to specify how to color graph cells: - EBGM/INTSS - No color

9. Click **Display**.

[The hierarchy graph appears.](#)

10. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the cell to see the full terms.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
 - a. To [display the cases underlying the bar](#), click **View Cases** to drill down to a list of cases for the bar.
 - b. To [create a case series](#) from the cases comprising the bar, click **Create Case Series**.
 - c. To [transfer to a different case series](#), click **Transfer to Case Series**.
 - d. To [download the cases](#) from the bar, click **Download Cases**.
 - e. To [download case details](#) of the bar, click **Download Case Details**.
 - f. To [run a report](#) about the bar, click **Reports**.
 - g. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Work with results graphs](#) for information about links below the graph.

Hierarchy graphs

Hierarchy graphs are available for three- dimensional results of MGPS data mining runs.

The score for an interaction is INTSS, which is calculated as the EB05 score for the combined drugs or events divided by the highest EB95 score found for an individual component drug or event. [Hierarchy graphs](#) are built within the context provided by the drug or event specified on the Select Criteria page.

The key below the graph shows the statistical ranges that determine the cell colors. The ranges are for EBGM and INTSS values. On the Choose Graph page, you can [modify the graph key](#) (that is, the cutpoints and colors).

If Notes is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.

View an overlap graph

Overlap graphs highlight situations in which there are interaction effects (such as drug interactions or event syndromes), where the score for an interaction or syndrome is not predicted simply by the scores of its components.

1. In the left navigation pane, hover on the **Data Analysis** icon , then click **Data Mining Runs**.
2. Perform one of the following:

- Click the **Header Action menu** () for the run, and then click **View Results**.
- Hover on the **Data Analysis** icon (), in the left navigation pane then click **Data Mining Results**.

The [Select Criteria page](#) appears.

3. From the **Run name** drop-down list, select the three-dimensional run you want to view. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one drug or event.
5. Click **Choose Graph**.
6. Select an overlap graph.
7. On the Overlap Graph page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#).

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most ____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Subset	Available only if you selected All on the Select Criteria page. The available subsets are all those selected during run creation.

8. Specify the following display options:

Display Option	Description
Show value of	Select N or EBGM/INTSS as the statistic to show in cells. You can also leave cells blank. For 3D run results, the EBGM score applies to the two-way combinations, which appear in the cells in the left column. The INTSS score applies to the three-way combinations, which appear in the remainder of the graph (in the right column).

 Note

If the data mining run results do not include items of the same type (an option during run creation), statistics do not appear for items of the same type (such as a drug+drug or event+event combinations).

Color by

Check to specify how to color graph cells:

- EBGM/INTSS
- No color

9. Click **Display**.

[The overlap graph appears.](#)

10. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the cell to see the full terms.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
 - a. To [display the cases underlying the bar](#), click **View Cases** to drill down to a list of cases for the bar.
 - b. To [create a case series](#) from the cases comprising the bar, click **Create Case Series**.
 - c. To [transfer to a different case series](#), click **Transfer to Case Series**.
 - d. To [download the cases](#) from the bar, click **Download Cases**.
 - e. To [download case details](#) of the bar, click **Download Case Details**.
 - f. To [run a report](#) about the bar, click **Reports**.
 - g. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Work with results graphs](#) for information about links below the graph.

Overlap graphs

An overlap graph is available for three- dimensional results of MGPS data mining runs.

The score for the interaction or syndrome in an [Overlap graph](#) is shown as INTSS, which is computed as the EB05 score for the combined drugs or events divided by the highest EB95 score found for the component drugs or events. The graph is built within the context provided by the drug or event specified on the Select Criteria page.

The key below the graph shows the statistical ranges that determine the cell colors. The ranges are for EBGM and INTSS values. On the Choose Graph page, you can [modify the graph key](#) (that is, the cutpoints and colors).

If Notes is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.

View a nested confidence interval graph

To help you investigate possible drug interactions or multi-event syndromes, the nested confidence interval graph displays sets of confidence intervals.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
2. Perform one of the following:
 - Click the **Header Action menu** () for the run, and then click **View Results**.
 - Hover on the **Data Analysis** icon () , in the left navigation pane then click **Data Mining Results**.

The [Select Criteria page](#) appears.

3. From the **Run name** drop-down list, select the three-dimensional MGPS run. (Your [user preference](#), **Default Run**, determines which run, if any, is selected by default.) You can also click **Browse** next to the Run name field to [find and select a run](#).
4. Type at least one drug or event.
5. Click **Choose Graph**.
6. Select a nested confidence interval graph.
7. On the Nested Confidence Interval Graph page, specify restrictions, which will be applied in addition to any restrictions that you specified on the [Select Criteria page](#).

Restriction	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most ____ combinations	Display no more than the specified number of combinations. You can display graphs for up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Subset	Available only if you selected All on the Select Criteria page. The available subsets are all those selected during run creation.

8. Specify the following display options:

Display Option	Description
Order by	The application sorts the combinations by the value of the score that you select. For example, if you select INTSS, the 3D combination with the highest INTSS value appears first.
Axis Type	Select either Linear or Log (logarithmic). When you use a logarithmic axis, the confidence intervals for the lower-level combinations appear more clearly.
Highlight confidence intervals where INTSS >	Enter the INTSS value above which confidence interval bars are highlighted.
Show N at end of confidence interval	Check to display the value of N at the end of each bar.
Use gray-scale instead of colors	Check to use shades of gray instead of colors in the graph.

9. Click **Display**.
[The nested confidence interval graph appears.](#)
10. You can point to a bar of the graph to display statistics for the combination represented by the bar. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the bar to see the full terms.
11. Click a bar in the graph to display a menu. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.
 - a. To [display the cases underlying the bar](#), click **View Cases** to drill down to a list of cases for the bar.
 - b. To [create a case series](#) from the cases comprising the bar, click **Create Case Series**.

- c. To [transfer to a different case series](#), click **Transfer to Case Series**.
- d. To [download the cases](#) from the bar, click **Download Cases**.
- e. To [download case details](#) of the bar, click **Download Case Details**.
- f. To [run a report](#) about the bar, click **Reports**.
- g. To [save the graph as an attachment to a topic](#), click **Save to Topic**. (This option is available if **Links** is checked and the topics feature has been set up.) The graph is attached in a PDF file.

See [Work with results graphs](#) for information about links below the graph.

Nested confidence interval graphs

In each nested confidence interval graph set, the first confidence interval is for the 3D combination for the specified pattern (such as Drug+Drug+Event). Subsequent confidence intervals in the set are for the 2D combinations (such as Drug+Event.)

In each [nested confidence interval graph](#) bar, the EB05 value is at the left end, the EBGM value is the dot on the bar, and the EB95 value is at the right end. The application highlights a confidence interval bar if its INTSS value is greater than the limit that you specify as a display option. For more information about INTSS, see [interaction scores](#).

To conserve space in labeling, the drug or event name indicated above the graph is referred to by the label Drug or Event in the graph. In the example below, Drug means Aminoglutethimide.

The key below the graph indicates INTSS values represented by the confidence interval bars. Settings you make to [cutpoints and palette choices](#) do not affect this graph type.

If Notes is checked when you display the graph, a Notes section provides information about the selection criteria and display options used for the graph.

6

Query the safety database

- [View existing queries](#)
The Queries page provides information about existing queries and enables you to define new queries.
- [Queries and the query library](#)
A query is the specification of criteria based on variables and values in the source data. When you run a query, Oracle Empirica Signal retrieves cases that match the specified criteria.
- [Create, edit, and run a query](#)
- [Manage your queries](#)

View existing queries

The Queries page provides information about existing queries and enables you to define new queries.

For the selected project and data configuration, the Queries page lists [queries](#) that you have created or that are published to you. If you have the Administer Users permission, the page also lists unpublished queries created by any users in your login group.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Queries**.
2. Filter the list of your queries and queries published to you as necessary.
 - From the **Project** drop-down list, select the [project](#) for which you want to view queries or -- to include all projects.
 - From the **Configuration** drop-down list, select the [data configuration](#) for which you want to view queries or -- to include all configurations.
 - From the **Origin** drop-down list, select the origin of the queries you want to view; select -- to include all types.

What you can do next

- To view, print, or download the table, or to change the way data displays in the table, see [About tables](#).
- To print, download, or delete multiple queries, click **Select Rows**. Select the check box for one or more rows or click the **Select All** link to check all rows (or **Clear All** to uncheck all rows). Then click **Print**, **Download**, or **Delete**.
- To create a query using the built-in Query Wizard, click the **Create Using Query Wizard** link.
- Click a query's **Header Action** menu (), to do the following:
 - To [run the query](#), click **Run** and select a data configuration.
 - To run the query and [create a case series](#) from the query results, click **Create Case Series**. You select a data configuration, review variables and values, and optionally change the name, description, and project assignment before saving the case series.

- To [view the query logic](#), click **View**. This option shows the variables and values that make up the query, as well as the logic.
- To run the query and then run a report against cases found by the query, click **Report** and select a data configuration. After you run the query, the [Report Definitions page](#) appears.

For queries you created, click a query's **Header Action** menu () to do the following:

- To copy a query, click **Copy**. Then provide a name for the copy and save it.
- To edit the query, click **Edit**. You can click **Back** to select a different data configuration.
- To [rename the query](#), click **Rename**. You can also change its description or assign it to a different project.
- To publish a query, click **Publish**, select the login group(s), then click **Back**. (If you have the Administer Users permission, you can publish configurations created by any user in your login group.)

✓ Tip

- If you are a superuser and the object is not multi-enterprise support-related, you can publish to multiple login groups, including —All—. From the Publish to Login Groups list, select one row and hold **Ctrl+ left** click to select more rows.
- If you publish to —All— and later add a new login group, the object is published automatically to the new login group.
- If you are a superuser and the object is multi-enterprise support-related, then you can only publish to the object owner's login group.

- To [run the query](#) and then run a report against cases found by the query, click **Report** and select a data configuration. After you run the query, the Report Definitions page appears.
- To delete a query, click **Delete**. At the message asking if you want to delete the query, click **OK**. The query is deleted and no longer appears on the Queries page.

📘 Note

Editing or deleting a query has no effect on any case series, database restrictions, custom terms, or interactive reports that were created using the query.

Queries and the query library

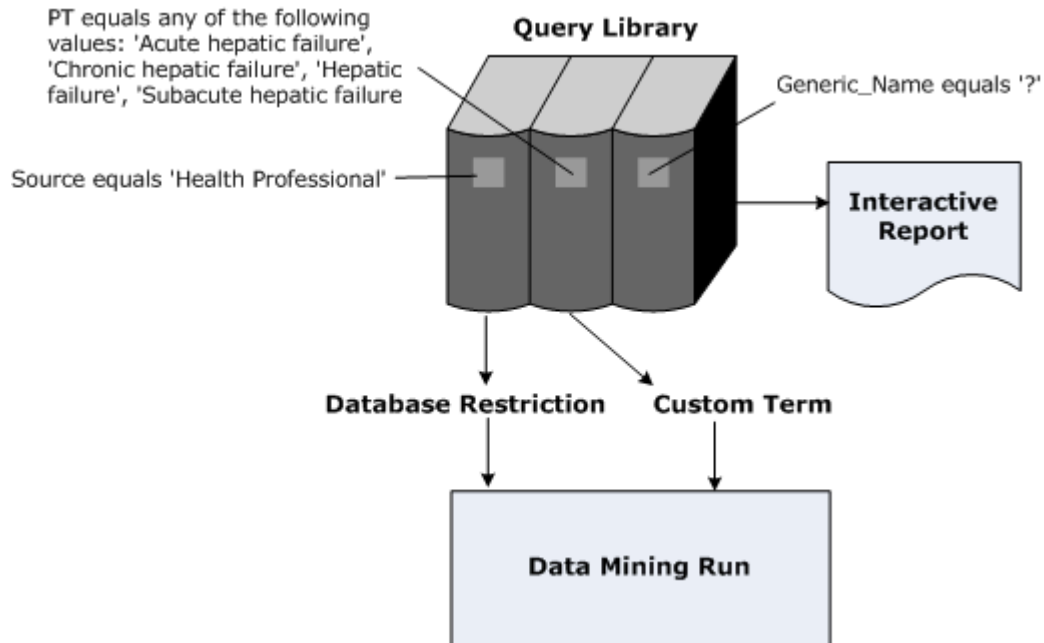
A query is the specification of criteria based on variables and values in the source data. When you run a query, Oracle Empirica Signal retrieves cases that match the specified criteria.

To create or edit a query, use the [Query Wizard](#) to guide you through the steps of selecting variables, selecting values, and specifying query logic.

For variables in a query, values do not need to be predefined. Users can supply values at the time they run the query. For example, you can set up a query to look for cases that include both of two products, where the two products are specified at the time you run the query.

A query is a dynamic object that is re-applied each time you run the query. If data has changed since the last time you ran the query, the query results can differ. In contrast, a [case series](#) is a saved list of cases.

When creating [database restrictions](#), [custom terms](#), [query-based case series](#), or [interactive reports](#), you can create new queries or use existing queries. The list of existing queries is the Query Library. To use an existing query, you select it from the Query Library. For example, there is an existing query that finds females under age 65. To perform a data mining run based only on females under age 65, you define a database restriction based on that query.



When using an existing query in the process of defining another object, you work with a copy of the query. Modifying the copy does not affect the query in the Query Library. Likewise, changes to the query in the library do not affect the copies of the query associated with any existing objects.

Note

Because queries run on [source data](#) (not data mining results), they do not include [custom terms](#) or values created by [data transformations](#).

Create, edit, and run a query

- [Step 1: Create and edit a query](#)
When you create or edit a query, the Define Query page appears. On the Define Query page, you specify conditions and link them with operators.
- [Step 2 \(Optional\): Specify query logic](#)
When you specify conditions in a query, they are connected using default operators. You can modify the operators as needed.
- [Step 3: Preview the query](#)
The Query Wizard allows you to select the configuration and variables and preview the results of the query.

- [Step 4: Save the query](#)
After you are satisfied with the query you can save it to an existing project or to a new project.
- [Step 5: Run a query](#)
Each time that you run a query, Oracle Empirica Signal executes the query. Even if you do not change values for variables in the query, if the source data changed since the last time you ran the query, the query results can differ from when you last ran the query.
- [Step 6: Work with the cases retrieved by the query](#)
When you run a query, the cases Oracle Empirica Signal retrieves from the source data appear on the Cases page. You can download case details and run reports against the cases found by the query.

Step 1: Create and edit a query

When you create or edit a query, the Define Query page appears. On the Define Query page, you specify conditions and link them with operators.

For information about operators, see [Specifying query logic](#).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Queries**.
2. At the top left of the **Queries** page, click **Create Using Query Wizard**.
3. On the **Select Configuration** page, select a [data configuration](#) from the **Configuration** drop-down list or click **Browse** to select from a list of data configurations.
4. Click **Next**.
5. On the **Define Query** page, click **Select Variables**.
6. (Optional) If you want information about the variable shown, click **Show Variables**.
7. From the **All Variables in All Tables** list, select one or multiple variables on which to base conditions and use the right-arrow button to move them to the **Selected Variables** list.
8. Click **OK**.

A field for each variable you selected appears on the Define Query page. Oracle Empirica Signal assigns a number to each variable. When you [specify query logic](#), you use that number to refer to the condition that is based on that variable. If you point to the field name, a description of the field appears.

9. Choose one of the following:
 - If you are creating or editing a query from the Queries page or for an interactive report, you can specify values for each variable in the query. When running the query, you can change the specified values or enter values (if none were provided in the original query).
 - If you are creating or editing a query in the process of defining a database restriction, custom term, or case series, you must specify values for each variable or remove the variable.
 - The way in which you specify values depends on the type of variable. For more information, see [Specify query values](#).
 - Each condition that you specify must be referenced by the query logic. If you are not going to reference a condition, you must remove the condition from the query, by clicking the [X] in the upper right corner of the box containing the variable.

Note

You can include the same variable in the query multiple times. For example, cases for which the subject's age is between 17 and 25 or above 65. You include the AGE variable and set it to 17-25; include the AGE variable again and set it to above 65; then connect the variables with the OR operator.

10. Specify query logic by clicking **Edit** and entering a logical expression, referring to variables by their numbers, then click **OK**. For more information, see [How to specify logic in a query](#).

Note

If you add or delete another query variable after this step, the query logic is reset to a default.

11. If your [user preferences](#) include **Show case count by default on preview page**, you can check **Display Case Count in Query Preview**. You must specify values for all variables. Computation of the case count can be time-consuming, so we recommend that you display counts only when necessary.
12. Click **Next** to [preview the query](#).

Step 2 (Optional): Specify query logic

When you specify conditions in a query, they are connected using default operators. You can modify the operators as needed.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Queries**.
2. At the top left of the **Queries** page, click **Create Using Query Wizard**.
3. On the **Select Configuration** page, from the **Configuration** drop-down list, select a [data configuration](#) or click **Browse** to select from a descriptive list of data.
4. Click **Next**.
5. On the Define Query page, click **Select Variables**.
6. From the **All Variables in All Tables** list, select one or multiple variables on which to base conditions and use the right-arrow button to move them to the Selected Variables list.
7. Click **OK**.

A field for each variable you selected appears on the Define Query page. Oracle Empirica Signal assigns a number to each variable. When you specify query logic, you use that number to refer to the condition that is based on that variable.

8. Specify values for each variable.
9. Click **Edit**.
10. Specify query logic by entering a logical expression, referring to variables by their numbers. [Use logical operators and set operators](#).
11. Type in logical operators, set operators, and parentheses as needed.
 - The conditions in a query must be joined by the AND, OR, INTERSECT, UNION, or MINUS operator. The NOT operator is available to negate a condition (for example, 1 AND NOT 2).

- Each condition must be referenced by the query logic at least once. You can refer to the same condition multiple times in a query. For example, you can specify: (1 AND NOT 2) OR 2.

12. Click **OK**.

Step 3: Preview the query

The Query Wizard allows you to select the configuration and variables and preview the results of the query.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Queries**.
2. At the top left of the **Queries** page, click **Create Using Query Wizard**.
3. On the Select Configuration page, select a [data configuration](#) from the **Configuration** drop-down list or click **Browse** to select from a list of data configurations.
4. Click **Next**.
5. On the Define Query page, click **Select Variables**.
6. Follow the directions in steps 5 through 13 on [Step 1: Use the Query Wizard to create a query](#), then click **Next**.

The Preview Query page appears, providing the following information:

- The data source, which is the name of the data configuration on which the query is based.
- The logic of the query and a description of each condition in the query.

Note

If query values were not specified for a variable, the value for the variable appears as ?.

The number of cases to be retrieved by the query (if you checked **Display Case Count in Query Preview** on the Define Query page).

7. To preview the query results, click **Preview Cases**.

This option is available only if you specified values for all variables and site option **Allow Case Count on Query Preview page** is enabled.

8. Click **Next** to [save the query](#).

Step 4: Save the query

After you are satisfied with the query you can save it to an existing project or to a new project.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Queries**.
2. At the top left of the **Queries** page, click **Create Using Query Wizard**.
3. On the Select Configuration page, select a [data configuration](#) from the **Configuration** drop-down list or click **Browse** to select from a list of data configurations.
4. Click **Next**.
5. On the Define Query page, click **Select Variables**.

6. Follow the directions in steps 5 through 13 on [Create a query](#), then click **Next**.
7. [Preview the query results](#), then click **Next**.
8. In the **Name** field, enter a name for the query. The name does not need to be unique, although we recommend that you use a unique name.
9. (Optional) In the **Description** field, enter an informative description of the query.
10. Choose one of the following options:
 - To assign the query to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.
 - To create a new project and assign the query to it, click **Add to a new project named** and enter a project name.
11. Click **OK**.

When you create or edit a query, the Define Query page appears. On the Define Query page, you specify conditions and link them with operators. For information about operators, see [Specifying query logic](#).

Step 5: Run a query

Each time that you run a query, Oracle Empirica Signal executes the query. Even if you do not change values for variables in the query, if the source data changed since the last time you ran the query, the query results can differ from when you last ran the query.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Queries**.
2. Click the query's **Header Action** menu(), and then click **Run**.

Note

When you run an [interactive report](#), you also run a query.

3. From the [Configuration](#) drop-down list, [select a data configuration](#) from a list of [compatible data configurations](#). This is the source data against which the query runs.
4. Click **Next**.
5. On the **Run Query** page, specify values for query variables. For more information, see [Specify query values](#).

If the operators in the query are all AND, all OR, all INTERSECT, or all UNION, you do not need to specify values for every variable. If you do not specify a value for a variable and you do not check **Include Null values** for the variable, then the application ignores that variable. If all of the operators in the query are MINUS or if you use a mixture of different operators in the query, you must specify values for every variable.

Note

You can set up a query-based interactive report to use [query values](#) as breakdown details. If a column or row variable has no breakdown values because you do not supply query values when running the report, the application drops the column or row from the report. If the resulting report has no rows or no columns, you cannot run the report until you supply query values.

6. Click Next.

The cases matching the query appear on the Cases page. See [View query results](#).

Step 6: Work with the cases retrieved by the query

When you run a query, the cases Oracle Empirica Signal retrieves from the source data appear on the Cases page. You can download case details and run reports against the cases found by the query.

Oracle Empirica Signal lists the cases in a tabular format. The variable representing the Report ID is the first column of the table. Other information in the table is customizable and determined by the [data configuration](#). The Cases page does not include [custom terms](#) or values created by [data transformations](#).

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Queries**.
2. Click the query's **Header Action** menu (), and then click **Run**.
3. From the [Configuration](#) drop-down list, [select a data configuration](#) and click **Next**.
4. On the **Run Query** page, specify values for query variables. For more information, see [Specify query values](#).
5. Click **Next** to display the cases that match the query.

You can do the following on the Cases page:

- To run a report against cases found by the query, click **Report**. The [Report Definitions page](#) appears.
- To [download case details](#) for all cases in the list to an Excel spreadsheet or a Word Rich Text Format file, click **Download Case Details**. You can download case details only if the appropriate site option has been set. (When viewing a particular case, you can also download case details for that one case.)
- To [save a case series](#) from the query results, click **Save As Case Series**.
- To [save the query results as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).
- [View case details](#) for a single case in the list, if the appropriate site option has been set. Click the **case ID** link in the case list. The Case Details page appears. For information about how visited case ID links change color, see [Case ID links](#).

Manage your queries

- [Create a query from an existing query](#)
The Select Query from Library page appears if you use an existing query when defining a custom term, database restriction, or query-based interactive report.

- [Specify query values](#)
The way in which you specify values depends on the type of variable.
- [Use logical and set operators](#)
Logical operators act on individual rows of source data tables. Set operators act on sets of cases that are retrieved by the conditions on each side of the set operator.
- [View query logic](#)
You can view a query from the Queries page or examine a query used by a case series.
- [Rename a query](#)
You can rename only those queries that you created.

Create a query from an existing query

The Select Query from Library page appears if you use an existing query when defining a custom term, database restriction, or query-based interactive report.

The queries must have been created by you or published to you. (If you have the Administer Users permission, you can select from published or unpublished queries created by any user in your login group.)

Once you use an existing [query](#) for a custom term, database restriction, or query-based interactive report, subsequent changes to the query in the library do not affect the custom term, database restriction or report.

1. Select **Create from Existing Query**.
2. From the **Project** drop-down list, select a specific [project](#), or select -- to include all projects.
3. From the **Configuration** drop-down list, [select the data configuration](#), or select -- to include all configurations. Available queries are those that are [compatible](#) with the data configuration for the data mining run (if you are creating a custom term or database restriction) or report definition (if you are creating a report).
4. From the **Origin** drop-down list, select one of the following values:
 - **Query**—The query was created and saved from the Queries page.
 - **Case Series**—The query was created and saved during the creation of query-based case series on the Case Series page.
 - **Custom Term**—The query was created and saved during the creation of a custom term for a data mining run.
 - **Restriction**—The query was created and saved during the creation of a database restriction for a data mining run.
 - **Interactive Report**—The query was created and saved during the creation of an interactive report.
5. Click the radio button of the row for the query that you want to select.
6. Click **Next**.

If you are defining a custom term or database restriction, the Refine Query page appears. Optionally, you can [refine the query](#).

Specify query values

The way in which you specify values depends on the type of variable.

- If the **Select <hierarchy> Terms** link appears for a variable, click it to select terms from the [hierarchy](#). For example, if an event variable is associated with a MedDRA account and

your [user preference](#), **Enable Adverse Event Hierarchy Browser**, is checked, you can click **Select MedDRA Terms**.

- To [select values from a list](#), click **Select Available Values**.
- To refer to a [saved list](#) of terms, click **Select Saved List**. You can specify a saved list that uses the same data configuration as the query.
- To type the terms, review the rules in [Typing values in text boxes](#).

Note

To prevent spelling and capitalization errors, Oracle recommends that you select rather than type values.

- To [look up a drug name](#) for a drug variable, click **Trade/Generic Lookup**. You can find the generic name for a drug (if you only know its trade name) or vice versa. (This link is available if the data configuration's source data included trade name-generic name mapping.)

Matching a text string

If the options **Contains**, **Starts with**, **Ends with**, or **Equals** appear for a variable, enter a text string and select an option to indicate the type of matching. You can also check **Ignore capitalization** to retrieve matching values regardless of upper or lower case.

Specifying ranges

For numeric or date variables, specify a range by entering **From** and **To** values. Values equal to or greater than the From value and equal to or less than the To value are found. If you leave the From field empty, there is no lower bound. If you leave the To field empty, there is no upper bound.

If a date variable is stored as a date field in the source data, you must enter the date in the format MM/DD/YYYY or use the calendar icon to select a date.

If you do not specify a time, the application considers the time to be midnight of the specified date.

Note

If a date variable is stored as a text field in the Oracle database, you can search for it as you would search for any text string.

Specifying report IDs

For a variable specified with the type Report ID in the data configuration, you can enter a string of report IDs separated by commas.

Check **Include Null values** to include null (empty) values along with the other values that you specify for a variable, and click **Next**. For more information, including how the NOT operator works if you include null values, see [Specifying query logic](#).

Use logical and set operators

Logical operators act on individual rows of source data tables. Set operators act on sets of cases that are retrieved by the conditions on each side of the set operator.

Logical operators

You can use the following logical operators between conditions:

- **AND**—Find cases for which both conditions occurred simultaneously.
- **OR**—Find cases for which either of the conditions occurred.

You can use the logical operator **NOT** to negate a condition. (You cannot use **NOT** alone to connect conditions.)

Set operators

You can use the following set operators between conditions:

- **INTERSECT**—Find cases that are in both sets.
- **UNION**—Find cases that are in either set.
- **MINUS**—Find cases that are in the set to the left of the operator, and subtract from that list the cases that are in the set to the right of the operator.

Sometimes it is possible to specify the same query using either logical operators or set operators. It is preferable to use logical operators because they are more efficient.

Operator priority

When the application interprets the query expression, it applies operators in the following order:

- **NOT**
- **AND**
- **OR**
- **INTERSECT, UNION, MINUS** (same priority)

The only restriction on how logical and set operators can interact is that logical operators cannot act on the results of set operators. For example, the following query is invalid: 1 **AND** (2 **INTERSECT** 3).

You can use parentheses to change the way in which a query expression is interpreted. If you do not use parentheses explicitly, the query is interpreted as if there are parentheses, based on the default order of operators.

For example, suppose the query is:

```
1 AND 2 OR 3 INTERSECT 4
```

With no supplied parentheses, the application reads the query as:

```
((1 AND 2) OR 3) INTERSECT 4
```

If you use parentheses, the meaning of the query is different:

```
1 AND (2 OR 3) INTERSECT 4
```

Examples

You specify the following conditions:

The image shows three windows for defining query conditions:

- 1 Trade_Name**: Contains a text box with "Thiamine", three links ("Select Available Values", "Select Saved List", "Trade/Generic Lookup"), and an "Include Null values" checkbox.
- 2 Trade_Name**: Contains a text box with "Niacin", three links ("Select Available Values", "Select Saved List", "Trade/Generic Lookup"), and an "Include Null values" checkbox.
- 3 Drug dose amount**: Contains "From:" and "To:" text boxes with values "20" and an empty box respectively, and an "Include Null values" checkbox.

Below the windows is a summary bar: "Logic: 1 and 2 and 3" and an "Edit" button.

In the following examples, the query logic does not always refer to all three values. When you create a query within the Oracle Empirica Signal application, the query logic must reference all conditions in the query.

Note

A condition can refer to multiple values. For example, you can include the DRUG variable once and select Thiamine and Niacin as one condition. The example includes the DRUG variable twice to illustrate complex logic.

If the source data includes cases A through G with the following data:

CASE_ID	DRUG	DOSE
A	Thiamine	25
A	Niacin	15
B	Thiamine	15
B	Niacin	25
C	Calcium	15

CASE_ID	DRUG	DOSE
D	Thiamine	15
E	Thiamine	25
F	Niacin	25
G	Calcium	25

1 AND 3

The query retrieves cases with rows in which Thiamine occurred and DOSE >= 20 for that row:

A

E

1 OR 3

The query retrieves cases with rows in which either Thiamine occurred or DOSE >= 20 for any DRUG:

A

B

C

D

E

F

G

If you use OR between variables from different tables, only cases that are in each of those tables are retrieved. For example, if a query specifies that Death Date from the DEMO table is within a specified range OR Outcome from the OUTCOME table is Died OR PT from the REACTION table is Death, the application retrieves only cases that meet the criteria and are in all three tables. You can use set operators instead of logical operators. For example, replace OR with UNION in the query to find DEMO table cases with Death Date within the range plus OUTCOME table cases where the Outcome is Died plus REACTION table cases where the PT is Death.

1 AND 2

No cases are retrieved because no one row for a case can have both Thiamine and Niacin for a DRUG.

You can use the set operator INTERSECT if you want to find cases with both Thiamine and Niacin. See the 1 INTERSECT 2 example.

1 AND 2 OR 3

The query retrieves cases with rows in which Thiamine occurred and, for that row, Niacin occurred (not possible, because a row can have only one DRUG), or DOSE >= 20 for any DRUG:

A

B

E

F

G

1 AND 2 OR 3

The query retrieves cases with rows in which Thiamine occurred and, for the same row, either Niacin occurred (not possible, since a row can have only one DRUG) or DOSE $\geq$ 20:

A

E

1 AND NOT 3

The query retrieves cases with rows in which Thiamine occurred and DOSE is not $\geq$ 20 for that row:

B

D

NOT 1 AND 3

The query retrieves cases with rows in which Thiamine did not occur and DOSE $\geq$ 20:

B

F

G

NOT (1 AND 3)

The query retrieves cases with rows in which Thiamine with DOSE $\Rightarrow$ 20 did not occur:

A

B

C

D

F

G

NOT 1 AND NOT 3

The query retrieves cases with rows in which Thiamine did not occur and, for the DRUG that occurred, DOSE is not $\geq$ 20:

A

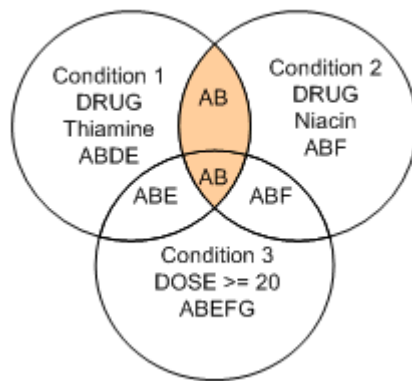
C

1 INTERSECT 2

The query finds the intersection of the two sets:

A

B

**1 INTERSECT 3**

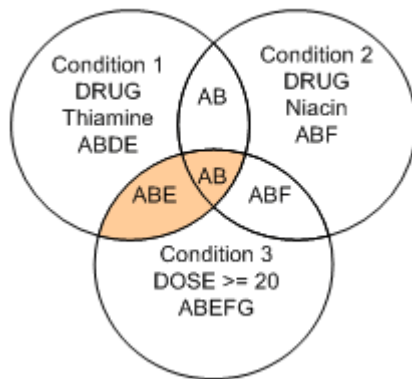
The query finds the intersection of the two sets:

A

B

E

Note that for case B, there is no occurrence of Thiamine where DOSE >= 20, but case B was in the set created by Condition 3 as well as the set created by condition 1, so the query retrieves it.

**1 UNION 2**

The query finds the union of the two sets:

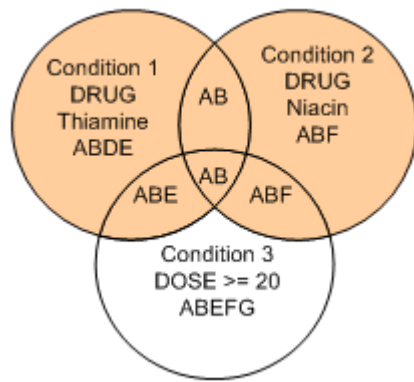
A

B

D

E

F



3 MINUS 1

The query finds the cases that remain when cases in set 1 are removed from set 3:

F

G

1 INTERSECT 2 AND 3

The query finds the following case:

B

1 UNION 2 AND 3

The query finds the following cases:

A

B

D

E

F

Null values

If you check **Include Null values** for a condition, the condition finds cases with rows for which the condition is true or the variable referenced by the condition is null. If you precede the condition with **NOT**, the condition finds cases with rows for which the condition is not true or the variable referenced by the condition is not null.

For example, suppose that the source data has four null values for DOSE (indicated by dashes (-) in the following table):

CASE_ID	DRUG	DOSE
A	Thiamine	-
A	Niacin	15
B	Thiamine	-
B	Niacin	25
C	Calcium	-
D	Thiamine	15

CASE_ID	DRUG	DOSE
E	Thiamine	25
F	Niacin	-
G	Calcium	25

If you specify the condition `DOSE >= 20` and check **Include Null values**, the application finds the following cases:

A
B
C
E
F
G

When you specify that values for a query should include nulls and then you precede the condition with the `NOT` operator, the query retrieves cases with rows for which the condition is not true and the variable used in the condition is not null.

If you specify `NOT 3` (meaning not condition 3, which is `DOSE >= 20`) and you have checked **Include Null values**, the following cases are found:

A
D

View query logic

You can view a query from the Queries page or examine a query used by a case series.

To view a query from the Queries page:

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Queries**.
2. Click the query's **Header Action** menu () , and then click **View**
The query logic for the selected query appears.
3. Click **OK**.

To view the query used by a case series:

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Case Series**.
The query logic for the case series appear in the Description column.
2. Click **OK**.

Rename a query

You can rename only those queries that you created.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Queries**.

2. Click the query's **Header Action menu** (), and then click **Rename**.
3. In the **Name** field, type a query name. The name does not need to be unique, although we recommend that you use a unique name.
4. In the **Description** field, optionally modify the description of the query.
5. Choose one of the following options:
 - To assign the query to an existing [project](#), click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.
 - To create a new project and assign the query to it, click **Add to a new project named** and enter a project name.
6. Click **Save**.

7

Create and manage case series

On the Case Series page, you can view information about existing case series that you have created or that have been published to you. You can also create a versioned case series for use in Signal Review.

- [About case series](#)
A case series is a list of cases of interest that you selected and saved. A versioned case series is a list of annotations added to cases during signal review.
- [Case Series page](#)
On the Case Series page, you can view information about existing case series that you have created or that have been published to you.
- [View existing case series](#)
The Case Series page provides information about existing case series and enables you to define new case series.
- [Copy a case series](#)
One way to create a new case series is to use an existing case series as the basis for a new one.
- [Publish a case series](#)
Publication of a case series is a way to make it available to other users. By default, the publication level of every newly created object is Private.
- [Delete a case series](#)
You can delete case series and versioned case series. However, versioned case series can only be deleted if they are not referenced by a signal configuration.
- [Create a case series](#)
There are several ways to create a case series. Once created, you must add cases, save the case series, and publish it for others to use.
- [Work with case series](#)
The results may differ for query-based case series.
- [Work with versioned case series](#)
The features described in this section apply to versioned case series.
- [Case series background processing](#)

About case series

A case series is a list of cases of interest that you selected and saved. A versioned case series is a list of annotations added to cases during signal review.

You can access the details of each case as well as determine the cases against which to run a report. For example, a case series might be a list of all cases that involved a particular class of products administered to patients of a particular demographic profile.

A versioned case series contains annotations on cases added during signal review. To use a versioned case series:

1. [Create an empty versioned case series.](#)

2. [Associate the versioned case series with a signal configuration.](#)
3. [Add cases to the versioned case series](#) while working with cases on the Product-Event Combinations page.

Case Series page

On the Case Series page, you can view information about existing case series that you have created or that have been published to you.

You can also define new case series if you have the Create Queries/Case Series permission.

General activities

The following links appear the top of the page and affect the entire page:

- [Create Using Query Wizard](#)
- [Create Empty Case Series](#)
- [Create Versioned Case Series](#)
- [PRR Calculator](#)
- [Columns](#)
- Print
- [Download](#)
- [Select Rows](#)

The following filters appear the top of the page and affect the entire page:

- **Filter by project:** From the Project drop-down list, select the project for which you want to view case series or -- to include all projects.
- **Filter by configuration:** From the Configuration drop-down list, select the data configuration for which you want to view case series or -- to include all configurations.

The following links appear the top of the page when the page is in the Select Rows mode. The links affect the multiple cases:

- [Print](#)
- [Download](#)
- Delete
- [Combine Case Series](#)
- Select All
- Clear All
- Back

Row-specific activities

The following menu options may be available from the Row Action menu, located in the left-most column of the table, and affect an individual row in the table:

- Cancel
To cancel a **Running** or **In Queue** case series background processing job, click **Cancel**. The Cancel option is available only when a background processing job exists for the case series.

- [View Cases](#)
- [View Query](#)
- [Edit Query](#)

To [edit the query portion](#) of a case series that was created with the Query Wizard, click **Edit Query**. You can click **Back** to select a different data configuration.

If the Cases Added column shows Yes, then cases have been transferred or added manually to the case series. If you re-execute the case series, those cases will no longer be part of the case series.

Note

Your edits to the query portion of the case series have no effect on the query in the Query Library (the Queries page). Likewise, editing or deleting the query in the library has no effect on the case series.

- [Rename a case series](#)
To [rename a case series](#), click **Rename**. You can also change its description or assign it to a different project
- [Report](#)
- [Publish](#)
- [Add Query to Library](#)
To add the query portion of the case series to the [Query Library](#), click **Add Query to Library**. You must have access to the [data configuration](#) on which the case series is based. If the query is added to the Query Library (the Queries page), that query is separate from the case series. Subsequent modification or deletion of the query in the library has no effect on the case series.
- [Copy](#)
To [copy a case series](#), click **Copy**. You must have access to the configuration on which the case series is based. You can copy any case series that you created or that has been published to your login group. If you have the *Administer Users* permission, you can copy a case series published to any login group.
- Delete
- [View annotations](#)
- [Edit](#)

Field descriptions—Case Series page

The Case Series page can provide the following information about each case series. You can customize the information shown using the Columns link at the top of the page.

Column	Description
Name	Name of the case series.
Description	Description of the case series.
Project	Name of the project to which the case series is assigned.
Configuration	Name of the data configuration associated with the case series.

Column	Description
# of Cases	Number of cases in the case series.
Created By	Name of the user who created the case series.
Created	Date and time on which the case series was created.
Modified By	Name of the user who last modified the case series.
Modified	Date and time when the case series was last modified.
Status	The current status of the background processing job .
As Of	Applies if the configuration supports timestamped data . The As Of date associated with the case series. If you created the case series when drilling down , this is the As Of date associated with what you were viewing before you drilled down.

Note

A date and time appear in this column even if the configuration does not support timestamped data. In this case, the date and time is approximately the same as the date and time in the Created column.

Associated Run	Name of the data mining run that generated the results from which the case series was created. If the run associated with a case series is deleted, the application retains the case series but it is no longer associated with the run. If the case series was not created from run results, this column is empty.

Column	Description
Cases Added	One of the following values: Yes—For a query-based case series, cases have been manually added to or transferred to the case series since the query portion of the case series was last executed (by clicking the , and then clicking Edit Query.) If you re-execute the query portion of the case series in this way, the manually added or transferred cases are dropped from the case series. No—For a query-based case series, cases have not been manually added to or transferred to the case series since the query portion of the case series was last executed (by clicking the Row Action menu () , and then clicking Edit Query.) NA—Not Applicable because the case series is not based on a query.
ID	Identifier the application assigned when the case series was created. Each case series ID is unique and is not re-used if the case series is deleted.
Versioned	Yes or No.
# of Entries	For versioned case series, the number of annotations in the case series. Otherwise, this will contain the same value as # of Cases.

View existing case series

The Case Series page provides information about existing case series and enables you to define new case series.

For the selected project and data configuration, the Case Series page lists [case series](#) that you have created or that have been published to you. If you have the Administer Users permission, the page also lists unpublished case series created by any users in your login group.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. (Optional) Filter the list as necessary.
 - From the **Project** drop-down list, select the [project](#) for which you want to view case series or -- to include all projects.
 - From the **Configuration** drop-down list, select the [data configuration](#) for which you want to view case series or -- to include all configurations.

The selected case series appear. See [About case series](#) for information about the case series.

Links that apply to case series and versioned case series

Use the links at the top of the page to create empty case series and versioned case series, [customize the columns](#), print the table, and [download the data](#).

- To create a case series by defining a query, select [Create Using Query Wizard](#).

- To [create an empty case series](#) to which you manually add case IDs, select **Create Empty Case Series**.
- To create a versioned case series, select [Create Versioned Case Series](#).
- To compute [Proportional Reporting Ratios](#) (PRR) for a set of previously defined case series, select **PRR Calculator**.
- To print, download, delete, or combine multiple case series, select [Select Rows](#). You can then select the rows for the case series on which you want to act. You can also select **Select All** to select all rows (or select **Clear All** to deselect all rows). From the menu, select the action that you want to perform on the selected rows. For more information see [About tables](#).

Row actions that apply to selected case series

The Row Action menus () in the first column offer actions you can perform on the selected case series.

For all case series and versioned case series

These actions can be performed on all case series and versioned case series:

- To [publish a case series](#), select **Publish**. You can publish any case series that you created. If you have the Administer Users permission, you can publish a case series created by any user in your login group.
- To [copy a case series](#), select **Copy**. You must have access to the configuration on which the case series is based. You can copy any case series that you created or that has been published to your login group. If you have the Administer Users permission, you can copy a case series published to any login group.
- To delete a case series, select **Delete**. You can delete any case series that you created. When a message asks if you want to delete the case series, select OK. The case series is deleted and no longer appears on your Case Series page. If a case series is versioned and it is referenced by a signal management configuration, it cannot be deleted.

If the case series isn't versioned

- To [view a case series](#), select **View Cases**.
- To [rename a case series](#), select **Rename**. You can also change its description or assign it to a different project.
- To [view existing report definitions](#), which you can run on the case series, select **Report**.

These actions can be performed on case series created with the Query Wizard:

- To [view a query](#), select **View Query**.
- To [edit a query](#), select **Edit Query**.
- To [add a query to the library](#), select **Add Query to Library**.

Note

Before deleting a query-based case series, you can save the query portion of the case series with the **Add Query to Library** option.

If the case series is versioned

These actions can be performed on all versioned case series:

- To view the annotations associated with the case series, select **View Annotations**.
- To edit the case series, select **Edit**.

Copy a case series

One way to create a new case series is to use an existing case series as the basis for a new one.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. Select the **Row Action menu** () for a case series, and then select **Copy**.
3. If the **Select a configuration** drop-down list appears on the Copy Case Series page, you can [select a data configuration](#). By default, the application uses the data configuration associated with the original case series (and you must have permissions to use that configuration). If you are copying a query-based case series, this page does not appear.

Note

If you select a different data configuration, case IDs that match in both data configurations are copied, but may represent different cases if the source data for the two data configurations differs.

4. Select **Next**.
5. On the Copy Case Series page, provide a name and description for the copied case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
6. Choose one of the following:
 - To assign the case series to an existing [project](#), select **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.
 - To create a new project and assign the case series to it, select **Add to a new project named** and enter a project name.
7. Select **Save**.

A message tells you that the case series has been copied and shows the names of the original case series (Source), the copy of the case series (Destination), and the number of entries in the two lists. If you copy a versioned case series, all annotations are included in the resulting copy.

If you copy a [query-based case series](#), you can then edit the copy to create the new case series. Oracle Empirica Signal uses the query that was in effect at the time of the original case series for the copy. Any indication of cases as Reviewed or Excluded, and any attached comments, are included in the copy of a case series.

Note

The copy of a case series includes any cases that were [transferred](#) or [added manually](#) to the case series. If you re-execute the query portion of the copy of a query-based case series, however, Oracle Empirica Signal drops those cases from the case series if they do not meet the query criteria.

Publish a case series

Publication of a case series is a way to make it available to other users. By default, the publication level of every newly created object is Private.

Note

Users without the Administer Users permission can publish only objects they have created. Users with the Administer Users permission can publish objects that they or any users in their login group created.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. Select a case series' **Row Action menu** () and select **Publish**.

Note

You can publish a single case series. Although you can print, download, delete, and combine multiple case series, you cannot publish them all at once.

3. From the **Publish to Login Groups** drop-down list, select the login groups who may use this case series.
 - If you are a superuser and the object is multi-enterprise support-related, then you can only publish to the object owner's login group.
 - If you are a superuser and the object is not multi-enterprise support-related, you can publish to multiple login groups, including —All—. In the **Publish to Login Groups** list, select one or more rows.
 - If you publish to —All— and later add a new login group, the object is published automatically to the new login group.
4. Select **Publish**.

On the Publish Case Series page, Oracle Empirica displays the selected login groups in the Publication Level field.
5. Select **Back**.

Delete a case series

You can delete case series and versioned case series. However, versioned case series can only be deleted if they are not referenced by a signal configuration.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. Select the case series' **Row Action menu** (), and then select **Delete**.
3. Confirm the deletion by selecting **OK**.

Create a case series

There are several ways to create a case series. Once created, you must add cases, save the case series, and publish it for others to use.

- [Create a query-based case series](#)
You can create a query and include the cases found by the query in a new case series.
- [When to use the Query Wizard to create a case series](#)
Use a query-based case series to retrieve and view source data as needed in your review and analysis of data. For example, you can retrieve cases that meet specified criteria, and then run a report against that case series.
- [Create an empty case series](#)
One way to create a case series is to create an empty case series and then manually add (type in or paste in) a list of case IDs, or transfer cases to the empty case series.
- [Transfer cases to a case series](#)
On pages and in reports that display a list of cases, you can transfer cases to an empty or existing case series.
- [Manually add cases to a case series](#)
You can add cases manually from source data to an empty case series or to a case series that already includes cases that you created or have been published to your login group.
- [Save a case series](#)
After you have created the case series and added cases to it, save it with a name that identifies its content.

Create a query-based case series

You can create a query and include the cases found by the query in a new case series.

To create or edit a query-based case series, use the Query Wizard, which guides you through the process of selecting variables, selecting values, and specifying query logic.

Note

If you edit and re-execute the query portion of a query-based case series to which cases have been [transferred](#) or [added manually](#), Oracle Empirica Signal drops those cases from the case series if they do not meet the query criteria.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. Select **Create Using Query Wizard**.
3. From the **Configuration** drop-down list, [select a data configuration](#). You can select **Browse** to select from a list of data configurations.
4. Select **Next** to [define the query conditions](#).
5. Select **Select Variables**.

6. Select variables from the left-hand list and move them to the Selected Variables list on the right.
7. From the **Table** drop-down list, select **All Tables** or a specific table.
8. In the **Match** field, enter a variable to find.
9. Select **OK**.
10. Build the query on the Define Query page by [selecting the values to include](#).
11. Select **Next**.
12. Review the data source and query logic. To preview the query results, select **Preview Cases**. This option is available only if you specified values for all variables and your user preference **Show case count by default on preview page** is enabled.
13. Select **Close**, then **Next**.
14. Save the query by specifying a name for the query. The name does not need to be unique, although Oracle recommends that you use a unique name.
15. In the **Description** field, leave the description or add a description of the query.
16. Choose one of the following:
 - To assign the case series to an existing [project](#), select **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.
 - To create a new project and assign the case series to it, select **Add to a new project named** and enter a project name.
17. Select **OK**.

Oracle Empirica Signal submits the case series to the [background processing job queue](#). For larger datasets, the Background Processing indicator appears next to your user name at the top of the page.

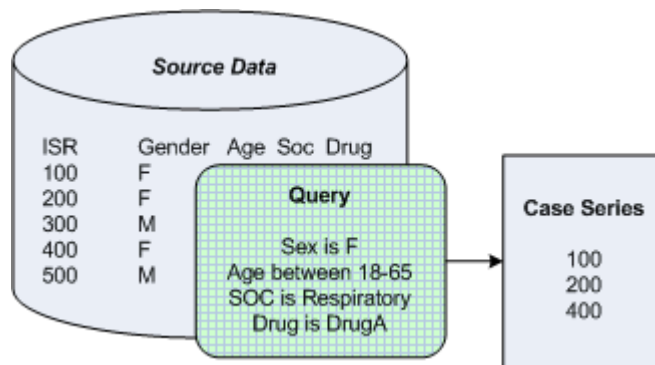
Note

The Background Processing indicator may not appear if you create a case series from a small data set that processes quickly.

When to use the Query Wizard to create a case series

Use a query-based case series to retrieve and view source data as needed in your review and analysis of data. For example, you can retrieve cases that meet specified criteria, and then run a report against that case series.

A query is based on variables and values in the source data. When you run a query, Oracle Empirica Signal retrieves cases that match the specified criteria. To create or edit a query, [use the Query Wizard](#) to guide you through selecting variables, selecting values, and specifying query logic. For example, you can query for cases in which the patient is a female between age 18 and 65 who has experienced events in the Respiratory SOC (System Organ Class) and has taken DrugA.



Using the Query Wizard, you select variables from the source data, and then select values for each variable. You can use logical operators (AND, OR, and NOT) or set operators (INTERSECT, UNION, and MINUS) between the variables to construct a logical expression. The query retrieves a list of cases. The case series consists of case IDs of those cases. If the query retrieves a case multiple times, its case ID appears once in the case series.

You can add the query portion of a case series to the [Query Library](#) (the Queries page). The query in the Query Library is completely separate from the query that is part of the case series. For example, if you modify the query in the Query Library, the modification does not affect the case series. If you modify the query portion of a case series, the modification does not affect the query in the library.

Typically, a case series is a static list of cases; however, if you edit and re-execute the query portion of a query-based case series, Oracle Empirica drops any cases that you manually added or transferred to the case series if they do not meet the query criteria.

Create an empty case series

One way to create a case series is to create an empty case series and then manually add (type in or paste in) a list of case IDs, or transfer cases to the empty case series.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. Select the **Create Empty Case Series** link.
3. On the Create Empty Case Series page, from the **Select a configuration** drop-down list, select a configuration. You can click **Browse** to select from a list of data configurations.
4. Select **Next**.

If you selected a data configuration that supports [timestamped data](#), the Select As Of page appears so that you can specify an As Of data.

5. In the **Name** field, enter a name for the case series. The name does not need to be unique, although we recommend that you use a unique name.
6. In the **Description** field, enter an informative description of the case series.
7. Choose one of the following:
 - To assign the case series to an existing project, click **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.
 - To create a new project and assign the case series to it, click **Add to a new project named** and enter a project name.
8. Select **Save**.

The empty case series is added to the top of the Case Series page.

9. You can add or transfer cases to the empty case series.
 - To [manually add cases](#), on the Case Series page from the case series' **Row Action** menu () select **View Cases**, select the **Manually Enter IDs** link, and append one or more case IDs.
 - To [transfer cases](#) to the empty case series, open a page or report that displays a list of cases, select a case, and then select **Transfer to Case Series**.

Transfer cases to a case series

On pages and in reports that display a list of cases, you can transfer cases to an empty or existing case series.

You can also [create a new case series](#) containing the cases.

For [timestamped data](#), when cases are transferred to a case series, Oracle Empirica Signal uses the As Of date associated with the target case series to determine whether the cases are legitimate to add. For example, if the As Of date of the case series is 06/15/2019 and the case ID 1554 did not exist until 07/21/2019, if you try to add case ID 1554 to the case series, it is not added because it did not exist on 06/25/2019.

1. Navigate to a page or report that display a list of cases. For example:
 - By selecting a cell in a Product-Event Combinations page.
 - By viewing the Results Table when working with data mining results.
For example:
 - a. In the left navigation pane, hover over the **Data Analysis** icon () , then select **Data Mining Results**.
 - b. On the **Select Criteria** page, choose the run from the **Run name** drop-down list.
 - c. Specify the selection criteria.
 - d. Select **View Results Table**.
2. Select the **Row Action** menu () for a product, and then select **Transfer to Case Series**. Alternatively, select a **count (N)** of cases in a table or select the element of a graph, and then select **Transfer to Case Series** from the Row Action menu.
3. Select the row for the case series that you want to select, and then select **OK**.

Oracle Empirica Signal adds the case IDs to the case series if they were not already in it. A message states how many cases were added to the case series.

Note

It is possible, but not recommended, to transfer cases that do not meet query criteria to a query-based case series. If the query is executed again, the transferred cases are dropped if they do not meet the query criteria.

Manually add cases to a case series

You can add cases manually from source data to an empty case series or to a case series that already includes cases that you created or have been published to your login group.

If you have the Administer Users permission, you can add cases manually to a published or unpublished case series created by any user in your login group.

For [timestamped data](#), when cases are added manually to a case series, the application uses the As Of date associated with the target case series to determine whether the cases are legitimate to add. For example, the As Of date of the case series is 06/25/2019 and case ID 1554 did not exist until 07/21/2019. If you try to add case ID 1554 to the case series, the application does not add it, because the case did not exist on 06/25/2019.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. Select the **Row Action menu** () for the case series to which you want to add cases, and then select **View Cases**.
3. Select **Manually Enter IDs**.
4. Type or paste in a list of case IDs. Each case must be on a separate line or separated from the next case ID by a comma.
5. Select **Append**.

Oracle Empirica Signal searches the source data for the specified case IDs and refreshes the case series list with the number of case IDs that you manually entered, the number of case IDs added to the case series, and the total number of case now included in the case series. If a manually added case ID does not exist in the source data, the application does not add that case ID to the case series.
6. Select **Close**.

Note

It is possible, but not recommended, to add cases that do not meet query criteria to a query-based case series. If you execute the query again, Oracle Empirica Signal does not include the added cases because they do not meet the query criteria.

Save a case series

After you have created the case series and added cases to it, save it with a name that identifies its content.

You can assign the case series to a specific project or create a new project to include the case series.

1. Create or edit a query. For more information, see [Create a query-based case series](#) or [Create an empty case series](#).
2. On the **Save Case Series** page, in the **Name** field, enter a name for the case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
3. In the **Description** field, enter an informative description of the case series.
4. To assign the case series to a [project](#) perform one of the following:

- To assign a case series to an existing project, select **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.
 - To create a new project and assign the case series to it, select **Add to a new project named** and enter a project name
5. Select **OK**.

A message tells you that the case series is being saved. If you select **Cancel** at this point or navigate to another page, the application does not create the case series.

Work with case series

The results may differ for query-based case series.

- [View cases in a case series](#)
From the Case Series page, you can view a list of the cases in a case series as well as details of a case. You can also add cases to the series.
- [View case details from the Case Series page](#)
When viewing a case series from the Case Series page, you can select a case ID to view case details.
- [Rename a case series](#)
You can rename only those case series that you created.
- [Combine case series](#)
If you have the Create Queries/Case Series permission, you can combine two or more case series in the same configuration.

View cases in a case series

From the Case Series page, you can view a list of the cases in a case series as well as details of a case. You can also add cases to the series.

To view the cases in a case series:

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. (Optional) Filter the list as necessary by selecting a project and a configuration from the drop-down menus.
3. Select the case series' **Row Action menu** (), and then select **View Cases**.

Note

Because Oracle Empirica Signal retrieves the data from the source data, it does not include [custom terms](#) or values created by [data transformations](#).

The Cases page lists the cases in the case series in a table. The variable representing the case ID is the first column of the table. The data configurations associated with the case series determine the additional columns that appear. For example, if the site option **All Case Comment/Review/Exclusion** is enabled, additional columns indicate whether the case has been reviewed or excluded, and whether comments have been added by a reviewer.

4. Perform additional actions on cases:

- To [view case details](#), select the **case ID** in the first column.
- To [add cases manually](#), select the **Manually Enter IDs** link, enter case IDs, separated by lines or commas, in the text box, and then select **Append**.
- To see the reports that can be run on the case series, select the **Report** link.
- To [download case details](#) for all cases in the list to an Excel spreadsheet or a Word Rich Text Format File, select the **Download Case Details** link. (When viewing a particular case, you can also download case details for that one case.) Oracle Empirica Signal does not include cases that are marked as excluded and that are hidden at the time of the download.
- To [save the list of cases as an attachment to a topic](#), select the **Save to Topic** link (available if the Topics feature has been set up). The application does not include cases that are marked as excluded and that are hidden at the time you save the list as an attachment.
- If any cases have been marked as excluded as part of reviewer input, you can select the **Hide Excluded** link. Excluded cases are not visible on the Cases page. If you select **Show Excluded**, such cases are visible.

View case details from the Case Series page

When viewing a case series from the Case Series page, you can select a case ID to view case details.

If the **Allow Case Comment/Review/Exclusion** option is enabled, you can indicate that you have reviewed the case details and provide a comment.

At a minimum, the Case Details page typically includes the following information:

- Case Information (demographic information)
- Reported Drugs/Vaccines
- Reported Events/Symptoms

Additional information includes reported outcomes, case report sources, narrative text, and so on.

If specified by the configuration, a description of the source data appears below the case details. For example: Source Data: AERS data as of 4th quarter 2009 from NTIS Public Release loaded on 2010-04-18.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. (Optional) Filter the list as necessary by selecting a project and a configuration from the drop-down menus.
3. Select the case series' **Row Action menu** (), and then select **View Cases**.

Note

Because Oracle Empirica Signal retrieves the data from the source data, it does not include [custom terms](#) or values created by [data transformations](#).

The Cases page lists the cases in the case series in a table. The variable representing the case ID is the first column of the table and is a link to the details of that case. The data

configurations associated with the case series determine the additional columns that appear. For example, if the site option **All Case Comment/Review/Exclusion** is enabled, additional columns indicate whether the case has been reviewed or excluded, and whether comments have been added by a reviewer.

4. Select a case ID link.

Oracle Empirica displays the Case Details page. At a minimum, the following information appears:

- Case information (demographic information)
- Reported Drugs/Vaccines
- Reported Events/Symptoms

There might also be additional information about reported outcomes, case report sources, narrative text, and so on.

If you have [set your user preferences](#) to show a table of contents for case details, there is a Contents section at the top of the page. It includes links that you can select to jump to various types of data on the page.

5. In the **Reviewer Input** section at the bottom of the dialog box, you can do the following:

- To indicate that source data for a case has been reviewed, select **Reviewed**.
- If you do not want the case to appear on the Cases page when you hide excluded cases, select **Excluded**.
- In the **Comments** text box, enter comments about the data.

Note

The Reviewer Input section appears only if the appropriate site option has been set.

6. You can also perform the following actions:

- To print case details, select the **Print** link.
- To [download case details](#) to an Excel spreadsheet or a Word Rich Text Format file, select the **Download** link.
- To [save the case details as an attachment to a topic](#), select the **Save to Topic** link (available if the topics feature has been set up).
- To go to a third-party application showing further information about the case, select the custom link (available only if configured for the data configuration on which the case series is based).

7. Several buttons provide additional actions:

- To save your changes and close the Case Details dialog box, select **Save**.
- To save your changes and keep the Case Details dialog box open, select **Apply**.
- To view the case details for another case in the case series, select **Prior** or **Next**.

These buttons are unavailable for case series that contain 50,000 cases or greater.

Rename a case series

You can rename only those case series that you created.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. (Optional) Filter the list as necessary by selecting a project and a configuration from the drop-down menus.
3. Select the case series' **Row Action menu** (), and then select **Rename**.
4. On the Rename Case Series page, in the **Name** field, type a new name for the case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
5. In the **Description** field, leave the description or modify the description of the case series.
6. Choose one of the following:
 - To assign the case series to an existing [project](#) select **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.
 - To create a new project and assign the case series to it, select **Add to a new project named** and enter a project name.
7. Select **OK**.

 Note

When you rename a case series, the case series name attached to any existing report outputs is not changed.

Combine case series

If you have the Create Queries/Case Series permission, you can combine two or more case series in the same configuration.

Oracle Empirica Signal copies all cases in the selected case series into a new case series, but retains the original case series selected. Oracle Empirica Signal sets the Reviewed and Excluded statuses for all cases to *null* in the new case series.

 Note

To combine case series, the status of the case series that you select must be *Completed*, and the cases must have the same data configuration. For [timestamped](#) data, the application prompts you to select an As Of date.

1. In the left navigation pane, hover on **Data Analysis** () , then select **Case Series**.
2. Select the **Select Rows** to enter row selection mode.
3. Select the check boxes next to the case series that you want to combine. You must select at least two case series.
 - You must select at least two case series.
 - The selected case series must be in the same configuration.
 - You cannot include versioned case series.
4. Select the **Combine Case Series** link.

5. If the case series contains timestamped data, [specify an As Of date](#).
6. On the Combine Case Series page, in the **Name** field, enter a name for the combined case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
7. In the **Description** field, enter an informative description of the combined case series.
8. Select one of the following:
 - To assign the combined case series to an existing [project](#), select **Add to existing project** and then select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.
 - To create a new project and assign the case series to it, select **Add to a new project named** and enter a project name.
9. Select **Create**.

You can work with the combined case series as you would with any other case series.

Work with versioned case series

The features described in this section apply to versioned case series.

- [About annotating a specific case](#)
To add annotations to individual cases and make them available as you work with the case series, you must create a special type of case series; that is, a versioned case series.
- [Add or edit an annotation type](#)
Annotation types are predefined comments that you can apply to cases in a versioned case series; for example, *Suspected duplicate*.
- [Change the sort order of the annotation types](#)
You can change the order in which the annotation types appear when adding an annotation.
- [Delete an annotation type](#)
You can delete an annotation type if you are a superuser or the owner of the versioned case series.
- [Create a versioned case series](#)
Create a versioned case series from the Case Series page.
- [Associate a versioned case series with a signal configuration](#)
You must associate the versioned case series with a signal configuration based on the same data source you just established for the versioned case series.
- [Add annotations to a specific case in a case series](#)
To add annotations to a specific case in a case series, open the Signal Review page, drill down to case details, and add an annotation to the case.
- [View annotations for a case series](#)
From the Case Series page, you can view all the annotations associated with a case series in an annotations table.
- [View the details of a versioned case series annotation](#)
Once you have displayed the annotations in a versioned case series, you can view the details of an annotation.
- [Work with annotations associated with a selected case](#)
If you select a case ID from the Cases page, the Case Details page includes the case version date, an additional Annotation section with detailed information about annotations for the case, and a link to add an annotation.

About annotating a specific case

To add annotations to individual cases and make them available as you work with the case series, you must create a special type of case series; that is, a versioned case series.

This involves three steps:

1. [Create a versioned case series](#) from the Case Series page.
2. [Associate the versioned case series with a signal configuration](#).
3. In Signal Review, annotate individual cases within the versioned case series by [drilling down to case details](#) and adding an annotation to the case.

Note

You must define the [annotation types](#) before you can annotate specific cases.

Add or edit an annotation type

Annotation types are predefined comments that you can apply to cases in a versioned case series; for example, *Suspected duplicate*.

A default set of annotation types is installed with Oracle Empirica. You can also create distinctive annotation types for each versioned case series.

Note

To add or delete an annotation type, you must be a superuser or the owner of the case series.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. On the Case Series page, select the versioned case series' **Row Action menu** () for the data configuration, then select **Edit**.
3. On the Edit Versioned Case Series page, select the **Edit Table** button in the **Annotation types** field.
4. Add an annotation type or edit a type shown.

Add an annotation type

- a. Select the **Add Annotation Type** link.
- b. On the Add/Edit Annotation Type page, fill in the fields shown:
 - **Annotation text:** The annotation. When users add an annotation on the Case Details page, this value appears in the **Annotation Type** drop-down list.
 - **Abbreviated annotation text:** Shortened version of the annotation text.
 - **Requires detailed annotation?** If you select Yes, you must enter an additional free-text when adding an annotation in Signal Review.

- c. Select **Save**.

Edit an annotation type

- a. From the table of defined annotation types, select the annotation's **Edit** link.
- b. On the Add/Edit Annotation Type page, edit the fields and then select **Save**.

Change the sort order of the annotation types

You can change the order in which the annotation types appear when adding an annotation.

To get to the Annotation Type Sort Order page, select the **Change Sort Order** link on the Edit Annotation Types page.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. On the Case Series page, select the versioned case series' **Row Action menu** () for the data configuration, then select **Edit**.
3. On the Edit Versioned Case Series page, select the **Edit Table** button in the **Annotation types** field.
4. On the Edit Annotation Types page, select the **Change Sort Order** link.
5. On the Annotation Type Sort Order page, select an annotation type and use the up and down arrows to change the position of the annotation type.
6. When you are satisfied with the sort order, select **OK**.

The new sort order is reflected wherever there is an Annotation type drop-down list.

Delete an annotation type

You can delete an annotation type if you are a superuser or the owner of the versioned case series.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. On the Case Series page, select the versioned case series' **Row Action menu** () for the data configuration, then select **Edit**.
3. On the Edit Versioned Case Series page, select the **Edit Table** button in the **Annotation types** field.
4. From the table of defined annotation types, select the annotation's **Delete** link.

Oracle Empirica deletes the annotation type.

Create a versioned case series

Create a versioned case series from the Case Series page.

You must have the Manage Signal Configuration permission, as well as Create Case Series permission to create a versioned case series.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. On the Case Series page, select the **Create Versioned Case Series** link to create a new versioned case series.

3. On the Create Versioned Case Series page, identify the source of the data by selecting a configuration or an alias from the **Configuration** drop-down.

The selected data configuration must have appropriate [variables types set for use with versioned case series](#).
4. In the **Name** field, enter a name for the case series. The name does not need to be unique, although Oracle recommends that you use a unique name.
5. In the **Description** field, enter an informative description of the case series.
6. Choose one of the following:
 - To assign the case series to an existing project, select **Add to existing project** and select the project from the drop-down list. Only projects associated with objects that you created or that are published to you appear in the list.
 - To create a new project and assign the case series to it, select **Add to a new project named** and enter a project name.
7. Select **Save**.

An empty versioned case series is added to the Case Series page and Oracle Empirica identifies the case series as versioned by adding the Yes value to the Versioned column. The # of Entries column displays 0 because no annotations have been added. The only way to add annotations (that are associated with cases) to the new versioned case series is to go to the Signal Review page and add annotations to those cases.

Note

The next step is to [associate the versioned case series with a signal configuration](#).

Associate a versioned case series with a signal configuration

You must associate the versioned case series with a signal configuration based on the same data source you just established for the versioned case series.

1. In the left navigation pane, select the **Settings** icon (.
2. In the Configure System section, select **Manage Signal Configurations**.
3. On the Manage Signal Configurations page, find a signal configuration based on the same data source you just established for the versioned case series.
4. On the Manage Signal Configurations page, select the **Row Action menu** () for the signal configuration you want to associate the versioned cases series with, and then select **Edit**.
5. On the Edit Signal Configuration page, select the versioned case series from the **Versioned Case Series** drop-down.
6. Select **Save**.

The versioned case series and the signal configuration are now linked and you can go to Signal Review to [populate the versioned case series](#).

Add annotations to a specific case in a case series

To add annotations to a specific case in a case series, open the Signal Review page, drill down to case details, and add an annotation to the case.

1. In the left navigation pane, select **Signal Review** () to display the Products page.
2. From the drop-down to the right of the Signal Review page title, select the signal configuration you just associated with the versioned case series.
3. Identify the product whose cases you want to annotate to add them to the versioned case series and then [drill down to the cases details](#) associated with that product by selecting the case count displayed in one of the associated columns.

Oracle Empirica displays the product-event combinations table.

4. Now drill down to the actual cases by selecting the case count displayed in one of the associated columns and select **View Cases** from the drop-down menu.

The Cases page shows the cases associated with the selected product-event combination.

5. To annotate a case, select the ISR number to display the case details.
6. On the Case Details page, select the **Add Annotation** link, and then complete the Add Annotation page.
 - a. From the **Annotation** drop-down, select an annotation type. A default set of annotation types is installed with Oracle Empirica. You can also [create annotation types](#) for each versioned case series.
 - b. In the **Detailed Annotation** text box, enter your annotation, and then select **OK**.

The annotation is added to the versioned case series and summarized on the Case Details page. The most current annotation displays there.

7. You can continue populating the versioned case series from the Case Details page by entering additional annotations using the **Add Annotation** link.

View annotations for a case series

From the Case Series page, you can view all the annotations associated with a case series in an annotations table.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then select **Case Series**.
2. (Optional) Filter the list as necessary.
 - From the **Project** drop-down list, select the [project](#) for which you want to view case series or -- to include all projects.
 - From the **Configuration** drop-down list, select the [data configuration](#) for which you want to view case series or -- to include all configurations.
3. Select the versioned case series' **Row Action menu** () , and then select **View Annotations**.

Note

Versioned case series are identified by a Yes in the Versioned column. If you don't see the Versioned column, select the **Columns** link and add the Versioned column.

The Annotations page displays all the annotations associated with the selected versioned case series. Each row includes:

- **Case ID:** ID that identifies the specific case.
 - **Annotation Date:** The date and time the annotation was added.
 - **Case Version Date:** Latest update date of the case, at the time the annotation was added.
 - **Annotator:** User who added the annotation.
 - **Annotation:** The annotation type.
 - **Detailed Annotation:** Detailed text of the annotation.
 - **Report ID:** Unique identifier of the case report.
 - **As Of Date:** The date that the dataset was updated, at the time the annotation was added.
 - **Configuration:** Data configuration in effect when the annotation was added.
 - **ID:** Unique identifier of the annotation.
4. Filter the annotations by selecting options and then selecting **Apply**.
 - View all annotations or just the latest ones.
By default, only the latest annotation on each case is shown.
 - Enter a range of dates to filter by the annotation creation date.
 - All annotation types or a specific type.
 5. View the details of an annotation by selecting an annotation's **Annotation Type** column.
 6. View case details for an annotation by selecting the **Case Report Id** column to link to a details page similar to the Case Details page, except it displays information for a specific annotation. You can use the Next/Prev buttons to navigate through the list of annotations.
 7. Perform additional actions on the annotations table by selecting these links:
 - Save to Topic
 - Print
 - Download

Note

When downloaded as text or .xlsx format, Oracle Empirica truncates the annotation after 32,768 characters. This truncation is done intentionally for all long text fields including narrative and versioned case series annotation.

View the details of a versioned case series annotation

Once you have displayed the annotations in a versioned case series, you can view the details of an annotation.

You can view annotation details:

- For the latest annotation from the Case Details page by selecting the **View** link.
- For the previous annotations from the Other Annotations table on the Case Details page by selecting the annotation.
- For all annotations associated with a versioned case series from the Case Series page by selecting View Annotations from the case series' **Row Action Menu** () and then selecting an annotation.

The View Annotation Detail page provides these details about the current annotation.

- Annotation for <Case Id>
- Case Version Date
- Annotation Date: Date the annotation was created
- Annotator: Who created the annotation
- Annotation: Annotation type
- Detailed Annotation: Detailed text

Work with annotations associated with a selected case

If you select a case ID from the Cases page, the Case Details page includes the case version date, an additional Annotation section with detailed information about annotations for the case, and a link to add an annotation.

1. From the Cases page, select the case by selecting its case ID to view the Case Details page for the selected case.

When associated with a versioned case series, the Case Details page includes the case version date and an additional Annotation section with detailed information about annotations for the case. The section includes:

- Information about the latest annotation for the current case version, if there is one. This includes the user who created the annotation and the creation date, the annotation type, and the detail of the annotation.

To view additional details of the latest annotation, select the **View** link to the right of the annotation type.

- An **Add Annotation** link to add an annotation to the case.
- An Other Annotations table, if annotations other than the current one exist. This table includes Annotation Date, Case Version Date, Annotator, Annotation, and Detailed Annotation.

For each row, select the **Annotation Date** to view case details for the selected annotation. The case information in other sections is shown as of the date of the annotation. The current annotation is replaced with the selected annotation.

Select the **Annotation** field to view additional details for the selected annotation.

2. Select the **Prior** or **Next** button to cycle through the cases in the case series.

Case series background processing

- [What is background processing for case series?](#)
Background processing allows processes, such as case series creation, to run without user intervention and interruption, so that you can perform other tasks simultaneously.
- [How does the background processing job queue for case series work?](#)
A background processing job queue is a temporary container that the application creates on demand when one or more sequential jobs are awaiting background processing.
- [Background processing job status for case series](#)
As case series background processing progresses, the status of the processing job changes.
- [Cancel a background processing job for a case series](#)
You can cancel a background processing job at any time from the Case Series page, depending on the job type.

What is background processing for case series?

Background processing allows processes, such as case series creation, to run without user intervention and interruption, so that you can perform other tasks simultaneously.

Uninterrupted background processing also allows you to exit the application without affecting job processing or completion. Background processing is a standard feature and occurs automatically. You do not need to enable background processing.

One background processing job exists per task when you perform any of the following:

- [Create a case series](#) using the Query Wizard.
- [Create a case series from an existing query](#).
- [Edit and save](#) a query-based case series.

How does the background processing job queue for case series work?

A background processing job queue is a temporary container that the application creates on demand when one or more sequential jobs are awaiting background processing.

Jobs in the queue [awaiting background processing](#) run one at a time in the order in which the application added them to the queue. The job queue is specific to your user account, and contains only jobs that you created. You cannot view another user's job queue, even if you are a superuser.

Your queue can hold an unlimited number of jobs. The application adds jobs to your queue when you perform specific case series tasks, as described in [What is background processing?](#). The application can add jobs while a job is running without interrupting that job.

When a background processing job is running, you can view the job queue and the current status of the jobs in your queue by hovering the Background Processing indicator (). The Background Processing indicator appears next to your username at the top of the page, and remains visible until there are no unprocessed jobs remaining.

You can also view the current job status for background processing jobs for individual case series on the Case Series page. If *Completed* appears in the **Status** column, background processing is complete.

You can [cancel](#) **Running** or **In Queue** jobs in your background processing queue from individual case series on the Case Series page. If you are a superuser, you can also cancel other users' jobs from these pages.

Background processing job status for case series

As case series background processing progresses, the status of the processing job changes.

Case series background processing jobs can have one of the following statuses:

- **In Queue**—Job is awaiting processing.
- **Running**—Job is currently processing.
- **Cancelled**—Superuser or the user who submitted the job cancelled it.
- **Error Occurred**—Job did not finish processing. You may see this status if, for example, the database fails during processing.
- **Completed**—Job finished processing successfully.

Note

- You can [cancel](#) In Queue or Running jobs, if necessary, from the Case Series page.
- You cannot restart Error Occurred jobs. To complete the job processing, edit and then save the case series.

Cancel a background processing job for a case series

You can cancel a background processing job at any time from the Case Series page, depending on the job type.

The **Cancel** action menu command is available for In Queue or Running case series or report outputs in your background processing queue.

You cannot cancel jobs when hovering your mouse over the Background Processing indicator.

If you are a superuser, you can:

- Cancel jobs that you submitted.
 - Cancel jobs that other users submitted.
1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Case Series**.
 2. Locate the case series for which you submitted a background processing job. The status in the Status column must be *In Queue* or *Running*. If you are a superuser, you can locate the case series that another user submitted.

If necessary, hover your mouse over the Background Processing indicator, located next to your username at the top of the page, to obtain the case series name from your job queue. You can sort case series by status to locate In Queue or Running jobs.

3. Click the **Row Action menu** () next to the case series, and click **Cancel**.

8

Manage report definitions and output

- [About reports](#)
Oracle Empirica Signal supports line listings and summary reports that reflect the data found in a set of safety reports.
- [Report structure](#)
A report is a tabular display of source data, according to the specifications of a report definition.
- [View existing report definitions](#)
For the selected project and data configuration, the Report Definitions page lists report definitions that you created or that are published to you. If you have the Administer Users permission, the page also lists unpublished report definitions that were created by any user in your login group.
- [Built-in reports](#)
The Oracle Empirica Signal application includes a set of built-in report definitions that you can run from the Report Definitions page. You can also copy them and modify the copies as needed. Only a superuser can edit the original built-in reports.
- [Create report definitions](#)
- [Create and run interactive reports](#)
- [Work with report outputs](#)
- [Work with report graphs](#)

About reports

Oracle Empirica Signal supports line listings and summary reports that reflect the data found in a set of safety reports.

The set of safety reports can be from:

- Case series
- Hyperlinked N in bold (such as the count of a particular product-event combination found in run results)
- Element of a graph, such as a bar in a bar graph
- Query results
- Interactive report

Using Oracle Empirica Signal's reporting feature you can:

- Run [built-in reports](#) that are delivered with the product. You can use these reports as is, or copy and modify them.
- Retrieve source data and present it in a tabular format.
- View graphs of report data.
- Determine which variables to use to define rows and columns of the report.

- Define break-down variables, such as counts of PTs for males and counts of PTs for females within each age group, at multiple levels.
- Indicate how to aggregate multiple values for variables in the report.
- Create various types of reports, from line listings to summary reports that show statistics for cross-tabulations of variables.
- Use the drill-down feature to view case details for a report that includes case IDs or counts.
- Create a report definition. A report definition is the specification of the format of a report and restrictions on the data that the report displays. You must have the appropriate permissions to create a report definition and publish it for other users to view.

Note

Because reports run on source data (not data mining results), they do not include custom terms or values created by [data transformations](#).

Report structure

A report is a tabular display of source data, according to the specifications of a report definition.

Because data that appears in a report is source data, the report does not contain [custom terms](#) or values created by [data transformations](#).

A report includes one row for each variable (or combination of variables) that you specify as a row variable in the report definition. For each row, the report includes columns that you identify as column variables in the report definition. Each column is called an analysis variable.

The report definition may include multiple levels of column variables, as in the following example. A variable that groups values for another variable is called a breakdown variable. Any row variable can be a breakdown variable, and the column variable at the top of the report can also be a breakdown variable.

Figure 8-1 Output: Report for Doc reports

Age	Gender	Body System		
		Cardiac disorders	Gastrointestinal disorders	Vascular disorders
		Count	Count	Count
		N	N	N
0	F	12	14	7
0	M	15	25	6
0	U	3	1	3
0.01	F	0	2	0
0.01	M	1	10	2
0.01	U	2	0	0
0.02	F	0	1	0
0.02	M	0	14	4
0.02	U	2	0	0
0.03	F	0	1	0

View existing report definitions

For the selected project and data configuration, the Report Definitions page lists report definitions that you created or that are published to you. If you have the Administer Users permission, the page also lists unpublished report definitions that were created by any user in your login group.

A report definition specifies:

- Which variables from the source data appear as columns in the report, and how they are broken down based on other variables.
- Which variable or combination of variables provide unique keys for the report. There is one row in the report for each unique key value (or key value combination).
- How to aggregate multiple values in individual cells.
- The subset of rows that appear in the report, based on conditions specified by a SQL WHERE clause.

The Report Definitions page lists reports based on data configurations that are [compatible](#) with the data configuration used by the selected case series.

Display the Report Definitions page

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. At the top of the Report Definitions page, to the right of **Case Series**, click **Browse**.

3. On the Select Case Series page, [filter the case series](#).
4. Select the case series to report on and click **OK**, or double-click on the case series.

Display the Report Definitions page from the Case Series or Queries page

Click the **Row Action menu** () for a case series or query, and click **Report**. On the Cases page, click the **Report** link.

The names of valid report definitions appear in bold on the Report Definitions page. A report definition is a valid (and, therefore, can be run) if it includes at least one row variable and one column variable, and no error messages appear for the variables.

Filter the report definitions as necessary

1. From the **Project** drop-down list, select the [project](#) for which you want to view report definitions or -- to include all projects.
2. From the **Configuration** drop-down list, select the [data configuration](#) for which you want to view report definitions or -- to include all configurations.

The selected report definitions appears. See the Report Definitions page for information about the information shown.

Built-in reports

The Oracle Empirica Signal application includes a set of built-in report definitions that you can run from the Report Definitions page. You can also copy them and modify the copies as needed. Only a superuser can edit the original built-in reports.

Note

The built-in reports are available only if a data stub has been set up as described in AERS (1q03: S) Configuration Installation Instructions (located in the Data_Stub folder on the installation CD).

Examples of the built-in reports follow. Each heading shows the report name and description.

Age Group: Gender [N] – Summary: Counts by Age Group by Gender

Age Group	Gender		
	Female	Male	Unknown
	Reports	Reports	Reports
	N	N	N
18 - 64	98	14	0
65 - above	10	1	0
Unknown	37	11	2

Drugs and Events – Detail: ISR, Gender, Age (years), Generic Drugs, Events

ISR	Gender	Age (yrs)	Generic Drug(s)	Event(s)
			All (U)	All
3295675	F	73	Bupropion, Grepafloxacin	Chest discomfort, Dry mouth, Insomnia, Tension headache, Urinary incontinence, Dyspnoea, Fatigue
3332519	F	49	Bupropion	Headache, Myalgia, Drug use disorder, Sinus headache, Paraesthesia, Neck pain
3368431	M	28	Budesonide	Sinus headache, Epistaxis, Laceration
3369579	U		Budesonide	Drug ineffective, Sinus headache
3427897	F	35	Bupropion	Dry mouth, Sinus headache, Hyperhidrosis, Headache, Sedation, Nausea, Insomnia
3495768	F	41	Budesonide	Sinusitis, Sinus headache
3573266	M	55	Budesonide	Sinus headache
3573851	F	54	Budesonide	Sinus headache
3749780	M	55	Budesonide	Sinus headache
3769500	F	50	Budesonide	Sinus headache, Facial pain

Outcome [%] – Summary: Percentages by Outcome

Outcome	Reports
	Col % (U)
Died	4.05
Disabled	5.2
Hospitalized	13.87
Life-threatening	0.58
Other	30.64
Required Intervention to Prevent Permanent Damage	1.73
NULL	55.49
All	100

Report Type: SOC [N] – Summary: Counts by Report Type by SOC

Report Type	SOC
	All (N)
DIR	Blood (1), Card (2), Ear (4), Eye (17), Gastr (15), Genrl (15), Intec (2), Inj&P (1), Inv (4), Metab (1), Musc (15), Nerv (31), Prod (1), Psych (14), Resp (8), Skin (3), SocCi (1), Vasc (1)
EXP	Blood (6), Card (4), Cong (1), Ear (7), Endo (1), Eye (57), Gastr (60), Genrl (96), Hepat (1), Immun (4), Intec (26), Inj&P (32), Inv (19), Metab (9), Musc (48), Neopl (5), Nerv (143), Prod (3), Psych (47), Renal (13), Repro (1)
PER	Blood (3), Card (3), Ear (10), Eye (45), Gastr (42), Genrl (89), Immun (5), Intec (23), Inj&P (33), Inv (8), Metab (5), Musc (34), Nerv (194), Preg (1), Prod (4), Psych (32), Renal (8), Repro (1), Resp (64), Skin (32), SocCi (3)

Route of Administrations [N,%] – Summary: Counts and Percentages by Route of Administration

Route of Administration	Drugs	
	N	Col %
INHALATION	35	12.77
INTRAMUSCULAR	72	26.28
INTRAOCULAR	5	1.82
INTRASINAL	1	0.36
INTRATHECAL	11	4.01
INTRAVENOUS	6	2.19
INTRAVENOUS (NOT OTHERWISE SPECIFIED)	14	5.11
NASAL	37	13.5
ORAL	42	15.33
OTHER	2	0.73
PARENTERAL	1	0.36
RESPIRATORY (INHALATION)	16	5.84
SUBCUTANEOUS	12	4.38
UNKNOWN	20	7.3
All	274	100

Sample Counts – Compares a variety of report counts

SOC	ISR_demog		ISR_reac		PT		
	N	N (U)	N	N (U)	N	N (U)	
Blood	7	7	10	7	10	7	Anaemia (2), Increased tendency to bruise (1), Iron deficiency anaemia (1), Leukopenia (1), Lymph
Card	7	7	9	7	9	4	Angina unstable (1), Cardiac arrest (1), Palpitations (4), Tachycardia (3)
Cong	1	1	1	1	1	1	Syringomyelia (1)
Ear	15	15	21	15	21	10	Deafness (1), Deafness unilateral (1), Ear discomfort (3), Ear disorder (1), Ear pain (4), Eustachian
Endo	1	1	1	1	1	1	Adrenal insufficiency (1)
Eye	53	53	119	53	119	41	Abnormal sensation in eye (2), Altered visual depth perception (2), Asthenopia (2), Binocular eye m
Gastr	58	58	117	58	117	36	Abdominal discomfort (4), Abdominal distension (6), Abdominal pain (2), Abdominal pain upper (2),
Genri	96	96	203	96	203	57	Adverse event (2), Asthenia (15), Chest discomfort (8), Chest pain (10), Chills (2), Complication as
Hepat	1	1	1	1	1	1	Liver disorder (1)

SOC [%] – Summary: Percentages by SOC

SOC	Preferred Terms
	Col %
Blood	0.67
Card	0.6
Cong	0.07
Ear	1.4
Endo	0.07
Eye	7.94
Gastr	7.81
Genrl	13.54
Hepat	0.07
Immun	0.6

SOC/HLGT/HLT [N] – Summary: Counts by SOC, HLGT and HLT

SOC	HLGT	HLT	Reports	Preferred Terms
			N	N
Blood	Anaemias nonhaemolytic and marrow depression	Anaemia deficiencies	1	1
Blood	Anaemias nonhaemolytic and marrow depression	Anaemias NEC	2	2
Blood	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Bleeding tendencies	1	1
Blood	Platelet disorders	Thrombocytopenias	1	1
Blood	Spleen, lymphatic and reticuloendothelial system disorders	Lymphatic system disorders NEC	3	3
Blood	White blood cell disorders	Leukopenias NEC	1	1
Blood	White blood cell disorders	Neutropenias	1	1
Card	Cardiac arrhythmias	Rate and rhythm disorders NEC	3	3
Card	Cardiac arrhythmias	Ventricular arrhythmias and cardiac arrest	1	1
Card	Cardiac disorder signs and symptoms	Cardiac signs and symptoms NEC	4	4

Source [N, %] – Summary: Counts and Percentages by Source

Source	Reports	
	N	Col %
Company Representative	5	2.89
Consumer	13	7.51
E-Submission	133	76.88
Foreign	3	1.73
Health Professional	16	9.25
Literature	3	1.73
All	173	100

Sources and Outcomes – Detail: ISR, Gender, Age (years), Source(s), Serious? and Outcome(s)

ISR	Gender	Age (yrs)	Source(s)	Serious?	Outcome(s)
			All		All
3295675	F	73	Consumer	NO	
3332519	F	49	Consumer	NO	
3368431	M	28	Consumer	YES	Other
3369579	U		Consumer	YES	Other
3427897	F	35	Health Professional	NO	
3495768	F	41	Consumer	YES	Other
3573266	M	55	Health Professional	YES	Other
3573851	F	54	Health Professional	YES	Other
3749780	M	55	Health Professional	YES	Other
3769500	F	50	Consumer	YES	Other

**Year: Report Type/Seriousness [N] – Summary: Counts by Year by Report Type/
Seriousness**

FDA Year	Serious?					
	No			Yes		
	Report Type			Report Type		
	Direct	Expedited	Periodic	Direct	Expedited	Periodic
	Reports	Reports	Reports	Reports	Reports	Reports
	N	N	N	N	N	N
1999	0	0	3	0	0	2
2000	0	0	0	0	0	3
2001	0	0	0	0	2	2
2003	0	0	2	0	3	0
2004	0	0	0	0	1	0
2005	0	0	1	0	0	0
2006	0	0	2	0	1	0
2007	0	0	4	0	1	0
2008	0	0	5	1	2	0
2009	0	0	3	0	4	0

Create report definitions

- [Create a report definition](#)
Select a case series and then specify the report options on the Report Definitions page.
- [Step 1: Select a case series for a report](#)
On the Report Definitions page, you must select a case series before you can run, edit, copy, or delete a report definition. If you run the report, it is only for cases from the selected case series.
- [Step 2: Name a report definition](#)
When you have clicked **Create Definition** on the Report Definitions page or you have clicked **Save As** while editing a report definition, you must name the report definition.
- [Step 3: Add rows and columns to a report definition](#)
You specify the variables and values (from source data) to define rows and columns in the report, the labels of report columns, and the aggregation method (such as count,

percentage, mean, or actual value) to be used to show values in the report on the Edit Report Columns page.

- [Step 4: Specify a data source in a report](#)
In a report definition, the data source of a column variable or row variable is the name of the source database variable from which data will be retrieved for the report. You also specify the label that will identify the variable in the report.
- [Step 5: Specify content details](#)
Content details specify how to display values of an analysis variable; that is, the aggregation method for values.
- [Step 6: Preview a report](#)
You can preview only a valid report definition. A report definition is valid if it includes at least one row variable and one column variable, and there are no error messages displayed on the Edit Report Columns page.
- [Step 7: Run a report and work with report data](#)
There are several ways to run a report.
- [Step 8: Save a report output](#)
Follow the steps here to use the **Create Output** link to save the report output so that it can be viewed later without regenerating the report.
- [Work with report definitions](#)
- [Specify report attributes/descriptors](#)
- [Specify variable breakdowns](#)
- [Report background processing](#)

Create a report definition

Select a case series and then specify the report options on the Report Definitions page.

Note

You must [select a case series](#) before you can run, edit, copy, or delete a report definition (this requirement does not apply to interactive report definitions). If you run the report, it will be only for cases in the selected case series.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. At the top of the Report Definitions page, to the right of **Case Series**, click **Browse**.
3. On the Select Case Series page, filter the case series.
4. Choose one of the following:
 - Select the case series to report on and click **OK**, or double-click on the case series.
 - On the Case Series page or Queries page, click the **Row Action menu** () for a case series or query, and click **Report**. On the Cases page, click the **Report** link.

The names of valid report definitions appear in bold font on the Report Definitions page. A report definition is valid (and, therefore, can be run) if it includes at least one row variable and one column variable, and no error messages appear for the variables.

5. To create a report definition, click **Create Definition**.
6. In the **Name for Report** field, type a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
7. In the **Description of Report** field, type a report description that differentiates the report definition from others on the Report Definitions page.
8. Choose one of the following to assign the report definition to a [project](#):
 - To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.
9. Click **Save**.

Field descriptions—Report Definitions page

The Report Definitions page provides the following information about each report definition:

Field	Description
Definition	Name of the report definition. If bold, the report definition is valid to run.
Description	Description of the report definition.
Project	Name of the project with which the report definition is associated.
Configuration	Name of the data configuration used by the case series on which the report definition is based.
Created By	Name of the user who created the report definition.
Created	Date and time when the report definition was created. The Created By and Created fields are filled in when the Create Definition page is completed.
Modified	Date and time when the report definition was last modified.
Modified By	Name of the user who last modified the report definition. The Modified and Modified By fields are filled in each time the report definition is saved.
ID	Identifier that was assigned automatically to the report definition when the report definition was saved. Each report definition ID is unique (across all report definitions, regardless of whether or not they are interactive) and is not re-used if the report definition is deleted.
Category	Category of the report (intended only for informational purposes).

Error messages

An error message appears if any of the following are true:

- You have not specified breakdown details for a column breakdown variable that has more than 10 values. (If there are 10 or fewer values, the application automatically uses the values as distinct values for the breakdown variable.)
- You have specified breakdown details for an analysis variable.
- In a SQL WHERE clause for the report definition, one of the variables referenced by the WHERE clause has been removed from the report definition.

- You specified breakdown details as grouped values, but there is at least one group that includes no values.

Step 1: Select a case series for a report

On the Report Definitions page, you must select a case series before you can run, edit, copy, or delete a report definition. If you run the report, it is only for cases from the selected case series.

① Note

Your case series selection does not affect the Report Outputs page or the [Interactive Reports page](#).

Once you select a case series, only report definitions based on data configurations that are [compatible](#) with that of the cases series appear.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Case Series** page.
3. (Optional) filter the case series by **Project** or by **Configuration**.
 - From the **Project** drop-down list, select the [project](#) you want to view the report definitions of – or set it to view all projects.
 - From the **Configurations** drop-down list, select the [data configuration](#) you want to view the report definitions of – or set it to view all configurations.
4. Select the case series to report on and click **OK**, or double-click on the case series.

The Report Definitions page appears and shows the name of the selected case series and the number of cases in it. Cases [marked as excluded](#) as part of review input are included in the number, but a report that you run does not include those case.

Step 2: Name a report definition

When you have clicked **Create Definition** on the Report Definitions page or you have clicked **Save As** while editing a report definition, you must name the report definition.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. To create a report definition, click **Create Definition**.
4. In the **Name for Report** field, type a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
5. In the **Description of Report** field, type a report description that differentiates the report definition from others on the Report Definitions page.
6. Choose one of the following to assign the report definition to a [project](#).

- To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
- To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.

7. Click **Save**.

Step 3: Add rows and columns to a report definition

You specify the variables and values (from source data) to define rows and columns in the report, the labels of report columns, and the aggregation method (such as count, percentage, mean, or actual value) to be used to show values in the report on the Edit Report Columns page.

A report can include columns from multiple tables. The application assumes that the tables can be linked by the case ID. As a result, only tables containing a case ID column are suitable for use with reports.

If you are creating a report definition, a placeholder appears for the variables that define rows and columns for the report in a tabular display:

	{New Column Variable}
{New Row Variable}	

The following instructions do not include [changing the labels](#) of row and column variables or changing the [aggregation method](#). These instructions use default labels, which are the variable names, and the default aggregation method (Value).

Access Report Definitions

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of Case Series to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.

The Edit Report Columns page appears. It also provides links to the Edit Report Attributes and Edit Report Descriptors pages.

Define the first row variable

1. To define the first row variable, click **{New Row Variable}** to highlight it in yellow.
2. To specify the corresponding source data variable, to the right of the **Data Source** field, click **Select**.
3. On the Edit Data Source page, [specify a data source](#).

4. Click **OK**.

The selected variable appears as the row variable.

Define the first column variable

1. To define the first column variable, click **{New Column Variable}** to highlight it in yellow.
2. To specify the corresponding source data variable, next to **Data Source**, click **Select**.
3. On the Edit Data Source page, [specify a data source](#).
4. Click **OK**.

Add a row variable

1. To add a row variable, click the name of an existing row to highlight it in yellow.
2. Click **Insert Left** or **Insert Right**.
3. On the Edit Data Source page, [specify a data source](#).
4. Click **OK**.

Add a column variable

1. To add a column variable, click the name of an existing column variable to highlight it in yellow.
2. Click **Insert Left**, **Insert Right**, **Insert Above**, or **Insert Below**.
3. On the Edit Data Source page, [specify a data source](#).
4. Click **OK**.

Note

For a column breakdown variable, you are required to specify breakdown values. If there are 10 or fewer distinct values for the variable in the source data, the application automatically uses those values as breakdown values. You can modify them as needed. If there are more than 10 distinct values, a message informs you that breakdown details are missing and you must specify them.

Specify column attributes variables

1. Add rows and columns as described above.
2. To select an aggregation method for an analysis variable, highlight the variable in the cell.
3. Next to **Content Details**, click **Select**.
4. [Specify content details](#).
5. Click **OK**.
6. To select which source values for a variable will appear in the report, highlight the variable in the cell.
7. Next to Breakdown Details, click **Select**.
8. [Specify breakdown details](#).
9. Click **OK**.
 - You can [edit report attributes](#), [edit report descriptors](#), or save or run the report definition. For an interactive report definition, you can [define a query](#).

- To [view a histogram](#) showing the distribution of values for a numeric variable, click **View Column Statistics**.
- To delete a variable, highlight the variable and click **Delete**. At the message asking if you are sure you want to delete the variable, click **OK**. You cannot delete the last row variable or last column variable.

Tips when specifying columns and rows

- Click **Save** frequently to save the report, especially when building a complex report definition.
- Click **Preview** to [preview the report](#). (This feature is not available for interactive reports.)
- Click **Undo** to remove the last change you made to the report definition since you last saved the report definition. Click **Redo** to add back the last undone change. You can click Undo and Redo successive times.

Step 4: Specify a data source in a report

In a report definition, the data source of a column variable or row variable is the name of the source database variable from which data will be retrieved for the report. You also specify the label that will identify the variable in the report.

Note

If a row variable's underlying column has the same name as any column in an analysis variable's table, then a SQL inner join of the same-named columns occurs in addition to the usual join on report ID.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the [Edit Report Columns](#) page, next to **Data Source**, click **Select**.
5. On the Edit Data Source page, in the **Table** field, select the name of the database table that contains the variable that you want to use, or select **All Tables**.

Note

If you want to look at all cases, use the report ID (that is, the variable of the Report ID type in the configuration) in the demographics table. It is possible that a report has no record in the other tables. If you are not interested in getting all report IDs, but only those that have records in the table from which you are getting other data, use the report ID from that table.

6. Select a variable.
7. When you highlight a variable in the list, the **Label** field shows the variable name by default. You can type in a different label, which appears in the report as the column heading for the variable.

For example, suppose that you use default labels for the `ISR_drug` and `Generic_Name` variables. The column headings in the report look like this:

ISR_drug	Generic_Name
3295675	Bupropion

For clarity, you could modify them as follows:

ISR_drug	Drug
3295675	Bupropion

8. To change the label, select the default label and change it.
9. Click **OK**.
10. If you chose a numeric value, you can click **View Column Statistics** to display a histogram showing the distribution of values for the variable in the source data.

Step 5: Specify content details

Content details specify how to display values of an analysis variable; that is, the aggregation method for values.

For example, you may want to show an actual value, a count of records with a value, a percentage of records with the value, and so on. You can specify multiple aggregation methods for an [analysis variable](#); each aggregation method is represented in the report.

When you add an analysis variable to a report, the term **Value** appears by default as the aggregation method:

	<i>Case ID</i>
Gender	Value

Value stands for First value, which is the default aggregation method. (It is used when no other aggregation method is selected.) When you change the aggregation method, an abbreviation of that aggregation method appears in the table cell. For example, if you select Count as the aggregation method, N appears in the table cell:

	Case ID
Gender	N

Note

If the source table for a column or row can include multiple records per case, the count and unique count for the column or row can differ.

Percentages in the columns or rows can add up to greater than 100 percent. For example, the breakdown variable is PT severity. Adverse events data can include multiple records per case. Suppose that each of 10 cases has an event with the severity Mild, an event with the severity Moderate, and an event with the severity Severe. The count of cases with each severity is 10. The count of cases with any severity will also be 10. So the percentage of cases with each severity will be 10/10, which is 100%. The total of percentages for each severity would be 300%.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the [Edit Report Columns](#) page, highlight the aggregation method that appears in the table cell below the analysis variable. You must click the aggregation method, not the column heading. You can choose more than one aggregation method for a variable.
5. Next to **Content Details**, click **Select**.
6. Select the desired aggregation methods and percentages. Available aggregation methods depend on the data type of a variable.
7. Click **OK**.

Aggregation methods for text or date variables

For an analysis variable with a data type of text or date, check one or more of the following check boxes. The abbreviation appears in the report column heading.

Check box	Abbreviation	Meaning
Count	N	The number of non-NULL values.
Count (Unique)	N (U)	The number of unique non-NULL values.

Check box	Abbreviation	Meaning
Row %	Row %	Count of non-unique values for the row and column/Count of non-unique values for the row for all columns. (There must be a column for All.)
Column %	Column %	Count of non-unique values for the column and row/Count of non-unique values for the column for all rows. (There must be a row for All.)
Overall %	Overall %	Count of non-unique values for the column and row/Count of non-unique values for all columns and all rows. (There must be a column for All and a row for All.)
Row % (Unique)	Row % (U)	Count of unique values for the row and column/Count of unique values for the row for all columns. (There must be a column for All.)
Column % (Unique)	Col % (U)	Count of unique values for the column and row/Count of unique values for the column for all rows. (There must be a row for All.)
Overall % (Unique)	% (U)	Count of unique values for the column and row/Count of unique values for all columns and all rows. (There must be a column for All and a row for All.)
All values	ALL	All values, including null values, separated by commas. Null values are shown as blanks, so you may see a list of values like "DrugA, , DrugC".
All values (excluding NULLs)	All	All values except null values, separated by commas.
Unique values	ALL (U)	Unique values (in ascending order), including NULL values, separated by commas. Null values are represented in the list by the string "null".
Unique values (excluding NULL)	All (U)	Unique values (in ascending order), excluding NULL values, separated by commas.
Unique values and counts	ALL (N)	Unique values (in ascending order), including NULL values, separated by commas; after each value is the count of the value. Null values are represented in the list by the string "null".
Unique values and counts (Excluding NULL)	All (N)	Unique values (in ascending order), excluding NULL values, separated by commas; after each value is the count of the value.
First value	Value	First non-NULL value from the database (for the case series or query being used). If you do not specify an aggregation method, this method is used by default.

Aggregation methods for numeric variables

For an analysis variable with a data type of number, check one or more of the following check boxes. The abbreviation appears in the report column heading.

Note

If a case is counted in multiple columns or rows, a count in the All column or row is not necessarily the same as the total of counts in other columns or rows of the report. Also, percentages in the columns or rows can add up to greater than 100 percent.

Check box	Abbreviation	Meaning
Count	N	The number of non-NULL values.
Count (Unique)	N (U)	The number of unique non-NULL values.
Row %	Row %	Count of non-unique values for the row and column/Count of non-unique values for the row for all columns. (There must be a column for All.)
Column %	Col %	Count of non-unique values for the column and row/Count of non-unique values for the column for all rows. (There must be a row for All.)
Overall %	%	Count of non-unique values for the column and row/Count of non-unique values for all columns and all rows. (There must be a column for All and a row for All.)
Row % (Unique)	Row % (U)	Count of unique values for the row and column/Count of unique values for the row for all columns. (There must be a column for All.)
Column % (Unique)	Col % (U)	Count of unique values for the column and row/Count of unique values for the column for all rows. (There must be a row for All.)
Overall % (Unique)	% (U)	Count of unique values for the column and row/Count of unique values for all columns and all rows. (There must be a column for All and a row for All.)
Sum	Sum	The sum of the values.
Mean	Mean	The mean of the values.
Median	Median	The median of the values.
Standard Deviation	SD	The standard deviation of the values.
1st Quartile	Q1	The first quartile of the values.
3rd Quartile	Q3	The third quartile of the values.
Min	Min	The minimum value.
Max	Max	The maximum value.

For example, suppose that a report includes counts like this:

	Severity			
	Mild	Mod	Severe	All
	Case ID	Case ID	Case ID	Case ID
Male	200	300	500	1000
Female	100	600	700	1400
All	300	900	1200	2400

If you replace the counts in the report with row, column, and overall percentages, the report display changes to this:

	Severity											
	Mild			Mod			Severe			All		
	Case ID			Case ID			Case ID			Case ID		
	Row %	Col %	%	Row %	Col %	%	Row %	Col %	%	Row %	Col %	%
Male	200/1000	200/300	200/2400	300/1000	300/900	300/2400	500/1000	500/1200	500/2400	1000/1000	1000/2400	1000/2400
Female	100/1400	100/300	100/2400	600/1400	600/900	600/2400	700/1400	700/1200	700/2400	1400/1400	1400/2400	1400/2400
All	300/2400	300/300	300/2400	900/2400	900/900	900/2400	1200/2400	1200/1200	1200/2400	2400/2400	2400/2400	2400/2400

Step 6: Preview a report

You can preview only a valid report definition. A report definition is valid if it includes at least one row variable and one column variable, and there are no error messages displayed on the Edit Report Columns page.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** () , then click **Edit**.
4. Create or edit a report definition.
5. Click **Preview** to check that the report definition is set up as you want it before you save or run the report. The Report Preview page shows data for only the first 10 cases of the selected case series or the first 10 cases found by the query.

Step 7: Run a report and work with report data

There are several ways to run a report.

Choose one of the following:

- On the [Report Definitions page](#), select a case series. Select the **Row Action menu** () for the report definition, and select **Run**.
- When [editing a report definition](#), click **Save & Run** or **Run**.

- On the [Interactive Reports page](#), click an interactive report's **Row Action menu** (), and then click **Run**.
- On the [Queries page](#), click a query's **Row Action menu** (), and then click **Report**.
- [Drill down to the Cases page](#), and click **Report**.
- You can [drill down](#) on a count or graph element elsewhere in the application to run a report definition against cases that make up the count or are represented by the graph element.

Oracle Empirica Signal runs the report and displays the report output.

Work with report data

- If you have the Create Report Definitions permission, you can click **Edit Definition**. The Edit Report columns page appears and you can modify the definition as needed.
- To [save report output](#) so it can be viewed later, click **Save Output**. (This option is not available if you are running a report definition after drilling down.) You can also run a report definition and save its output in a single step. For more information, see [Creating a Report Output](#).
- To create a new case series containing cases in the report, click **Create Case Series**. This option is available only if the case IDs in the first column of the report contains links.
- To show the report data in a graph format, click [Choose Graph](#).
- To [save the report as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).
- To [print the](#) report, click **Print**.
- To [download report data](#), click **Download**. The column names are created from the labels in the report definition, followed by the breakdown specifications.
- To show descriptive information below the report, click **Show Notes**.

Manage report rows

- To specify how many rows should display at a time, enter a number in the **Rows per Page** field and press the **Enter** key. You can display up to 999 rows on each page.
- To go to another page, you can do the following:
 - To view the next page, click .
 - To view the previous page, click .
 - To view a specific page, enter a number in the Page field and press the **Enter** key.
- To find specific text on a page, press **Ctrl+F**. For efficiency, you may want to set the Rows per Page to a large number before using the Find feature.

Sort the report

You can sort a table by up to three columns. The current sort order appears above the table. You can sort a column as follows:

- To sort a column, click the column header. The column is sorted, and an arrow is displayed next to the column name to indicate the sort order. To sort in reverse order, click the column header again. The previous primary sort order (if any) becomes the secondary sort order. The previous secondary sort order (if any) becomes the tertiary sort order.

- Click **Columns** or **Columns and Rows**. (See [Arrange table columns](#).)

Note

In displayed reports, sorting is case-insensitive.

Bold counts (N) are links. Click the number to display a menu from which you can [drill-down](#). If specific case IDs appear in the report as a link, click a case ID to [view case details](#).

Step 8: Save a report output

Follow the steps here to use the **Create Output** link to save the report output so that it can be viewed later without regenerating the report.

Or, if you are displaying a report that you ran from the [Report Definitions page](#), you have the option to save the output.

- In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
- Click the **Row Action menu** () for the report definition, and then click **Create Output**.
- Fill in the fields on the **Create Output** page:
- In the **Name for Output** field, type a name for the saved output. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
- In the **Output Description** field, enter a description of the saved output that differentiates the report output from entries on the Report Outputs page.
- From the **Output Category** drop-down list, select **Ad Hoc** or **Standard**. The application uses the category for organizing reports and the category is not related to report availability. You can include a column showing report categories on the Report Definitions and Report Outputs pages.
- Assign the report output to a [project](#) by choosing one of the following:
 - To assign the report output to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the report output to it, click **Add to a new project named** and enter a project name.
- Click **Save**.

Oracle Empirica Signal saves the report output. Modification or deletion of the report definition does not affect the saved report output.

Note

The current sort order of a report is not saved as part of the report output.

Work with report definitions

- [Select entries using a match string](#)
When you type a string into the Match field of the window, Oracle Empirica searches the entire hierarchy and all entries containing that string may be selected.
- [Edit a report definition](#)
- [Copy a report definition](#)
- [Rename a report definition](#)
- [Publish a built-in or interactive report definition](#)
- [Use XML to create a report definition](#)

Select entries using a match string

When you type a string into the Match field of the window, Oracle Empirica searches the entire hierarchy and all entries containing that string may be selected.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the [Edit Report Columns page](#), next to **Data Source**, click **Select**.

Note

If you want to look at all cases, use the report ID (that is, the variable of the Report ID type in the configuration) in the demographics table. It is possible that a report has no record in the other tables. If you are not interested in getting all report IDs, but only those that have records in the table from which you are getting other data, use the report ID from that table.

5. In the **Match String** field type a string and click **Find**.
All entries containing that string are listed; the matching does not distinguish between cases (upper, lower, mixed). See below for tips on how to search for entries using the Match field.
6. To list all entries again, click **Show All**.

Note

When an entry is highlighted in the list, you can go to the next occurrence of an entry starting with a character that you type. For example, you can highlight the first entry in the list and type "H" to go to the first entry starting with "H".

7. To highlight an entry, click the entry in the list.
8. You can also do the following:

- Highlight multiple non-contiguous entries: hold down the **Ctrl** key while clicking each entry.
 - Highlight multiple contiguous entries: click an entry, hold down the **Shift** key, and click another entry.
 - Entries between and including those entries are highlighted.
 - Remove highlighting from an entry: hold down the **Ctrl** key while clicking the selected entry.
9. To move entries back and forth between the list of all entries and the list of selected entries, double-click a highlighted entry or use the arrow keys as follows:

Button	Use To
	Move highlighted entries from the list of all entries to the list of selected entries.
	Move all entries from the list of all entries to the list of selected entries.
	Move highlighted entries from the list of selected entries to the list of available entries.
	Move all entries from the list of selected entries to the list of available entries.

- If **Clear** is available, you can click it to clear out the list of selected entries.
10. If up and down arrows are available for the list of selected entries, you can use them to order the selected entries. For example, when specifying breakdown details in a report definition, you can order the selected entries as you want them to appear in the report.
11. When you are satisfied with the selected entries, click **OK**. (In some contexts, the button may instead be **Save** or **Copy**.)

Special characters

To search for the following special characters, you must precede each special character with a backslash (\):

+
*
?
.
\
(
)
[
]

Example	Description
NAUSEA \+ VOMITING	NAUSEA + VOMITING
\(R\) ELBOW PAIN	(R) ELBOW PAIN

Match string syntax

In the **Match String** field, you can use the following syntax:

Syntax	What Is Matched	Syntax Example	Found by Example
^	Letter(s) at the beginning of a value.	^V	VERTIGO VOMITING Does not find SEVERE VOMITING.
\$	Letter(s) at the end of a value.	on\$	AGITATION DEPRESSION Does not find ANEMIA IRON DEFIC.
.	Any single character.	D.stonia	DYSTONIA
[abcdef]	Any character included in the set.	[gq]	All terms that have any of the letters g or q, including: ANGINA FREQUENT URINATION
\b	A word boundary in a term.	\bDr	ABNORMAL DREAMS DRY MOUTH
\s	White space in a term.	en\s	PATHOGEN RESISTANCE SUDDEN INFANT DEATH SYNDROM
\s		\sen	ABDO ENLARGE

Edit a report definition

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. At the top of the Report Definitions page, to the right of **Case Series**, click **Browse**.
3. On the Select Case Series page, filter the case series.
4. Select the case series to report on and click **OK**, or double-click on the case series.

You can also select a case series or query to report on from the Case Series page, Queries page, or Cases page.

- On the **Case Series** page or **Queries** page, click the **Row Action menu** () for a case series or query, and click **Report**.
- On the **Cases** page, click the **Report** link.

The names of valid report definitions appear in **bold** font on the Report Definitions page. A report definition is valid (and, therefore, can be run) if it includes at least one row variable and one column variable, and no error messages appear for the variables.

5. To edit a report definition, click the report definition's **Row Action menu** (), and click **Edit**.

Note

You cannot edit a report definition you didn't create.

6. On the Edit Report Columns page, you can [edit the report columns](#), the [report attributes](#), and the [report descriptors](#). Click the corresponding radial button.
7. Perform your edits, then click **Save**. If you are working on a complex report definition, click **Save** periodically.

Each time you save the report definition, Oracle Empirica Signal fills in the Modified and Modified By columns on the Report Definitions page.

Copy a report definition

If you cannot edit a report definition, you can copy it and modify the copy as needed.

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Copy**.
4. In the **Name for Report** field, type a report name. The name does not need to be unique, although we recommend that you provide a unique and meaningful name.
5. In the **Description of Report** field, type a report description that differentiates the report definition from others on the Report Definitions page.
6. Click **Save**.

[Edit](#) the copy of the report definition as needed. For example, if you want to assign the report definition to a project, edit the report definition to provide a project name on the Report Descriptors page.

Rename a report definition

You can rename only those report definitions that you created.

1. In the left navigation pane, hover on the **Data Analysis** icon (), click **Report Definitions** or **Interactive Reports**.
2. Select the **Row Action menu** () for the report definition, and then click **Rename**.
3. In the **Name for Report** field, type a name. The name does not need to be unique, although Oracle recommends that you use a unique name.
4. In the **Description of Report** field, enter an informative description of the report definition.
5. Assign the report definition to a [project](#) by choosing one of the following:

- To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.
6. Click **Save**.

Publish a built-in or interactive report definition

Publication of a report definition is a way to make built-in and interactive reports available to other users. By default, the publication level of every newly created object is Private.

Note

Users without the Administer Users permission can publish only objects they have created. Users with the Administer Users permission can publish objects that they or any users in their login group created.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions** or **Interactive Reports**.
2. Click a report definition's **Row Action menu** () and click **Publish**. To publish multiple report definitions, click the **Select Rows** link, select the radio buttons of the definitions, then click the **Publish** link.
3. To publish to all the users in your login group, click **Publish**.
 - If you are a superuser, you can publish to multiple login groups, including —All—. In the **Publish to Login Groups** drop-down list, click or Ctrl+click to select login groups.
 - If you publish to —All— and later add a new login group, the object is published automatically to the new login group.
4. Click **Back**.

Use XML to create a report definition

Each report definition is stored internally as XML (eXtensible Markup Language). Superusers can create definitions using XML.

1. Log into the Oracle Empirica Signal application as a superuser.
2. Obtain the XML that you want to use. You can copy the text from the XML field on the [Edit Report Descriptors page](#).

Note

Copied XML for a non-interactive report can only be used to create a non-interactive report. Copied XML for an interactive report can only be used to create an interactive report.

3. On the [Report Definitions page](#), click **Create Definition from XML**.
4. Provide the following information. The values that you specify appear on the Report Definitions page or [Interactive Reports page](#), where users can sort by them.

Column	Description	Notes
Name	Name of the report.	Required.
Description	Description of the report.	None
Category	Category containing the report. By default, this value is Ad Hoc. Alternatively, you can select Standard.	Required.
Creator	Name of the user who created the report.	Read-only.
Data	Applies to (non-interactive) report definitions only. Specifies the configuration on which the currently selected case series is based.	Read-only.
Configuration to report	Applies to interactive report definitions only. Specifies the configuration to supply source data when the report is run.	Required.
Status	Under Development status indicates that the report is not ready to be run until you have saved it.	Read-only.

5. In the **XML Definition** field, paste in the copied XML.

6. Click **Save**.

If you want to assign the report definition to a project, [edit the report definition](#) to provide a project name on the Edit Report Descriptors page.

Specify report attributes/descriptors

- [Edit report attributes](#)
- [Allow report drilldown](#)
- [Specify report restrictions](#)
- [Edit report descriptors](#)

Edit report attributes

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the **Edit Report Columns** page, click the **Report Attributes** radio button.
5. To disable [drilldown](#) for column variables in the report, click **Generate drill-down Information**, then change the value of the field to **No**.

This option is not available for an all cases summary interactive report.

Note

When generated, drilldown information increases the amount of memory used for report output. For large reports, this option should be set to No.

6. To [specify report restrictions](#), click **Restrict by SQL WHERE Clause**.

Only cases that meet the criteria of the Where clause that you specify are included in the report.

7. Type the **SQL WHERE clause**.
8. To see the columns defined for the report, click **Show Columns**.

Note

To know the list of supported SQL functions, see [SQL functions](#).

9. Click **Apply**.

Select another radio button to edit report columns or [edit report descriptors](#). You can also save or run the report definition. For an interactive report definition, you can also [define or edit a query](#).

Allow report drilldown

If drill-down is allowed for reports, users can [drill down](#) on report column variables that show counts of cases, or on elements of graphs based on such reports. If the running of a report generates an out-of-memory error, you can turn off drilldown in the report definition and try running the report again. When drilldown is off, less memory is used to run the report; however, the report may take longer to run.

Note

For an all cases summary report, this option on the Edit Report Attributes page is not available. However, on the Drug Profiles page, users are able to drill down on charts based on the output of this type of report.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the **Edit Report Columns** page, click the **Report Attributes** radio button.
5. On the [Edit Report Attributes page](#), click **Generate drill-down Information**.
6. To allow drilldown in reports, click **Yes** (the default). To disallow drilldown, click **No**.

Note

Even if you click **No**, users can drill down to case details from a case ID that appears as a row variable in a report.

Specify report restrictions

You can restrict a report to data that meets a specified condition by using a SQL WHERE clause. For example, you might want the report to include only males who reside in the United States and are between 18 and 55 years old. The application applies the report restriction, if specified, after generating the report, but before displaying the report.

For an interactive report, the query run as part of the report determines which cases are included in the report. A SQL restriction, on the other hand, acts on the data for those cases. For example, suppose you want a report that shows drug counts for only suspect drugs. If you include a suspect drug indicator as a query variable, the report runs against all cases including suspect drugs. Some of these cases might also have non-suspect drugs. However, you could specify a SQL restriction to include only suspect drugs in the report.

Note

Columns of the type CLOB are truncated in reports. Therefore, if a column referenced in the restriction has the type CLOB (as is typical with narrative text), the application applies the restriction to the truncated values for that column.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the **Report Definitions** page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** () , then click **Edit**.
4. On the **Edit Report Columns** page, click the **Report Attributes** radio button.
5. On the [Edit Report Attributes page](#), click **Restrict by SQL WHERE Clause**.
6. Click **Show columns**.
The Select Table Columns dialog box appears listing the column names and types.
7. Click the name of the column to include in the WHERE clause.
 - Note the column type, so that you know what syntax is valid for that column in the WHERE clause.
 - On the Restrict by SQL WHERE Clause page, the column you selected appears in the SQL WHERE clause field in square brackets. The Select Table Columns page remains open, so that you can select other columns.
8. In the **SQL WHERE clause** field, complete the SQL condition. You might, for example, select the AGE column (placing AGE into the field), and then type ">=65" to restrict the report to patients who are at least 65.
9. When you are satisfied with the WHERE clause, click **Apply**.

If the SQL syntax is valid, the Edit Report Attributes page appears, showing the SQL WHERE clause and the number of rows that meet the criteria of the WHERE clause, or

if there are errors in the SQL syntax, an error message appears when you try to run the report.

Note

To know the list of supported SQL functions, see [SQL functions](#).

Edit report descriptors

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On a Report Definitions page, such as Edit Report Columns, Edit Report Attributes, or Edit Report Descriptors, click the **Report Descriptors** radio button.
5. View or modify the information shown.

Column	Description
Name of Report	Name of the report definition.
Description of Report	Description of the report definition.
Category	Category of the report definition, either Ad Hoc or Standard. The category is for informational purposes. You can display it as a column on the Report Definitions page, the Interactive Reports page , or the Report Outputs page.
Built-in	This field is available for superusers only. It is for use by Oracle when creating built-in report definitions, which are predefined reports supplied with the Oracle Empirica Signal application and available if the appropriate data configuration has been set up during installation. For more information, see Built-in reports .
Type	Applies to interactive reports only. One of the following values: • Query-based —Indicates a report definition that includes a query. Users can provide values to the query when the report is run. • Summary of all cases —Indicates a report definition that includes all cases and can be used by a drug profile configuration. Reports that can be added as charts on the Drug Profiles page are based on this type of report. If you are a superuser, this field can also show a customer-specific report that has been provided by Oracle.

Column	Description
Project	You can assign the report to an existing project by clicking Add to existing project and selecting the project from the drop-down list containing projects associated with objects that you created or that are published to you. To create a new project and assign the report to it, click Add to a new project named and enter a project name.
Status	Ready or Under Development. If the report definition can be run, the application applies the Ready status denoting that the report definition is valid. A report definition is valid if it has at least one row variable, at least one column variable, and no error messages appear for report variables. For a query-based report, a query must be part of the report definition. For an all cases summary report, the definition must conform to certain criteria. If the report definition is not ready to be run, the application assigns it the status Under Development.
Configuration	Description of the source data of the report definition.
XML	This field is available for superusers only. You can copy and paste this XML to create a report using XML .

- Click **Save**.

Specify variable breakdowns

- [Define breakdown details](#)
- [Define breakdown by distinct values](#)
- [Define breakdown by individual values](#)
- [Edit individual value labels](#)
- [Define breakdown by grouped values](#)
- [Cutpoints](#)
- [Define breakdown by cutpoints](#)
- [View column statistics](#)
- [Define breakdown by query values](#)

Define breakdown details

Breakdown details are the specification of values for a [breakdown variable](#). If a breakdown variable is a text or date variable, you can define breakdown details using individual selected values, distinct values, or grouped values. If a breakdown variable is a numeric variable, you define breakdown details using cutpoints. For an [interactive report](#), you can define a query whose user-supplied values are used as breakdown details when the report is run.

Note

If there are 10 or fewer values for a column breakdown value, the application uses them by default as distinct values for the breakdown variable. For a row variable, the application uses all values by default as distinct values for the breakdown variable. You can modify these default breakdowns as needed.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the Edit Report Columns page, next to **Breakdown Details**, click **Select**.
5. Select the breakdown type by selecting the Every Distinct Value, Individual Values, Grouped Values, or Query Values radio button.
 - To define breakdown details by distinct value, see [Defining breakdown by distinct values](#). The report includes a column or row for every distinct (unique) value of the variable. This option uses the values available at the time you run the report, not at the time you define it.
 - To define breakdown details by individual values, see [Defining breakdown by individual values](#). The report includes a column or row for every value that you select. This option results in a static list of breakdown values that does not automatically adjust to changing source data.
 - To define breakdown details by grouped values, see [Defining breakdown by grouped values](#). The report includes a column or row for every group that you define.
 - To define breakdown details by query values, see [Defining breakdown by query values](#). This choice allows you to [substitute values from the query](#) that is run as part of an [interactive report](#).
 - To define breakdown details for a numeric variable, see [Defining breakdown by cutpoints](#).
6. Click **OK**.

Report performance with breakdown details

The performance of a report with breakdown details can depend on whether the analysis variable that you use comes from the same source table as the row variables. If the analysis variable is from the same table as the row variables, the performance of a report definition with breakdown details is much faster. This may be important when you are working with a sizeable case series (containing 5,000 or more cases). The speed difference is several orders of magnitude. When possible, select the analysis variable from the same table as the row variables.

All column

For a breakdown variable, you can include a category for All values. The All column is not based on values for other columns in the report. For example, if the report shows counts, the All column is not a total of counts for the other columns.

In the following example, the same case may have PTs in both the Card SOC and Other SOC:

PT: Sex	SOC: Card - Cases N(U)	SOC: Other - Cases N(U)	SOC: Null- Cases N(U)	SOC: All - Cases N(U)
F	5000	11000	0	12000
M	6000	13000	0	16500

The N (U) value for the All column and F row is not 5000 + 11000. The value in the All column is:

- 4000 who have a PT in the Card SOC and a PT in other SOC.
- + 1000 who have a PT in the Card SOC only.
- + 7000 (computed as 11000 - 4000) who have a PT in any SOC except Card.
- = 12000.

Example

For example, you want a summary of the number of cases for each report type (direct, expedited, and periodic). For your report definition, you set up the FDA Year as the row variable and you specify Report Type as the column variable. You then need to specify the value you want to show for each report type; that is, the [analysis variable](#). You specify CASE_ID as the analysis variable, label it as Cases, and select the **Count** [aggregation method](#).

FDA Year	Report type		
	Direct	Expedited	Periodic
	Cases	Cases	Cases
	N	N	N
1999	0	0	5
2000	0	0	3
2001	0	2	2
2003	0	3	2
2004	0	1	0
2005	0	0	1
2006	0	1	2
2007	0	1	4
2008	1	2	5
2009	0	4	3

Define breakdown by distinct values

In the Breakdown Details dialog box, if you click **Every Distinct Value**, the report includes a column or row for every distinct (unique) value of the variable. This option uses the values available at the time the report is run, not at the time you define the report.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** () , then click **Edit**.

4. On the Edit Report Columns page, next to **Breakdown Details**, click **Select**.
5. In the [Breakdown Details](#) dialog box, click **Every Distinct Value**.
6. To include a column or row in the report to represent all values for the variable (including null values if **Include a category for Null values** is checked), check **Include a category for ALL selected values**. For reports that display percentages, the report must include a row or column for **All**.

Note

If a case is counted in multiple columns or rows, a count in the All column or row is not necessarily the same as the total of counts in other columns or rows of the report. Also, percentages in the columns or rows may add up to greater than 100 percent.

7. To include a column or row to represent null (missing) values for the variable, check **Include a category for Null values**.
8. Click **OK**.

Example

In the following example, the **All** row shows the number of cases with any of the Gender values for each Age Group. The **All** column shows the number of cases with any Age Group for each Gender. Also, the **NULL** column shows the number of cases (in this example, none) that have no Age Group for each Gender.

Gender	Age Group										
	00_01	02_04	05_12	13_16	17_45	46_75	76_85	86_above	UNK	NULL	All
	Cases	Cases	Cases	Cases	Cases	Cases	Cases	Cases	Cases	Cases	Cases
	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)	N (U)
F	0	0	0	0	2	4	0	0	0	0	6
M	0	0	0	0	1	2	0	0	0	0	3
U	0	0	0	0	0	0	0	0	1	0	1
All	0	0	0	0	3	6	0	0	1	0	10

Note

See [Specifying Content Details](#) for information about the behavior of the All row when unique counts are shown for column variables.

Define breakdown by individual values

In the Breakdown Details dialog box, if you click **Individual Values**, the report includes a column or row for every value that you select. This option results in a static list of breakdown values that does not automatically adjust to changing source data.

Note

If there are more than 20,000 available values for the breakdown variable, you cannot use a breakdown by individual values.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the Edit Report Columns page, next to **Breakdown Details**, click **Select**.
5. In the [Breakdown Details](#) dialog box, click **Individual Values**.
6. To include a column or row to represent null (missing) values for the variable, check **Include a category for Null values**.
7. To include a column or row in the report to represent all selected values for the variable (including null values if **Include a category for Null values** is checked), check **Include a category for ALL selected values**. For reports that display percentages, the report must include a row or column for **All**.

Note

If a case is counted in multiple columns or rows, a count in the **All** column or row is not necessarily the same as the total of counts in other columns or rows of the report. Also, percentages in the columns or rows may add up to greater than 100 percent.

8. To include a column or row for values that are not represented by any other columns, check **Include a category for all unselected values**.
9. From the **All Values** list, select values for the variable.
 - To find a value, you can type a string into the **Find** field, then click **Find**. All values containing that string appear. The matching does not distinguish between cases (upper, lower, mixed). To list all values again, you can click **Show All**.
 - To search for the following special characters, you must precede each special character with a backslash (\): + * ? . \ () []

Note

When a value is highlighted in the list, you can go to the next occurrence of a value starting with a character that you type. For example, you can highlight the first value in the list and type H to go to the first value starting with H.

10. Highlight one or more values in the list of all values. You can also do the following:

- To highlight multiple non-contiguous values, hold down the **Ctrl** key while clicking each value.
- To highlight multiple contiguous values, click a value, hold down the **Shift** key, and click another value. Values between and including those values are highlighted.
- To remove highlighting from a value, hold down the **Ctrl** key while clicking the selected value.
- To move values back and forth between the list of all values and the list of selected values, you can double-click a highlighted value or use the arrow keys as follows:

Button	Use To
	Move highlighted values from the list of all values to the list of selected entries.
	Move all values from the list of all values to the list of selected values.
	Removes highlighted values from the list of selected values.
	Removes all values from the list of selected values.

- If **Clear** is available, you can click it to clear out the list of selected values.
- If up and down arrows are available for the list of selected values, you can use them to order the selected values as you want them to appear in the report.

11. From the **Breakdown values order** field, select the breakdown values order.

- To sort the values in ascending order, click **Sorted**.
- To show values in the order in which they appear in the Selected Values list, click **Listed order**.

12. When you are satisfied with the Selected Values list, click **OK**.

The Edit Report Columns page shows the selected values. Click **Save** to save your report definition so far.

13. To [edit value labels](#) for breakdown values, in the **Breakdown Details** section, click **Edit Labels**.

14. Click **OK**.

Example

The following example shows a report in which three different SOCs were selected:

Gender	SOC		
	Card	Cong	Infec
	Cases	Cases	Cases
	N	N	N
F	9	1	49
M	0	0	2
U	0	0	0

In the following example, the **All** row shows the number of cases with any of the Gender values for each SOC. The **All** column shows the number of cases with any of the SOCs for each Gender. The **Null** column shows the number of cases (in this example, none) with no SOC for each Gender. All SOCs that are not any of the three selected SOCs are represented by the **Other** column:

Gender	SOC					
	Card	Cong	Infec	Null	All	Other
	Cases	Cases	Cases	Cases	Cases	Cases
	N	N	N	N	N	N
F	9	1	49	0	59	1282
M	0	0	2	0	2	149
U	0	0	0	0	0	7
All	9	1	51	0	61	1438

① Note

See [Specifying content details](#) for information about the behavior of the **All** row when unique counts are shown for column variables.

Edit individual value labels

If you define breakdown details using individual values, the default labels for values are the exact values from the source data. You can modify the labels that appear in the report. Editing the labels has no effect on the source data.

Note

When you add reports as charts on the Drug Profiles page, the configuration variable name is always used in the reports, instead of any specified labels from the report definition (the all cases summary interactive report).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the Select **Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the Edit Report Columns page, next to **Breakdown Details**, click **Edit Labels**.
Each value that you have selected appears in the Value column.
5. In the **Label** field for any of the values, type in a different label.
6. Click **OK**.

The modified labels are shown on the Edit Report Columns page.

Define breakdown by grouped values

If you click Grouped Values in the Breakdown Details window, the report will include a column or row for every group that you define. This option results in a static list of breakdown values that does not automatically adjust to changing source data.

Note

If there are more than 20,000 available values for the breakdown variable, you cannot use a breakdown by grouped values.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu**, then click **Edit**.
4. On the Edit Report Columns page, next to **Breakdown Details**, click **Select**.
5. In the [Breakdown Details window](#), click **Grouped Values**.
6. Next to the **Groups** field, click **New**.

A message asks for the new group's name.

7. Enter a name for the new group, and click **OK**.
8. To include a column or row to represent null (missing) values for the variable, check **Include a category for Null values**.
9. From the **All Values** list, select values to include in the group.
10. Create other groups and select values to be included in them. Make sure that each group includes at least one value.
11. From the **Breakdown values order** field, select the breakdown values order:
12. To include a column or row for values that are not represented by any other columns, check **Include a category for all unselected values**.
13. When you are satisfied with the groups and other options, click **OK**.
14. The Edit Definition page shows the selected values. Click **Save** to save your report definition so far.

Note

You cannot save the report definition if all groups are empty (that is, have no values in them). If some groups are empty, the report definition is saved and the empty groups are ignored.

Cutpoints

If you are defining breakdown details for a numeric variable, you must define cutpoints. Cutpoints are consecutive, user-defined value ranges that categorize data for both numeric and date variables. You use cutpoints to subset data, which allows you to group specific portions of data that are of interest to your organization. You define cutpoints for both numeric and date variables when you define breakdown details in a report definition.

For example, suppose that you want to create a report definition that includes the number of deaths that occurred:

- Before 2009
- During 2009
- After 2009

You could then define the following cutpoints for the Death Date variable in the Breakdown Details dialog box:

Define Cutpoints for Variable DEMO_AERS.DEATH_DATE (Death date)

	Value	Label
VALUE <=	12/31/2008	2008 and before
12/31/2008 < VALUE <=	12/31/2009	2009
12/31/2009 < VALUE		2010 and later

You can define cutpoints for both row variables and column variables in report definitions.

Note

You can also define cutpoints when you specify a data transformation for a data configuration variable. For more information, see [Defining variable cutpoints](#).

With the numeric variable highlighted on the [Edit Report Columns page](#), you can click **View Column Statistics** to [view a histogram](#) of variable values.

Defining date cutpoints

You define cutpoints for date variables in report definition breakdown details as you would define cutpoints for numeric variables. When you define cutpoints for dates, you must ensure that you enter dates in the format **MM/DD/YYYY**. You must ensure that you enter non-breaking and consecutive date ranges. You cannot set cutpoints with gaps in the ranges.

In defining cutpoints, you may encounter the following cases:

- Cutpoints appear in the report output in alphabetical order by label name, rather than chronological date order.
- The **Save** button may become inaccessible. To correct the situation, place the cursor in the last available **Value** field, and then press **Tab** until you reach the **Save** button.

Existing report definitions and date variables

Prior to Oracle Empirica Signal 7.3.337, you specified breakdown details for date variables by Individual Values or by Grouped Values. Report definitions created prior to Oracle Empirica Signal 7.3.337 continue to maintain the previous date variable functionality. To define breakdown details by cutpoints for these reports, you must delete the date variables, and then re-add them to the reports.

For information on deleting variables from breakdown details, see [Edit report columns](#).

Adding additional rows

When you define cutpoints, a limited number of rows are available for date and label entry. Should you require additional rows, do the following:

1. Click **Save**.
2. Click **Select** next to the **Breakdown Details** field.

The Breakdown Details dialog box reopens with additional rows available.

Define breakdown by cutpoints

If you are defining breakdown details for a numeric variable, you must define cutpoints. To define cutpoints, you specify ranges of numbers by indicating their boundaries. This option uses the values available at the time the report is run, not at the time you define the report.

With the numeric variable highlighted on the [Edit Report Columns page](#), you can click **View Column Statistics** to [view a histogram](#) of variable values.

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the Edit Report Columns page, next to **Breakdown Details**, click **Select**.
5. In the first value field (after **VALUE <=**), enter the maximum value for the first category.
6. Enter a label for the value.
7. In the next row, in the **Value** field, enter the maximum value for the second category. (The cutpoint values must be in ascending order.)
8. Enter a label.
9. Continue defining categories until you are ready to define the last category.
10. For the last category, enter only a label. Do not enter a value. This is the label for all values greater than the previous cutpoint.
11. To include a column or row to represent null values for the variable, check **Include a category for NULL values**.
12. To include a column or row to represent all values for the variable (including null values if **Include a category for NULL values** is checked), check **Include a category for ALL selected values**. For reports that display percentages, the report must include a row or column for **All**.
13. When you are satisfied with the cutpoints, click **Save**.

The Edit Report Columns page shows the selected values. Click **Save** to save your report definition so far.

View column statistics

When you are [adding a column](#) for a numeric variable to a report definition on the Edit Data Source dialog box, or [defining cutpoints](#) for a numeric or date variable in a data configuration on the **Cutpoints for Variable** dialog box, you can click **View Column Statistics** to view information about the distribution of values for the variable in the source data.

The following information is provided for numeric and date variables:

- **A histogram**—A graph of grouped (binned) data showing frequency distribution. The x-axis represents values from the source data and the y-axis represents counts of cases. A shaded rectangular block in the graph represents each bin. A bin is a range of x-axis values. The top of each block indicates the count of cases for the bin.
- **Minimum**—Minimum value.
- **Maximum**—Maximum value.
- **Distinct Values**—Number of distinct values.
- **Total Values**—Total number of values.

The following additional information is provided for date variables:

- **Average**—Average value.
- **Standard Deviation**—Standard deviation of values.
- **Variance**—Variance of values.

When you point to a block in the histogram, the following information appears:

- The range of x-axis values for the bin.
- The cumulative count of cases with that range of values.
- The cumulative percentage of cases with that range of values.

Define breakdown by query values

When you [create an interactive report definition](#), you define a query that will be run when the report is run. The report is run against the cases found by the query. You can set up a breakdown variable to use user-specified query values as the breakdown details. For example, you can define a report that uses user-specified values for Outcome as breakdown values.

Note

You cannot define breakdown by query values for numeric or date variables.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Definitions**.
2. On the Report Definitions page, accept the case series shown or click **Browse** to the right of **Case Series** to display the **Select Case Series** page and [select a case series](#).
3. Click a Report Definition's **Row Action menu** (), then click **Edit**.
4. On the Edit Report Columns page, next to **Breakdown Details**, click **Select**.

5. In the [Breakdown Details](#) dialog box, click **Query Values**.
6. To include a column or row to represent null (missing) values for the variable, check **Include a category for NULL values**.
7. To include a column or row in the report to represent all the values provided to the query, including null values, check **Include a category for ALL selected values**. For reports that display percentages, the report must include a row or column for **All**.

Note

If a case is counted in multiple columns, a count in the All column is not necessarily the same as the total of counts in other columns of the report.

8. To include a column or row for values that are not represented by any other columns, check **Include a category for all unselected values**.
9. Click **OK**.

Make sure that the query for the report definition includes the breakdown variable.

Report background processing

- [About background processing for reports](#)
- [About background processing job queues for reports](#)
- [About background processing job status for reports](#)
- [View background processing job status for reports](#)
- [Cancel a background processing job for a report](#)

About background processing for reports

Background processing allows processes, such as reports, to run without user intervention and interruption, so that you can perform other tasks simultaneously. Uninterrupted background processing also allows you to exit the application without affecting job processing or completion. Background processing is a standard feature and occurs automatically. You do not need to enable background processing.

One background processing job exists per task when you perform any of the following:

- [Create output from a report definition](#).
- [Create output from an interactive report definition](#).
- [Create and edit an interactive report definition](#).

Note

Background processing does not occur for query-based interactive report outputs.

About background processing job queues for reports

A background processing job queue is a temporary container that the application creates on demand when one or more sequential jobs are [awaiting background processing](#). Jobs in the queue run one at a time in the order in which the application added them to the queue. The job

queue is specific to your user account, and contains only jobs that you created. You cannot view another user's job queue, even if you are a superuser.

Your queue can hold an unlimited number of jobs. The application adds jobs to your queue when you perform specific report tasks, as described in [About background processing](#). The application can add jobs while a job is running without interrupting that job.

When a background processing job is running, you can view the job queue and the current status of the jobs in your queue by hovering the Background Processing indicator (). The Background Processing indicator appears next your username at the top of the page, and remains visible until there are no unprocessed jobs remaining.

You can [cancel](#) **Running** or **In Queue** jobs in your background processing queue from individual cases from individual report outputs on the [Report Outputs page](#). If you are a superuser, you can also cancel other users' jobs from these pages.

About background processing job status for reports

Report background processing jobs can have one of the following statuses:

- **In Queue**—Job is awaiting processing.
- **Running**—Job is currently processing.
- **Cancelled**—Superuser or the user who submitted the job cancelled it.
- **Error Occurred**—Job did not finish processing. You may see this status if, for example, the database fails during processing.
- **Completed**—Job finished processing successfully.

Note

You can [cancel](#) In Queue or Running jobs, if necessary, from the Report Outputs page.

You cannot restart Error Occurred jobs. To complete the job processing, create a new report output from the report definition.

View background processing job status for reports

You can view the current job status for background processing jobs:

- On the [Report Outputs page](#), in the **Status** column.
- By hovering over the **Background Processing** indicator.

For information on background processing job status, see [About background processing job status](#).

Cancel a background processing job for a report

The **Cancel** action menu command is available for In Queue or Running case series or report outputs in your background processing queue. You can cancel these jobs at any time from the Report Outputs page, depending on the job type you submitted. You cannot cancel jobs when hovering your mouse over the Background Processing indicator.

If you are a superuser, you can:

- Cancel jobs that you submitted.
- Cancel jobs that other users submitted.
- Cancel other users' jobs on the Report Outputs page.

To cancel a report background processing job:

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Outputs**.
2. Click **Report Outputs**.
3. Locate the report output for which you submitted a background processing job. The status in the Status column is Running. If you are a superuser, you can locate the report output that another user submitted.
4. If necessary, mouse over to the **Background Processing** indicator located next to your username at the top of the page to obtain the report output name from your job queue.
5. Click the report output's **Row Action menu** () , and click **Cancel**.

Oracle Empirica Signal cancels the job and sets the report output status to Cancelled.

Create and run interactive reports

- [About interactive reports](#)
- [Interactive Reports page](#)
- [Create or edit an interactive report definition](#)
- [Run an interactive report](#)
- [Create a report definition file](#)
- [Run a report using a report definition file](#)
- [Query-based interactive reports](#)
- [Summary of all cases interactive reports](#)
- [Manage interactive reports](#)

About interactive reports

Oracle Empirica Signal provides three types of interactive reports:

- **Query-based**—Reports are based on a query for which you can provide values. The application runs the report against the cases found by the query. You can use the query values as breakdown details in the report.
- **Summary of all cases**—Reports include all cases and generates a report output that can be used as the source data for the tables and graphs in drug profiles.
- **Customer-specific**—Reports provided by Oracle.

Interactive report definitions

An interactive report definition specifies:

- Variables from the source data to appear as columns in the report. The definition also specifies how data is broken down based on other variables.

- A variable or combination of variables that provide unique keys for the report. The report has a row for each unique key value, or key value combination.
- How to aggregate multiple values in individual cells.
- The subset of rows to appear in the report, based on conditions specified by a SQL WHERE clause.
- Queries for query-based interactive reports.

Valid report definitions

The names of valid report definitions appear in bold. A report definition is valid if it includes at least one row variable and one column variable, and no error messages appear for report variables. For a query-based report, a query must be part of the report definition. For an all cases summary report, the definition must conform to certain [criteria](#).

Interactive Reports page

On the Interactive Reports page, you can view interactive report definitions that you created or were published to you for select projects and data configurations. This page also lists all published and unpublished interactive report definitions created by users in your login group, if you have the Administer Users permission.

General activities

The following links appear at the top of the page and affect the entire page:

- [Create Definition](#)
- [Create Definition from XML](#)
- [Columns](#)
- [Print](#)
- [Download](#)

Note

The **Create Definition from XML** link is only available for users with the superuser permission.

The following filters appear at the top of the page and affect the report definition list:

- [Project](#)
- [Configuration](#)

Row-specific activities

The following menu options are available from the Row Action menu, located in the first column of the table, and affect an individual row in the table:

- Run
- Create Output (See [Creating an all cases summary report output](#) or [Creating a query-based report output](#).)
- [Create Definition File](#)
- [Edit](#)

- [Rename](#)
- [Copy](#)
- [Publish](#)
- [Delete](#)

The **Create Output** Row Action menu option appears only for valid report definitions of type **Query-based** or **Summary of all cases**.

The **Copy** Row Action menu option appears only if you have the Create Report permission. This option is available for report definitions created by other users. You cannot edit such report definitions, but you can copy and modify them.

Field descriptions—Interactive Reports page

Field	Description
Definition	Name of the interactive report definition.
Description	Description of the interactive report definition.
Project	Name of the project that the interactive report definition is associated.
Configuration	Name of the data configuration that the interactive report definition is based on.
Created By	Name of the user who created the interactive report definition.
Created	Date and time when the interactive report definition was created. The Created By and Created fields are filled in when the Create Definition page is completed.
Modified	Date and time the interactive report definition was last modified.
Modified By	Name of the user who last modified the interactive report definition. The Modified and Modified By fields are filled in each time the report definition is saved.
ID	Identifier that was assigned automatically to the interactive report definition when it was saved. Each report definition ID is unique across all report definitions and is not reused if the report definition is deleted.
Category	Category of the report. The category is intended only for informational purposes.
Type	Type of report. For example, Query-based or Summary of all Cases.

Create or edit an interactive report definition

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Interactive Reports**.
2. Do one of the following:
 - To create an interactive report definition, click **Create Definition**, then enter this information on the Create Definition page:

- a. Select the **Configuration** from the drop-down list.
- b. Enter a **Name** and **Description**.
- c. Select **Add to existing project** or **Add to new project named** and specify the project name.
- d. From the **Type** drop-down list, select the type of interactive report to create: **Query-based** or **Summary of All Cases**.
- e. Click **Save**.

The Edit Report Query appears. If you selected **Query-based**, the **Query** radio button is selected. If you select **Summary of All Cases**, the **Report Columns** radio button is selected.

- To edit an existing interactive report definition, click the **Row Action menu** () for the report definition, and then click **Edit**.
The Edit Report page appears. The **Report Columns** radio button is selected.
3. From the Edit Report page, use the radio buttons to select, then edit, the various parts of the interactive report.
 - Select the [Report Columns](#) radio button to define the rows, columns, and values of the report
 - For query-based reports, select the **Query** radio button to edit the query associated with the report.
 - Optionally, select [Report Attributes](#) to specify attributes such as drilldown and SQL WHERE Clause restrictions.
 - Optionally, select [Report Descriptors](#) to specify or review report descriptors.
 4. If you have made changes to an interactive report definition since the last time it was saved, save the interactive report definition without running it by clicking **Save**. If you are working on a complex report definition, click **Save** periodically.

Note

If you edit a report definition that you did not create, the **Save** button does not appear.

- To save the interactive report definition with a different name, without running it, click **Save As**. Provide a [name for the new report definition](#).
 - Save the interactive report definition and run it. For a valid report definition, click **Save & Run**. A report is considered valid if it includes at least one row variable and one column variable, and there are no error messages for the report definition. For a query-based interactive report, a query must be part of the report definition. For an all cases summary interactive report, the definition must conform to certain [criteria](#).
5. To run the report definition, for a valid report definition, click **Run**. A report is considered valid if it includes at least one row variable and one column variable, and there are no error messages for the report definition. For a query-based interactive report, a query must be part of the report definition. For an all cases summary interactive report, the definition must conform to certain [criteria](#).
 - If you run the report, you must [select a data configuration](#) to indicate the source data against which the report will be run.

- To run a query-based report, you must also [run the query](#). The report will be run against cases that meet the query criteria.
- To run an all cases summary report, you must [specify report parameters](#).
- Each time you save the report definition, the application fills in the Modified and Modified By columns on the [Interactive Reports page](#).

Run an interactive report

You can run a report definition and save its output in a single step.

- For a query-based interactive report, you must [select a data configuration](#) and [run a query](#). The application runs the query and the report against source data for that data configuration. The report is run against only cases that meet the query criteria.
- When you view a query-based report from the [Interactive Reports page](#), you select a data configuration against which to run a query. The source data for the report is the set of cases in the selected data configuration that match the report's query.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Interactive Reports**.

2. Click the **Row Action menu** () for the report definition, and then click **Run**.

3. From the **configuration** drop-down list, [select a configuration](#).

The report runs against source data for the selected data configuration. When you save the report output, the application verifies that the selected data configuration has a Drug type variable with a subtype of Generic, Trade, or Ingredient.

4. Click **Next**.
5. On the **Run Query** page, fill in the fields and click **Next**.

Oracle Empirica Signal runs the report and displays the report output.

Create a report definition file

If you are a superuser, you can create a report definition file from a valid All Cases Summary report.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Interactive Reports**.

2. Select the **Row Action menu** (), and click **Create Definition File**.

3. From the **Configuration** drop-down list, select a data configuration to indicate the source data on which to base the report. You can click **Browse** to select from a descriptive list of data configurations.

4. In the **Name for Output** field, type a report name.

5. In the **Output Description** field, type a description.

6. Assign the report definition to a project.

Only the **Add to existing project:** option should be used. If the selected project, based on its ID, exists on the instance in which the report is run, the report output is placed in that project. If the project doesn't exist on the instance in which the report is run, the output can go into the Unassigned project. The **Add to new project named:** has no affect.

7. Click Save.

The [Input File](#) page appears. The page displays the content that you can use in a report definition file.

Run a report using a report definition file

If you are a superuser, you can [create a report definition file](#) from a valid All Cases Summary report. You can copy the content of the Input File page into a text file and save the file using the extension **.in**. You can then place the file in the input folder of the application server in order to be processed by the Oracle Empirica Signal application. The input folder is located in the path defined by `temp_dir` in `webvdme.properties`.

The input file (report definition file) contains the following information.

Line in the Report Definition File	Description
#datetime	Date and time of creation of the report definition file. The comments are preceded by #.
ACTION=CREATE REPORT	Represents the type of batch file. Reports appear as CREATE REPORT. Data mining runs appear as CREATE RUN.
Description	Description of the report definition used with Create Definition File.
Name	Name of the report definition used with Create Definition File.
Owner	Owner of the report definition used with Create Definition File.
Project_id	Project ID of the report definition used with Create Definition File. The Report Batch Runs page relies on the project ID.
Type	0
Report.classname	com.lincolntechnologies.webvdme.reports.batch.RunAllCasesReportProc
Report.configuration	Configuration on which the report runs. If the configuration does not exist when the batch report is run, an error message displays: Configuration named '<configuration name>' does not exist

Line in the Report Definition File	Description
Report.name	Name of the report definition used with Create Definition File. The same name will appear in the Definition column of Report Output.
Report.output_name	Name entered on the Create Definition File page. This name is used as Output in the Report Output table.
Report.output_description	Description entered on the Create Definition File page. This description is used as Description in the Report Output table.
Report.project_id	ID of an existing project selected on the source server. It can be used as a filter on the Report Batch Runs page. If the file is to be used on an instance other than the one on which it was created, it is unlikely that the ID is on the receiving server. Omit or assign 0.
Report.reportid	Report ID of the report definition used with Create Definition File. This line should be removed in order to force use of the XML referenced by report.reportxml, especially if the file is to be used on an instance other than the one on which it was created.
Report.reportxml	XML of the report definition used with Create Definition File.

Note

For consistency in report outputs that rely on a report definition coming from another instance, the report.name should match the value of Name\="All Drug Summary Report" in XML.

Line in the Report Definition File	Description
report.Project\ Name	If the specified project name exists on the server on which report is ultimately run, the report output is placed in that project. Else, the report output is assigned to project with ID matching report.project_id.
report.Alias\ Names	Report Output Alias. If the Report Output Alias exists, it is updated with Report.output_name. If the Report Output Alias does not exist, it is created and assigned the specified value.

Query-based interactive reports

- [Define a query for an interactive report definition](#)
- [Create a query-based report output](#)

Define a query for an interactive report definition

A query-based interactive report has a query associated with it. When the user runs the report, the user specifies values for the variables in the query. The application then runs the report against cases that meet the criteria of the query.

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Interactive Reports**.
2. Click **Create Definition**.
3. From the **Configuration** drop-down list, [select a data configuration](#) to indicate the source data on which to base the report. You can click **Browse** to select from a descriptive list of data configurations.
4. In the **Name** field, type a report name. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
5. In the **Description** field, type a description that differentiates the report definition from others on the Interactive Report Definitions page.
6. Assign the report definition to a [project](#).
 - To assign the report definition to an existing project, click **Add to existing project** and select from a list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the report definition to it, click **Add to a new project named** and enter a project name.
7. Click **Save**.

The Edit Report Query page appears. You can also display the page by clicking **Query** on other pages of the interactive report definition.

8. To create a new query, choose one of the following:
 - To use the Query Wizard, click **Create Using Query Wizard**. The [Define Query page](#) appears. For more information, see [Defining a query](#).
 - To create a query based on an existing query, click **Create from Existing Query**. The [Select Query from Library page](#) appears. Subsequent changes to the query in the library do not affect the report. For more information, see [Defining a query](#).

The defined query appears on the Edit Report Query page in the **Query** field.

Note

If you saved the query to the library and then you edit from this page, your changes are not saved to the library. If the query includes a variable that you want to use as a breakdown variable in the report, remember to set up the breakdown details to use query values.

Breakdown details

If you want user-specified values from a query to be used as breakdown details for a report column or row, you must do both of the following:

- Include the breakdown variable in the query.
- Specify **Query Values** for the variable's breakdown details.

If you set up a breakdown variable to use query values but you do not include the variable in the query that is part of the report definition, the application cannot determine the breakdown values. If a column or row variable has no breakdown values, the application drops it when running the report. If this results in a report without rows or columns, the report cannot be run.

If you include a breakdown variable in the query but do not set up the breakdown variable to use query values, the application uses any values that a user specifies for the query to select cases to include in the report, but does not use those values as breakdown details. For example, the query is for generic name and generic name is a breakdown variable with **Every Distinct Value** specified for breakdown details. If the user specifies DrugA as the query value, the report includes only cases with DrugA, and it includes a column for each value of generic name for those cases.

Create a query-based report output

You can run a query-based report definition and save its output in a single step.

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Interactive Reports**.
2. Click the **Row Action menu** () for the report definition, and then click **Create Output**.
3. From the **configuration** drop-down list, [select a configuration](#).
The report runs against source data for the selected data configuration. When you save the report output, the application verifies that the selected data configuration has a Drug type variable with a subtype of Generic, Trade, or Ingredient.
4. Click **Next**.
5. On the Run Query page, fill in the fields, and click **Next**.
6. Fill in the fields on the Create Output page:
 - **Name for Output**—Name for the saved output. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
 - **Output Description**—Description of the saved output that differentiates the report output from entries on the Report Outputs page.
 - **Output Category**—Type of report output: **Ad Hoc** or **Standard**. The application uses the category for organizing reports and the category is not related to report availability. You can include a column showing report categories on the Report Outputs pages.
7. Select an option for assigning the report output to a [project](#):
 - **Add to existing project**—Assign the report output to an existing project by selecting from a list of projects associated with objects that you created or that are published to you.
 - **Add to a new project named**—Create a new project and assign the report output to it.
8. Click **Save**.

Oracle Empirica Signal submits the report output to your [background processing job queue](#), and the Background Processing indicator appears next to the Preferences link.

Summary of all cases interactive reports

- [About all cases summary reports](#)
- [Create an all cases summary report output](#)

About all cases summary reports

An all cases summary report runs on all cases in a specific data configuration. You can select report outputs from this report type in the **Report Output** field in a [drug profile configuration](#). You can also add a report chart to a drug profile layout for each breakdown variable in the report definition.

To create this type of report, you [create an interactive report](#), and then select the report type, **Summary of all cases**. The report definition is not valid until all of the following criteria are true:

- There is only one row variable.
- The row variable is based on a [data configuration variable](#) with the variable type Drug and the variable subtype Generic, Ingredient, or Trade.
- To support reports for all three subtypes on the Drug Profiles page, you can create a different All Cases Summary report for each of the three subtypes.
- Breakdown variables are based on variables for which the Oracle data type of the underlying database column is VARCHAR2 or CHAR.
- The **Every Distinct Value** radio button is selected in breakdown details for the row variable.
- There is at least one column breakdown variable.
- Each column contains both a [breakdown variable](#) and an [analysis variable](#).

We recommend that the breakdown variable and the analysis variable be from the same source table. You cannot use a continuous variable as a breakdown variable.

The breakdown details for each column breakdown variable are:

- The **Every Distinct Value** radio button is selected.
- The **Include a category for NULL values** check box is selected.
- The **Include a category for ALL selected values** is deselected.
- The content detail for the analysis variable is specified as Count (Unique).

If the report does not meet all criteria, a message appears below the report, indicating that the report is not valid. The exception to this is that the check for the drug variable subtype is not performed until you run the report.

Example

The following example shows a report definition for an All Cases Summary report:

Figure 8-2 Define All cases summary report

	AgeGroup9	Gender
	ISR_demog	ISR_demog
Generic_Name	N (U)	N (U)

Available report charts in a drug profile include Distribution of <variable-name>, where <variable-name> is the label of the breakdown variable from the report definition. The label may differ from the variable name.

Report output for this report definition makes the following report charts available to add to a drug profile layout:

Figure 8-3 All Cases Summary report

Help

Drug Type:

Drug Name: [Select](#)

Chart: **MGPS 2D Run**

- Sector Map Graph
- EBGM Graph
- EBGM Confidence Interval Graph
- ROR Graph
- ROR Confidence Interval Graph
- PRR Graph

MGPS 3D Run

- Nested Confidence Interval Graph

Reports

- Distribution by AgeGroup9**
- Distribution by Gender

Create an all cases summary report output

You can run an [all cases summary report](#) definition and save its output in a single step.

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Interactive Reports**.

2. Click the **Row Action menu** () for the report definition, and then click **Create Output**.
3. From the **configuration** drop-down list, [select a configuration](#).

The report runs against source data for the selected data configuration. When you save the report output, the application verifies that the selected data configuration has a Drug type variable with a subtype of Generic, Trade, or Ingredient.
4. Click **Next**.
5. On the **Run Query** page, fill in the fields and click **Next**.
6. Fill in the fields on the **Create Output** page:
 - **Name for Output**—Name for the saved output. The name does not need to be unique, although Oracle recommends that you provide a unique and meaningful name.
 - **Output Description**—Description of the saved output that differentiates the report output from entries on the Report Outputs page.
 - **Output Category**—Type of report output: **Ad Hoc** or **Standard**. The application uses the category for organizing reports and the category is not related to report availability. You can include a column showing report categories on the Report Outputs pages.
7. Select an option for assigning the report output to a [project](#):
 - **Add to existing project**—Assign the report output to an existing project by selecting from a list of projects associated with objects that you created or that are published to you.
 - **Add to a new project named**—Create a new project and assign the report output to it.
8. Click **Save**.

Manage interactive reports

- [View an interactive report definition](#)
- [Delete an interactive report definition](#)

View an interactive report definition

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Interactive Reports**.

Note

You do not need to select a case series to work with these reports. If a case series is selected, it is not used for the interactive report.

2. Select the report definition's **Row Action menu** (), and click **Run**.

Note

For a query-based report or an all cases summary report, you must [select a data configuration](#) from a list of [compatible data configurations](#).

3. For a query-based report, you must also run the query.

4. For an all cases summary report, you must [specify report parameters](#).

Delete an interactive report definition

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Interactive Reports**.
2. Select the report definition's **Row Action menu** (), and select **Delete**.
3. Confirm the deletion by clicking **OK**.

The [Interactive Reports page](#) refreshes with the updated list. Any report that was created using the deleted report definition remains accessible on the Report Outputs page.

Work with report outputs

- [View existing report outputs](#)
- [Rename a report output](#)
- [Work with a report output](#)

View existing report outputs

A report output is the result of applying a report definition to the cases in a selected case series or found by a query, and saving the result. A report output is static. If there is a change in a report definition or the set of cases against which the report was run to produce the output, you can run the report again and save another report output.

When you run a report, you can name and save the output. You can view the saved output without any need to rerun the report. Once report output is saved, it remains available until you explicitly delete it. Modification or deletion of the report definition, or of the case series or query on which the report was based, do not affect the saved report output.

For the selected project and data configuration, the Report Outputs page shows report outputs that you have created or that are published to you. If you have the Administer Users permission, the page also lists published and unpublished report outputs created by any users in your login group.

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Report Outputs**.
2. From the **Project** drop-down list, select the [project](#) for which you want to view report outputs or -- to include all projects.
3. From the **Configuration** drop-down list, select the [data configuration](#) from which you want to view report outputs or -- to include all configurations.

Oracle Empirica Signal provides the following information about each report output:

Column	Description
Output	Name of the saved output.
Description	Description of the saved output, if provided.
Project	Name of the project associated with the report output.

Column	Description
Configuration	Name of the data configuration used by the case series or query to run the report definition.
Case Series	Applies to non-interactive reports. Name of the case series for which the report was run.
Created By	Name of the user who saved the report output.
Created	Date and time when the report output was saved.
Status	The current status of the background processing job .
As Of	As Of date of the case series or query for which the report definition was run. Appears only if the data configuration supports timestamp data . For output from an interactive report: As Of date selected when the report was run.
Category	Category of the report. The category is for informational purposes.
Definition	Name of the report definition.
ID	Identifier that was assigned automatically to the report output when the report output was saved. Each report output ID is unique and is not re-used if the report output is deleted.

General activities

- For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).
- To print, download, delete, or [publish](#) multiple report outputs, click **Select Rows** and check the report outputs on which you want to act.
- To check all rows, click **Select All** (or **Clear All** to uncheck all rows), then click the action that you want to perform on the selected rows.

Row Action menu options

If you click the **Row Action menu** () for a report output, you can do the following:

- To view the report output, click **View**.
- To rename the report output that you created, click **Rename**.

Note

When you rename a report output that is the target of an alias, the application updates the name of the alias target.

- To cancel a Running or In Queue report output background processing job, click **Cancel**.
 - The **Cancel** option is available only when a background processing job exists for the report output.
- To publish a report output that you created, click **Publish**.

Note

If the object is multi-enterprise support-related, then you can only publish to the object owner's login group.

- To delete a report output that you created, click **Delete** and, at the prompt asking if you want to delete the report output, click **OK**.
 - Before deleting a report output, make sure that it is not referenced by any drug profile configurations, because the application will remove these references.

Note

When you delete a report output that is associated with an alias, the target status of the alias becomes Broken.

Rename a report output

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Outputs**.
2. On the Report Outputs page, click the **Row Action menu** () of a report output, and then click **Rename**.
3. Modify the report name, description, category, or project. For more information, see [Save a report output](#).
4. Click **Save**.

The following information also appears but you cannot modify it:

Column	Description
Configuration	Name of the data configuration for which the report definition was run.
Case Series	Name of the case series for which the (non-interactive) report was run.
Report Definition	Name of the report definition that was run to create the output.

Work with a report output

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Outputs**.
2. From the **Project** drop-down list, select the [project](#) for which you want to view report outputs or -- to include all projects.
3. From the **Configuration** drop-down list, select the [data configuration](#) from which you want to view report outputs or -- to include all configurations.

The selected report outputs appear.

4. To display the report output, select the **Row Action menu** () of a report output, and click **View**.

If the report includes an underlined count (N) of cases, the count is a link that you can click to display a menu from which you can [drill down](#). If specific case IDs appear underlined in the report, you can click a case ID to [view case details](#).

5. To publish the report output to other users, click a report output's **Row Action menu** () and then click **Publish**. To publish multiple report outputs, click the **Select Rows** link, select the radio buttons of the definitions, then click the **Publish** link.

Objects that are multi-enterprise support-related are not available in select rows mode.

6. To publish to all the users in your login group, click **Publish**.
 - If you are a superuser and the object is not multi-enterprise support-related, you can publish to multiple login groups, including —All—. From the Publish to Login Groups list, select one row and hold Ctrl + left click to select more rows.
 - If you publish to —All— and later add a new login group, the object is published automatically to the new login group.
 - If you are a superuser and the object is multi-enterprise support-related, then you can only publish to the object owner's login group.

The selected login group is added to the Publication Level list.

7. Click **Back**.

Work with report data

- To [choose a graph](#) to show data in the report, click **Choose Graph**.
- To [save the report output as an attachment to a topic](#), click **Save to Topic** (available if the topics feature has been set up).
- To [print the table](#) (that is, the report), click **Print**.
- To [download report data](#), click **Download**. The column names will be created from the labels in the report definition, followed by the breakdown specifications.
- To show descriptive information below the report, click **Show Notes**.

Manage report rows

- To specify how many rows should display at a time, enter a number in the **Rows per Page** field and press the **Enter** key. You can display up to 999 rows on each page.
- To go to another page, you can do the following:
 - To view the next page, click .
 - To view the previous page, click .
 - To view the specific page, enter a number in the **Page** field and press the **Enter** key.
- To find specific text on a page, you can use the browser's Find feature. For efficiency, you might want to set the Rows per Page to a large number before using the **Find** feature.

Sort the report output

You can sort a table by up to three columns. The current sort order appears above the table. You can sort a column as follows:

- To sort a column, click the column header. The column is sorted, and an arrow is displayed next to the column name to indicate the sort order. To sort in reverse order, click the column header again. The previous primary sort order (if any) becomes the secondary sort order. The previous secondary sort order (if any) becomes the tertiary sort order.
- Click **Columns** or **Columns and Rows**. (See [Arrange table columns](#).)

Note

In displayed reports, sorting is case-insensitive.

Work with report graphs

- [Work with report graphs](#)
- [Report graph types](#)
- [Graph display options](#)
- [Aggregate bar graphs](#)
- [Detail bar graphs](#)
- [Box plot graphs](#)
- [Scatter plot graphs](#)

Work with report graphs

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Outputs**.
2. Select the **Row Action menu** () for a report output, and click **View**.
3. On the **Display Output** page, click **Choose Graph**.
Only those graph types that are appropriate for the report data appear.
4. Click the graph type.
 - For information about aggregate bar graphs, see [About aggregate bar graphs](#).
 - For information about detail bar graphs, see [About detail bar graphs](#).
 - For information about box plots, see [About box plots](#).
 - For information about scatter plots, see [About scatter plots](#).
5. Specify the options for the selected graph type.
 - For information about aggregate bar graphs, see [Viewing an aggregate bar graph](#).
 - For information about detail bar graphs, see [Viewing a detail bar graph](#).
 - For information about box plots, see [Viewing a box plot](#).
 - For information about scatter plots, see [Viewing a scatter plot](#).
6. Click **Display**.
The selected graph appears.

Print a graph

1. Click **Print**.
2. Select print options.
3. Click **Print**.

Save the graph as an attachment to a topic

1. Click **Save to Topic**. The graph is attached as a PDF file.

Note

This option is available only if the Topics feature has been set up.

Report graph types

When displaying a report or report output, you have the option to view a graphical representation of the report data. On the Display Report or the Display Output page, when you click **Choose Graph**, the Choose Graph page appears. Different graphs are available depending on the types of columns in the report, as follows:

Graph Type	Report Variables
Aggregate bar graph	All column variables or all column variables except one are numeric. A variable with Variable Type <i>Report ID</i> does not need to be in the report. Link name: Bar graph (where rows are aggregate values).
Detail bar graph	The row variable in the report is a variable with Variable Type <i>Report ID</i> . Link name: Bar graph (where rows are detail records).
Box plot	The row variable in the report is a variable with Variable Type <i>Report ID</i> . At least one column variable is numeric. Link name: Box plot (where rows are detail records).
Scatter Plot	The row variable in the report is a variable with Variable Type <i>Report ID</i> . At least two column variables are numeric. Link name: Scatter plot (where rows are detail records).

Note

A numeric variable is one for which source data is numeric or a numeric value such as count or percentage is specified as content detail.

The [graph key](#) and color palette that you set for graphs based on data mining results does not affect the report graphs. The report graphs appear in color unless you choose the display option, **Use gray-scale instead of colors**.

Graph display options

The following display options are available for most report-based graphs:

Option	Check to
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.
Popup	Display each graph in an individual window. If you have popup blocking software installed on your browser, it may prevent these windows from opening. You may want to disable your popup blocking software.
Key	Display a color key below the graph to show which value each graph element (such as a bar or region of the graph) represents.
Notes	Display notes about the graph. The notes are the same as for the displayed report.
Links	Show the following: • Information about what a graph component (such as a bar, cell, or region) represents, or statistics for the component, that appear when you point to that component. • A menu that allows you to drill down when you click a graph component. • Print link. • A Save to Topic link (if Topics has been configured).

Aggregate bar graphs

- [About aggregate bar graphs](#)
- [View an aggregate bar graph](#)

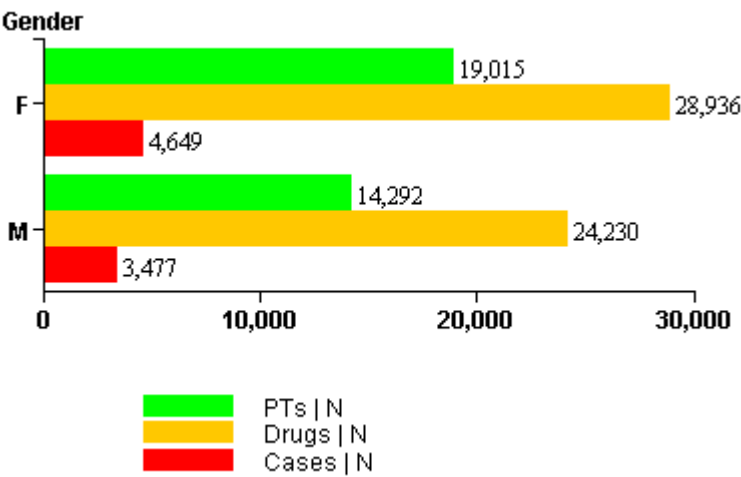
About aggregate bar graphs

In an aggregate bar graph, the row variable of the report appears on the y-axis. Each numeric column variable in the report appears on the x-axis. A key appears below the graph describing each bar.

For example, a report includes counts of PTs, drugs, and cases for each gender:

Gender	PT	Drugs	Cases
	N ▼	N	N
F	1765	3179	179
M	1579	2189	144
U	34	100	4

Depending on the [display options](#) that you specify, the graph might look like this:



View an aggregate bar graph

For an overview of aggregate bar graphs, see [About aggregate bar graphs](#).

- 1. In the left navigation pane, hover on the **Data Analysis** icon (📊), then click **Report Outputs**.
- 2. Select the **Row Action menu** (⋮) for a report output, and click **View**.
- 3. On the **Display Output** page, click **Choose Graph**.
Only those graph types that are appropriate for the report data appear.
- 4. Select **Bar graph (where rows are aggregate values)**.
- 5. Specify the following display options:

Option	Description	Notes
Labels X and Y	Label the x-axis and y-axis to clarify what is represented by the axes.	Required.
Show counts at the ends of bars	Show case counts at the end of bars in the graph.	If the report shows numeric values that are not case counts and you check this option, the values are shown instead of counts.
Transpose rows and columns	Switch the roles of the rows and columns in displaying the graph.	
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.	
Popup	Display each graph in an individual window. If you have popup blocking software installed on your browser, it may prevent these windows from opening. You may want to disable your popup blocking software. For details, see Graph display options .	

6. Click **Display**.

Oracle Empirica Signal creates the graph using the specified display options. These options apply only to this graph.

7. To see the exact values represented by a bar in the graph, point to the bar.

If you click a bar, you can [drill down](#) to cases for the bar. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.

For information about copying, printing, or saving a graph as an attachment to a topic, see [Work with report graphs](#).

Detail bar graphs

- [About detail bar graphs](#)
- [View a detail bar graph](#)

About detail bar graphs

With a detail bar graph, you determine the row variables and column variables of the report that appear on the y-axis, and the subject counts that appear on the x-axis. There is a subject count for each primary variable that you select as a display option. You can break down the case counts for the primary variable by specifying a secondary variable. If you specify a secondary variable, a graph key indicates the meaning of each bar.

You can also create multiple graphs, one for each value of a row or column variable that you specify as a subset variable.

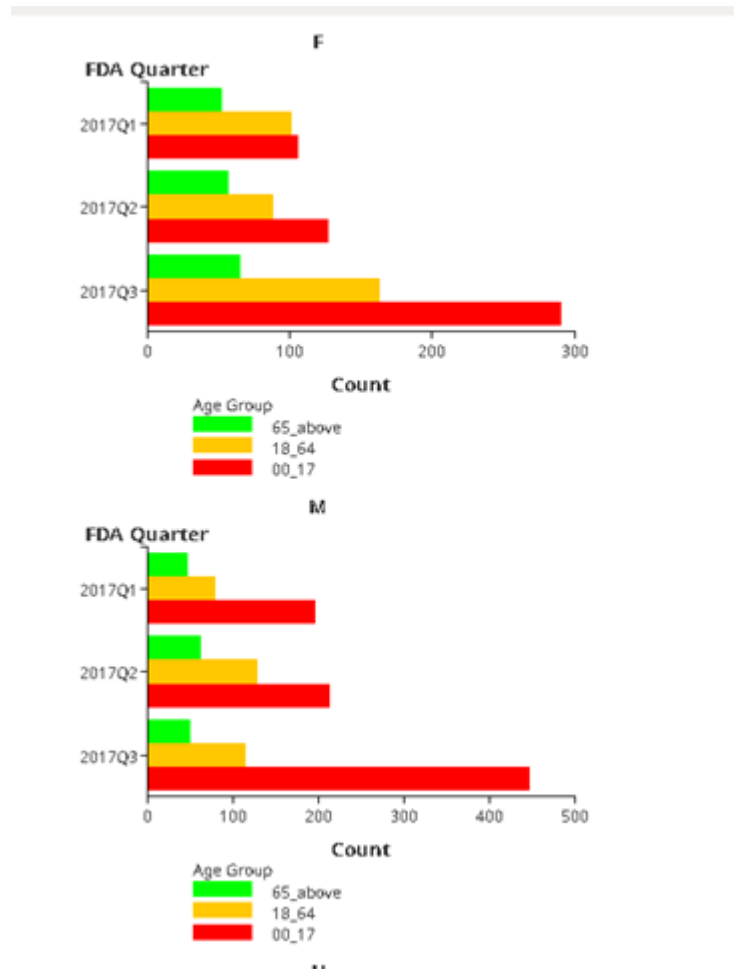
For example, a report shows gender, age group, and quarter from FDA date for each case ID:

Figure 8-4 Report detail bar graph

Case ID	Gender	Age Group	FDA Quarter
F120102427	M	UNK	2017Q1
F129019911	U	UNK	2016Q4
F129019941	U	UNK	2016Q4
F129020891	U	UNK	2016Q4
F130958051	U	UNK	2017Q1
F130961361	U	UNK	2017Q1
F130962121	U	UNK	2017Q1
F130962141	U	UNK	2017Q1
F130964371	U	UNK	2017Q1
F130964471	U	UNK	2017Q1
F130964571	U	UNK	2017Q1

Depending on the [display options](#) that you specify, the graph might look like this, where **Gender** is the subset variable, **Quarter from FDA date** is the primary variable, and **Age Group** is the secondary variable:

Figure 8-5 Detail bar graphs



View a detail bar graph

For an overview of detail bar graphs, see [About detail bar graphs](#).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Outputs**.
2. Select the **Row Action menu** () for a report output, and click **View**.
3. On the **Display Output** page, click **Choose Graph**.
Only those graph types that are appropriate for the report data appear.
4. Select **Bar graph (where rows are detail records)**.
5. From the **Subset Variable (for multiple graphs)** drop-down list, select a subset variable. There creates one graph for each value of the selected variable.
6. From the **Primary Variable (bar groups)** drop-down list, select a primary variable to appear on the x-axis.
7. From the **Secondary Variable (bars within groups)** drop-down list, select a secondary variable (optional). Each bar in the graph represents a value of the secondary variable, as identified by the color key below the graph.

8. Specify the following display options:

Option	Description	Notes
Labels X and Y	Label the x-axis and y-axis to clarify what is represented by the axes.	Required.
Show counts at the ends of bars	Show case counts at the end of bars in the graph.	NA
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.	NA
Popup	Display each graph in an individual window. If you have popup blocking software installed on your browser, it may prevent these windows from opening. You may want to disable your popup blocking software. For details, see Graph display options .	NA

9. Click **Display**.

Oracle Empirica Signal creates the graph using the specified display options. These options apply only to this graph.

10. To see the exact values represented by a bar in the graph, point to the bar.

If you click a bar, you can [drill down](#) to cases for the bar. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs appear.

For information about copying, printing, or saving a graph as an attachment to a topic, see [Work with report graphs](#).

Box plot graphs

- [About box plots](#)
- [View a box plot](#)

About box plots

A box plot (also known as a box-and-whisker plot) is the plotting of data points against horizontal and vertical axes to show the distribution of a continuous variable. In a box plot:

- The box represents the middle 50% or so of the numeric values.
- A horizontal line within the rectangle represents the median of all values (specifically, the value that is exactly in the middle of all values).
- The top end of the box represents the upper quartile (specifically, the median of the ordered set of values that is greater than the overall median).
- The bottom end of the box represents the lower quartile (specifically, the median of the ordered set of values that is less than the overall median).

The interquartile range, which is the difference between the upper quartile and the lower quartile, is a measure of the spread of the distribution. The relative distances of the upper and lower quartiles from the median describe the shape of the distribution of data.

In the box plot:

- The whisker above the box plot extends from the upper quartile to the highest actual value that is within the $(75\text{th percentile} + 1.5 * (\text{interquartile range}))$.
- The whisker below the box plot extends from the lower quartile to the lowest actual value that is within the $(25\text{th percentile} - 1.5 * (\text{interquartile range}))$.
- Outliers are plotted as individual points in the graph. An outlier is considered to be a value that falls outside of the upper or lower whisker.

Note

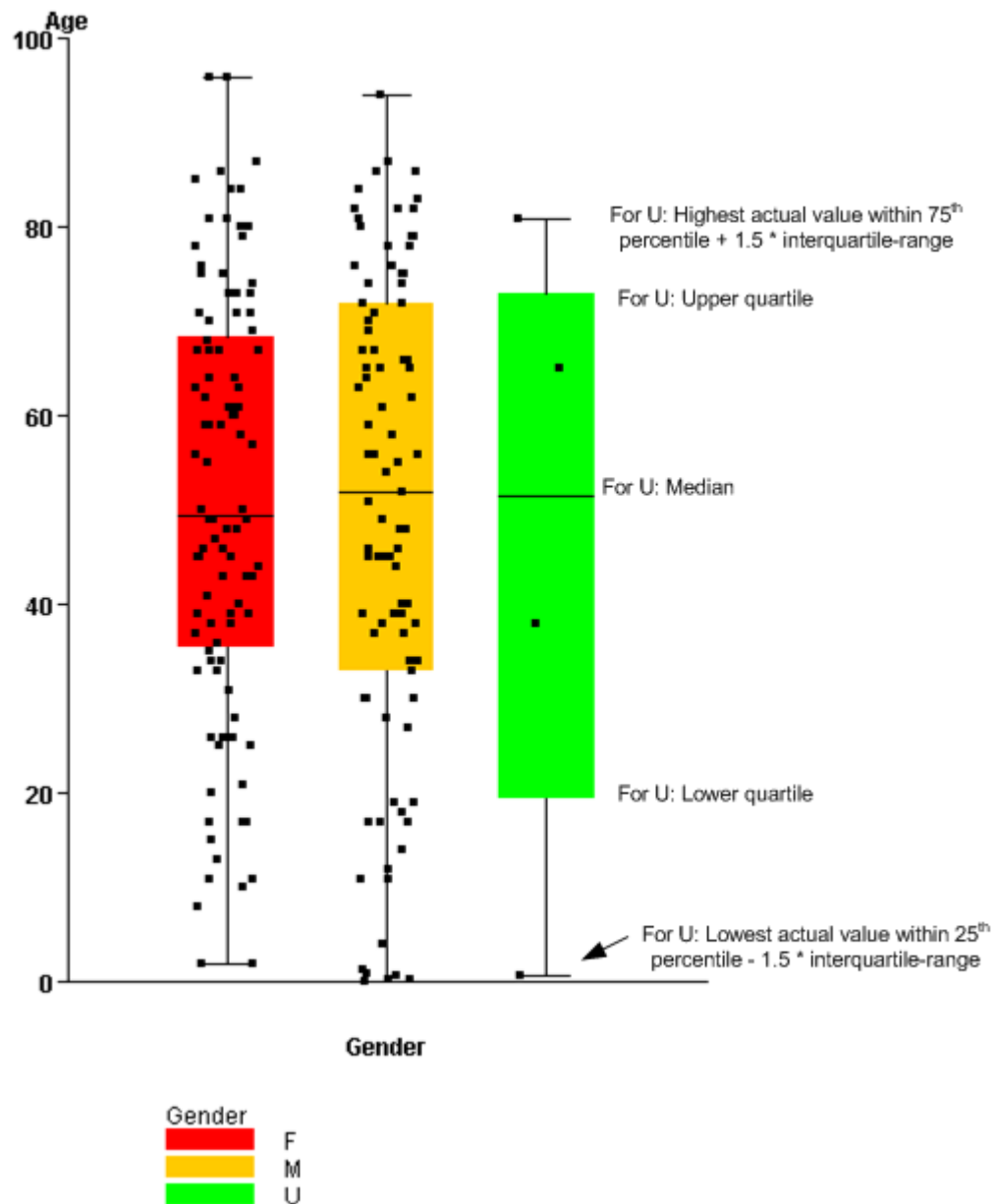
Points in a box plot are jittered (displayed at small random offsets from the center line). This ensures that if two records have the same value, a point is likely to be displayed for each of them.

Several box plots might be shown in a single graph if you select a secondary variable. If so, a key appears below the box plot to relate the individual box plots to the values of the secondary variable.

For example, a report shows age and gender for each case ID:

Case ID	Age	Gender
00647036	35	M
01801272	49	F
01994166	36	M
3069009	47	M
3305097	43	M

Depending on the [display options](#) that you specify, the graph might look like this:



View a box plot

For an overview of box plots, see [About box plots](#).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Outputs**.
2. Select the **Row Action menu** () for a report output, and click **View**.
3. On the **Display Output** page, click **Choose Graph**.
Only those graph types that are appropriate for the report data appear.
4. Select **Box plot (where rows are detail records)**.
5. From the **Subset Variable (for multiple graphs)** drop-down list, select a subset variable.
Oracle Empirica Signal creates one graph for each value of the selected variable.

6. From the **Primary Variable (defines individual boxplots)** drop-down list, select a primary variable from a list of numeric variables in the report definition. Each point in the box plot represents a value of the primary variable.
7. From the **Secondary Variable (defined boxplot groups)** drop-down list, select a secondary variable (optional). Each box represents a value of the secondary variable, as identified by the color key below the graph.
8. Specify the following display options:

Option	Description	Notes
Labels X and Y	Label the x-axis and y-axis to clarify what is represented by the axes.	Required.
Show all points as overlay	Show all points on the box plot. If cleared, only points outside the upper and lower whiskers are shown.	Points in a box plot are jittered, so that if two records have the same value, a point is likely to be displayed for each of them.
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.	NA
Popup	Display each graph in an individual popup window. If you have popup blocking software installed on your browser, it may prevent these windows from opening. You may want to disable your popup blocking software. For details, see Graph display options .	NA

9. Click **Display**.

Oracle Empirica Signal creates the graph using the specified display options. These options apply only to this graph.

For information about copying, printing, or saving a graph as an attachment to a topic, see [Work with report graphs](#).

10. If you point to a region of the graph, the following information appears:

- The region of the box (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier).
- The value of the secondary variable, if any.
- The count of data points for the primary variable (and secondary variable, if any) for that region of the box.

The count may be more than the number of cases because there may be more than one data point for the same case. For example, a case might have multiple adverse events, where each adverse event is a separate data point.

11. If you click a region (Upper Outlier, Upper Whisker, Upper Box, Lower Box, Lower Whisker, or Lower Outlier) of the graph, you can [drill down](#) to cases for that region. If you are displaying multiple graphs on the same page, do not click any graph until all the graphs are displayed.

If a case has a value on the boundary between any regions (not including the Upper Outlier or Lower Outlier regions), the case ID is included when you drill down on either of the regions. Cases with values on the boundary of the Upper Whisker or Lower Whisker are not included when you drill down on the Upper Outlier or Lower Outlier regions.

Scatter plot graphs

- [About scatter plots](#)
- [View a scatter plot](#)

About scatter plots

A scatter plot is the plotting of data points against horizontal and vertical axes to show the correlation between two or more continuous variables. You select a variable to plot against the x-axis of the scatter plot, and one or two variables to plot against the y-axis.

You can select a variable by which to subset data. For example, you can view a different scatter plot for each adverse event.

If you want to use a color key to associate each dot on the graph with a particular value, you can specify an inner breakdown variable. For example, to determine the particular case ID associated with each dot, you can use the case ID as the inner breakdown variable.

Note

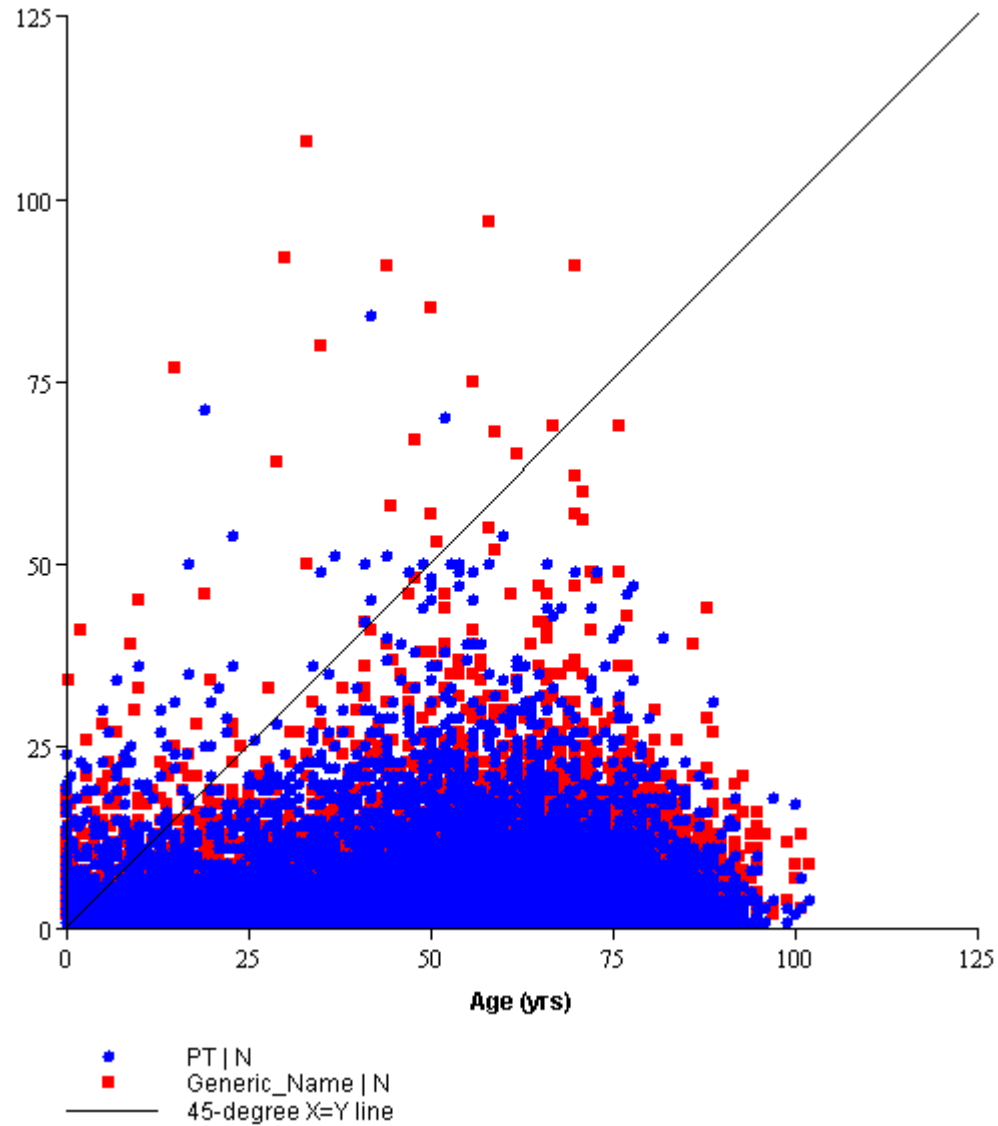
- No data point is plotted for a record if either the X variable or the Y variable is empty.
- If you select two y-axis variables, each of them uses a different shape, as shown in the color key below the scatter plot.
- If the X and Y values for one record coincide with the X and Y values for another record, the two data points are plotted in the same position. It is not possible to distinguish whether that data point represents one record or several records.

The color key below the scatter plot shows which value of the inner breakdown variable each dot represents.

For example, a report shows age, count of PTs, and count of drugs for each case ID:

Case ID	Age (yrs)	Count of PTs	Count of Drugs
00647036	35	1	5
01801272	49	4	2
01994166	36	2	3
3069009	47	1	4
3305097	43	4	4

Depending on the [display options](#) that you specify, the graph might look like this:



View a scatter plot

For an overview of scatter plots, see [About scatter plots](#).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Report Outputs**.
2. Select the **Row Action** menu () for a report output, and click **View**.
3. On the **Display Output** page, click **Choose Graph**.
Only those graph types that are appropriate for the report data appear.
4. Select **Scatterplot**.
5. From the **Subset Variable** drop-down list, select a subset variable.
Oracle Empirica Signal creates one scatter plot for each value of the subset variable.
6. Select an **X variable**; that is, a numeric variable to be plotted against the x-axis.

7. Select a **Y variable**; that is, a numeric variable to be plotted against the y-axis.
8. You can select another **Y variable**. Each of the two Y variables are plotted against the y-axis. Each Y variable corresponds to a different-shaped point, as shown in the key below the scatter plot.
9. You can also select a text variable as an inner breakdown variable. The color key associates each point on the scatter plot with a particular value of the inner breakdown variable.
10. Specify the following display options:

Option	Description
Labels X and Y	Label the x-axis and y-axis to clarify what is represented by the axes.
Include linear regression lines	Include a linear regression line to identify trends in the data.
Include 45-degree line and matched axes	Include a 45-degree line in the scatter plot. This is useful if you are plotting two similar variables and you are interested in the differences.
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.
Popup	Display each graph in an individual window. If you have popup blocking software installed on your browser, it may prevent these windows from opening. You may want to disable your popup blocking software. For details, see Graph display options .

11. Click **Display**.
Oracle Empirica Signal creates the graph using the specified display options. These options apply only to this graph.
12. To [drill down](#) to case information, point to the graph, click, and hold down the mouse button while you draw a red rectangle around the data points for which you want to drill down. When you release the mouse button, a menu appears and you can drill down. Note that a single point in the graph may represent several data points.

Note

If you are displaying multiple graphs on the same page, do not try to drill down until all the graphs are displayed.

For information about copying, printing, or saving a graph as an attachment to a topic, see [Work with report graphs](#).

9

Set up and use drug profiles

- [About drug profiles and layouts](#)
A drug profile is the presentation of statistical and other information about one or more drugs. A drug profile layout is a saved collection of charts, as well as their placement and display options.
- [Drug Profile page](#)
A drug profile is a presentation of graphs and reports related to one or more drugs.
- [Select drugs for a drug profile](#)
When you select drugs for a drug profile, there is a primary drug and a comparator drug. The primary drug is shown in the Drug Profile title area next to the layout name. The comparator drugs are the drugs for which other chart windows appear in the current layout.
- [Select a drug profile layout](#)
Your most recent drug profile layout with your most recent primary drug is saved but you can override this selection.
- [Add a chart to a drug profile layout](#)
The list of available drugs depends on the chart that is currently highlighted in the list of available charts. You can add a chart to a drug profile layout.
- [Print or copy charts \(Drug Profile page\)](#)
You can print or copy a selected chart or all charts.
- [Link to an outside URL](#)
By default, Oracle Empirica Signal links to PubMed literature references, NIH label information, FDA drug information and EMA medicines publications for the drug associated with the current chart window.
- [Define the Links menu](#)
The Drug Profile page includes a Links menu that provides access to specified URLs.
- [Manage drug profile layouts](#)
- [Publish a drug profile layout](#)
Publishing a drug profile layout makes it available to all the users in your login group.
- [Chart types and options](#)

About drug profiles and layouts

A drug profile is the presentation of statistical and other information about one or more drugs. A drug profile layout is a saved collection of charts, as well as their placement and display options.

A chart can be either of the following:

- A graph based on the results of a data mining run.
- A graphical or tabular report based on source data, showing distribution of cases by such variables as gender and age.

Charts in a drug profile layout can be for the same or different drugs. For example, a layout might include charts for the drug that you are studying and for comparator drugs.

Drug profile layouts are available on the Drug Profile page. If you have appropriate permissions, you can create new drug profile layouts.

To use drug profiles, you must have the View Drug Profiles permission and you must set a drug profile configuration as a user preference. The drug profile configuration determines which data mining runs are the source of charts that can be added to a drug profile layout. For information on setting up the drug profiles feature, see [Set up drug profiles](#).

Drug Profile page

A drug profile is a presentation of graphs and reports related to one or more drugs.

What can I do on the Drug Profile page?

[Select a drug to add to a drug profile](#)

[Attach a layout to the drug profile](#)

[Manage your drug profile layouts](#)

Select drugs for a drug profile

When you select drugs for a drug profile, there is a primary drug and a comparator drug. The primary drug is shown in the Drug Profile title area next to the layout name. The comparator drugs are the drugs for which other chart windows appear in the current layout.

Drug names in the title bars of charts end with one of the following suffixes:

- (G) – Generic name
 - (T) – Trade name
 - (I) – Ingredient
1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Drug Profiles**.
 2. In the drug profile menu bar, from the **Drug** menu, click **Select**.

There is a **Primary Drug** field and, if the layout includes chart windows for different drugs, there are **Comparator Drug** fields.

3. Optionally, click **Recent** in the **Drug** menu and select from primary drugs for which you viewed charts recently.

Note

The Drug menu is available only if you are viewing a layout that has been saved at least once.

4. From the **Primary Drug** or **Comparator Drug** drop-down lists, select the type of drug (Generic, Trade, or Ingredient) that you want to specify. Any or all of the drug types might be available depending on the [drug profile configuration](#) you are using.

Primary Drug: Generic ▼ TYLENOL Select

Generic

Ingredient

Trade

Reset Cancel

Note

If you remove the comparator drug, charts for the drug are not displayed although they are still part of the layout, unless you save the layout without them.

5. In the **Primary Drug** field, type a drug name or click **Select** to [select a drug from a list](#).

Note

The list of available drugs that you can select on the Drug menu is determined by an algorithm described in [Add a drug profile configuration](#).

6. If you want to select the drugs with which the layout was last saved by you or another user, click **Reset**.
7. When you are satisfied with the drug selections, click **OK**.

Select a drug profile layout

Your most recent drug profile layout with your most recent primary drug is saved but you can override this selection.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Drug Profiles**.
2. In the drug profile menu bar, from the **Layout** menu, click **Select**.

Your most recent drug profile layout with your most recent primary drug appears, unless one of the following is true:

- This drug profile layout was deleted.
- A drug profile layout has never been used.
- The Drug Profile page was accessed from the Products table on the Signal Review page by selecting Drug Profile from the Row Action menu () for a product.

In these cases, the layout is determined by your **Drug Profile Layout** user preference.

3. To select a layout, from the **Layout** menu, click **Select**.

The Select Drug Profile Layout dialog box provides the following information about each layout:

Column	Description
Name	Name of the layout. Available layouts are those that you created or that are published to you. If you have the Administer Users permission, available layouts are published or unpublished layouts created by any users in your login group.
Description	Description of the layout.
Created By	Name of the user who created the layout.
Created	Date and time when the layout was created.
Modified By	Name of the user who last modified the layout.
Modified	Date and time when the layout was last modified.

4. Perform one of the following:
 - Click the radio button of the layout
 - To select a recent layout, hover over **Layout** and click **Recent**.
5. Click a recent layout name.
 - The primary drug for the layout that you are viewing becomes the primary drug for the selected layout. If you modify the layout, an asterisk appears in the Drug Profile title area after the layout name.
 - If the layout uses only one drug, it appears with the primary drug from the last layout you viewed.
 - If the layout uses multiple drugs, you must specify the primary and comparator drugs. By default:
 - The primary drug is from the last layout that you viewed.
 - The comparator drugs are those that you used the last time you viewed that particular layout. If you never viewed the layout before, the comparator drugs are from the original definition of the layout.

Add a chart to a drug profile layout

The list of available drugs depends on the chart that is currently highlighted in the list of available charts. You can add a chart to a drug profile layout.

You must have the *Create Drug Profiles Layouts* permission to save the layout with the new chart.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Drug Profiles**.
2. In the drug profile menu bar, from the **Layout** menu, click **Add Chart**.
3. From the **Drug Type** drop-down list, select **Generic**, **Ingredient**, or **Trade**. Any or all of these values might be available, depending on the [drug profile configuration](#) that you are using.
4. Perform one of the following:
 - In the **Drug Name** field, type a drug name.
 - Click **Select** to [select a drug from a list](#), then click **OK**.

For a report chart, available drugs are determined by the [data configuration](#) associated with the report output on which the chart is based. For a data mining results graph, available drugs are from the corresponding data mining results.

Note

The set of drugs included in logistic regression results is typically smaller than the set of drugs in MGPS results. Graphs for logistic regression results will be available only if the selected drug was included in the model or added explicitly during creation of the run.

5. Select a chart. The chart types that are available depend on the data mining runs and report outputs referenced by the drug profile configuration that you are using. Possible chart types are as follows:

Data Source	Chart Types
MGPS 2D Run	Sector map graph EBGM graph ERAM graph EBGM confidence interval ERAM confidence interval ROR graph ROR confidence interval graph PRR graph
MGPS 3D Run	Nested confidence interval graph
MGPS 2D by Year Run	Cumulative map graph
LR 2D Run	LROR graph LROR confidence interval graph
Reports	Distribution by <variable-name> , where <variable-name> may be gender, outcome, and so on.

6. Click **OK**.

The chart appears. If the selected drug is not in the run results or report output that is the source for the selected chart, the chart cannot be displayed.

In some cases, a chart window appears but displays a message that the chart cannot be displayed with your current display options. If you click **Options** below the chart and modify the display options, you might be able to display the chart.

7. To select multiple charts, repeats steps 5 and 6.
8. When you have finished adding charts, from the **Layout** menu, click **Save**.

If you have modified a layout, the **Save Layout As** dialog box appears. Enter the information and click **OK**. For more information, see [Saving a drug profile layout](#).

Print or copy charts (Drug Profile page)

You can print or copy a selected chart or all charts.

Print a chart

1. In the left navigation pane, hover over the **Data Analysis** icon () , then click **Drug Profiles**.
2. In the drug profile menu bar, from the **Layout** menu, click **Select**.
3. Perform one of the following:
 - To print the selected chart, under the chart, click **Print**.
 - To print all charts in the layout, from the **Layout** menu, click **Print**.

A preview of the printed chart appears in the Drug Profile dialog box and the Print window appears.

4. Click **Print**.

Link to an outside URL

By default, Oracle Empirica Signal links to PubMed literature references, NIH label information, FDA drug information and EMA medicines publications for the drug associated with the current chart window.

Your organization can [define the Links menu](#) by changing the default links or adding other links.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Drug Profiles**.
2. In the drug profile menu bar, from the **Links** menu, click a URL name to open that configured page.

A separate browser window opens and the page for the selected URL appears.

Define the Links menu

The Drug Profile page includes a Links menu that provides access to specified URLs.

The Drug Profile page includes a Links menu that provides access to specified URLs. By default, the menu includes links to PubMed literature references, NIH label information, FDA drug information and EMA medicines publications for the drug associated with the current chart window. You can change the default links or add other links.

1. In the `Signal\WEB-INF\classes` subdirectory of the server location where the Oracle Empirica Signal application was installed, open the **webvdme.properties** file.
2. Find lines starting with `URLLINK`. Lines for the default links are:

```
URLLINK.1.LINK_NAME=PubMed Literature References
```

```
URLLINK.1.LINK_URL=https://pubmed.ncbi.nlm.nih.gov/?term=\$DRUG\$
```

```
URLLINK.2.LINK_NAME=NIH DailyMed Label Information
```

```
URLLINK.2.LINK_URL=https://dailymed.nlm.nih.gov/dailymed/search.cfm?query=\$DRUG\$
```

URLLINK.3.LINK_NAME=FDA Drug Information

URLLINK.3.LINK_URL=https://www.fda.gov/search?s=\\$DRUG\\$

URLLINK.4.LINK_NAME=EMA Medicines Publications

URLLINK.5.LINK_URL=https://www.ema.europa.eu/en/medicines?
search_api_views_fulltext=\\$DRUG\\$

3. Modify or add links.

- For each link on the Links menu, there must be a pair of lines, one defining the name of the menu option and one specifying the URL.
- In the URL, use the following string if you need to substitute in the drug name associated with the current chart window: `\$DRUG\$`
- The number after URLLINK determines the order of options in the Links menu. For example, to add a link to the two default links, you add two lines starting with URLLINK.3. You can renumber links, but the numbers must start with 1, and you cannot skip numbers.

Manage drug profile layouts

- [Manage existing drug profile layouts](#)
The Drug Profile Layouts page lists layouts that you created or that are published to you.
- [Create a new drug profile layout](#)
You can create a new drug profile layout by selecting one or more charts
- [Save a drug profile layout](#)
When a drug profile layout has been modified but not yet saved, an asterisk appears the Drug Profile title area after the layout name. If the layout has never been saved, the layout name shows as "Not Saved*."
- [Order charts in a drug profile layout](#)
You can specify the order in which you want to print charts or display them in slide show mode. The order does not affect the displayed layout.
- [Rename a drug profile layout](#)
When you rename a drug profile layout be sure to type a description of the layout to differentiate layouts.

Manage existing drug profile layouts

The Drug Profile Layouts page lists layouts that you created or that are published to you.

If you have the Administer Users permission, the page also lists unpublished layouts created by any users in your login group.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Drug Profiles**.
2. In the drug profile menu bar, from the **Layout** menu, click **Manage Layouts**.

The Drug Profile Layouts page appears and provides the following information about each drug profile layout:

Column	Description
Name	Name of the layout.
Description	Description of the layout.

Column	Description
Created By	Name of the user who created the layout.
Created	Date and time when the layout was created.
Modified By	Name of the user who last modified the layout.
Modified	Date and time when the layout was last modified.

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

3. If you click the **Row Action** menu () for a drug profile layout, you can do the following:
 - To view or select the layout, click **View**. The layout appears on the Drug Profile page.
 - To [rename a layout](#) that you created, click **Rename**.
 - To [publish a layout](#), click **Publish**.
 - To delete a layout that you created, click **Delete**.

Create a new drug profile layout

You can create a new drug profile layout by selecting one or more charts

1. In the left navigation pane, hover on the **Data Analysis** icon (), then click **Drug Profiles**.
2. In the drug profile menu bar, from the **Layout** menu, click **Create**.

The Drug Profile page is cleared and the Drug Profile title area shows the layout name as **Not Saved***.

Note

The Create menu is enabled if you have the [Create Drug Profile Layouts permission](#).

3. From the **Layout** menu, click **Add Chart**.
4. From the **Drug Type** drop-down list, select **Generic**, **Ingredient**, or **Trade**. Any or all of these values might be available, depending on the [drug profile configuration](#) that you are using.
5. Perform one of the following:
 - In the **Drug Name** field, type a drug name.
 - Click **Select** to [select a drug from a list](#), and click **OK**.

The list of available drugs depends on the chart that is currently highlighted in the list of available charts. For a report chart, available drugs are determined by the [data configuration](#) associated with the report output on which the chart is based. For a data mining results graph, available drugs are from the corresponding data mining results.

Note

The set of drugs included in logistic regression results is typically smaller than the set of drugs in MGPS results. Graphs for logistic regression results will be available only if the selected drug was included in the model or added explicitly during creation of the run.

6. Select a chart. The chart types that are available depend on the data mining runs and report outputs referenced by the drug profile configuration that you are using. Possible chart types are as follows:

Data Source	Chart Types
MGPS 2D Run	Sector map graph EBGM graph ERAM graph EBGM confidence interval ERAM confidence interval ROR graph ROR confidence interval graph PRR graph
MGPS 3D Run	Nested confidence interval graph
MGPS 2D by Year Run	Cumulative map graph
LR 2D Run	LROR graph LROR confidence interval graph
Reports	Distribution by <variable-name> , where <variable-name> may be gender, outcome, and so on.

7. Click **OK**.

The chart appears. If the selected drug is not in the run results or report output that is the source for the selected chart, the chart cannot be displayed.

In some cases, a chart window appears but displays a message that the chart cannot be displayed with your current display options. If you click **Options** below the chart and modify the display options, you might be able to display the chart.

8. To select multiple charts, repeats steps 5 and 6.
9. To order the selected charts, from the **Layout** menu, click **View**.
10. Select a view option:
- **Stack**—Staggers the charts. Part of each chart window is visible so you can click to bring that chart window forward.
 - **Tile**—Show all chart windows without any overlap.
 - **Order**—Order charts in the layout. The order affects only printing and the slide show mode.
 - **Slide Show**—View each chart on its own page.
11. In Slide Show mode, use the following keys:

Key	Description
Esc	Exit slide show mode and return to the Drug Profile page.
Home	Go to the first chart in the layout.
Up arrow, Page Up, or left arrow	Go to the previous chart in the layout.
Down arrow, Page Down, or right arrow	Go to the next chart in the layout.
End	Go to the last chart in the layout
Ctrl (or Shift) + Home	Go to the top of the current chart.
Ctrl (or Shift) + Up arrow, Page Up, or left arrow	Scroll up in the current chart.
Ctrl (or Shift) + Down arrow, Page Down, or right arrow	Scroll down in the current chart.
Ctrl (or Shift) + End	Go to the bottom of the current chart.

For additional chart ordering options, see [Order charts in a drug profile layout](#).

12. Perform one of the following:

- To save the updated layout, from the **Layout** menu, click **Save**.
- To add the currently displayed charts as a single PDF attachment to a topic, from the **Layout** menu, click **Save to Topic**. The notes of each chart are included, even if they are not currently displayed.

Save a drug profile layout

When a drug profile layout has been modified but not yet saved, an asterisk appears the Drug Profile title area after the layout name. If the layout has never been saved, the layout name shows as "Not Saved*."

- In the left navigation pane, hover on the **Data Analysis** icon () , then click **Drug Profiles**.
- In the drug profile menu bar, from the **Layout** menu, click **Save**. (This option is available if you have the Create Drug Profile Layouts permission.)

If you have modified a layout and you try to navigate away without saving it, the application prompts you to save the layout. Click **OK**.
- If you have modified a layout that you created (or if you have the Administer Users permission and you have modified a layout that someone in your login group created), you can check **Replace existing**. If you check this option, you cannot modify the layout name or description. If you want to rename a layout, use the Rename option on the [Drug Profile Layouts page](#).
- In the **Layout name** field, type a name for the layout. Keep in mind that the layout is not associated with a particular [drug profile configuration](#). You might want to avoid identifying a data source in the layout name or description.
- Optionally, enter a description of the layout to differentiate this layout from other layouts.
- Click **OK**.

When Oracle Empirica Signal saves a layout, currently displayed chart windows are saved as part of the layout. Even if a chart window shows a message that the chart cannot be displayed with the current options, the chart window is saved. Additionally, the drugs associated with the saved charts are saved as the primary drug and comparator drugs (if any).

Note

Only displayed chart windows are saved as part of a layout. For example, an existing layout includes a sector map for DrugA. You change the drug profile configuration to point to different run results that do not include DrugA. When you view the layout, a message tells you that the drug is not in the run results. No chart window appears. If you save the layout again, the DrugA sector map will not be part of the layout.

Order charts in a drug profile layout

You can specify the order in which you want to print charts or display them in slide show mode. The order does not affect the displayed layout.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Drug Profiles**.
2. In the drug profile menu bar, from the **Layout** menu, click **View**, and then click **Order**.
3. Use the arrow buttons to specify the order in which charts are displayed in slide show mode or printed:

Arrow	Description
	Move the chart to become the first one.
	Move the chart to before the previous chart.
	Move the chart to after the next chart.
	Move the chart to become the last one.

4. To remove a chart from the layout, select it and click **Remove**.
5. To find a particular chart in the layout, select the chart name and click **Find**.
6. When you are finished reordering charts, click **OK**.

Rename a drug profile layout

When you rename a drug profile layout be sure to type a description of the layout to differentiate layouts.

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Drug Profiles**.
2. In the drug profile menu bar, from the **Layout** menu, click **Manage Layouts**.
3. Click the **Row Action menu** () for the layout, and then click **Rename**.
4. In the **Name** field, type a name for the layout. Keep in mind that the layout is not associated with a particular drug profile configuration. You may want to avoid identifying a data source in the layout name or description.
5. Optionally, in the **Description** field, type a description of the layout to differentiate layouts.
6. Click **OK**.

Publish a drug profile layout

Publishing a drug profile layout makes it available to all the users in your login group.

1. In the left navigation pane, hover on the **Data Analysis** , then click **Drug Profiles**.
2. In the drug profile menu bar, from the **Layout** menu, click **Manage Layouts**.
3. Click the **Row Action** menu () for the layout, and then click **Publish**.
4. To publish to all the users in your login group, click **Publish**.
 - If you are a superuser, you can publish to multiple login groups, including —All—. In the **Publish to Login Groups** drop-down list, click or Ctrl+click to select login groups.
 - If you publish to —All— and later add a new login group, the object is published automatically to the new login group.
5. Click **Back**.

Chart types and options

- [Work with chart options](#)
A number of display options are available at the bottom of a chart.
- [Sector map graph \(Drug Profile page\)](#)
A sector map is a visual presentation of data for a selected drug across all System Organ Classes (SOCs).
- [Bar graph \(Drug Profile page\)](#)
Bar graphs provide a straightforward way to display the items most closely associated with a selected drug, showing the strength of association by plotting each computed statistical score as the length of a horizontal bar.
- [Confidence interval graph \(Drug Profile page\)](#)
Confidence interval graphs are similar to bar graphs but also include a confidence interval or error bar superimposed on each bar to show the 5% and 95% confidence limits.
- [Nested confidence interval graph \(Drug Profile page\)](#)
To help you investigate possible drug interactions, the nested confidence interval graph displays sets of confidence intervals.
- [Cumulative map graph \(Drug Profile page\)](#)
Cumulative map graphs provide a way to compare strength of associations between a selected drug and events across multiple subsets, which are typically based on a continuous variable such as year.
- [Reports \(Drug Profile page\)](#)
The reports that you can add as charts to a drug profile are based on report output generated by an all cases summary report.

Work with chart options

A number of display options are available at the bottom of a chart.

Select an option at the bottom of a chart to perform the following actions:

- To redraw the chart as a table, bar graph, or pie chart, click **Options**. From the Chart Options dialog box, select the chart type and click **OK**.

- To display the notes about the chart below the chart, click **+Notes**. To hide the notes, click **-Notes**.
- To display a key below the chart, click **+Key**. To hide the key, click **-Key**.
- To determine the default color used for graphs, set the user preferences, **Graph Color Palette**. You can [modify the graph](#) key for your current session on the Choose Graph page for data mining run results.
- To resize the chart, click the diagonal lines in the lower right corner and drag the right and bottom borders to the desired size.

Sector map graph (Drug Profile page)

A sector map is a visual presentation of data for a selected drug across all System Organ Classes (SOCs).

Each System Organ Class (SOC) is represented by a large tile in the sector map. Smaller tiles within each SOC tile represent Preferred Terms (PTs).

PTs are ranked in descending order of values of the statistic (EBGM, EB05, Chi-statistic, or PRR) that you choose. A color key indicates relative ranking. You can also list the ranked PTs below the sector map. (You must include the key in the graph to display both the color key and the list of ranked PTs.)

Note

The primary path of a PT determines where it appears in the sector map. If a PT is not in the event hierarchy associated with the data mining run results, it appears in a SOC tile named Unknown.

The list of ranked PTs below the sector map includes the following information:

Column	Description
Rank	Ranking of the term (combined with the drug) according to values of the statistic you have configured the sector map to use (via the Color controlled by option).
SOC	SOC containing the term.
Term (PT)	Specific PT.
EBGM, EB05, ERAM, ER05, Chi-statistic, or PRR	Value of the statistic you have configured the sector map to use (via the Color controlled by option).

1. To set options for the graph, click **Options**. Specify the following options and click **OK**. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
Color controlled by	Name of the statistic whose values will be ranked and used for coloring the sector map tiles. Available values are those computed by the data mining run and may include EBGM, EB05, Chi-statistic (signed), and PRR.

Option	Description
Term box size controlled by	One of the following options indicating what controls the size of PT tiles: Relative importance of term—Bases the size of PT tiles on an algorithm that determines the relative public health impact of PTs. Using a recent version of AERS data, the public health impact for a PT is computed as: (number of times the PT occurs in serious cases) * (proportion of cases with that PT that are serious or fatal). A higher Public Health Impact score corresponds to a larger tile in the sector map. Because size is based on the number of cases of the PT alone (not the number of cases that have the PT and a particular drug), the tile size is stable over sector maps for different drugs. All terms have equal size—All PT tiles have the same size. Note For PTs that are new in the MedDRA version associated with the AERS data used to assess public health impact, the tile size cannot be determined. Such PTs are represented as small tiles.
Display maximum intensity at signal score of	All tiles for which scores are above this value are displayed at the maximum-intensity color as shown in the color key below the graph.
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.
Show low scores in green for color graph	Check to show low scores in varying shades of green. Clear to show low signal scores in black. Note This setting has no effect if you display the sector map in gray-scale.
Omit rare terms used fewer than __ times in AERS	Number indicating how many times a PT must be in the AERS database (the same one used for Relative importance of term) for that PT to be shown in the sector map. Note The notes for a sector map indicate any rare terms that are omitted because of this restriction.
Group by HLT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLT. If you also group by HLGT, the tiles for PTs are grouped by HLT within each HLGT.
Group by HLGT	Within a SOC tile, group in the same rectangular area the tiles for PTs that are in the same HLGT.

Option	Description
List __ top scores	Number indicating how many (up to 1000) terms with the top scores are ranked and listed below the sector map. The score is the statistic selected for Color controlled by. If multiple terms have the same score, each term is counted separately. For example, suppose that you enter 20 as the limit. If the 20th row has a score that other terms after that also have, those additional terms are shown as well. The list below the sector map appears when you display the key.
Show top score indexes	If checked, tiles in the sector map are numbered to show their rank, up to the number of scores specified in List __ top scores. For this option to take effect, there must be a value specified for List __ top scores".

2. If you point to a PT tile, the MedDRA PT, HLT, HLGT, and SOC appears. The following information for the combination of the drug and the term that the tile represents also appears:
 - **N**—Observed number of cases with drug-event combination.
 - **EBGM**—Empirical Bayesian Geometric Mean. A more stable estimate than RR; the so-called shrinkage estimate.
 - **EB05**—A value such that there is approximately a 5% probability that the true Relative Ratio lies below it.
 - **ERAM**—Empirical-Bayes Regression-adjusted Arithmetic Mean. This estimate is computed as the shrunken observed-to-expected reporting ratio adjusted for covariates and concomitant drugs.
 - **ER05**—A value that there is approximately a 5% probability that the ERAM lies below it.

Note

The ERAM and ER05 are available only if the data mining run was set up to compute RGPS.

- **PRR**—Proportional Reporting Ratio.
- **Chi-statistic**—Chi-statistic associated with PRR. (If EBGM < 1, the Chi-statistic is expressed as a negative number, indicating that the drug-event combination is more rare than expected). The Chi-statistic is the signed square root of Chi-square.

Note

The PRR and Chi-statistic are available only if the data mining run was set up to compute PRR.

For information about these statistics, see [MGPS computations](#) or [PRR computations](#).

3. To [zoom in](#) on a particular SOC, click anywhere on the SOC tile and select **Zoom** from the menu that appears.
4. If you click a tile for which N is at least 1, you can then [drill down](#) to a list of cases for the tile or [view statistics](#) for the tile.

Bar graph (Drug Profile page)

Bar graphs provide a straightforward way to display the items most closely associated with a selected drug, showing the strength of association by plotting each computed statistical score as the length of a horizontal bar.

For information about statistics in the graph, see [MGPS computations](#), [ROR computations](#), [PRR computations](#), or [Logistic regression computations](#).

1. To set options for the graph, click **Options**. Specify the following options and click **OK**. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most ____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
<score> at least	Display only combinations with a score (EBGM, LROR, PRR, or ROR) of at least the specified number.
<score> at least	Display only combinations with a lower confidence limit (EB05, LR05, ROR05) of at least the specified number.
Bar length controlled by	Indicate whether you want bars to show in descending order by: • N (observed count). • The score (EBGM, LROR, PRR, or ROR). • The lower confidence interval score (EB05, LR05, ROR05).
Bar color controlled by	Indicate whether bar color should be controlled by: • EBGM, LROR, PRR, or ROR, as defined by the graph key. • EB05, LR05, ROR05, as defined by the graph key. • A single color for all graph bars.
Order by bar length	Show the bars of the graph in descending order based on bar length.
Order by item	Show the bars of the graph in alphabetical order.

2. You can point to a bar of the graph to display statistics for the combination represented by the bar.
3. If you click on a bar, you can then [drill down](#) to a list of cases for the bar, [create a case series](#), [transfer to case series](#), [download cases](#), [download case details](#), or [run reports for those cases](#).

Confidence interval graph (Drug Profile page)

Confidence interval graphs are similar to bar graphs but also include a confidence interval or error bar superimposed on each bar to show the 5% and 95% confidence limits.

For information about statistics in the graph, see [MGPS computations](#), [ROR computations](#), [PRR computations](#), or [Logistic regression computations](#).

1. To set options for the graph, click **Options**. Specify the following options and click **OK**. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
At most ____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
<score> at least	Display only combinations with a score (EBGM, LROR, or ROR) of at least the specified number.
<score> at least	Display only combinations with a lower confidence limit (EB05, LR05, ROR05) of at least the specified number.
Bar color controlled by	Indicate whether bar color should be controlled by: • EBGM, LROR, or ROR, as defined by the graph key. • EB05, LR05, ROR05, as defined by the graph key. • A different color for each bar in the graph. • A single color for all graph bars.
Order by bar length	Show the bars of the graph in descending order based on bar length.
Order by item	Show the bars of the graph in ascending alphabetical order.
Show N at end of confidence interval	Display the value of N at the end of each confidence interval bar.

2. You can point to a bar of the graph to display statistics for the combination represented by the bar.
3. If you click on a bar, you can then [drill down](#) to a list of cases for the bar, [create a case series](#), [transfer to case series](#), [download cases](#), [download case details](#), or [run reports for those cases](#).

Nested confidence interval graph (Drug Profile page)

To help you investigate possible drug interactions, the nested confidence interval graph displays sets of confidence intervals.

In each set, the first confidence interval is for the three-way combination of drug, drug, and event, and subsequent confidence intervals are for the two-way combinations. In each confidence interval bar, the EB05 value is at the left end, the EBGM value is the dot on the bar,

and the EB95 value is at the right end. A confidence interval bar is highlighted if its INTSS value is greater than the limit that you specify as a display option. For more information about INTSS, see [interaction scores](#).

To conserve space in labeling, the drug indicated in the title bar of the graph window is referred to by the label "Drug" in the graph.

The key below the graph indicates INTSS values represented by the confidence interval bars.

1. To set options for the graph, click **Options**. Specify the following options and click **OK**. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
N at least	Display only those drug-drug-event combinations with an observed count (N) of at least the specified number.
At most _____ combinations	Display no more than the specified number of drug-drug-event combinations. You can display graphs for up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Order by	The value of the score that you select here for the drug-drug-event combinations is used to sort the graphs. For example, if you select INTSS, the graph with the highest INTSS value for the drug-drug-event combination appears first.
Axis Type	Select either Linear or Log (logarithmic). When you use a logarithmic axis, the confidence intervals for the two-way combinations may appear more clearly.
Highlight confidence intervals where INTSS >	Enter the INTSS value above which confidence interval bars will be highlighted.
Show N at end of confidence interval	Display the value of N at the end of each bar
Use gray-scale instead of colors	Use shades of gray instead of colors in the graph.

2. You can point to a line in the graph to display statistics for the combination represented by the line. Long drug or event terms may end in an ellipsis in the label on the graph itself; in this case, you can point to the line to see the full terms.
3. If you click on a bar, you can then [drill down](#) to a list of cases for the bar, [create a case series](#), [transfer to case series](#), [download cases](#), [download case details](#), or [run reports for those cases](#).

Cumulative map graph (Drug Profile page)

Cumulative map graphs provide a way to compare strength of associations between a selected drug and events across multiple subsets, which are typically based on a continuous variable such as year.

See [Using a subset variable](#) for more information.

The map graph on the Drug Profile page shows data for all subsets included in the data mining run.

For information about statistics in the graph, see [MGPS computations](#).

1. To set options for the graph, click **Options**.
2. Specify the following options and click **OK**. The options apply to the specific chart, and are saved as part of the layout.

Option	Description
N at least	Display only combinations with an observed count (N) of at least the specified number.
EBGM at least	Display only combinations with an EBGM score of at least the specified number.
EB05 at least	Display only combinations with an EB05 value of at least the specified number.
At most ____ associations	Display no more than the specified number of combinations. You can display up to 200 combinations. If combinations are excluded because of this limit, a message appears below the graph.
Show value of	In each cell of the grid, display the numeric value of N (observed), EBGM, or EB05. You can also select Leave blank to display a grid without labels. Cells with no occurrences are empty.
Color by	Indicate whether the cell color should be controlled by: • EBGM, according to the graph cutpoints and palette. • EB05, according to the graph cutpoints and palette. • No color.

Option	Description																												
Order by first occurrence of	Indicates how to order drug-event combinations in the graph, based on descending order of N, EBGM, or EB05 values. This ordering is applied to combinations for the first subset. If the maximum number of combinations is not reached, the ordering is applied to combinations for the second subset, and so on until the maximum number of combinations is reached. (The maximum number of combinations is determined by the At most __ associations option.) For example, suppose that the graph shows values of EBGM and has at most six combinations. You order by the first occurrence of EBGM > 2. Combinations are ordered in descending order of EBGM as follows:																												
	<table><tr><th>Combination</th><th>Subset1</th><th>Subset2</th><th>Subset3</th></tr><tr><td>DrugA-EventB</td><td>EBGM=3.1</td><td>EBGM=1.1</td><td>-</td></tr><tr><td>DrugA-EventD</td><td>EBGM=2.7</td><td>-</td><td>EBGM=2.4</td></tr><tr><td>DrugA-EventA</td><td>EBGM=2.0</td><td>EBGM=3.8</td><td>EBGM=1.4</td></tr><tr><td>DrugA-EventC</td><td>EBGM=1.5</td><td>EBGM=2.6</td><td>EBMG=2.8</td></tr><tr><td>DrugA-EventE</td><td>EBGM=0.5</td><td>EBGM=2.5</td><td>EBGM=0.8</td></tr><tr><td>DrugA-EventF</td><td>-</td><td>EBGM=1.1</td><td>EBGM=2.1</td></tr></table>	Combination	Subset1	Subset2	Subset3	DrugA-EventB	EBGM=3.1	EBGM=1.1	-	DrugA-EventD	EBGM=2.7	-	EBGM=2.4	DrugA-EventA	EBGM=2.0	EBGM=3.8	EBGM=1.4	DrugA-EventC	EBGM=1.5	EBGM=2.6	EBMG=2.8	DrugA-EventE	EBGM=0.5	EBGM=2.5	EBGM=0.8	DrugA-EventF	-	EBGM=1.1	EBGM=2.1
Combination	Subset1	Subset2	Subset3																										
DrugA-EventB	EBGM=3.1	EBGM=1.1	-																										
DrugA-EventD	EBGM=2.7	-	EBGM=2.4																										
DrugA-EventA	EBGM=2.0	EBGM=3.8	EBGM=1.4																										
DrugA-EventC	EBGM=1.5	EBGM=2.6	EBMG=2.8																										
DrugA-EventE	EBGM=0.5	EBGM=2.5	EBGM=0.8																										
DrugA-EventF	-	EBGM=1.1	EBGM=2.1																										

3. You can point to a cell of the graph to display statistics for the combination represented by the cell. Long drug or event terms may end in an ellipsis in the label on the graph itself. In these cases, you can point to the cell to see the full terms.
4. If you click on a cell, you can then [drill down](#) to a list of cases for the cell, [create a case series](#), [transfer to case series](#), [download cases](#), [download case details](#), or [run reports for those cases](#).

Reports (Drug Profile page)

The reports that you can add as charts to a drug profile are based on report output generated by an all cases summary report.

If the report output uses a breakdown variable such as gender, you can add a report chart showing distribution by that variable.

N represents a count of unique cases with at least one occurrence of the row value. Percentages are computed as N divided by the total of N for all rows in the report chart. The percentage values are meaningful only for demographic data, such as gender, where there is one row value per case, so the total of N is the total of unique cases. In this context, the percentage is for the number of cases with the row value out of the total number of cases.

If there are multiple row values (for example, outcomes) per case, the total of N for all rows is the number of non-unique cases. Thus, percentage values are the number of cases with the

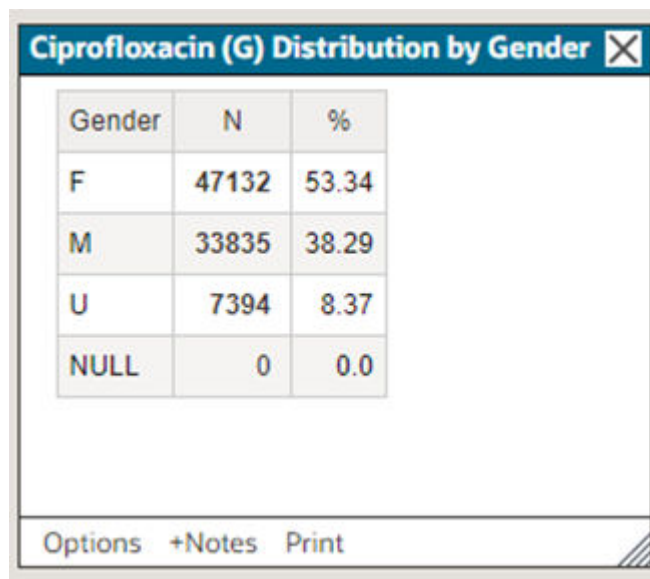
row value out of the number of non-unique cases with any of the row values. This is not likely to be a meaningful statistic.

1. To set options for the report chart, click **Options**.
2. Specify whether you want to view the report chart as a table, a bar graph, or a pie chart, and then click **OK**.
3. For a table or bar graph, you can click on a cell or bar and [drill down](#) to a list of cases, [create a case series](#), [transfer to case series](#), [download cases](#), [download case details](#), or [run reports for those cases](#).

Examples

In the following report chart, each case can be counted for only one row. The total of N represents the unique number of cases, which is 57999. The percentage of unique cases for gender F is 32107/57999, which is 55.36.

Figure 9-1 Drug profile Ciprofloxacin (G) Distribution by Gender



Gender	N	%
F	47132	53.34
M	33835	38.29
U	7394	8.37
NULL	0	0.0

Options +Notes Print

In the following report chart, each case can be counted for multiple rows. The total of N (4776) for all rows is more than the unique number of cases (4532). Thus, the % is not based on a count of unique cases.

Figure 9-2 Drug profile Ciprofloxacin (G) Distribution by Outcome

Ciprofloxacin (G) Distribution by Outcome				
Outcome	N	%		
Congenital Anomaly	0	0.0		
Died	36	10.08		
Disabled	12	3.36		
Hospitalized	172	48.18		
Life-threatening	21	5.88		
None	1	0.28		
Other	103	28.85		
Recovered	0	0.0		
Required Intervention to Prevent Permanent Damage	12	3.36		
Treated with Rx Drug	0	0.0		
NULL	0	0.0		
			Options +Notes Print	

10

Settings and administration

- [Specify settings](#)
When you click **Settings** in the left navigation pane, the Settings page appears.
- [View server version, versioning details, component libraries, and other documents](#)
The About page, accessed from the Settings page, provides version information and links to the Oracle Help Center and other documents, including the sample GVP Module IX topic workflow configuration.
- [View release notes and download other documents](#)
From the About page, you can access release notes and other system-related documents maintained on the server.
- [Manage users, login groups, and work teams](#)
- [Configure the system](#)
- [Administer the system](#)
- [Monitor the system](#)
- [Set up saved lists](#)

Specify settings

When you click **Settings** in the left navigation pane, the Settings page appears.

Your [user permissions](#) determine the options you see on the Settings page. For most users, this page includes only the following options:

- [Change Password](#) (available when not using single sign-on or LDAP)
- [Remove Visited Status for Case ID Links](#)
- [Manage Saved Lists](#)
- [About](#)

Settings for managing users

- [Edit Users](#)
- [Edit User Profiles](#)
- [Edit Roles](#)
- [Edit Login Groups](#)
- [Edit Work Teams](#)

Settings for monitoring the system

- [View Currently Logged In Users](#)
- [View User Activity Audit Trail](#)
- [View Server Status](#)
- [View Free Space](#)

- [View Batch Report Queue](#)

Settings for administering the system

- [Set Site Options](#)
- [Send Message to All Users](#)
- [Restart Listener](#)
- [Manage Run Storage](#)
- [Change User Default Runs](#)

Settings for configuring the system

- [Manage Subscription Data Releases](#)
- [Manage Configurations](#)
- [Manage Aliases](#)
- [Manage Drug Profile Configurations](#)
- [Manage Signal Configurations](#)
- [Manage Topic Workflow Configurations](#)

View server version, versioning details, component libraries, and other documents

The About page, accessed from the Settings page, provides version information and links to the Oracle Help Center and other documents, including the sample GVP Module IX topic workflow configuration.

To view the About page:

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. Click the **About** link.
3. Perform the following tasks:
 - View the version of the Oracle Empirica Signal server.
 - (Superuser) View the library versions installed, including:
 - Secure Coding
 - Empirica
 - Empirica Core
 - Datamine
 - (Superusers) View the versions of the MGPS (Multi-Item Gamma Poisson Shrinker) algorithm and the Logistic Regression statistical tool.
If the site option, **Enable RGPS Option in MGPS Data Mining Runs**, has been enabled, you can view the Regression-Adjusted Gamma Poisson Shrinker Algorithm (RGPS) version. If the version cannot be determined or hasn't been enabled, this parameter doesn't appear.
 - View additional versioning information, such as the Oracle Database, the JDBC Driver, and the Topic Schema.
 - Access the Oracle Help Center.

- Access the release notes and other system-related documents maintained on the server.

View release notes and download other documents

From the About page, you can access release notes and other system-related documents maintained on the server.

1. In the left navigation pane, click the **Settings** icon (.
2. Click the **About** link.
3. Use the links provided to access the release notes and other system-related documents maintained on the server.
 - The Release Notes section provides links to release notes for data releases.
 - The Other Documents section includes an exported copy of the sample GVP Module IX topic workflow configuration. A topic administrator can import this file into Oracle Analytics Server to create a GVP Module IX topic workflow. See the Empirica Topics Reporting and Oracle Analytics Configuration Guide.

Manage users, login groups, and work teams

- [Ways to administer users](#)
- [How user permissions work](#)
This topic includes a table describing all user permissions.
- [What superusers can do](#)
- [Manage users](#)
- [Manage user profiles](#)
- [Manage user roles](#)
- [Manage work teams](#)
- [Use single sign-on](#)
- [Manage LDAP users](#)
- [Manage login groups](#)

Ways to administer users

How you administer users depends on your installation type and authentication method:

- **Oracle-hosted installations with single sign-on**—Create users in a cloud identity service console, such as Oracle Identity Cloud Service (IDCS) or Oracle Life Sciences Identity and Access Management Service (IAMS). New users are provisioned with the default user profile specified as the Default User Profile [site option](#). The users [login group, roles and permissions](#) can be further modified on the Oracle Empirica Signal Users page. For more information, see the appropriate documentation for your cloud identity management service, either *Managing Oracle Empirica Signal Cloud Users with Oracle Health IAMS* or *Managing Oracle Empirica Signal Cloud Users with Oracle IDCS*.
- **Self-hosted installations with single sign-on**—Create users in Oracle Access Manager or another single sign-on application, and provision users in the Oracle Empirica Signal Users page.

- **Self-hosted installations with LDAP**—Import user data from an LDAP directory, and provision users in the Oracle Empirica Signal Users page. For more information, see [Configure Oracle Empirica Signal for use with LDAP](#).
- **Self-hosted installations without external authentication**—Create and provision users in the Empirica Signal Users page.

You provide each user with a user name and password for the Oracle Empirica Signal application.

Note

For Oracle-hosted installations, you provide Oracle Empirica Signal credentials only for superusers. Superusers log into the application directly.

In addition, you provision users with:

- **Permissions**—Rights to perform specific tasks in Oracle Empirica Signal. For example, you can enable a user to create data mining runs, and prevent the user from creating report definitions. For a list of permissions, see [User permissions](#).
- **User roles**—Sets of permissions associated with a user's role. For example, you might create a user role that includes the permissions to create data mining runs and view data mining run results. You can assign one or more user roles to a user. Oracle Empirica Signal includes pre-defined user roles, and you can create custom user roles.
- **Login group**—Group to which a user belongs. When a user publishes an object (for example, a query or report), the object can be used by other users in the same login group. Each login group can have a customized Home page, with links to customer-specific information.

Note

Users with the Administer Users permission can use both published and unpublished objects created by users in their login group.

- **Work teams**—Subsets of users in a login group. A user can be in multiple work teams for the same login group. Work teams are used only in the context of the [topics](#) feature and are intended to structure the level of access that different users have to topics.
- **User profiles**—Sets of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users as a convenience in setting up users. If you do not use a user profile, you must set the attributes, user roles, and permissions for users individually, and individual users must set their own preferences.

How user permissions work

This topic includes a table describing all user permissions.

The following table shows the user permissions required to perform activities in Oracle Empirica Signal. You assign permissions to individual users, [user roles](#), or [user profiles](#).

A user can act on an object (for example, a data mining run) if:

- The user created the object.
- The object was published to the user's login group.

- The object was created by a different user in the user's login group, and the user has the Administer User permission.

Permission	Activities	More information	Available with license
View Raw Safety Database	Drill down to view case details.	You grant this permission to most users. To save queries to the Query Library, a user must also have the Create Queries/Case Series permission.	Any (Signal or Topics)
Download Raw Data	Download case series details and data for results graphs .	--	Any (Signal or Topics)
View Data Mining Results	• View results of data mining runs. • Create, edit, and delete saved lists.	--	Signal
Create Data Mining Run	• Create and re-run data mining runs. • Rename, cancel, and delete data mining runs that you create. • View jobs for data mining runs. • Create queries to add a database restriction or custom terms to a data mining run.	--	Signal
Save Intermediate Files	Save intermediate data files created during data mining runs.	--	Signal
Delete Any Run	Cancel and delete any runs visible to the user.	--	Signal
View Topics	View topics on the Topics page.	If the user is a member of a work team, the user must also have work team permissions. Work team permissions determine the level of access that a user has to topics. For example, work team permissions determine whether a user can view topics, edit topics and topic actions, edit attachments, and so on.	Topics

Permission	Activities	More information	Available with license
View Topics across Work Teams	• View all topics that are visible to any of the work teams in that user's login group. • View topics, topic actions, and attachments without membership in a work team or work team permissions.	A user must also have the View Topics permission.	Topics
Hide Queries/Case Series/Report pages	Users with this permission cannot view the Queries, Case Series, and Report pages, regardless of their other permissions.	--	Any (Signal or Topics)
View Drug Profiles	View drug profiles on the Drug Profile page.	--	Any (Signal or Topics)
Create Drug Profile Layouts	Create, edit, and manage drug profile layouts on the Drug Profile page.	A user must also have the View Drug Profile permission.	Any (Signal or Topics)
Create Queries/Case Series	Transfer cases to an existing case series.	To create, copy, edit, rename, and delete queries and case series, a user must also have the View Raw Safety Database permission.	Any (Signal or Topics)
Create Report Definitions	Create , copy , edit , and delete report definitions.	All users can run report definitions.	Signal
Create Report Outputs	Create , edit , copy , and delete report outputs .	All users can view report outputs.	Any (Signal or Topics)
BI Consumer	View Oracle Analytics Topics reports.	The BI Consumer permission in Oracle Empirica Signal corresponds to the BI Consumer role in Oracle Analytics. You must implement the Oracle Analytics Topics reporting feature to enable this permission.	Topics
BI Author	Perform activities that correspond to the BI Author role in Oracle Analytics.	You must implement the Oracle Analytics Topics reporting feature to enable this permission.	Topics
BI Administrator	Perform activities that correspond to the BI Administrator role in Oracle Analytics.	You must implement the Oracle Analytics Topics reporting feature to enable this permission.	Topics

Permission	Activities	More information	Available with license
View Signal Management	User with this permission can only view the Signal Review page. To perform all activities on the Signal Review page, you require the <i>Annotate signal management</i> permission.	Users can always manage signal views that they have created.	Topics

Permission	Activities	More information	Available with license
Annotate Signal Management	Perform the following activities: Enter a note about a product Add a comment Submit a review for a product-event combination Add a private comment, if enabled Add Annotation on Case Detail page		Topics ① N o t e Y o u m u s t h a v e V i e w S i g n a I M a n a g e m e n t p e r m i s s i o n t o u s e t h e A

Permission	Activities	More information	Available with license
			n n o t a t i o n S i g n a l M a n a g e m e n t p e r m i s s i o n .
Manage Signal Views	Manage signal views created by users in your login group.	A user must also have the View Signal Management permission.	Topics

Permission	Activities	More information	Available with license
Manage Signaling Terms	• Add, edit, and delete products and product-event combinations. • Assign products and product-event combinations to reviewers. For interactive signal configurations only: • Rename products. • Manage designated medical events, custom terms, targeted medical events, and listed events for interactive signal configurations.	A user must also have the View Signal Management permission.	Topics
Manage Signal Configurations	• View and edit existing signal configurations. • For interactive signal configurations, refresh signal configurations. • For multisource signal configuration, create, refresh, and delete signal configurations.	To assign signal configurations to login groups, a user must also have the Administer Users permission.	Topics

Permission	Activities	More information	Available with license
Administer Users	• View and edit user names, user profiles, and work teams in your login group. • For self-hosted installations only, add user names, user profiles, and work teams in your login group. • Update user information from LDAP. • Send a message to users in the same login group. • Arrange table columns and set the column layout as the default for your login group. • View the User Activity Audit Trail for users in the same login group. • View currently logged in users in the same login group.	Users with this permission cannot create or delete login groups. For some activities, users with this permission can act on objects (including unpublished objects) created by users in the same login group. Users with the Administer Users permission see the following activities performed by the system, irrespective of login group: • Users: Create User or Profile • Users: Edit User or Profile • Users: Delete User or Profile	None If the account is exclusively used for managing users with SSO (for example, no other Oracle Empirica features are used) then no separate license is required. This means no other roles or permissions must be assigned to this account.
Administer LDAP	• Import LDAP users. • Refresh LDAP users. • Change LDAP/Local authentication.	--	Same as Administer Users.
Administer Drug Profiles	Create and manage drug profile configurations .	A user must also have the View Drug Profile Layouts permission.	Any (Signal or Topics)
Manage Configurations	• View data configurations. • Create, import, copy, validate, and edit a data configuration for which you have the Edit permission. • Delete a data configuration that does not have runs, case series, saved lists, report definitions, or report outputs associated with it. • Manage subscription data.	Manage subscription data is only available if the client machine has been provisioned for shared data.	Signal

Permission	Activities	More information	Available with license
Manage Topic Workflow Configurations	Create and manage topic workflow configurations.	A user must also have: - The View Topics permission. - The Administer Users permission to assign the configuration to a login group or define permissions for work team members.	Topic
Manage Aliases	Add, edit , and delete aliases.	--	Any (Signal or Topics)

What superusers can do

Superusers can perform any activities in the Oracle Empirica Signal application, with the following exception:

Superusers must also have the Administer User permission to arrange the columns of a table and define that layout as the default for a login group.

Superusers can act on objects (for example, data mining runs) created by users in any login group. In contrast, users with the Administer Users permission who are not superusers can act only on objects created by users in their login groups.

Only a superuser can:

- [Publish an object to multiple login groups](#).
- Create, edit, or delete [user roles](#).
- [Create](#) or [delete](#) login groups.
- [Restart](#) the listener process.
- Set any [site options](#).
- View the [server status](#).
- View [free space](#).
- [Create a report definition using XML](#).
- Create or edit [built-in report definitions](#).
- [Permanently delete a topic workflow configuration](#).
- [Create a run definition file](#).
- [Create a report definition file](#).
- [Change default runs](#) for users.
- [View data source tables](#) for runs.
- [Delete any runs](#).
- [Manage run storage](#).
- [View the batch report queue](#).

- [Delete a data configuration](#) that has runs, case series, saved lists, report definitions, or report outputs associated with it.
- [Add saved lists in bulk mode](#).
- Assign, edit, or publish in multi-enterprise support (MES).

Superuser accounts in Oracle Empirica are intended for global system management and user administration activities, and should not typically be used for routine business tasks. If the same individual in your organization performs both types of activities, you might want to consider assigning that user separate accounts so that user signs in as a superuser only when needed.

When customers use superuser accounts exclusively for system and user management, Oracle does not require separate Oracle Empirica application licensing for these accounts.

However, if a superuser is assigned other roles and privileges, licensing for Oracle Empirica Signal and Oracle Empirica Topics usage is required.

Manage users

- [View existing users](#)
The Users page provides information about each user. You can also add users, view the licenses needed for each user and print or download the table.
- [Display active licensed user counts](#)
From the License Usage page, users can clearly identify which user roles require Oracle Empirica Signal and which require Oracle Empirica Topics product licenses and other relevant details.
- [Add or edit a user in a self-hosted environment](#)
- [Add or edit a user in an Oracle-hosted environment](#)
- [Assign roles to a user](#)
- [Assign permissions to a user](#)
- [Change user passwords](#)
- [Rename a user](#)
- [Change the authentication method for a user](#)
- [Delete a user](#)
- [Purge users](#)

View existing users

The Users page provides information about each user. You can also add users, view the licenses needed for each user and print or download the table.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Users**.

The Users page lists users who are in the same login group as you. If you are a superuser, all users are listed. The information includes:

Column	Description
User Name	Unique name of the user account.

Column	Description
ID	Unique number of the user account.
Name	Full name (first name and last name) associated with the user account.
Created	Date and time when the user was created.
Email	Email address associated with the user name. This address (or addresses, separated by commas) is the default notification address for runs if the run creator chooses email notification. This address is also used when a user with the Administer Users permission sends a message to all users and is used when a message is generated by a Topic email notification rule.
Authentication	One of the following values: • Local—Standard Oracle Empirica Signal authentication. • SSO—Single sign-on authentication using Oracle Access Manager or another application. • LDAP—LDAP authentication. For more information, see Configure Oracle Empirica Signal for use with LDAP.
Login Group	Appears only if you are a superuser. This is the login group associated with the user.
Status	One of the following values: • Enabled—The user can log in to the application. • Disabled—The user cannot log in.
 Note This value is determined by the Account disabled check box on the Edit User page.	
Quota	Maximum amount of server space in megabytes (MB) that the user is permitted to use for creating runs. Blank for users who do not have a quota (that is, unlimited runs permitted).

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

3. Select a link at the top of the page to perform additional actions:
 - Click **Add a New User** to [add or edit a user in a self-hosted environment](#).
 - Click **License Usage** to [view active licensed user counts](#).
 - Click **Columns** to [arrange the table columns and rows](#).
 - Click **Back** to return to the Settings page.

Display active licensed user counts

From the License Usage page, users can clearly identify which user roles require Oracle Empirica Signal and which require Oracle Empirica Topics product licenses and other relevant details.

Superusers can track how many active licenses are needed by each user. User Administrators can track licenses needed for users in their login group.

To view this page, you need to be assigned the *Administer Users* permission or be a superuser.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the Manage Users section, click **Edit Users**
3. If you are a superuser, you can also select a specific login group from the **Login Group** drop-down list.
4. Select the **License Usage** link.

📘 **Note**

- Non-superusers view the License Usage page with users only in their login group.
- Superusers view the License Usage page with all users.

5. On the License Usage page, you can see the licenses needed and assigned roles.

The information shown includes:

Column	Description
Created	Date and time when user was created.
Email	Email address of the user.
First name	First name entered at the time of the creation (up to 64 characters).
ID	Unique user identifier.
Last name	Last name entered at the time of the creation (up to 64 characters).
Login Group	Login Group to which the user belongs. Only appears for superusers.
User name	Unique name of the user account.
Name	Full name (first name and last name) associated with the user account.

Column	Description
License Required	Name of the product licenses the user needs. Options are: • Signal • Topics • Any • Signal and Topics • Blank Note • The License Required value is determined from the user's effective permissions. • If you are a user with no effective permissions or just <i>Administer Users</i> or <i>Administer LDAP</i> permissions, the License Required column will show a blank value.
Roles	Roles assigned to the user. See description of all Predefined user roles. Note If you are a superuser without any roles or user permissions explicitly assigned, you will have no effective permissions. If you are an active superuser, "superuser" appears first in the list of Roles.
Effective Permissions	Permissions assigned via a role or assigned individually. See description of How user permissions work.

6. Select a link at the top of the page to perform additional actions:
 - Click the [Print](#) link to print the table or only the currently displayed page of a table.
 - Click the [Download](#) link to download the table.
 - Click [Columns](#) to arrange the table columns and rows.
 - Click **Back** to return to the Users page.

Add or edit a user in a self-hosted environment

Note

This procedure does not apply for Oracle-hosted installations, unless you are a superuser. For more information, see [Add and edit a user in an Oracle-hosted environment](#).

1. To use single sign-on for authentication in a self-hosted environment, create the user in your single sign-on application.
2. In the left navigation pane, click the **Settings** icon (.
3. In the **Manage Users** section, click **Edit Users**.
4. To add a user:
 - a. Click **Add a New User**.
 - b. Fill in the according to the table below.
5. To edit a user:
 - a. Locate the user in the table.
 - b. Click the **Row Action menu** () for the user, and then click **Edit**.

Note

You can edit only users in your login group.

- c. Fill in the according to the table below.
6. Click **Save**.
7. Provision newly created users with [roles](#) and [permissions](#).

Note

If you selected a user profile, the user is already provisioned with roles and permissions.

8. (Optional) If you plan to use the Topics feature of Oracle Empirica Signal, do the following for newly created users:
 - a. [Add the user to one or more work teams](#).
 - b. [Assign work team permissions to the user](#).

Field descriptions

Field	Description
Authentication	Authentication method.
Username (Add User page only)	Unique name of the user account (up to 100 characters). You can reuse deleted user names. Does not apply if LDAP authentication is used. For more information, see Rename a user .
First Name	First name of the user (up to 64 characters).
Last Name	Last name of the user (up to 64 characters).

Field	Description
Email	Email address of the user. This address (or addresses, separated by a comma) is used: - As the default email address if the user chooses to be notified of data mining run completion notification. - When a message is generated by a topic email notification rule. - When you use the Send Message to All Users link on the Settings page. It is recommended that all users have an associated email address.
User Profile	The user profile, or set of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users. The default is specified on the Site Options page by making a selection from the Default User Profile drop-down list.
Quota	Maximum amount of server space in megabytes (M) that the user is permitted to use for creating runs. If this limit is exceeded, the user cannot submit new runs (or re-runs). To indicate an unlimited amount of storage space, leave this field blank. If you enter 0, the user cannot create any runs even if the user has appropriate permissions.
Login Group	Name of the login group to which the user belongs. Only a superuser can change the login group and will see a Change link. When a superuser selects the Change link, Oracle Empirica Signal asks for confirmation because Oracle discourages changing a user's login group. The superuser must click OK to enable the Login Group field.
Password (Local authentication only)	Password for the user account (up to 64 characters). The password does not need to be unique. Note that users can also modify their own passwords. Follow any recommendations by your organization related to creating secure (hard-to-guess) passwords. You must create passwords according to the password restrictions set by your site administrator. Does not apply if LDAP or SSO authentication is used.
Confirm Password (Local authentication only)	Re-enter the password for the user account to confirm it. Does not apply if LDAP or SSO authentication is used.
Superuser	If selected, the user can perform any activity. This check box is available only if you are logged in as a superuser. If you are not a superuser, the label Superuser appears (without a check box) for any previously created superuser.

Field	Description
Password never expires (Local authentication only)	If selected, the user password never expires.
User must change password at next login (Local authentication only)	Does not apply if LDAP or SSO authentication is used. If selected, the user is required to change the password when next logging in. This option is cleared automatically once the user has changed the password. Does not apply if LDAP or SSO authentication is used.
Account locked (Local authentication only)	If selected, the user cannot log in until you clear the check box. This check box is selected automatically for a user who tries to log in with an incorrect password more than the number of times allowed by the site option, Number of Attempts Allowed. Does not apply if LDAP or SSO authentication is used.
Account disabled	If selected, the user account is disabled. Disabled users cannot log in, receive notifications, or have objects such as topics assigned to them.

Note

If a user password has expired, a message at the top of the Edit User page tells you this when you edit the user.

Note

When a local user password has expired, the user account becomes disabled. To allow the user to log in again, you must both assign a new password to the user and re-enable the user account.

Add or edit a user in an Oracle-hosted environment

Note

This procedure does not apply for self-hosted installations. For more information, see [Add and edit a user in a self-hosted environment](#).

For Oracle-hosted installations, you first create users in the appropriate cloud identity management console, then manage their roles and permissions on the Oracle Empirica Signal Users page.

1. Perform the following steps in the cloud identity management console:
 - a. Create the user.
 - b. Provide access to Oracle Empirica Signal as follows, depending on the specific cloud identity management service:
 - If using IAMS, assign the **Signal** role to the user
 - If using IDCS, assign the **Signal** group to the user

Note

For more information, see the appropriate documentation for your cloud identity management service, either *Managing Oracle Empirica Signal Cloud Users with Oracle Health IAMS* or *Managing Oracle Empirica Signal Cloud Users with Oracle IDCS*.

After a few minutes, the user is created in Oracle Empirica Signal, and an entry appears in the Oracle Empirica Signal userprovisioning.log file on the application server. The user is provisioned with the default user profile specified as a [site option](#).

2. Optionally, change the [login group](#), [roles](#), and [permissions](#) assigned to the user.
3. If you plan to use the Topics feature of Oracle Empirica Signal, optionally do the following for newly created users:
 - a. [Add the user to one or more work teams](#).
 - b. [Assign work team permissions to the user](#).

Edit the user's roles and permissions

1. Log in to the Oracle Empirica Signal application
2. In the left navigation pane, click the **Settings** icon (.
3. In the **Manage Users** section, click **Edit Users**.
4. Locate the user to edit in the table.
5. Click the user's **Row Action menu** () , and then click **Edit**.

Note

You can edit only users in your login group.

6. Fill in the fields, and then click **Save**.

Field descriptions

Field	Description
Authentication (read only)	Indicates that the user is authenticated with single sign-on.

Field	Description
Username (read only)	Unique name of the user account (up to 100 characters). You can reuse deleted user names. Does not apply if LDAP authentication is used. For more information, see Rename a user.
First Name (read only)	First name of the user (up to 64 characters).
Last Name (read only)	Last name of the user (up to 64 characters).
Email (read only)	Email address of the user. This address (or addresses, separated by a comma) is used: - As the default email address if the user chooses to be notified of data mining run completion notification. - When a message is generated by a topic email notification rule. - When you use the Send Message to All Users link on the Settings page. It is recommended that all users have an associated email address.
User Profile	The user profile, or set of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users. By default, new users are provisioned with the <i>user</i> profile. The <i>user</i> profile does not include any permissions or roles.
Quota	Maximum amount of server space in megabytes (M) that the user is permitted to use for creating runs. If this limit is exceeded, the user cannot submit new runs (or re-runs). To indicate an unlimited amount of storage space, leave this field blank. If you enter 0, the user cannot create any runs even if the user has appropriate permissions.
Login Group	Name of the login group to which the user belongs. Appears only if you are a superuser. By default, new users belong to the Users login group
Password (disabled)	Does not apply for SSO.
Confirm Password (disabled)	Does not apply for SSO.
Superuser	If selected, the user can perform any activity. This check box is available only if you are logged in as a superuser. If you are not a superuser, the label Superuser appears (without a check box) for any previously created superuser.

Field	Description
Password never expires	Does not apply for SSO.
User must change password at next login	Does not apply for SSO.
Account locked	Does not apply for SSO.
Account disabled	If selected, the user account is disabled and the user cannot log in.

Assign roles to a user

A user role is the name of a set of permissions that are needed by a particular group of users (such as data mining results reviewers). The application includes predefined user roles, which can be modified or added to by a superuser. When you create a user, you can assign one or more user roles to the user. (You can also explicitly [assign individual permissions](#) to the user.)

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Users**.
3. Click the User's **Row Action menu** () , and then click **Edit**. You can edit only users in the same login group as you.
4. Click **Assign Roles**.
5. Select or deselect checkboxes to assign roles to, or remove roles from, the user.
6. Click **Save**.

Note

If you modify the user's roles and the user is currently running Oracle Empirica Signal, the changes take effect the next time the user logs in to Oracle Empirica Signal.

Assign permissions to a user

You can assign additional permissions to an individual user; however, you cannot disable permissions that have been assigned via a user role.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Users**.
3. Click the user's **Row Action menu** () , and then click **Edit**. You can edit only users in the same login group as you.
4. Click **Assign Permissions**.

Permissions that have been granted to the user are indicated by selected checkboxes.

See [User permissions](#) for information about which Oracle Empirica Signal activities are made available by each permission.
5. Check or clear permission checkboxes to assign permissions to or remove permissions from the user.
6. Click **Save**.

Note

If you modify the user's permissions and the user is currently running Oracle Empirica Signal, the changes take effect the next time the user logs in to Oracle Empirica Signal.

Change user passwords

Note

This procedure does not apply for single sign-on environments. You must use the single sign-on application to change or reset user passwords.

If you have the Administer Users permission, you can change the passwords of other users in your login group.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Users**.
3. Click the user's **Row Action menu** () , and then click **Edit**. You can edit only users in the same login group as you.
4. Click **Change Password**.
5. In the **New Password** field, type a new password.
6. In the **Confirm Password** field, re-enter the same password.
7. Click **Change Password**.

The site administrator sets the required password length and the types of characters allowed (alphabetic, numeric, non-alphanumeric, lowercase, and uppercase). There may be restrictions on the re-use of old passwords.

The password expiration period, if one has been set as a [site option](#), begins for the new password. The next time the user logs in, the user must use the new password.

Rename a user

Note

This procedure does not apply for Oracle-hosted installations unless you are a superuser renaming a local user. You rename single sign-on users in the identity management service, not in the Oracle Empirica Signal application. See [Ways to administer users](#).

When you change a user name:

- The original user name cannot be used to log into the Oracle Empirica Signal application.
- The new user name appears throughout the application, including historical activities in the User Activity Audit Trail.
- It is possible to create another user with the same, original user name after a rename.

- The application converts user names to lowercase automatically upon creation and, thus, does not allow duplicate user names that differ only in case. For example, if you create user jkelley, and then attempt to create user JKelley, an error occurs.

Note

Before you begin, if you work in a self-hosted environment with single sign-on, rename the user in Oracle Access Manager (OAM) or your single sign-on application. The user name in the single sign-on application must always match the user name in Oracle Empirica Signal.

1. In the left navigation pane, click the **Settings** icon ()
2. In the **Manage Users** section, click **Edit Users**.
3. Click the user's **Row Action menu** () , and then click **Edit**. You can edit only users in the same login group as you.
4. Click **Rename User**.
5. In the **Username** field, type the new user name for the user.
The name must be unique within the application, and can be up to 100 characters long. If you are implementing single sign-on, type the single sign-on user name.
6. Click **Save**.

The new user name is displayed at the top of the Edit User page.

If the affected user is logged into the application, the user can continue working. However, the user must use the new user name for future logins.

Change the authentication method for a user

Note

This procedure does not apply for Oracle-hosted installations. User authentication is managed when [creating the user](#) in the identity management service.

You can change the authentication method for a user to Local, SSO (single sign-on), or LDAP.

Before you begin:

- If you plan to change a user's authentication method to SSO and you work in a self-hosted environment, create the user in your single sign-on application.
 - If you plan to change a user's authentication method to LDAP, [import the user](#).
1. In the left navigation pane, click the **Settings** icon ()
 2. In the **Manage Users** section, click **Edit Users**.
 3. Click the user's **Row Action menu** () , and then click **Edit**.
 4. From the **Authentication** drop-down list, select one of the following:
 - Local

- SSO
 - LDAP
5. Click **Save**.

Delete a user

Note

This procedure does not apply for Oracle-hosted installations unless you are a superuser deleting a local user. You delete Oracle-hosted single sign-on users using the identity management service, then, if necessary, [purge users](#) from Oracle Empirica Signal. See [Ways to administer users](#).

When you delete a user:

- You become the owner of objects created by the user except topics or topic actions.
 - The user cannot log in to the application.
 - If the user is assigned to a product or product-event combination, Oracle Empirica Signal removes the assignments.
 - The deleted user's user name can be reused for a new user.
 - Objects cannot be assigned to the user.
 - Comments created by the user on the Product-Event Combinations page remain attributed to the user.
 - The user's user name remains associated with the user's previous actions in the User Activity Audit Trail. The user name is followed by (deleted).
 - Action type, Topic Template, and Topic Action Template assignments will not prevent deletion of the user and are not affected. You must remove the user manually from the **Assigned to** list.
1. If the user is assigned to a topic or topic action, reassign the topic or topic action. Note the following about reassigning topics or topic actions:
 - To reassign a topic or topic action, you must be on the user's work team and have the appropriate work team permissions.
 - If topics or topic actions assigned to the user are in different topic workflow configurations, you can reassign topics and topic actions for only one topic workflow configuration in a login session.

For example, if you reassign a topic in a topic workflow configuration, you must log out and then log back in to reassign a topic in a different topic workflow configuration.

2. In the left navigation pane, click the **Settings** icon (.
3. In the **Manage Users** section, click **Edit Users**.
4. Click the user's **Row Action menu** () , and then click **Delete**.
5. If the deleted user is logged in to Oracle Empirica Signal, the user can continue working. However, after the user logs out, the user cannot log in again.

Note

If the user has one or more private topics, Oracle Empirica Signal prevents you from deleting the user and displays the name or ID of the private topic. Contact a superuser to reassign or delete the private topic.

Purge users

For Oracle-hosted installations with single sign-on, you delete a user by first removing the user's access to Oracle Empirica Signal in the [identity cloud service console](#). If objects are assigned to the deleted user, you must also purge the user in Oracle Empirica Signal as described below.

Note

This procedure applies only to Oracle-hosted installations. For information about deleting users in a self-hosted environment, see [Delete a user](#).

When you purge a user:

- You become the owner of objects created by the user except topics or topic actions.
- If the user is assigned to a product or product-event combination, Oracle Empirica Signal removes the assignments.

To purge users, you must have Administer Users or superuser permissions.

1. If the user is assigned to a topic or topic action, reassign the topic or topic action.
 - You must be on the user's work team and have the appropriate work team permissions.
 - You can reassign topics and topic actions in only one workflow configuration within a login session. For example, if you reassign a topic in a topic workflow configuration, you must log out and then log back in to reassign a topic in a different topic workflow configuration.

For more information, see [Edit a topic](#).

2. In the left navigation pane, click the **Settings** icon (.
3. In the **Manage Users** section, click **Edit Users**.
4. Click **Purge Users** at the top of the page.
5. Click the user's **Row Action menu** () , and then click **Purge**.

Note

If the user has one or more private topics, Oracle Empirica Signal prevents you from purging the user and displays the name or ID of the private topic. Contact a superuser to reassign or delete the private topic.

Manage user profiles

- [View user profiles](#)
- [Add or edit a user profile](#)
- [Assign roles to a user profile](#)
- [Assign permissions to a user profile](#)
- [Assign preferences to a user profile](#)
- [Apply a user profile](#)

View user profiles

A user profile is a set of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users. You can set up a user profile and apply it as needed to new or existing users. Once you have applied a user profile to a user, subsequent changes to the user profile do not affect that user.

Note

If you [set user preferences](#) by applying a user profile to users, those user preferences are defaults that the individual users can override.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit User Profiles**.

The User Profiles page provides the following information:

Column	Description
User Profile Name	Name of the user profile.
Login Group	Name of the login group associated with the user profile. Appears only if you are a superuser.
Quota	Maximum amount of server space in megabytes (M) that users with the user profile are permitted to use for creating runs. If this limit is exceeded, users cannot submit new runs (or re-runs). To indicate an unlimited amount of storage space, leave this field blank. If the quota is 0, users cannot create any runs even if the user has appropriate permissions.

3. Click a user profile's **Row Action menu** () to [edit or delete](#) the profile.

Add or edit a user profile

Note

Modifications to a user profile are not automatically applied to users who with that profile. To apply those changes to existing users, you need to re-apply the user profile to those users.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit User Profiles**.
3. Choose one of the following:
 - To add a user profile, click **Add a New User Profile**.
 - To edit a user profile, click the User profile's **Row Action menu** () , and then click **Edit**.
4. Enter or change the following information:

User Profile Fields

Field	Description
Edit User Profile:	Name of the user profile. Can't be edited.
Quota	Maximum amount of server space in megabytes (M) that users with this user profile are permitted to use for creating runs. If this limit is exceeded, users cannot submit new runs (or re-runs). To indicate an unlimited amount of storage space, leave this field blank. If you enter 0, users cannot create any runs even if the user has appropriate permissions.
Login Group	Name of the login group associated with the user profile. Appears only if you are a superuser. If this field does not appear, the login group for the user profile is the same as your login group.

5. Click **Save**.
6. [Assign roles](#) or [assign permissions](#) to the user profile or [set user preferences](#) for the user profile.

Assign roles to a user profile

A user role is the name of a set of permissions that are needed by a particular group of users (such as data mining results reviewers). The application includes predefined user roles, which can be modified or added to by a superuser.

A user role is the name of a set of permissions that are needed by a particular group of users (such as data mining results reviewers). The application includes predefined user roles, which can be modified or added to by a superuser. When you create a user profile, you can assign one or more user roles to the user profile.

1. In the left navigation pane, click the **Settings** icon (.

2. In the **Manage Users** section, click **Edit User Profiles**.
3. Click the user profile's **Row Action menu** (), and then click **Edit**.
4. Click **Assign Roles**.
5. To assign roles to or remove roles from the user profile, select or de-select the user role checkboxes
6. Click **Save**.

Assign permissions to a user profile

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Manage Users** section, click **Edit User Profiles**.
3. To [edit a user profile](#), click the **Row Action menu** () for a user profile, and then click **Edit**.
4. Click **Assign Permissions**.
5. To assign permissions to the user profile or remove permissions from the user profile, select or de-select the permission checkboxes. See [User permissions](#) for information about which activities are made available by each permission.
6. Click **Save**.

Assign preferences to a user profile

Note

Preferences that you can assign to a user profile are dependent on your permissions and the user preferences available to you.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Manage Users** section, click **Edit User Profiles**.
3. To [edit a user profile](#), click the **Row Action menu** () for a user profile, and then click **Edit**.
4. Click the **Preferences** link.
5. To assign user preferences to the user profile or remove user preferences from the user profile, select or de-select the preference checkboxes and make selections from the drop-down lists. See [User permissions](#) for information about which activities are made available by each permission.

For details about each user preference, see [Set your user preferences](#).
6. Click **Save**.

Apply a user profile

A user profile is a set of attributes (login group and quota), user roles, permissions, and default user preferences that can be applied to users. (For more details, see [Add or edit a user profile](#).)

When you apply a user profile to an existing user, the information in the profile replaces any previous settings for the user.

After applying a user profile to a user, you can modify settings further for the user. (However, the changes are lost if you re-apply the profile.)

Note

Once you have applied a user profile to a user, there is no further association between the user profile and the user. For example, if the user profile is subsequently modified or deleted, users to whom the profile was applied are not affected.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Users**.
3. Click the user's **Row Action menu** () , and then click **Edit**. You can edit only users in the same login group as you.
4. Click **Apply User Profile** (which is available only if there are existing user profiles).
5. From the **User Profiles** list, click a user profile, associated with your login group, to be associated with the user.
6. Click **Save**.

Note

If you apply a user profile to a user who is currently logged in, any changes that you make to the profile affect that user the next time the user logs in.

Manage user roles

- [Predefined user roles](#)
- [View existing user roles](#)
- [Create a user role](#)
- [Edit a user role](#)
- [Delete a user role](#)

Predefined user roles

Oracle Empirica Signal includes the following predefined user roles, which have one or more user permissions assigned to them. When you assign a role to a user or user profile, all of the permissions for that role are given to the user or user profile.

Note

The following table includes only permissions that are assigned to at least one predefined user role. For a description of every permission, see [User permissions](#).

Permissions:	Data Mining Run Reviewer	Data Mining Run Designer	Customer Administrator	Report Designer	Report Producer	Signals Reviewer	Oracle Empirica Signal Administrator
Available with License	Signal	Signal	None	Signal	Signal or Topics	Topics	Topics
View Raw Safety Database	X	X	-	X	X	X	
Download Raw Data	X	X	-	-	-	X	-
View Data Mining Results	X	X	-	-	-	-	-
Create Data Mining Run	-	X	-	-	-	-	-
Save Intermediate Files	-	X	-	-	-	-	-
Create Drug Profile Layouts	-	X	-	X	-	-	-
Create Queries/Case Series	X	X	-	X	X	X	-
Create Report Definitions	-	-	-	X	-	-	-
Create Report Outputs	-	-	-	X	X	-	-
View Signal Management	-	-	-	-	-	X	X
Annotate Signal Management	-	-	-	-	-	X	-
Manage Signaling Terms	-	-	-	-	-	-	X

Permissions:	Data Mining Run Reviewer	Data Mining Run Designer	Customer Administrator	Report Designer	Report Producer	Signals Reviewer	Oracle Empirica Signal Administrator
Manage Signal Configurations	-	-	-	-	-	-	X
Administer Users	-	-	X	-	-	-	X
Administer Drug Profiles	-	-	-	-	-	-	X
Manage Configurations	-	-	-	-	-	-	X
Manage Topic Workflow Configurations	-	-	-	-	-	-	X
Manage Aliases	-	-	-	-	-	-	X

View existing user roles

A user role is a set of permissions needed by a particular type of user. The application includes a set of predefined user roles, which you can modify or supplement.

When a user or user profile is created, one or more roles can be assigned to the user or user profile. You can also assign permissions individually and explicitly to a user or user profile. Individually assigned permissions are in addition to any permissions granted by a role.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Roles**.
 - To [edit a user role](#), click **Edit** for the role.
 - To [delete a user role](#), click **Delete** for the role.
 - To [create a user role](#), click **Create New Role**.

Create a user role

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Roles**.
3. Click **Create New Role**.
4. In the **Enter name for a new role** field, type a unique name for the user role, and then click **Save**.
5. On the [Edit Roles page](#) for the new user role, select or deselect the **Permissions** check boxes to assign permissions to, or remove permissions from, the user role.

For more information, see [User permissions](#).

6. Click **Save**.

Edit a user role

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Roles**.
3. For the user role you want to edit, click **Edit**.
4. On the [Edit Roles page](#), check or clear the **Permissions** check boxes to assign permissions to, or remove permissions from, the user role. See [User permissions](#) for information about which Oracle Empirica Signal activities are made available by each permission.
5. Click **Save**.

If you modify permissions for an existing user role, then users currently logged in and associated with the user role are not affected by the changes during their current session. The changes take effect the next time they log into the application.

Delete a user role

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Roles**.
3. For the user role you want to delete, click **Delete**.

Users currently logged in with the deleted role can continue their current sessions. However, after the users log out, their permissions no longer include permissions granted solely through the deleted role.

Manage work teams

- [About work teams](#)
- [Work team permissions](#)
- [View existing work teams](#)
- [Add, edit, or delete a work team](#)
- [Assign permissions to work team members](#)

About work teams

A work team is a subset of the users who belong to a single login group. Work teams are used only in the context of the [topics](#) feature, and are intended to structure the level of access that different users have to topics. Work teams have properties that control the availability of the work team for selection in the **Visible to work team** and **Assigned to** fields of the topic and action.

When adding or editing a topic, users can make the topic visible to a work team or teams. Users can either specify a single work team for a topic or zero, one, or more work teams (as defined by the topic workflow configuration that is in use). Only members of the specified work team(s) can see or act on the topic, and then only in the ways permitted by their assigned work team permissions. (A topic that is not made visible to any work team can only be viewed and acted on by its creator. For work on these topics, work team permissions are not needed.)

Note

When assigning work team permissions, note that only users with the [View Topics user permission](#) can access the Topics page and work with associated topics on the Signal Review page. Work team permissions grant different levels of access to the topics on those pages, but not to the topics feature itself.

You can define multiple work teams within the same login group. For example, different work teams can represent various therapeutic areas. A user can be a member of one, several, or none of the login group's work teams.

Users with the Administer Users user permission can add and delete work teams, and edit work teams to specify members and assign work team permissions to them. (One of the work team permissions, Administer Work Team, can be used to give designated members editing access only to a work team.)

Note

Work team deletion is prevented if the work team has ever been used by Oracle Empirica Topics for visibility or by a topic or action for assignment. If a work team is referenced in a template, you cannot delete the work team unless the template is deleted.

Work team permissions

Note

To use the [topics](#) feature and access the Topic Management page or work with associated topics on the Signal Review page, users must be given the [View Topics user permission](#). Work team permissions give users different levels of access to the topics that appear on those tabs.

Permissions that can be assigned to work teams

The following permissions can be assigned to the members of a work team. Each permission is independent of the others, but some actions require multiple permissions.

- For a member to edit a topic, both the *View Topics/Actions/Attachments* permission and the *Edit Topics/Actions* permission must be granted to that member.
- For a member to edit a topic attachment, the *View Topics/Actions/Attachments* permission and the *Add/Edit/Delete Attachments in Open Topics/Actions* permission must be granted.

It is possible for one person to be a member of different work teams and have different work team permissions in each one. If a user has access to a topic that is visible to multiple work teams through membership in more than one of those work teams, the least restrictive permissions assigned to the user apply.

Permission	Activity
View Topics/Actions/Attachments	View topics, actions, and attachments to both topics and actions, and create .pdf or compressed .zip files of topic information. Note All work team members should be given this permission to allow topic review.
Edit Topics/Actions	Add and edit topics and actions, including adding comments (if enabled by the topic workflow configuration). Note This permission does not grant view access to topics or actions. Typically, members also are given the View Topics/Actions/Attachments work team permission.
Add/Edit/Delete Attachments in Open Topics/Actions	Add, edit, and delete attachments to topics and actions, including adding comments (if enabled by the topic workflow configuration). Grants access to attachments to topics and actions that are in a non-final state, such as Assigned.
Edit Attachments in Closed Topics/Actions	Edit topic or action attachments when the topic is in a final state, such as Closed, and edit action attachments when the action is in a final state. Note This permission does not allow members to add comments to attachments.

Permission	Activity
Reopen Topics/Actions	Reopen topics or actions by changing the state from a final state, such as Closed, to a non-final state, such as Assigned. No other edits are permitted by this permission.
Approve Topic State Changes	Change topic state for transitions that require approval. You must also have access to the object itself through work team security.
Delete Topics/Actions	Delete topics and actions.
Administer Work Team	See the <i>Administer Work Team permission</i> section below.

Note

For the Reopen option to be available for a topic or action, in the topic workflow configuration at least one state also must be defined as a **Next possible state** for the final state.

Note

This permission does not grant delete access to attachments.

Note

Work team permissions apply only in the context of working with topics and, as a result, are effective only for members who also have the *View topics* [user permission](#). Only members with the View topics user permission can access the Topic Management page, where they can make them visible to a work team (or teams) to initiate collaborative participation. Users who are members of the *visible to work team(s)* can then view and act on topics as granted by their assigned work team permissions. *View topics* [user permission](#) is also required to work with associated topics on the Signal Review page.

Administer Work Team permissions

An additional, managerial work team permission is available: *Administer Work Team*. This work team permission grants members access to a limited subset of the activities that can be performed with the *Administer Users* user permission. From the **Settings** page, select **Edit Work Teams**. From the **Edit Work Teams** page, members with this permission can:

- Edit work teams to add new members.
- Assign work team permissions to members.
- Specify the values that apply to a given work team for fields with constrained values (see [Constrain field values by work team](#)).

Default work team permissions

You can assign work team permissions individually to members, or you can define a set of default work team permissions and assign that set to the members of a work team. When a work team is added, each permission is designated as being in the default set for that work team or not, as follows:

Permission	Default
View Topics/Actions/Attachments	Yes
Add/Edit/Delete Attachments in Open Topics/Actions	No
Edit Attachments in Closed Topics/Actions	No
Reopen Topics/Actions	No
Approve Topic State Changes	No
Delete Topics/Actions	No
Administer Work Team	No

You can change this set of default permissions so that members are given additional permissions by default. When you add a member to a work team, the permissions in the default set are assigned to that new member automatically. You can edit each member's [assigned permissions](#) as needed.

If you make changes to the default set after it has been assigned to members, the permissions granted to those members by default are updated automatically to match the new default set.

View existing work teams

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Work Teams**.

The Edit Work Teams page provides the following information about each work team:

Field	Description
Name	Name of the work team.
Description	Description of the work team.
Login Group	Name of the work team's login group.
All Users	Yes, if the work team is set up to include all users in the login group automatically. When a new user is added to the login group, he or she is also added to the work team and given the default set of work team permissions. No, if users in the login group are selected individually for inclusion in the work team, and are listed in the Users column. New users must be added to the work team manually.
Users	Blank, if all users in the login group are in the work team. Otherwise, lists the name of each work team member.
Topic Visibility	Whether or not the topic is visible to the work team.

Field	Description
Topic/Action Assignment	Whether or not topics and actions can be assigned to the work team.
Created By	Name of the user who created the work team.
Created	Date and time when the work team was created.
Modified By	Name of the user who last modified the work team.
Modified	Date and time when the work team was last modified.
ID	Identifier that was assigned automatically when the work team was created. Each work team ID is unique and is not re-used if the work team is deleted.

The table might also include columns for custom fields added by your organization.

- Perform the following optional activity: [add a new work team](#). Click **Add Work Team**. Only users with the Administer Users user permission can add work teams. For more information, see [Add or edit a work team](#).
- If you click the **Row Action menu** () for a work team, you can do the following:
 - To [edit a work team](#), including adding new members, click **Edit**.
 - To [assign work team permissions](#) to members, click **Assign Work Team Permissions**.
 - To delete a work team, click **Delete**. Only users with the Administer Users user permission can delete a work team, and a work team cannot be deleted if any topics have been made visible to it.

Note

Work team deletion is prevented if the work team has ever been used by Oracle Empirica Topics for visibility or by a topic or action for assignment. If a work team is referenced in a template, you cannot delete the work team unless the template is deleted.

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

Add, edit, or delete a work team

- In the left navigation pane, click the **Settings** icon ().
- In the **Manage Users** section, click **Edit Work Teams**.
- Choose one of these activities.
 - To add a new work team, click the **Add Work Team** link. Only users with the Administer Users user permission can add work teams.
 - To edit a work team, click the **Row Action menu** () for the work team, and then click **Edit**.

- To delete a work team, click the **Row Action menu** () for the work team, and then click **Delete**. Confirm the deletion by clicking **OK**. The deletion is added to the User Activity Audit Trail in the Work Teams section.

 Note

Oracle Empirica Signal prevents you from deleting a work team if it is used in an action type.

4. If you are adding or editing a work team, in the **Name** and **Description** fields, enter or change the name and description of the work team.
5. If you are a superuser, from the **Login group** drop-down list, select the login group from which you want to add users to the work team. If you are not a superuser, this field does not appear and you add users from your own login group to the work team.
6. Select the **Allow topic visibility** check box to make the work team available in the **Visible to work team** field and **Browse work team** pages when creating and editing topics/topic templates.
7. Select the **Allow assignment of topics and actions** check box to make the work team available for selection in the **Assign to** topic and action fields.
8. Do one of the following:
 - To add all users in the login group to the work team, click the **Add all users** radio button. As new users are added to the login group, they are added to the work team and given the default set of work team permissions automatically.
 - To add users in the login group to the work team individually, click the **Select users** radio button. Click **Select Users** to individually [select users](#). As new users are added to the login group, you must add them to this work team manually.
9. Optionally, supply values in any custom fields present for work teams. Custom fields for work teams are defined in a topic workflow configuration, and a superuser must enable these fields for use by [setting the site option](#), Topic workflow configuration for work team custom fields.
10. When you click **OK**, your changes are saved and you can [assign work team permissions](#) to the members of the work team.

The initial settings for all fields, as well as modifications to the work team information and permissions, are recorded in the [User Activity Audit Trail](#).

Assign permissions to work team members

1. In the left navigation pane, click the **Settings** icon ().
2. In the Manage Users section, click **Edit Work Teams**.
3. Click the **Row Action menu** () for the work team, and then click **Assign Work Team Permissions**.

By default, each new work team member is assigned the default set of permissions and the check box in the Use Default column is checked.

4. To assign permissions individually, clear the **Use Default** check box, and then check or clear the check boxes in the row with the user's name.

Note

You must assign at least one work team permission to each member or the default set of permissions will be assigned.

For more information on the access level granted by each permission, see [Work team permissions](#).

5. Click **Save.**

All changes to the assigned work team permissions are recorded in the [User Activity Audit Trail](#).

If you modified permissions for a user who is currently logged into the application, the user is not affected by the changes during the current session. The changes take effect the next time the user logs in.

Use single sign-on

- [About single sign-on](#)
- [Configure single sign-on in a self-hosted environment](#)

About single sign-on

Single sign-on (SSO) is an authentication method that enables users to log in to the Oracle Empirica Signal application and other applications using a single user name and password combination. Users can log in to an SSO environment and access all the applications in the environment without reentering their credentials.

SSO simplifies user administration across applications by enabling you to manage fewer user accounts. Users do not need to remember multiple user names and passwords.

Oracle-hosted installations are configured for SSO with an identity management service, either Oracle Life Sciences Identity and Access Management Service (IAMS) or Oracle Identity Cloud Service (IDCS). Oracle provides the URL to access your identity management service.

For self-hosted installations, you must do the following to use SSO:

- Install and configure an SSO application, such as Oracle Access Manager.
- Install and configure the WebGate agent on the Oracle Empirica Signal application server.

Contact Oracle for assistance.

For more information, see [Configure single sign-on in a self-hosted environment](#).

Configure single sign-on in a self-hosted environment

Adding Oracle Empirica Signal to a single sign-on (SSO) self-hosted environment requires you to perform configuration tasks outside of the application before you enable SSO for Oracle Empirica Signal users. Your application environment determines the configuration responsibilities:

Single Sign-On configuration checklist

#	Task	Responsibility	Source for Instructions
1	Install and configure an SSO application such as Oracle Access Manager	Customer	Contact Oracle for assistance.
2	Configure a WebGate agent on the SSO server.	Oracle	Contact Oracle for assistance.
3	Install and configure WebGate on the Oracle Empirica Signal application server.	Oracle	Contact Oracle for assistance.
4	Uncomment single sign-on properties in the <code>webvdm.properties</code> file.	Customer	Oracle Life Sciences Empirica Signal Installation Guide.
5	Specify the URL for a custom logout page (optional).	Customer	Oracle Life Sciences Empirica Signal Installation Guide.
6	Change the Oracle Empirica Signal application session timeout to be longer than the SSO session timeout.	Customer	Oracle Life Sciences Empirica Signal Installation Guide.
7	Configure the Oracle Empirica Signal application server for native logins.	Customer	Oracle Life Sciences Empirica Signal Installation Guide.
8	Restart the Oracle Empirica Signal service.	Customer	Oracle Life Sciences Empirica Signal Installation Guide.
9	Validate SSO by logging in with your SSO user name and password.	Customer	Oracle Life Sciences Empirica Signal Installation Guide.
10	Create SSO users in the SSO application.	Customer	Oracle Access Manager documentation.
11	Rename existing Oracle Empirica Signal user names to match their associated SSO user names, or create new users as necessary.	Customer	Rename a user Add or edit a user
12	Select SSO in the Authentication drop-down list for users and user profiles.	Customer	Add or edit a user Add or editing a user profile

Manage LDAP users

- [Configure Oracle Empirica Signal for use with LDAP in a self-hosted environment](#)
- [LDAP properties](#)

- [Import LDAP users](#)
- [Change a user to LDAP authentication](#)
- [Refresh LDAP users](#)

Configure Oracle Empirica Signal for use with LDAP in a self-hosted environment

Note

This procedure does not apply for Oracle-hosted installations.

LDAP (Lightweight Directory Access Protocol) is an internet protocol used to look up information stored in a directory on a server. The Oracle Empirica Signal application provides a way for you to update user information using LDAP. Thus, user information can be maintained in an LDAP directory and imported into the application. User authentication is performed by LDAP instead of by the standard means of authentication in Oracle Empirica Signal.

When user information is stored in an LDAP directory, users can be identified by a unique user attribute that remains constant despite potential user name changes in the LDAP directory.

Note

The Oracle Empirica Signal application does not update information in the LDAP directory.

You can configure Oracle Empirica Signal to use LDAP by editing a properties file template for Active Directory, Sun One Directory, or Oracle Internet Directory. For more information, see your LDAP documentation.

1. Log in to Oracle Empirica Signal as a superuser.
2. In the left navigation pane, click the **Settings** icon (.
3. In the **Administer System** section, click **Set Site Options**.
4. Deselect **Enable LDAP**, and then click **Save**.
5. Navigate to `<INSTALL_DIR>/Signal/WEB-INF/classes`.

Note

The Oracle Empirica Signal application does not update information in the LDAP directory.

6. Copy the properties file that corresponds to your directory type to the same location, and then rename the file `ldap.properties`:
 - `template_ldap_ad_kerberosAuth.properties`—Active Directory using kerberos for authentication.
 - `template_ldap_ad_ldapAuth.properties`—Active Directory using ldap for authentication.
 - `template_ldap_sunone_ldapAuth.properties`—Sun One Directory.

- `template_ldap_oid_ldapAuth.properties`—Oracle Internet Directory.

Note

After the `ldap.properties` file is created, redeploy the application server using WebLogic Server Administration Console.

7. Open the `ldap.properties` file in a text editor.
8. Replace all placeholders (for example, `<HOSTNAME>`) with the relevant values. For more information on LDAP Properties, see [LDAP Properties](#).
9. Save your changes.
10. On the Settings page, click **Set Site Options**.
11. Select **Enable LDAP**, and then click **Save**.
12. On the Settings page, click **Edit Users**.
13. Click **Import LDAP Users** and search for users to verify the LDAP configuration. For more information, see [Import LDAP Users](#).

LDAP properties

For reference, you can use the following properties to configure the Oracle Empirica Signal application for use with LDAP. Some properties apply only to certain directory types. You configure these properties in the appropriate `ldap` properties file. For more information, see [Configure Oracle Empirica Signal for use with LDAP](#).

Property	Description
<code>auth.mode</code>	Authentication method. Specify <code>kerberos</code> or <code>ldap</code> .
<code>auth.jndi.java.naming.factory.initial</code>	Implementation class for JNDI LDAP provider used during LDAP user authentication. Specify <code>com.sun.jndi.ldap.LdapCtxFactory</code> .
<code>auth.kerberos.host</code>	Hostname for the Kerberos Key Distribution Center (KDC) used during Kerberos-based user authentication.
<code>auth.kerberos.port</code>	Port for the Kerberos Key Distribution Center (KDC) used during Kerberos-based user authentication.
<code>auth.kerberos.domain</code>	Domain used during Kerberos-based user authentication.
<code>auth.jndi.java.naming.security.protocol</code>	Security protocol used during LDAP-based user authentication. Specify one of the following: • <code>none</code> - LDAP • <code>ssl</code> - LDAPS
<code>auth.jndi.java.naming.provider.url</code>	Hostname and port used during LDAP-based user authentication.
<code>auth.jndi.java.naming.security.authentication</code>	Authentication mode used during LDAP-based user authentication. Specify <code>simple</code> .
<code>search.jndi.java.naming.factory.initial</code>	Implementation class for JNDI LDAP provider used during user search and import. Specify <code>com.sun.jndi.ldap.LdapCtxFactory</code> .

Property	Description
search.jndi.java.naming.security.protocol	Security protocol used during LDAP user search and import. Specify one of the following: • none - LDAP • ssl - LDAPS
search.jndi.java.naming.provider.url	Hostname and the port used during LDAP user search and import. When importing users or changing a user to LDAP authentication, all searches begin in the specified root.
search.jndi.java.naming.security.authentication	Authentication mode used during LDAP user search and import. Specify one of the following: • none - Anonymous connections. • simple - Search as a specific user.
search.jndi.java.naming.security.principal	Stores LDAP user name that resides in the LdapCredentials key. For more information, see Oracle Life Sciences Empirica Signal Installation Guide.
search.jndi.java.naming.security.credentials	Stores LDAP password that resides in the LdapCredentials key. For more information, see Oracle Life Sciences Empirica Signal Installation Guide.
search.jndi.java.naming.referral	Indicates whether the LDAP provider follows referrals during a user search and import. Specify follow.
search.controls.timelimit	Maximum number of seconds that a query of the LDAP server can take before the LDAP connection times out.
search.controls.countlimit	Maximum number of users that can be received from the LDAP server before the LDAP connection times out.
search.root	LDAP search root used during LDAP user search and import.
search.syncroot	LDAP search root used during LDAP refresh/sync of users. Generally should be the same as search.root.
search.nameAttribute	LDAP attribute which is searched upon in the Import LDAP User page.
search.emailAttribute	LDAP attribute used to populate a Signal user's email address during an import/sync operation.
search.usernameAttribute	LDAP attribute used to populate a Signal user's user name during an import/sync operation. Oracle Empirica Signal ensures that the user name in Oracle Empirica Signal matches the user name in the directory during an import or refresh operation.
search.firstNameAttribute	LDAP attribute used to populate an Oracle Empirica Signal user's first name during an import/sync operation.
search.lastNameAttribute	LDAP attribute used to populate an Oracle Empirica Signal user's last name during an import/sync operation.

Property	Description
search.kerberosIdAttribute	LDAP attribute used to identify an Oracle Empirica Signal user during Kerberos authentication.
search.syncIdAttribute	LDAP attribute used to identify an Oracle Empirica Signal user during a refresh/sync operation. Typically, this is an attribute that is not subject to change, such as an employee ID.
search.searchQuery	LDAP search query used when the user specifies a search string on the Import LDAP User page.
search.searchQueryNF	LDAP search query used when the user leaves the search string blank on the Import LDAP User page.
search.syncQuery	LDAP sync query used when refreshing users.

Import LDAP users

Note

This procedure does not apply for Oracle-hosted installations.

1. Log in to Oracle Empirica Signal as a user with the permissions **Administer Users** and **Administer LDAP**.

Note

Make sure that at least one [user profile](#) exists.

2. In the left navigation pane, click the **Settings** icon (.
3. In the **Manage Users** section, click **Edit Users**.
4. Click **Import LDAP Users**. This option is available only if an [LDAP configuration](#) has been set up.
5. From the **User Profile** drop-down list, select the user profile to apply to the LDAP users you import.
Available user profiles are those associated with your login group.
6. From the **Domain** drop-down list, select the domain from which you want to import LDAP users. The **Available LDAP Users** list shows users (up to 400) in that domain.
7. In the **Name** field, enter a text string, and then click **Find** to filter the list of available LDAP users (optional).
8. To move users from the **Available LDAP Users** list to the **Selected LDAP Users** list, use the arrow buttons. The double-arrow buttons move all users from one list to the other list.
9. Click **Import**.

Only selected users who do not have a user name in the Oracle Empirica Signal application are imported. The import operation does not refresh existing Oracle Empirica Signal users. See Refresh LDAP users. A message tells you if an LDAP user that you have selected for import already exists in the application.

10. Optionally, change the [roles](#) and [permissions](#) assigned to the user.
11. If you plan to use the Topics feature of Oracle Empirica Signal, do the following for imported users:
 - a. [Add the user to one or more work teams](#).
 - b. [Assign work team permissions to the user](#).

Change a user to LDAP authentication

Note

This procedure does not apply for Oracle-hosted installations.

1. Log in to Oracle Empirica Signal as a user with the permissions **Administer Users** and **Administer LDAP**.

Note

Make sure that at least one [user profile](#) exists.

2. In the left navigation pane, click the **Settings** icon (.
3. In the **Manage Users** section, click **Edit Users**.
4. Click the **Row Action menu** () for the user you want to edit, and then click **Edit**.

Note

You can edit only users in your login group.

5. In the **Authentication** drop-down list, select **LDAP**.
6. Click **Import LDAP Users**. This option is available only if an [LDAP configuration](#) has been set up.
7. In the **Name** field, enter a text string, and then click **Find** to filter the list of available LDAP users (optional).
8. Select a user in the **Available LDAP Users** list, and then click **OK**.

For more information, see [Import LDAP users](#).

Refresh LDAP users

User information in Oracle Empirica Signal is refreshed with user information from the LDAP directory if:

- The Oracle Empirica Signal user is an LDAP user.
- There is LDAP information for the user in the LDAP directory, and that information has changed since the last refresh of LDAP users.

User names can change as a result of refreshing LDAP users. Every place that the user name or other information appears in the application, including the User Activity Audit Trail, is updated with information from the LDAP directory.

- The refresh operation does not add new users from the LDAP server. See [Import LDAP users](#).
- For users who are LDAP users, do not make changes to user information in Oracle Empirica Signal. If you do so, the changes will be lost when you next refresh LDAP users.

Note

This procedure does not apply for Oracle-hosted installations.

1. Log in to Oracle Empirica Signal as a user with the permissions **Administer Users** and **Administer LDAP**.
2. In the left navigation pane, click the **Settings** icon (.
3. In the **Manage Users** section, click **Edit Users**.
4. Click **Refresh LDAP Users**. This option is available only if an [LDAP configuration](#) has been set up.

Messages tell you whether or not information for each Oracle Empirica Signal user who is an LDAP user is refreshed.

Manage login groups

- [View existing login groups](#)
- [Create a login group](#)
- [Edit a login group](#)
- [Delete a login group](#)

View existing login groups

A login group is a group of users. You can assign a different Home page, logo image, signal management configuration and topic workflow configuration for each login group.

When a user or user profile is created, a login group must be associated with the user or user profile. If you have the Administer Users permission, you can edit your own login group, but you cannot create or delete login groups.

Note

For Oracle-hosted installations, when a new user is created, the default user profile specified in [Site Options](#) is applied. The new user's login group is determined by the applied profile. By default, a login group named User s is included in Oracle Empirica Signal and associated with the default user profile named user.

When a user publishes an object (such as a query or report), the object is usable by other users in the same login group. (Users with the Administer Users permission can use and act on published or unpublished objects created by other users in the same login group.)

Additionally, [work teams](#) based on login groups can be defined for the purpose of sharing [topics](#).

1. Log in to Oracle Empirica Signal as a superuser.
2. In the left navigation pane, click the **Settings** icon (.
3. In the **Manage Users** section, click **Edit Login Groups**.
 - To [edit a login group](#), click **Edit**.
 - To [delete a login group](#), click **Delete**.
 - To [create a login group](#), click **Create New Login Group**.

Create a login group

1. Log in to Oracle Empirica Signal as a superuser. If you are not a superuser but you have the Administer Users permission, the Login Group Settings page appears for your own login group as soon as you click **Edit Login Groups** on the Settings page.
2. In the left navigation pane, click the **Settings** icon (.
3. In the **Manage Users** section, click **Edit Login Groups**.
4. Click **Create New Login Group**.
5. In the **Enter name for new login group** field, type a unique name for the login group, and then click **Save**.
6. On the [Login Group Settings page](#) for the new login group, in the **Logo Image** field, enter the name of an image file. (You cannot use a text file.) The image file must exist in the \image subdirectory of the server location in which the application was installed. The application scales any logo image that is not exactly 50 pixels in height to fit within the space allotted for the header. The aspect ratio is maintained so that the width of the image is also scaled.

By default the **Logo Image** field specifies logo.gif (the Oracle Empirica Signal logo). If you leave the Logo Image field blank, it is reset automatically to the default.

7. In the **Home Page** field, enter the name of the file that contains the customized page, in .html format, for the Home page. The .html file must exist in the \customhomes subdirectory of the server location in which the application was installed.

By default the Home Page field specifies home.inc (the default landing page). If you leave the Home Page field blank, it is reset automatically to the default.

8. If multi-enterprise support has been enabled then the **Argus Mart Enterprise** field will be available. From this field's drop-down list, select the Enterprise ID to be associated with the login group.

✓ Tip

Only a superuser can set or change this field. For non-superusers, the drop-down is read-only. If the drop-down is blank, the enterprise ID links to no login group. If the login group links to an enterprise ID, a **Change** link allows superusers to select a different ID.

9. From the **Signal Management Configuration** drop-down list, select a [signal configuration](#) from those published to the login group that you are editing.

The **Signal Review Page** is not available to users unless they are in a login group with an assigned signal configuration and they have the View Signal Management [permission](#).

Note

The same signal configuration can be assigned to multiple login groups.

10. From the **Topic workflow Configuration** drop-down list, select a topic workflow configuration from those published to the login group that you are editing. This will be the topic workflow configuration used on the Topic Management page (if Signal Management is integrated with Topics, the workflow configuration used on the Signal Review page is defined in the Signal Management Configuration). A user can make a topic visible to work teams that are based on login groups to which the topic workflow configuration is assigned.

The **Topic Management page** is not available to users unless they are in a login group with an assigned topic workflow configuration and they have the View Topics permission (the exception is that users with the Manage Topic Workflow Configurations permission can set a user preference as another way to make the Topic Management page accessible).

Note

The same topic workflow configuration can be assigned to multiple login groups.

11. Click **Save**.

Edit a login group

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Manage Users** section, click **Edit Login Groups**.
3. Click **Edit** for a login group.

If you are not a superuser but you have the Administer Users permission, the Login Group Settings page appears for your own login group as soon as you click **Edit Login Groups** on the Settings page.

4. In the **Logo Image** field, enter the name of an image file to appear on the page banner to the right of the Oracle Empirica Signal text (You cannot use a text file.) The image file must exist in the \image subdirectory of the server location to which the application was installed. The application scales any logo image to fit within the space allotted for the header. The aspect ratio is maintained so that the width of the image is also scaled.

By default the **Logo Image** field specifies logo.gif (the Oracle Empirica Signal logo). If you leave the Logo Image field blank, it is reset automatically to the default, and no image appears on the page banner to the right of the Oracle Empirica Signal text.

5. In the **Home Page** field, enter the name of the file that contains the customized page, in .html format, for the Home page. The .html file must exist in the \customhomes subdirectory of the server location to which the application was installed.

By default the Home Page field specifies home.inc. If you leave the Home Page field blank, it is reset automatically to the default.

6. If multi-enterprise support is enabled, an **Argus Mart Enterprise** field appears. Only a superuser can set or change this field. This is a read-only field for non-superusers.
 - a. If the field is blank, select an enterprise ID from the drop-down list.

- b. If the login group has already been saved with an enterprise ID, the field is read-only even for superusers. However, a **Change** link allows superusers to select a different enterprise ID.

✓ **Tip**

Changing the associated Enterprise ID value is discouraged and requires confirmation by the superuser. Previously created objects may yield unexpected results.

7. From the **Signal Management Configuration** drop-down list, select a [signal configuration](#) from those published to the login group that you are editing.

📘 **Note**

The same signal configuration can be assigned to multiple login groups.

8. From the **Topic workflow Configuration** drop-down list, select a topic workflow configuration from those published to the login group that you are editing. A user can make a topic visible to work teams that are based on login groups to which the topic workflow configuration is assigned.

Topic Management (🔒) is not available to users unless they are in a login group with an assigned topic workflow configuration and they have the View Topics permission (The exception is that users with the Manage Topic Workflow Configurations permission can set a user preference as another way to make the **Topics** page accessible).

📘 **Note**

The same topic workflow configuration can be assigned to multiple login groups.

9. Click **Save**.

If you modified settings for an existing login group, then users currently logged in who are associated with the login group are not affected by the changes during their current session. The changes take effect the next time they log in.

Delete a login group

1. Log into the application as a superuser.
2. In the left navigation pane, click the **Settings** icon (⚙️).
3. In the **Manage Users** section, click **Edit Login Groups**.
4. For the login group, click **Delete**

📘 **Note**

Only superusers can delete a login group and all users must be removed first, including users marked as inactive.

Configure the system

- [Select a data configuration](#)
- [Manage configurations](#)
- [Manage signal configurations](#)
- [Manage topic workflow configurations](#)
This section includes information about topic workflow configuration design and management as well as details and tasks for working with fields, field values, topic states, action states, templates, email notifications, and action types.
- [Manage subscription data releases](#)
- [Manage drug profile configurations](#)
- [Manage aliases](#)
- [Transform data](#)

Select a data configuration

A data configuration is a group of variables representing items (database table columns) in the source data. In several places in the Oracle Empirica Signal application, such as when creating a data mining run or query, you must select a data configuration to indicate which source data is used. You can select the data configuration from a list of data configurations to which you have access. If you do not know the name of the data configuration, you can browse a descriptive list of data configurations and select one. When you select a data configuration, it remains selected until you select a different one.

Lists of available configurations typically show only compatible configurations. See [Data configuration and object compatibility](#) for more information.

1. Next to the Configuration field, click **Browse**.

The Select Configuration dialog box appears and provides the following information about each data configuration to which you have access:

Column	Description
ID	Internal identifier of the data configuration.
Name	Name of the data configuration.
Description	Description of the data configuration.
Account	Name of the Oracle account in which the data configuration resides.

See [About tables](#) for information about viewing, printing, or downloading tables or changing the way data displays in the table.

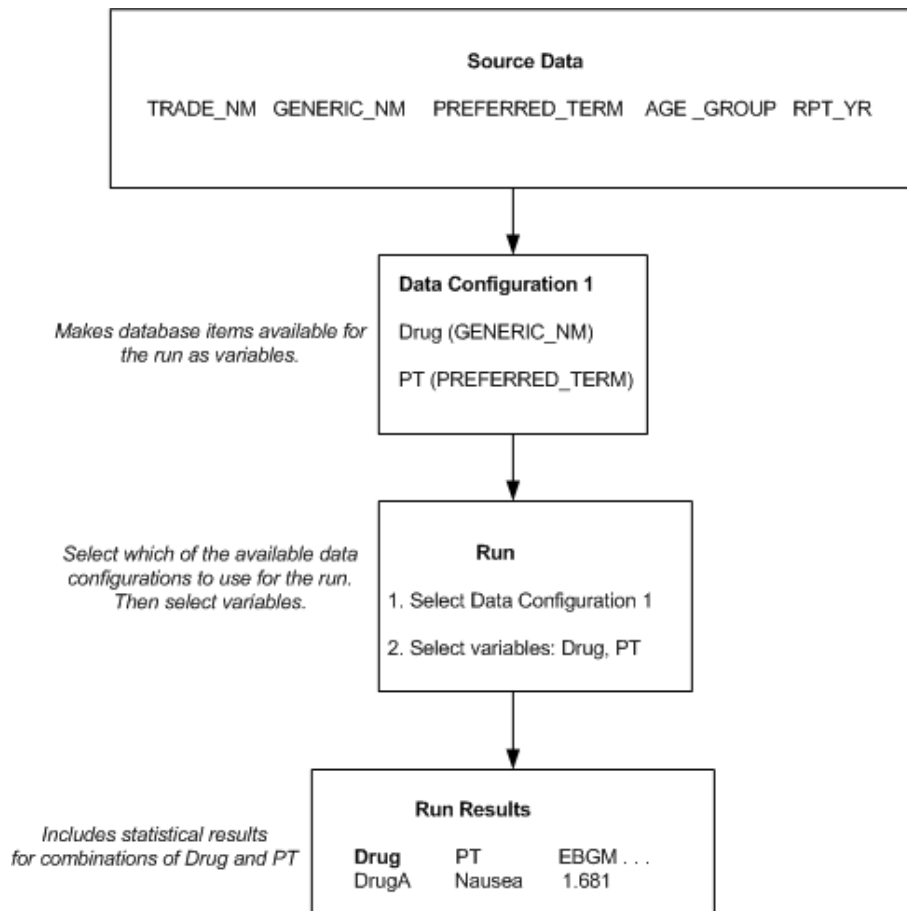
2. Click the row for the data configuration that you want to select.
3. Click **OK**.

Note

Some data configurations are set up to support [timestamped data](#). If you select this type of data configuration during certain activities, you must specify an As of date. See [Specify an As Of date](#).

Example

Suppose that the source data contains all the items shown in the following example. The data configuration specifies GENERIC_NM and PREFERRED_TERM as the items to be available in a data mining run. If the data configuration renames GENERIC_NM and PREFERRED_TERM to Drug and PT, when you create a run, you select Drug and PT as the items to study. The run results show you scores for combinations of Drug and PT values.



Manage configurations

- [About data configurations](#)
- [View existing data configurations](#)
- [Data configuration example](#)
- [Add a data configuration](#)
- [Modify a data configuration](#)

About data configurations

- A data configuration identifies and sets up variables from the [source data](#) for use in the Oracle Empirica Signal application. The configuration determines the drug variables (such as generic name or trade name) and the event variables (such as PT) that are available for such activities as data mining or querying. It also determines:
- The variables that are available for [subsetting](#) or [stratification](#) for a data mining run.
- Whether and how source data is transformed (for example, extraction of the year portion of a date variable) for use in data mining runs.
- The hierarchy of terms, such as MedDRA, that is available for browsing terms.
- Whether data is timestamped.
- The case information that is available when users drill down to a list of cases or case details.

You can create data configurations to exert varying degrees of control over user choices. A configuration can tightly control the variables that are available during activities such as creating data mining runs. A configuration can also make more variables available or leave the choice of variables up to the run creator.

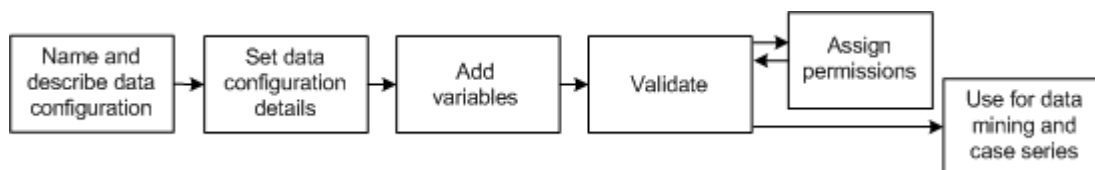
For example, suppose that source data includes both the trade name and generic name for drugs. You can create one data configuration that makes only trade names available, and another data configuration that makes only generic names available. You can also create a single configuration that makes both trade names and generic names available, and then let the run creator determine which one to use.

You work with configurations on the Manage Configurations page. A configuration becomes available for use during activities, such as data mining, only when you have [validated](#) it and granted permissions to it.

You can create a configuration by:

- Importing it.
- Setting it up from scratch.
- Copying and modifying an existing data configuration.

Regardless of how you create the data configuration, you generally perform the following tasks in sequence:



Data configuration tables

During Oracle Empirica Signal installation, a master configuration table for all source databases is created in another Oracle account. The application populates this master configuration table automatically as you add, copy, or import data configurations. When you create a data configuration, an Oracle table, referred to as a data configuration table, is created automatically. This configuration table resides in the same Oracle account as the source data. Multiple data configurations and data configuration tables might exist for an Oracle account.

A superuser can view the data configuration table for a current run and the master data configuration table for the account from the [Data Sources page](#).

View existing data configurations

The Manage Configurations page shows a list of the [data configurations](#) that have been added to any of the source databases. It lists configurations that you created or for which you have the Edit permission. The Is Valid column tells you whether or not a data configuration has been validated.

1. Log in to Oracle Empirica Signal as a user with the **Manage Configurations** permission.
2. In the left navigation pane, click the **Settings** icon (.
3. In the **Configure System** section, click **Manage Configurations**.

The Manage Configurations page provides the following information about each data configuration:

Column	Description
Name	Name of the configuration.
Desc	Description of the configuration.
Database Group	Name of the database group to which the configuration is assigned. Results reviewers can use the database group when finding and selecting a data mining run . The application also uses the database group when determining color changes for case ID links that are visited by users.
Owner	Name of the user who created the configuration.
Account	Name of the Oracle account in which the configuration resides.
Table	Name of the Oracle table representing the configuration.
Drilldown Map	Name of the drilldown map table , which specifies the source of case details that display when a user drills down .
Source Desc	Name of the source description table , which provides information about the source data.
Is Valid	Yes, if the configuration has been validated . No, if the configuration requires validation.
Type	The type of configurations created locally is <i>Local</i> . The type of configurations imported from Subscription Data Releases is <i>Managed</i> . After import, if the Enable multi-enterprise support checkbox was selected, then the imported Argus configurations will be listed on the Manage Configurations page as <i>Type Argus ME</i> .

Data configuration options

- To [add a data configuration](#), click **Add Configuration**.
- To [import data configurations](#), click **Import Configurations**.
- To [validate data configurations](#), click **Validate Configurations**.
- To print, download, or [publish](#) multiple data configurations, click **Select Rows**. You can then check the rows for the configurations on which you want to act. You can also click

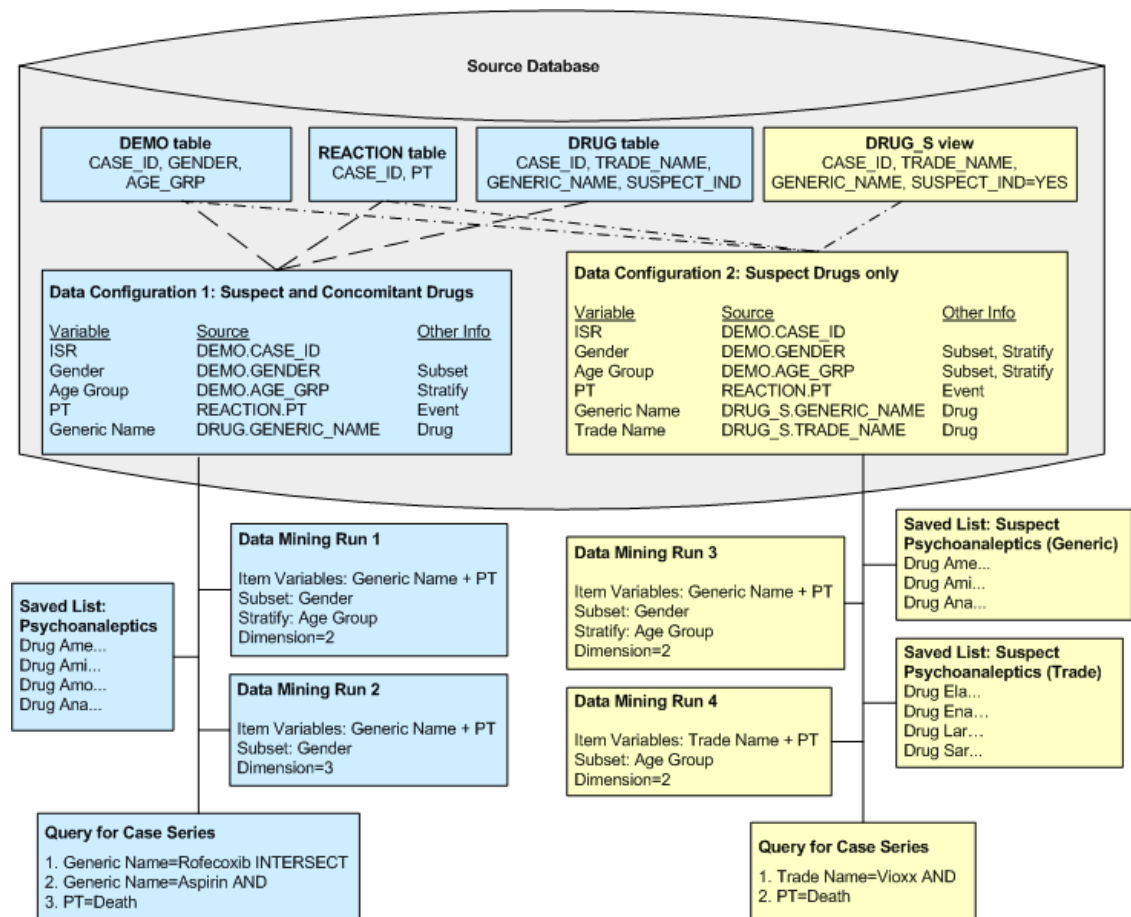
Select **All** to check all rows (or click **Clear All** to uncheck all rows). Then click the action that you want to perform on the selected rows.

Row Action menu options

If you click the **Row Action menu** () for a data configuration, you can click **Edit** to [view or edit the data configuration](#).

Data configuration example

This example shows two data configurations for the same source database. The database includes both tables and views. A view may not include all the data in the table on which it is based. For example, the DRUG table includes all reported drugs for each case, while the DRUG_S view on that table includes only drugs with a suspect indicator value of YES. The data mining runs and queries that are based on these distinct configurations are different, as both the data selected for each configuration, and the way the data can be used in the application, are different. Providing a variety of configurations can be useful for the comparative analyses conducted by Oracle Empirica Signal users.



Add a data configuration

- [Add a data configuration](#)
- [Connect to an Oracle account](#)
- [Specify a drilldown map table](#)
- [Add a drilldown map table](#)

- [Select an Oracle table or column](#)
- [Source description table](#)
- [Narrative text](#)
- [Unique values table](#)
- [Specify hierarchy versions for timestamped data](#)
- [Import a data configuration](#)
- [Validate a data configuration](#)
- [Publish a data configuration](#)

Add a data configuration

When you add a [data configuration](#), you specify information about the data configuration as a whole and you add data configuration variables. Another option is to [copy an existing data configuration](#) and edit it as needed.

The only required attributes of a data configuration are its name, drill-down map, and configuration table name. You might want to create the data configuration with only those attributes, [add variables to the data configuration](#), and then [edit the data configuration](#) to specify additional attributes. Also note that some data configuration attributes, such as permissions to the data configuration, must be specified during editing (not during creation).

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click **Add Configuration**.
4. If you have not already done so during your current Oracle Empirica Signal session, you must [connect to the Oracle account](#) that will contain the configuration.
 - a. From the list of accounts, click the account in which you want to add the new configuration.
 - b. In the **Oracle account** field, leave the existing value or enter a different value, and then click **OK**.

When the system has connected, the Add Configuration page appears.

5. In the **Name** and **Description** fields, enter a unique name and a description for the configuration.

During Oracle Empirica Signal activities, users select a configuration to use. The name and description are important and should provide information about the source data. For example, an AERS configuration might be named "2012Q4: AERS+SRS (S+C)", indicating the year and quarter, the fact that SRS data is included, and the fact that both suspect (S) and concomitant (C) drugs are included.

Note

If a data configuration was deleted by reference only, it is still in the database and you cannot create anew configuration with the same name.

6. Next to the **Drilldown Map** field, click **Select/Edit Table** to [specify a drill-down map table](#). Select the table from the **Select Drilldown Table** drop-down list and click **OK**. If you do not specify a drilldown map table, the configuration will not pass validation.

Note

If the source data is timestamped, then for each table referenced by the drilldown map table, there must be at least one variable with the same name.

7. Next to the **Source Description Table** field, click **Select Table** to [select a table](#) that has been set up as a [source description table](#) in the Oracle account to which you are connected. For [timestamped data](#), you should always specify a source description table. If the data is not timestamped, the source description table is optional. In the **Select Table** dialog box, click a table and click **Save**.
8. To make the configuration unavailable for data mining runs, check **Hide from Data Mining**. The configuration can then be used for other activities, such as querying and reporting, but not for data mining. For example, you should not use for data mining a configuration pointing to source data from which duplicates have not been removed.
9. To identify the configuration as including cases with suspect and concomitant drugs, check **Database includes Concomitant Drugs**. If the configuration includes suspect drugs only, clear this check box.
10. If the source data includes [timestamped data](#), allowing for the recreation of data as of a particular point in time, check **Database is Timestamped**.
11. Choose one of the following:
 - If you have not checked **Database is Timestamped**, provide the name of a Drug Hierarchy Account, an Event Hierarchy Account, or both by selecting them from the drop-down lists.
 - If you have checked **Database is Timestamped**, click **Select/Edit Table** to define hierarchy accounts for specified time periods.

If you want to associate drug variables or event variables in the configuration with a dictionary that defines a hierarchy of terms, see [Drug and event hierarchies](#).

- a. Select the drug hierarchy value from the **Drug Hierarchy Account** field.
By default, the value selected is None.
- b. Select the event hierarchy value from the **Event Hierarchy Account** field.
By default, the value selected is None.
12. In the **Configuration Table Name** field, enter the unique name of the table to hold the new configuration in the Oracle account to which you are connected. The table name cannot start with a number, and cannot be edited.
13. Click **Save**.
14. Prior to validating the configuration in the [Modify Configuration page](#), you must add variables. To add configuration variables to the configuration, click **Add New Variable**.

Connect to an Oracle account

When you add or import data or topic workflow configurations, the Oracle Empirica Signal application must connect to an Oracle account.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click **Add Configuration**.
4. Perform one of the following:

- To add a configuration, click the name of an existing Oracle account. For data configurations, click **Choose a Different Account** and provide the name of an Oracle account.
When the system has connected, the [Modify Configuration page](#) appears.
- To import a configuration, click the name of an Oracle account. For data configurations, click **Import Configurations from a Different Account** and provide the name of an Oracle account.

Specify a drilldown map table

During many activities, such as viewing data mining results, users can click case ID links to [drill down to a list of cases](#) (first-level drilldown), and can then drill down further to [view case details](#) (second-level drilldown). The type of data presented during drilldown is from the source database tables, and is determined by the drilldown map table associated with the data configuration.

Drilldown information comes from the [source data](#). Users do not see values for a variable that includes a [data transformation](#) defined in the configuration, or any values that are missing from the source data.

Note

Drilling down to view case details is possible only if the appropriate [site option](#) has been set and the user has the appropriate permission.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click the **Row Action menu** () for a configuration, and then click **Edit**.
4. In the right-most column of the configuration, click **Edit**.
5. Next to the **Drilldown Map** field, click **Select/Edit Table**.
6. From the **Select Drilldown table** drop-down list, select a drilldown map table and click **OK**. Available drilldown map tables are those in the Oracle account to which you are connected.

Add a drilldown map table

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click the **Row Action menu** () for a configuration, and then click **Edit**.
4. In the right-most column of the configuration, click **Edit**.
5. Next to the **Drilldown Map** field, click **Select/Edit Table**.
6. Click **Create New Table**.
7. In the **Enter name of new drilldown table** field, type a name for the new table. Table names cannot include:
 - Spaces

- ?, \, or "

It is recommended that you use a name that distinguishes the table from other drilldown map tables and indicates the table's purpose, such as DRILLDOWN_MAP.

8. Click **Create Table**.

The new table appears as the selected drilldown table. The first column of the drilldown map table shows the information type.

9. Edit the drilldown map table as necessary.

Note

The same drilldown map table may be used by more than one data configuration in the Oracle account. Before editing a drilldown map table, make sure you want the changes to apply to all data configurations that refer to the drilldown map table.

- a. Select the **Type** you want to edit and click **Edit**. (If you want to clear values for the type, click **Clear**.)

- b. In the **Table** field, click **Select** to open the **Select Table and Column** dialog box and select an available table and column for the drilldown table to reference.

The application populates the Table field and Report ID Column field with your selection. The column should be compatible with the column for case IDs in the source data used in data mining.

- c. In the **Section Title** field, type a label for the section of the drilldown map table.
The label appears on the Case Details page as the section heading.

- d. In the **Worksheet label** field, type a label for the application to apply to the table worksheet.

This label appears on the worksheet tabs when Case Details are downloaded to Excel.

- e. In the **Display Columns** section, select and label each column to include.

- f. From the first **Column** drop-down list, select a variable.

- g. In the corresponding **Label** column, type a label (column heading) to apply to the variable in the drilldown table.

In the drilldown information, variables appear in the order in which you specify them.

- h. If you want the drilldown information to show only distinct values for the variables, check **Distinct**.

- i. Click **Save**.

10. When you have finished specifying all types of information that you need, click **OK**.

The Select/Edit Drilldown Table dialog box appears with the Table, Report ID Field, and Display Columns columns filled in.

Drilldown information types

The following table lists the types of information that you can include in the drilldown map table and the corresponding label in the drilldown display. The LIST type determines contents of the Cases page (first-level drilldown), and its first variable must represent the case ID. All other types determine contents of the Case Details page (second-level drilldown). Typically, the CASE, DRUG, and EVENT types, at a minimum, are included on the Case Details page.

Type	Description
CASE	Case Information
DRUG	Reported Drugs/Vaccines
EVENT	Reported Events/Symptoms
OUTCOME	Reported Outcomes
SOURCE	Reported Sources
BATCH_LOT	Batches/Lots
DEVICE	Devices
DEVICE_CODE_DEV	Facility Device Codes
DEVICE_CODE_PAT	Facility Patient Codes
DEVICE_MANU_CONCLUDE	Manufacturer Conclusion Codes
DEVICE_MANU_METHOD	Manufacturer Method Codes
DEVICE_MANU_RESULT	Manufacturer Result Codes
DIAGNOSTIC	Diagnostic Procedures Performed
DRUG_HISTORY	Patient Drug History
DRUG_IND	Indications
DRUG_REACT	Drug-Reaction Information
LINKED_CASES	Linked Cases
LITERATURE	Literature References
MEDICAL_CONDITION	Medical Conditions
MEDICAL_HISTORY	Medical History
PATIENT_REGISTRY	Patient Registry Information
PREGNANCY	Pregnancy Information
PREGNANCY_OUTCOME	Pregnancy Outcome
REPORTER	Reporter Information
CAUSE_OF_DEATH	Cause of Death
PARENT	Parent
PARENT_DRUG_HISTORY	Parent Drug History
PARENT_MEDICAL_HISTORY	Parent Medical History
AES_ADDL_HISTORY	Chronological History
AES_ADDL_INFO	Additional Information
AES_CEV_DRUG	Drug-event Information
AES_CODES_DEV	Device Codes
AES_DEVICE_CODE	Device Problems
AES_DISEASE	Diseases
AES_DOSE	Dosing Regimens
AES_EVAL	Case Evaluation Information
AES_EXPOSED_DEVICE	Devices
AES_LAB	Associated Lab Results
AES_REPORTER	Reporter Information

Type	Description
NARRATIVE	Narrative For example, medical history or laboratory data for the case. See Narrative text for details about setting up narrative text.)

Select an Oracle table or column

1. If the activity you are performing requires you to specify a table, click the table name, and then click **Save**.
2. If you need to select a table and column, click a table name.
The Available Columns list shows columns in that table.
3. Click a column name, and then click **Save**.

Source description table

A source description table (or view) describes the [source data](#) that is used in the Oracle Empirica Signal application. Information from this table appears when users do the following:

- View case details.
- View a results table on the Data Mining Results page.
- Display notes when viewing source tables from the [Data Sources page](#).

Additionally, this table defines information needed for timestamped data. You must specify a source description table for a [data configuration](#) that supports timestamped data.

A source description table is created and populated outside of the Oracle Empirica Signal application using standard Oracle tools or any application that enables working with Oracle tables. The table must be in the Oracle account containing the source database tables. A data configuration in the Oracle Empirica Signal application then refers to the table. An existing data configuration can be edited to add a source description table to it.

Content of the source description table

For the table name, it is recommended that the name distinguishes the table from other source description tables and indicates the table's purpose. A source description table must include one row with the following columns. All columns must be included, even if they are not used.

Column	Data Type	Description
ID	NUMBER(1)	Unique identifier of the row. (There will be only one row.)
DESCRIPTION	VARCHAR2(30)	Description of the source data.
LOADDATE	DATE	Date and time when the source data was loaded.
SOURCE	VARCHAR2(30)	Source of the safety data.
DRUGDICTIONARY	VARCHAR2(30)	Reserved for future use.
DRUGDICTIONARYVER	VARCHAR2(30)	Reserved for future use.
EVENTDICTIONARY	VARCHAR2(30)	Reserved for future use.
EVENTDICTIONARYVER	VARCHAR2(30)	Reserved for future use.

Column	Data Type	Description
ASOFDATE	DATE	Supports use of timestamped data.
EARLIEST_ASOFDATE	DATE	Supports use of timestamped data.

For example, suppose the DESCRIPTION is TEST_AERS_2019, the LOADDATE is 02-Jan-2020, and the SOURCE is NTIS. The description of the source database appears in the application as:

Source Data: TEST_AERS_2019 from NTIS on 02-Jan-2020

You can view the source description table on the [Data Sources page](#).

Timestamped data

To support [timestamped data](#), the application must know the range of dates that are valid for users to enter when prompted for an As Of date. The following two columns of the source description table define the range:

- ASOFDATE—Latest date for which there is consistent source data.
- EARLIEST_ASOFDATE—Earliest date for which there is consistent source data.

The values of these columns are determined during the data preparation process.

On Oracle Empirica Signal pages where users specify an As Of date, the default date that appears is the ASOFDATE from the source description table. Users can change the displayed date to another date that is earlier than or equal to the ASOFDATE and later than or equal to the EARLIEST_ASOFDATE.

Narrative text

If the [source data](#) contains narrative text, you can include the narrative on the [Case Details page](#). There are several ways that narrative text may be set up in the source data.

Assume that there are three categories of narrative text (CAT_A, CAT_B, and CAT_C) and two report IDs (10, 11). The simplest way that narrative text may be stored is for each category of narrative text to have its own column in the source database table, with one row per report ID. This approach is used in the following example:

REPORT_ID	CAT_A	CAT_B	CAT_C
10	This is category A narrative text for case 10.	This is category B narrative text for case 10.	This is category C narrative text for case 10.
11	This is category A narrative text for case 11.	This is category B narrative text for case 11.	This is category C narrative text for case 11.

For the NARRATIVE type in the [drilldown map table](#), you would specify CAT_A, CAT_B, and CAT_C as display columns.

Concatenation of narrative text

If the narrative text for a column is too long to fit into a single column of data type VARCHAR2, it may be split up between columns that have the same root name and a two-digit sequence number.

REPORT_ID	CAT_A01	CAT_A02	CAT_A03	CAT_B	CAT_C
10	This is category A narrative text for case 10.	It is too long to fit into one column of the database table.	So it is split between three columns.	This is category B narrative text for case 10.	This is category C narrative text for case 10.
11	This is category A narrative text for case 11.	-	-	This is category B narrative text for case 11.	This is category C narrative text for case 11.

For the NARRATIVE type in the drilldown map table, you would specify CAT_A, CAT_B, and CAT_C as display columns. Oracle Empirica Signal would concatenate the values in the CAT_A01, CAT_A02, and CAT_A03 columns because their root name is the same (CAT_A). Values are concatenated in the order of the columns' two-digit sequence numbers.

Narrative text spanning multiple rows

In the source data, there may be a column that stores the category and another column that stores the narrative text. If there are multiple rows per report ID, you must use the option "NARRATIVE spans multiple rows" in the drilldown map table for the NARRATIVE type.

REPORT_ID	NARRATIVE_CATEGORY	NARRATIVE_TEXT
10	CAT_A	This is category A narrative text for case 10.
10	CAT_B	This is category B narrative text for case 10.
10	CAT_C	This is category C narrative text for case 10.
11	CAT_A	This is category A narrative text for case 11.
11	CAT_B	This is category B narrative text for case 11.
11	CAT_C	This is category C narrative text for case 11.

For narrative data stored this way, the Oracle data type of the column storing the narrative text is typically CLOB (character large object), so there is no restriction on narrative length. For the NARRATIVE type in the drilldown map table, you would specify NARRATIVE_CATEGORY and NARRATIVE_TEXT as display columns and you would check **NARRATIVE spans multiple rows**.

Unique values table

A unique values table (UVT) contains all unique values that exist in the [source data](#) for a specific configuration variable. When displaying all values for a variable, the Oracle Empirica Signal application references the unique values table for that variable. (The exception to this is on the Select Criteria page for results of a data mining run, where users select from a list of values in the data mining results.)

When you define [data configuration variables](#), if a variable's selection type is Distinct Value List, Select from Drug Hierarchy, or Select from Event Hierarchy, you can also specify a unique values table. If you do not specify a UVT for a variable, the application creates the corresponding UVT automatically when you [validate the data configuration](#). If the source data is updated, as in a timestamped data configuration, you must also update the unique values tables or delete them for the individual variables so that they will be re-created (and updated) automatically during validation.

A unique values table name starts with UVT by default. The table must have an ITEM_VALUE column, which contains one row for each unique value. The column type of the ITEM_VALUE column must match the column type of the corresponding column in the source database table.

If text values for a variable are [mapped](#), the unique values table contains source data values, not the mapped values.

Note

In a timestamped database there are no start dates and end dates associated with the unique values table, so all unique values that ever existed are in the unique values tables.

A superuser can view the unique values tables on the [Data Sources page](#).

Specify hierarchy versions for timestamped data

Note

In the Cloud, Oracle manages the MedDRA versions for connected Oracle Argus Mart configurations. Submit a service request to update MedDRA in Oracle Argus Cloud Service and the associated Oracle Empirica Signal configurations simultaneously.

If a data configuration supports [timestamped data](#), you must specify a [hierarchy](#) version for each time period in the source data. A time period is a range of dates during which only one hierarchy version was used to code the source data.

For example, suppose that the source data includes the following rows:

Case ID	Start	Stop
100	01-01-2004	06-01-2004
200	06-01-2004	01-01-2005
300	01-01-2005	NA

Additionally suppose that different versions of MedDRA were used to code the source data:

- MedDRA Version 6.1 was used until June 1, 2004.
- MedDRA Version 7.0 was used between June 1, 2004 and January 1, 2005.
- MedDRA Version 7.1 was used on January 1, 2005.

In Oracle Empirica Signal, you must specify the version of MedDRA used to code the source data for each time period as described below.

1. In the left navigation pane, click the **Settings** icon (.

- 2. In the **Configure System** section, click **Manage Configurations**.
- 3. Click the **Row Action** menu () for the configuration, and select **Edit**.
- 4. In the top table, click **Edit** in the far right column for the data configuration.
- 5. On the [Edit Configuration Details page](#), in the **Event Hierarchy Version Table** field, click **Select/Edit Table**.
- 6. To specify only one hierarchy version for all of the source data, type the Oracle database account name for the hierarchy version in the first row of the **Hierarchy Account** column, for example:

Figure 10-1 Define effective dates for the Event Hierarchy Accounts

	Date	Hierarchy Account
ALL DATES		MEDDRA2500_3

- 7. To specify different hierarchy versions:
 - a. In the first row of the **Date** column, type the last date of the earliest time period in the source data.
The date must be in the mm/dd/yyyy format

 Note

Each date includes a time stamp of 12:00:00 a.m. For example, if you specify that MedDRA Version 6.1 was used until ($\leq$) 06/01/2004 and MedDRA 7.0 was used thereafter, then MedDRA 7.0 is applied to source data coded at 12:00:01 a.m. on June 1, 2004.

- b. In the first row of the **Hierarchy Account** column, type the Oracle database account name for the hierarchy version.
- c. Fill in one row for each time period in the source data, for example:

[Help](#)

Define Effective Dates for the Event Hierarchy Accounts

	Date	Hierarchy Account
DATE $\leq$	01/01/2005	MEDDRA70
01/01/2005 < DATE $\leq$	03/01/2017	MEDDRA71
03/01/2017 < DATE		MEDDRA200

☐ Add additional empty rows upon saving

If you need additional rows, you can select **Add additional empty rows upon saving** and click **Save**.

For the last time period, type only the Oracle database account name for the hierarchy version.

8. Click **Save**.

Import a data configuration

When you import [data configurations](#) from an Oracle account, you register them for use with the Oracle Empirica Signal application. When you import, all of the data configurations in the specified Oracle account are imported or re-imported.

If a data configuration has been deleted permanently, it cannot be re-imported. If it has had references to it removed, but has not been deleted permanently, it can be re-imported.

A data configuration cannot be imported or re-imported if there is another data configuration with the same name in another Oracle account.

In most cases, data configurations are created within the Oracle Empirica Signal application. If created outside of the application, a data configuration must have the same table structure as if it was defined within the application.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click **Import Configurations**.
4. Select a configuration from the list, or select a different account by clicking **Import Configurations from a Different Account**.
 - a. Identify the Oracle account.
 - b. Choose whether to add the configurations to an existing database group or to a new database group.
 - c. Click **OK**.
5. Once imported, you can perform the following actions on the data configuration:
 - [Edit the data configurations](#) that you imported, as necessary. In some cases, changes to the Oracle tables that are referenced by the configuration (such as the [drilldown map table](#)) might be required. Existing data configurations that are re-imported retain their permissions, so you do not need to re-assign the permissions unless you want to change them.
 - [Validate the data configurations](#) that you imported. When a configuration is imported or re-imported, it must be revalidated before it can be used to create new runs, queries, case series, or saved lists. Existing runs, queries, case series, and saved lists based on a re-imported configuration might not work correctly until the configuration is revalidated.
 - If you have modified a data configuration, test it by selecting it for tasks in the application. You have not yet assigned permissions to the data configuration, but you can use it because you are the data configuration owner.
 - Validate the data configuration again if you made changes to it. Even if the only change was to assign permissions, you must validate the data configuration again.

Validate a data configuration

Only data configurations that have passed a validation process are available for use during Oracle Empirica Signal activities. You must validate or re-validate a data configuration in the following situations:

- When it has been newly created.
- When it has been modified in any way, including changes to permissions.
- When it has been newly imported.

The validation process might generate warnings and errors. If warnings (but no errors) are generated, you can ignore them so that the data configuration passes validation. If errors are generated, you must correct them before the data configuration passes validation.

You can either validate a single data configuration, after modifying it, or validate multiple data configurations at the same time. For example, if you import multiple configurations, you might want to validate them all at once.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. To validate a single data configuration that you have just modified:
 - a. Click the **Row Action menu** () for a configuration, and then click **Edit**.
 - b. Click **Validate Now**.
4. To validate multiple data configurations at the same time, on the [Manage Configurations page](#), click **Validate Configurations**. For example, if you [import](#) multiple data configurations, you can validate them all at once. When you validate multiple data configurations, the validation process is a background job that continues to run even if you exit the application.
 - a. Check the data configurations that you want to validate. (You can also check **Check All** or **Check None**.)
 - b. Click **Validate**.
5. When validation is complete, click **Continue**.
6. If necessary, [edit the configuration](#) and revalidate it.

Validation process

During validation, Oracle Empirica Signal does the following:

- **Shows errors and warnings, if any**—If there are errors, you cannot save the data configuration. Warning messages are prefaced by Warning. To ignore warning messages, check **Ignore Warnings**.
- **Gathers statistics for tables that contain actual case data**—Statistics are generated on the underlying data. Oracle uses the statistics to optimize the performance of SQL commands, which the application uses for such tasks as displaying results. Statistics are automatically generated during Oracle Empirica Signal installation. If views (rather than tables) are referenced, statistics are generated on the underlying table(s).
- **Creates a [unique values table](#) for any variable of the selection type Distinct Value List, Select from Drug Hierarchy, or Select from Event Hierarchy, but does not have an associated unique values table**—Although you cannot save a new data configuration in this state, it is possible for imported data configurations to be in this state.

- **Creates Oracle column indexes for columns referenced by any variable, if they do not already exist**—If a variable references a column in a view, no index is added.

Situations that generate error or warning messages

Situations that generate an error message or warning message include the following:

- There are no variables defined for the configuration.
- There is not a variable of the type **Report ID** for each source database table referenced by the data configuration.
- The configuration has more than one variable of the type **External Report ID**.
- There are leading or trailing white spaces in the source data for a variable. Manually entered values that do not also include the leading or trailing spaces do not match the source data. For example, when entering data values in the Query Wizard or specifying drugs or events as selection criteria for run results.
- **Database is timestamped** is checked for the data configuration, but each source database table referenced by the data configuration does not have a variable of the type **Valid Start Date** and a variable of the type **Valid End Date**. Note that the source database table must contain columns (of the Oracle data type **DATE**) representing start and end dates for the data configuration to reference them.
- There is no drilldown map table defined for the data configuration.
- The drilldown map table does not include a row for the LIST, CASE, DRUG, or EVENT sections.
- The data configuration includes a variable of the selection type **Select from Event Hierarchy** or **Select from Drug Hierarchy**, but no event or drug hierarchy account is specified for the configuration.
- The data configuration includes a variable of the selection type **Select from Event Hierarchy** or **Select from Drug Hierarchy**, but the variable type is not **Event** or **Drug**, or no hierarchy level is set for the variable.
- **Database is timestamped** is checked for the data configuration, but there is not at least one variable for each source database table referenced by the drilldown map table.

Publish a data configuration

Users with permission to manage Signal Configurations.

Users with Manage Signal Configuration permission will have access to configurations published to their login group or published individually to them.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the configuration's **Row Action** menu (

⋮

), then click **Publish**.

The Publish Signal Configuration window appears. Publication status is listed under Publication Level.

 Tip

If no publication status appears, the object has been published to all Login Groups by a superuser and only the superuser can change this status. If the signal configuration is marked as Private, then the signal configuration has been published to you individually or you are the owner.

4. To publish the configuration to your login group click **Publish**.
5. To unpublish the configuration, click **Make Private**.
6. Close the Publish Signal Configuration window to return to the Manage Signal Configurations page.
7. Perform one of the following:
 - To grant permissions for the configuration to your [login group](#), in the **Group Permissions** section next to the **Login Group**, click **No Access**, **Read**, or **Edit**.
 - To grant permissions to individual users in your login group, in the **Individual Permissions** section next to the **user**, click **No Access**, **Read**, or **Edit**.
 - A user's permissions for a configuration are determined by settings for both the individual user and the user's login group. For example, if the individual user has Read access, but that user's login group has Edit access, the user has Edit access.
 - Users with Read permission for a configuration can select the configuration for tasks such as creating a run or case series. Users with Edit permission can edit, copy, and delete the configuration, as well as use for tasks such as creating a run or case series.
8. Click **Save**.

Modify a data configuration

- [View data configuration details](#)
- [Edit a data configuration](#)
- [View data configuration variables](#)
- [Add or edit a data configuration variable](#)
- [Add a mapped variable to the configuration](#)
- [Copy a data configuration](#)
- [Delete a data configuration](#)
- [Data configuration and variables information](#)

View data configuration details

When you view a data configuration, information about the data configuration as a whole and about variables in the data configuration appears. You can edit the data configuration or the data configuration variables.

1. In the left navigation pane, click the **Settings** icon ()
2. In the **Configure System** section, click **Manage Configurations**.

3. Click the **Row Action menu** () for the configuration, and then click **Edit**.

The Modify Configuration page appears, displaying information about the data configuration as a whole and information about configuration variables.

Data configuration options

- To [add a data configuration variable](#), click **Add New Variable**. For more information, see [Add a data configuration](#).
- To copy the data configuration, click **Copy this Configuration**. For more information, see [Copy a data configuration](#).
- To delete the data configuration, click **Delete this Configuration**. For more information, see [Delete a data configuration](#).
- To edit the data configuration, click **Edit** in the right-most column of data configuration information. For more information, see [Edit a data configuration](#).

Row Action menu options

- To [edit a data configuration variable](#), click  for the variable, and then click **Edit**. For more information, see [Add or edit a data configuration variable](#).
- To delete a data configuration variable, click  for the variable, and then click **Delete**. Click **OK** for the message confirming the deletion.

Note

You cannot delete a data configuration variable if it is referenced by existing data mining runs.

Edit a data configuration

When editing a data configuration, you can modify the data configuration as a whole, or add, modify, or delete variables in the data configuration. Certain information about data configurations can be specified only during editing and not when creating the data configuration. This information includes fields related to third-party links from case details, database groups, and permissions.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Configurations**.
3. Click the **Row Action menu** () for the configuration, and then click **Edit**.
4. To modify the data configuration as a whole, next to the data configuration name in the top portion of the page, click **Edit**.
5. Modify fields as necessary. For descriptions of fields, except those related to third-party links, database group, and permissions, see [Add a data configuration](#). The type of all configurations will be *Local* after configuration details have been edited and saved.

Note

If you modify the name of an existing data configuration, all references to that name by existing runs, case series, and saved lists are updated automatically.

6. Optionally, select the drug hierarchy value from the **Drug Hierarchy Account** field.
See [drug and event hierarchies](#) for more information.
7. Optionally, select the event hierarchy value from the **Event Hierarchy Account** field.
8. You can specify a link to appear on the Case Details page. For example, you can provide a link to a third-party application page providing further information about the case.
 - a. In the **Third Party Link Text** field, enter the name of the link to appear on the Case Details page. If you do not specify a name, the link name is External Link.
 - b. In the **Third Party Link URL** field, enter the URL for the third-party application page. You can use the following substitution variables:
 - **\$REPORT_ID\$**—Will be replaced by the value of the variable specified as the Report ID Col for the LIST section of the drilldown map table for the configuration.
 - **\$EXTERNAL_REPORT_ID\$**—Will be replaced by the value of the external report ID for the case. If you use this substitution variable, the configuration must include a variable of the type, External Report ID.

For example: [https://Signal/caseinfo.asp?caseid=\\$REPORT_ID\\$](https://Signal/caseinfo.asp?caseid=$REPORT_ID$)

9. To assign the configuration to a **Database Group**, you can select an existing group from the drop-down list, or select **Add to new group** and enter a name for the new group. Results reviewers can use this information when [finding and selecting a data mining run](#). The application also uses the database group when determining color changes for [case ID links](#) that are visited by users.
10. Assign group permissions.
 - a. To grant permissions to your [login group](#), in the **Group Permissions**, Login Group section, next to the **Login Group**, click **Read** or **Edit**.
 - b. To grant permissions to individual users in your login group, in the **Individual Permissions**, User section, next to the **username**, click **Read** or **Edit**.

Users with Read permission for a configuration can select the data configuration for tasks such as creating a run or case series. Users with Edit permission can edit, copy, and delete the data configuration, as well as use it for tasks such as creating a run or case series.

A user's permissions for a data configuration are determined by settings for both the individual user and the user's login group. For example, if the individual user has Read access but that user's login group has Edit access, the user has Edit access.
11. Click **Save**.
12. Optionally, [add or edit data configuration variables](#). For more information, see [Add or edit a data configuration variable](#).

Note

Editing configuration variables will change the configuration type.

13. [Validate the data configuration](#). Even if the only change was to assign permissions, you must validate the data configuration again.

Certain attributes of a data configuration or its variables require you to log out of the application and log back in before they take effect. For this reason, Oracle suggests that you always log out and back in if you want to see the effect of your changes.

View data configuration variables

For certain activities, you must select a data configuration. If you are not certain which data configuration to use, viewing the variables in the data configurations can help you determine which data configuration to use.

On the [Select Configuration](#) dialog box, click the **Row Action menu** () for a data configuration, and then click **Show Variables**.

The Configuration Variables page provides the following information about each variable in the data configuration:

Column	Description
Variable	Name of the variable.
Description	Description of the variable.
Variable Type	Displays the variable type of the variable. For descriptions of the variable types, see Add or edit a data configuration variable .
Data Transform	Type of data transformation, if any, associated with the variable. See About data transformations .

Add or edit a data configuration variable

When creating or editing a data configuration, you can add or modify configuration variables as described below. You can also delete data configuration variables by clicking the **Row Action**

menu () for the variable on the Modify Configuration page and then clicking **Delete**.

If you edit or delete data configuration variables after the data configuration has been used to create a data mining run or a query-based case series, you might not be able to view results for that run or that case series properly. For example, if you use a variable as an item variable in a data mining run, then change its variable type so that it is no longer an item variable, Oracle Empirica Signal will not be able to display the run results properly.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Configurations**.
3. Click the **Row Action menu** () for the data configuration, then click **Edit**.
4. Click the **Add New Variable** link, or click the **Row Action menu** () for a configuration variable, and then click **Edit**.
5. In the **Name** field, enter the name of the variable.

Variable names display throughout the application, including when users select criteria for viewing data mining results, defining queries, or creating report definitions. For example, a column might be named SYMPTOM in the Oracle table, but renamed to appear as Event in the application.

Note

Commas and vertical bars are not permitted in the Name field.

6. In the **Description** field, type a description of the variable.

7. Next to the **Table** field, click **Select Table/Column**.

A data configuration can refer to one or more tables in a database, and one or more columns in each table. For example, you might create a data configuration that gets data from a demographics table, a drugs table, and an events table. However, if you already created an Oracle view that combines data from those three tables, you can refer to that view instead of to the three tables.

- a. From the **Available Columns** list, [select the column](#) and click **Save**. You can select any table in the Oracle account to which you are connected, and any column in that table.

The Edit Variable page appears with the column you selected displayed in the Column field.

- b. In the **Prefix** field, enter a prefix.

A prefix is required only if the variable type is Event, Drug, or Generalized Item. The alphabetical order of prefixes determines the column names for the variables in the [complete results table](#). For example, if the prefix for the drug variable is D and the prefix for the event variable is E, the drug variable is in the ITEM1 column and the event variable is in the ITEM2 column.

Note

Multiple variables with the same prefix cannot be used as item variables in the same data mining run.

8. From the **Variable Type** drop-down list, select a variable type.

To determine which variable type is appropriate, you might want to know the Oracle data type of the column. Select Table/Column next to the Table field. In the available Columns list, the data type appears in parentheses after the column name.

The variable type can be one of the following:

Variable Type	Meaning
Other	Identifies a variable that is not available as an item variable in data mining runs. If you want the variable to be available for subsetting or stratification of data mining runs, check Use as Subset Variable or Use as Stratification Variable . The column must have an Oracle data type of CHAR, VARCHAR2, NUMBER, FLOAT, INTEGER, DECIMAL, or SMALLINT.
Age	Identifies the patient age. The column must have an Oracle data type of CHAR, VARCHAR2, NUMBER, INTEGER, or SMALLINT. The selection type for this type of variable must be either Distinct Value List or Continuous.

Variable Type	Meaning
Drug	Identifies the drug or vaccine. All variables of this type are available as item variables in data mining runs. The column must have an Oracle data type of CHAR or VARCHAR2. A prefix must be specified for this type of variable, and its selection type must be either Distinct Value List or Select from Drug Hierarchy.
Event	Identifies the event or symptom. All variables of this type are available as item variables in data mining runs. The column must have an Oracle data type of CHAR or VARCHAR2. A prefix must be specified for this type of variable, and its selection type must be either Distinct Value List or Select from Event Hierarchy.
External Report ID	For use when you want to include a link to an external (third-party) application from case details. (To do so, you specify an external application URL on the Edit Configuration Details page.) To use this feature, there must be a mapping of Oracle Empirica Signal case IDs to the IDs used by the external application. A suggested way to provide the mapping is to include in the demographics table an additional column, such as EXTERNAL_ID, to contain the external ID associated with each case ID in the demographics table. In the data configuration, you must include a variable for that column and assign to it the variable type External Report ID. There can be only one variable of the type External Report ID in the data configuration. If the case IDs used by the external application are the same as the Oracle Empirica Signal case IDs, an external report ID is not needed to link to the external application.
Gender	Identifies the patient gender. The column must have an Oracle data type of CHAR or VARCHAR2. The selection type for this type of variable must be either Distinct Value List or Free Text.
Generalized Item	Identifies variables other than drug or event that are available as item variables in data mining runs. For example, if the Gender variable's type is Generalized Item, users can perform data mining for combinations for Drug, Event, and Gender values. The column must have an Oracle data type of CHAR or VARCHAR2. A prefix must be specified for this type of variable, and its selection type must be Distinct Value List.

Variable Type	Meaning
Report ID	Identifies the case ID (report ID or ISR). The column must have an Oracle data type of CHAR or VARCHAR2. You must include a Report ID variable for each source database table referenced by a configuration variable. As a result, the configuration might have several Report ID variables. The selection type for a Report ID variable must be Distinct Value List, and the variable cannot be identified as a subset variable or stratification variable. Note In the Query Wizard, this type of variable allows entry of a string of report IDs separated by commas.
Valid Start Date, Valid End Date	Applies only if the data configuration supports timestamped data (that is, Database is Timestamped is checked for the data configuration). Identifies the column in the source data that contains a start date or end date for each record. You must include a Valid Start Date variable and a Valid End Date variable for each source database table referenced by a configuration variable. As a result, a data configuration might have several start and end date variables. The selection type for this type of variable must be Continuous.
Miscellaneous	If the variable type is miscellaneous, you must also specify a subtype of : • Case ID: Use when annotating a case, if it's different from the Report ID. • Case Initial Period: Period or date the case was first entered. • Case Update Period: Period or date the last significant update of the case was performed. Note This type of variable must be set to use the Versioned Case Series feature.

Note

If the variable type is Drug, you must also specify a variable subtype of Generic, Ingredient, or Trade. Each subtype can be used for only one data configuration variable. The subtype makes the variable's values available for selection on the Drug Profile page as a generic name, an ingredient, or a trade name.

9. If you want the variable to be available for [subsetting](#) data mining runs, check **Use as subset variable**. Typically, the Variable Type of a subset variable is Other. You can define multiple variables in a data configuration as subset variables, though only one subset variable can be selected for a given data mining run.
10. If you want the variable to be available for [stratification](#) of a data mining run, check **Use as stratification variable**. Typically, the variable type of a stratification variable is Other. Although you can define a variable with a variable type of Drug, Event, or Generalized Item as a stratification variable, you cannot use the same variable as both an item variable and a stratification variable in the same run.

Note

Stratification variables that are not associated with [data transformations](#) are available as additional covariates in logistic regression runs.

11. From the **Selection Type** drop-down list, choose a selection type, which determines how users specify values for the variable when performing activities such as creating a query.

Selection Types

Selection Type	Meaning
Distinct Value List	Users choose values from a list. Variables with a variable type of Generalized Item, or of Other (with Use as subset variable or Use as stratification variable checked), must use this selection type. For variables with this selection type, you can identify a unique values table to supply the list of values. If you do not define a unique values table, the application creates one automatically when you validate the data configuration .

Selection Type	Meaning
Select from Drug Hierarchy, Select from Event Hierarchy	Use one of these selection types only if a drug or event hierarchy account is specified at the level of the configuration as a whole and you want users to be able to browse for and select terms from the hierarchy. (Users can also select values from a list.) If you do not specify this selection type, users need to select hierarchy terms from an alphabetized list instead of the hierarchy. See About drug and event hierarchies .
Continuous	Users specify a range of values by entering From and To values.
Free Text	Users type in a text string for which matches will be found.

Note

If there is a [hierarchy table](#) specified for the individual variable, select the variable type Distinct Value List for the variable.

12. In the **Hierarchy Level** field, select the hierarchy level.

If the selection type of the variable is **Select from Drug Hierarchy** or **Select from Event Hierarchy**, and a drug or event hierarchy account is specified at the level of the data configuration, you must select a hierarchy level to tell the application which level of the hierarchy is represented by the variable.

Note

This field has no effect if there is a hierarchy table specified for the individual variable.

13. If you do not want the variable to be available during creation of a query, from the **Hide from Query Wizard** drop-down list, select **Yes**.

Note

Regardless of this setting, a variable that uses a data transformation that maps values, defines cutpoints, or converts dates is not selectable in the [Query Wizard](#).

14. In the **Value Case** field for variables whose Oracle data type is CHAR or VARCHAR2, indicate the capitalization style that is used in the source data. The application automatically converts terms that users enter in the **Drug and Event Term** selection fields on the [Select Criteria page](#) to the capitalization style before a match is attempted, as follows:

- **Exact Match**—Entered values are not converted, and must match the case of the source data exactly.
- **All Upper**—Values are in all upper case in the source data. Entered values are converted to all upper case.

- **All Lower**—Values are in all lower case in the source data. Entered values are converted to all lower case.
 - **Upper First Letter Each Word**—The first letter of each word is capitalized in the source data. Entered values are converted so that the first letter of each word is in upper case and the rest are in lower case. For example, the entered value, Renal failure, becomes Renal Failure.
 - **Upper First Letter Each Term**—Values are in mixed case in the source data. Entered values are converted so that the first letter of each term is in upper case and the rest of the term is lower case. For example, the entered value, Drug Hypersensitivity, becomes Drug hypersensitivity.
15. In the **Unique Values Table** field, identify an Oracle table or view that contains the list of all possible values for the variable. You can specify an existing [unique values table](#) (from the Oracle account in which the configuration resides) by typing in its name.
- a. To select from a list of tables, click **Select Table**.
 - b. From the **Select Table** dialog box, select the table and click **Save**.
- If you leave this field blank, the application creates a unique values table during configuration [validation](#).

Note

In a timestamped database, no start and end dates are associated with the unique values table, so all unique values that ever existed are in the tables.

16. To specify a hierarchy table for the variable, in the **Hierarchy Table** field, type the table name, or click **Select Table** to choose from all tables in the Oracle account to which you are connected. To supply a table name, click **Create New Table**.
- The recommended way to set up event or drug hierarchies is to associate an Oracle account of hierarchy information with the configuration (on the Edit Configuration Details page). The ability to associate an individual variable with a hierarchy table still exists to provide backward compatibility with data configurations created in previous releases. For more information, see [Event and drug hierarchies](#).
17. In the **Data Transformation** field, specify a data transformation to transform source data into other values available for selection when data mining runs are created:
- If you do not want to transform source data for the variable, click **None** (the default).
 - To [map text values](#), click **Text mapping**. This option applies only to variables that are based on a CHAR or VARCHAR value in the source database.
 - To [define variable cutpoints](#), click **User-defined cutpoints**. This option applies only to variables that are based on a NUMBER or DATE value in the source database.
 - To [exclude synthetic values](#), such as the names of Standardized MedDRA Queries (SMQs), click **Synthetic values**. This option applies only to variables that are based on a CHAR or VARCHAR value in the source database.
 - To [convert date values](#), select **Date function** and enter the function in the field. To select a function from a list, click **Select Function**. This option applies only to variables that are based on a DATE value in the source database.
18. Click **Save**.
- If a warning message appears, as when there are leading or trailing white spaces in the source data for the variable, you can fix the problem or click **Ignore Warnings**, and then **Continue**.

19. Next, [validate the data configuration](#). For more information, see [Validate data configurations](#).

Add a mapped variable to the configuration

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click the **Row Action** menu () for the data configuration, and then click **Edit**.
4. On the [Modify Configuration page](#), click the **Add New Variable** link.
5. In the **Name** field, enter the name of the variable.

Variable names display throughout the application, including when users select criteria for viewing data mining results, defining queries, or creating report definitions. For example, a column might be named SYMPTOM in the Oracle table, but renamed to appear as Event in the application.
6. In the **Description** field, type a description of the variable.
7. Next to the **Table** field, click **Select Table/Column**.
8. As the **Column** of source data, select the drug or event variable containing values that you want to map. The source column must be a text value.
9. In the **Prefix** field, enter a prefix.
10. From the **Variable Type** drop-down list, select **Event** or **Drug**.
11. Do *not* check **Use as subset variable** or **Use as stratification** variable.
12. Optionally, set up the mapped variable to use a hierarchy.
13. Set **Hide From Query Wizard** to **Yes**. (Even if this setting is set to **No**, the mapped variable is not available in the Query Wizard.)
14. In the **Data Transformation** section, click **Text mapping**, and then click **Upload Table**.
15. From the **Upload Text Map CSV File** dialog box, next to the **File to Upload** field, click **Browse**.
16. Select the mapping file and click **Open**. The mapping file must be in the format described in [Map text values](#).
17. Click **Upload**.
18. To make sure the mappings are correct, click **View Current Mapping**.
19. Click **Save**.
20. [Validate](#) the configuration.

Note

If you map a variable in a configuration for which there are existing runs that use the variable, users cannot [drill down](#) correctly in the run results until the runs are re-executed.

Copy a data configuration

You can create a data configuration by copying an existing data configuration and editing the copy as necessary.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click the **Row Action menu** () for the configuration, and then click **Edit**.
4. Click **Copy this Configuration**.
5. In the **Name** field of the Add Configuration page, supply a unique name for the new data configuration. (The default name is Copy of, followed by the name of the original data configuration).
6. In the **Description** field, modify the supplied description as needed to describe the new data configuration.
7. In the **Configuration Table Name** field, enter the unique name of the table to hold the new data configuration in the Oracle account to which you are connected.
8. Click **Save**.

Note

The type of all copied configurations will be *Local*.

Delete a data configuration

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click the **Row Action menu** () for the configuration, and then click **Edit**.
4. Click **Delete this Configuration**.
5. If you are a superuser, you have two options:
 - To remove the data configuration from the application, but leave it in the database so that it can later be re-imported, click **Remove Reference Only**.
 - To delete the data configuration completely, including deleting it from the database, click **Delete Permanently**.

Note

If you are not a superuser, you cannot delete the data configuration if any objects are associated with it.

6. If any objects reference this configuration, you can transfer queries, report definitions, and saved lists to a [compatible data configuration](#). From the **What would you like to do with objects that reference this configuration?** drop-down list, select a configuration.

- Any queries, report definitions, and saved lists that are not compatible with the data configuration that you select are deleted.
 - To delete all queries, report definitions, and saved lists instead of transferring them, at the bottom of the list, select **Delete All Referenced Objects**.
 - All case series, data mining runs, and report outputs based on this configuration are permanently deleted.
7. Before continuing, you might wish to:
- Add the query portion of query-based case series to the Query Library (from the Case Series page).
 - Make sure that the configuration is not referenced by any [drug profile configurations](#) or [signal configurations](#), because such references are removed.
 - Attach run results, case lists or case details, and report outputs to a topic.
8. Click **Delete**.

Note

When you delete a data configuration that is associated with an [alias](#), the target status of the alias becomes Broken.

Data configuration and variables information

The Modify Configuration page provides information about the data configuration and the data configuration variable.

Data configuration information

The Modify Configuration page provides the following information about the data configuration:

Field	Description
ID	Unique identifier that is assigned automatically to the configuration.
Name	Name of the configuration.
Description	Description supplied for the configuration.
Database Group	Name of the database group to which the configuration is assigned. Results reviewers can use the database group when finding and selecting a data mining run . The application also uses the database group when determining color changes for case ID links that are visited by users.
Owner	Full name associated with the username that created the configuration.
Table	Name of the Oracle table containing the specification of the configuration.
Drill Down Map Table	Name of the drilldown map table , which specifies the source of case details that appear when a user drills down to view case details.
Source Description Table	Name of the source description table , which provides information about the source database.

Field	Description
Timestamped	YES, if the configuration supports timestamped data . NO, if the configuration does not support timestamped data.
Drug Hierarchy Account (or Drug Hierarchy Version Table)	Name of the Oracle account that drug variables with a selection type of Select from Drug Browser in the configuration use for hierarchical values. For timestamped configurations, name of the table that stores one or more valid hierarchy accounts by date.
Event Hierarchy Account (or Event Hierarchy Version Table)	Name of the Oracle account that event variables with a selection type of Select from Event Browser in the configuration use for hierarchical values. For timestamped data , name of the table that stores one or more valid hierarchy accounts by date.
Includes Concomitant Drugs	YES, if the configuration includes suspect and concomitant drugs. NO, if the configuration includes suspect drugs only. Results reviewers can use this information to find a data mining run .
Hide From Data Mining	YES, if the configuration can be used for case series and reporting only. NO, if the configuration can be used for data mining, case series and reporting.
Valid	YES, if the configuration has been validated successfully. NO, if the configuration has never been validated or failed validation.

Data configuration variable information

The Modify Configuration page provides the following information about each variable in the data configuration:

Field	Description
Variable	Unique name of the variable as it appears to Oracle Empirica Signal users on the Select Configuration page. For example, a column might be named SYMPTOM in the analysis table, and Event in the Oracle Empirica Signal application.
Desc	Description of the variable.
Table	Name of the source database table containing the column that corresponds to the variable.
Column	Name of the database table column that corresponds to the variable.

Field	Description
Variable Type	For possible variable types, see Add or edit a configuration variable . If a subtype (Generic, Trade, or Ingredient) is specified for a variable with a variable type of Drug, it appears after Drug in parentheses.
Selection Type	For possible selection types, see Add or edit a configuration variable .
Hierarchy Level	Displays the hierarchy level, if any, specified for event or drug variables with a selection type of Select from Drug (or Event) Hierarchy.
Visibility	DM & Q, if the variable is available for data mining runs and query-based case series. DM, if the variable is available for data mining runs but not for query-based case series.
Value Case	For possible value cases, see Add or edit a configuration variable .
Hierarchy Table	Name of the hierarchy table, if any, associated with the variable.
Unique Values Table	Name of the unique values table , if any, associated with the variable.
Data Transform	Name of the data transformation , if any, associated with the variable.

Manage signal configurations

- [About signal configurations](#)
- [Manage signal configuration reference data](#)
- [Manage Signal Configurations page](#)
- [Edit a signal configuration](#)
Change aspects of scripted, interactive, and multisource signal configurations.
- [Publish or unpublish a signal configuration for a user with Manage Signal Configurations permission](#)
Signal Configuration administrators, users with Manage Signal Configurations permission, will have access to Signal configurations for which they are the owner, and signal configurations that have been published to them individually or to their login group. Signal Configuration administrators can publish Signal configurations to their login group.
- [Publish or unpublish a signal configuration for superusers](#)
- [Configure alert types](#)
- [Manage monitored products](#)
- [Manage signal configuration refreshes](#)
- [Manage signal comment types](#)
- [Assign reviewers to products](#)
- [Manage events and custom terms](#)
- [Manage signal views](#)

- [Manage multisource signal configurations](#)
Perform safety surveillance across multiple data sources in one configuration using a multisource signal configuration.

About signal configurations

There are three types of signal configurations: scripted, interactive, and multisource.

- **Scripted signal configurations** require modifying most aspects of the signal configuration outside of the Oracle Empirica Signal application, based on your organization's requirements, and running command-line scripts to perform refreshes. Scripted signal configurations are available for other data sources, including proprietary databases.
- **Interactive signal configurations** allow a user, with appropriate permissions, to create, validate, and refresh the configuration in the Oracle Empirica Signal application. Interactive signal configurations are currently available for proprietary data maintained in Oracle Argus Mart and for various public safety data sources. See [What is source data?](#).
- **Multisource signal configurations** extend interactive signal configurations by combining the results of multiple safety datasets, both public and proprietary, into a single configuration. You can view data and results side-by-side on the Signal Review page. With the appropriate permissions, you can select the signal configurations you wish to combine, then create and manage the multisource configuration in the Oracle Empirica Signal application.

To set up the configurations, you must have the Manage Signal Configurations permission. See [Edit a signal configuration](#).

Scripted signal configurations

Most aspects of scripted signal configuration are defined or modified outside of the Oracle Empirica Signal application based on your organization's requirements. You can modify some aspects of the signal configuration.

For example, you can:

- [Add and edit signal comment types](#).
- [Enable or disable review periods](#).
- [Edit the column headers and column descriptions on the Products table](#).
- [Edit the column headers and column descriptions on the Product-Event Combinations tables](#).
- [Define values for Category, Complexity, and Organization product properties](#).

Interactive signal configurations

You can modify interactive signal configurations in the Oracle Empirica Signal application. For example, you can:

- [Select the data configurations used for reports and data mining runs](#).
- [Select drug and event variables used in data mining runs as well as stratification and subset variables](#).
- [Add and edit signal comment types](#).
- [Enable or disable review periods](#).
- [Edit the column headers and column descriptions on the Products table](#).

- [Edit the column headers and column descriptions on the Product-Event Combinations tables.](#)
- [Add, edit, activate, and deactivate alert types.](#)
- [Define values for Category, Complexity, and Organization product properties.](#)
- [Manually refresh the signal management data.](#)

Multisource signal configurations

You can create and modify multisource signal configurations in the Oracle Empirica Signal application. See [Get started with multisource signal configurations](#).

For example, you can add and edit multisource configurations and specify the lead and secondary configurations.

- [Add a multisource signal configuration.](#)
- [Edit a multisource signal configuration](#)
- [Add](#) and [edit signal comment types](#), changes shared with the lead configuration.
- [Edit the column headers and column descriptions on the Products table.](#)
- [Edit the column headers and column descriptions on the Product-Event Combinations tables.](#)
- [Add, edit](#), activate, and deactivate alert types.
- [Define values for Category, Complexity, and Organization product properties.](#)
- Manually [refresh the signal management data](#).

Manage signal configuration reference data

Just below your user name in the upper right corner of the Products and Product-Event Combinations pages is the **Manage Reference Data** menu ():

These menu choices apply to the signal configuration and require permissions to specify or change them:

- **Add Product:** Your organization chooses the products to monitor. For non-interactive signal configurations, Oracle creates the list of monitored products during preparation of the signal management data. You must have the Manage Signaling Terms permission to add to and to edit the product list.
- **Auto-Assign to Reviewers:** You must have the Manage Signaling Terms permission to automatically [assign reviewers](#) to products. You must have the Allow Automatic Assignment of Reviewers permission to auto-assign reviewers.
- **Modify Automatic Assignments:** There is one reviewer per product. The Modify Automatic Assignments page provides information about products that have been assigned automatically to a reviewer. This page does not show assignments that were made manually (when the drug was added or edited). You must have the Administer Signal Management permission to modify automatic review assignments.
- **Manage Designated Medical Events:** You can maintain a list of designated medical events (DMEs). A DME is an adverse event that your organization wants to monitor closely. DMEs are associated with particular products. You must have the Manage Signaling Terms permission to manage DMEs.

- [Manage Custom Terms](#): You can create custom terms to represent a pseudo-value for a product or event. You must have the Manage Signaling Terms permission to manage custom terms.
- [Manage Views](#): You can rename, publish, delete, or reorganize [saved views](#). You must have the Manage Signal Views permission to manage Views.

Managing reference data in a multisource signal configuration

When working with a [multisource signal configuration](#), changing the reference data will affect the underlying lead configuration, as follows:

Action	Effect
Adding products	Saved to the lead configuration
Auto-assigning reviewers	Saved to the lead configuration
Managing designated medical events	Saved to the lead configuration
Managing custom terms	Saved to the lead configuration
Managing views	Although the initial views are inherited from the lead configuration, changes made in the multisource signal configuration are independent and do not affect all connected configurations. A signal configuration may be included as the lead configuration in multiple multisource signal configurations.

Manage Signal Configurations page

On the Manage Signal Configurations page, you can modify, delete, and publish the signal configurations. You must have the Manage Signal Configurations permission or be a superuser to access this page.

General activities

The following links appear at the top of the page and affect the entire page:

- [Manage Refreshes](#)
- [Add Multisource Signal Configuration](#)
- [Columns](#)
- [Print](#)
- [Download](#)
- [Back](#)

Row-specific activities

The following options appear in the Row Action menu () for each signal configuration:

- [Edit](#)
- [Edit Comment Types](#)
- [Edit Product fields](#)
- [Edit Alert Types](#)

- [Edit Product Columns](#)
- [Edit Product-Event Combinations Columns](#)
- Publish
- Review periods

For interactive and multisource signal configurations:

- [View Refresh Details](#)
- [Refresh](#)
- [Validate](#)

For multisource signal configurations only:

- Add a multisource signal configuration
- Delete

Field descriptions—Manage Signal Configurations page

Field	Description
Name	Signal configuration name.
Description	Description of the signal configuration.
Topic Workflow Configuration	Name of the topic workflow configuration that is integrated with the signal management configuration. When this integration exists, users can associate topics with product-event combinations using the Submit Review dialog box, and topics are stored in this topic workflow configuration.
Note If product-event combinations have associated topics, you cannot change the associated topic workflow configuration until you remove the associated topics. The Signal History maintains a log of all changes.	
Topic Product Field	Topic field in which product names from product-event combinations associated with topics are stored. You can also use the Topic filter when browsing for existing topics from the Submit Review dialog box.
Modified By	Role or name of the user who modified the configuration.
Modified	Date and time when the configuration was modified.

Field	Description
Type	Type of signal configuration. The value can be Scripted, Interactive, or Multisource. For more information, see About signal configurations .
Created	Date and time when the configuration was created.
Created By	Role or name of the user who created the configuration.
ID	Identifier assigned automatically to the configuration when the configuration was created. Each configuration ID is unique and is not re-used if the configuration is deleted.
Current Period	Period used in last successful refresh; null if scripted.
Refreshed Date	Date of last successful refresh.

Edit a signal configuration

Change aspects of scripted, interactive, and multisource signal configurations.

The properties that you can edit vary depending on whether the configuration type is [scripted](#), [interactive](#), [multisource](#), or [multi-enterprise enabled](#).

Note

You must have Manage Signal Configurations user permission to perform the following actions.

In the product-event combinations panel, select a tab to display a specific product-event combinations table determined by the [tab view](#). By default, there is a tab for each active alert type. If a default view has been configured this will be the first tab on the left. The first tab on the left displays the default view if a default view has been configured for either the [product](#) or the signal configuration. Depending on the setup, the default view is:

- The product default view, if selected.
- The configuration's default view, if no product default view is selected.
- No default view tab, if no product or signal configuration default view is selected.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action menu** () for the signal configuration, and then click **Edit**.
4. Edit the fields according to the table below.

By default, there is a tab for each active alert type. Also if a default view has been configured this will be the first tab on the left. The first tab on the left displays the default view if a default view has been configured for either the [product](#) or the signal configuration. Depending on the setup, the default view is:

- The product default view, if selected.
- The configuration's default view, if no product default view is selected.

- No default view tab, if no product or signal configuration default view is selected.
- If the signal configuration Type is Interactive, an Interactive Signal Configuration Properties section appears in the Edit Signal Configuration page.
- If the signal configuration Type is Multisource, see [Edit a multisource signal configuration](#).

5. Click **Save**.

Oracle Empirica Signal validates the signal configuration, and any errors are displayed at the top of the page.

Field descriptions—Edit Signal Configurations

Fields marked with an asterisk (*) in the table are available only for interactive signal configurations.

Field	Description
Name	Signal configuration name. This name appears on the Signal Review page, above the product-event combination table.
Description	Description of the signal configuration.
Default signal view	Name of the default signal view appearing as the global default for the signal configuration. This view appears as the left-most tab when viewing the Panels of the Product-Event Combinations page on the Signal Review page. If a different default view is specified for a specific product , the product's default view takes precedence and is shown when viewing that product.

Field	Description
Topic workflow configuration	Name of the topic workflow configuration that is integrated with the signal management configuration. When this integration exists, users can associate topics with product-event combinations using the Submit Review dialog box, and topics are stored in this topic workflow configuration.

 Note

If product-event combinations have associated topics, you cannot change the associated topic workflow configuration until you remove the associated topics. The [Signal History](#) maintains a log of all changes.

 Note

If you do change the integrated topic workflow configuration, exit the application and log in to the application again.

Topic product field	Select a custom field to store the product name. When you click Submit Review for a Product-Event Combination and you create a new topic, the field designated as the Topic Product Field fills automatically with the product name. Use the Topic product field filter when browsing for existing topics from the Submit Review dialog box.

 Note

The Topic Product field is restricted to custom fields that must have values:

- Context = Topics
- Format = String
- Type = Single Value

Field	Description
Versioned Case Series	Select the versioned case series from the Versioned Case Series drop-down to associate a versioned case series with a signal configuration. The versioned case series and the signal configuration are now linked and you can go to Signal Review to populate the versioned case series .
Disable default view	Select to disable the default view on the Product-Event Combinations page . When disabled, both the default view for the signal configuration and the default view specified for a specific product are ignored.
Disable review period	Select to disable the Review Period column and Review Period filter on the Manage Signal Views page.
Disable private comment	Select to disable private comments for product-event combinations.
Allow reviewers to manage their product's reference data	Select to enable all reviewers of a product to configure Targeted Medical Events and Listed Events for the product in the Products table on the Signal Review page. If deselected, only superusers and reviewers with the Manage Signaling Terms user permission can configure Targeted Medical Events and Listed Events.
Suppress alert calculations	Select to disable calculation of alerts in the next refresh.
Enable analytics	Select to enable access to Signal Management data for reporting purposes. Enabling the analytics option for Signal Configuration results in additional reporting data processing as part of Signal refreshes. Users with at least a <i>BI consumer</i> permission will be able to view the Analytics icon on the side pane in Oracle Empirica and access the data in Oracle Analytics, after activating the option. Activate this option only if Oracle Analytics is used with Oracle Empirica Signal.

 Tip

After activation, the status of the option changes into *Status pending for refresh* and the data will be updated in the next refresh in the Oracle Analytics platform. If the update fails, you have to redo the action.

Field	Description
Interactive Signal Configuration Properties	When editing interactive signal configurations you can modify the following additional properties.
Data configuration for 2D runs	Name of the data configuration or an alias used to execute two-dimensional data mining runs. Typically, this data configuration excludes reports from studies and literature. Use the drop-down list to select a configuration or alias. Use Browse to select a configuration.
Data configuration for 3D runs	Name of the data configuration or an alias used to execute three-dimensional data mining runs. Typically, this data configuration includes concomitant products. Use the drop-down list to select a configuration or alias. Use Browse to select a configuration.
Drug variable	Drug Variable used in data mining runs, for example, Product Generic Name or Preferred Product Name.
Event variable for 2D runs	Event Variable used in two-dimensional data mining runs, for example, PT (Preferred Term) or SMQs (Standardised MedDRA Queries).
Event variable for 3D runs	Event variable used in three-dimensional data mining runs, for example, PT (Preferred Term). Typically, this variable does not include SMQs due to the size of the data mining results table. For three-dimensional data mining runs, the Drug variable is also used.
Stratification variables	Stratification variables used in data mining runs.
Subset variable for signal history	For data mining runs, subset variable that provides results in the winView Signal History page.
Subset variable for <i>Nsince</i> counts	For data mining runs, subset variable that provides results in the <i>Nsince</i> column on the Product-Event Combinations page.
Project for data mining runs	Name of the project used to store data mining runs that are part of a refresh.
Publish data mining runs	Select to publish the data mining runs created when a user refreshes the signal management configuration. By default, the runs are published to the same login group that the signal configuration is published to. A user can manually publish the data mining runs to additional login groups.

Publish or unpublish a signal configuration for a user with Manage Signal Configurations permission

Signal Configuration administrators, users with Manage Signal Configurations permission, will have access to Signal configurations for which they are the owner, and signal configurations

that have been published to them individually or to their login group. Signal Configuration administrators can publish Signal configurations to their login group.

Note

By default, the publication level of every newly created object is Private.

1. In the left navigation pane, click the **Settings** icon ()
 2. In the Configure System section, click **Manage Signal Configurations**.
 3. Click the configuration's **Row Action menu** () , then click **Publish**.
 - If the signal configuration was published to the winSignal Administrator's login group then the Publication Level is **This Signal Configuraion is marked Public**.
 - If the signal configuration was published to the Signal Administrator then the Publication Level is **This Signal Configuraion is marked Private**.
 - If the signal configuration was published to —All— login groups then Publication Level is blank. The Signal Administrator will be able to see this configuration but will have no control over its publishing.
- The Publish Signal Configuration window appears. The window contains the current publication status
4. If you wish to unpublish the configuration, click **Make private** next to the Publication Level. The configuration will no longer be available to the Signal Administrator's login group.
 5. If you wish to publish the configuration, click **Publish** next to the Publication Level. The configuration will be available to the Signal Administrator's login group.
 6. Close the Publish Signal Configuration window to return to the Manage Signal Configurations page.

Publish or unpublish a signal configuration for superusers

Only superusers have access to all signal configurations. Superusers can publish Signal Configurations to either individual users or to login groups. If the signal configuration is multi-enterprise support-related, then the superuser is restricted to either their login group or one user with *Manage Signal Configuration* permission who belongs to a login group with enterprise ID value set.

Note

By default, the publication level of every newly created object is Private.

1. In the left navigation pane, click the **Settings icon**
2. In the Configure System section, click **Manage Signal Configurations**.
3. Click the configuration's **Row Action menu** ()
()

Note

It is recommended that the superuser publishes signal configurations to individual users. This will provide users with *Manage Signal Configurations* permission, the individual Signal Configuration administrators access to the signal configuration and allow the individual administrator to control publishing to the login group.

- If the configuration is published to all login groups, then the *Signal configuration administrator* will have no control on publishing.
- If the configuration is published to the *Signal configuration administrator's* login group, then when the administrator unpublishes, the configuration will be unpublished to the entire login group including themselves.

The Publish Signal Configuration window appears. The window contains the current publication status, **Publish to Login Groups** and **Publish to Users** radio buttons.

4. If you wish to unpublish the configuration that has been published to All Login groups, click **Remove**.
5. If you wish to unpublish the configuration that has been published to a login group or a user click **Remove** next to the name of the [login group](#) or user.
6. To publish the configuration to Login Groups.
 - a. Select **Publish to Login Groups**
 - b. Select the login group to which you intend to publish. You can publish an object to multiple login groups. **Ctrl+click** to select multiple login groups from the list.

Note

If you publish to –All–, the object is automatically published to any new login groups you add later.

- c. If the configuration is Multi-enterprise enabled, then only your login group is available for selection.
 - d. Click **Publish**.
7. To publish the configuration to Users (recommended).
 - a. Select **Publish to Users**.
 - b. Optionally select login groups to filter the User list by.
 - c. Select the User to which you intend to publish. You can publish an object to multiple Users. **Ctrl+click** to select multiple login groups from the list.
 - d. If the configuration is Multi-enterprise enabled, then you are restricted to picking one user and the User list is restricted to users that have *Manage Signal Configuration* permission and belong to login group with an enterprise specified.
 - e. Click **Publish**.
 8. Close the Publish Signal Configuration window to return to the Manage Signal Configurations page.

Configure alert types

- [About alert types](#)
- [Create or edit an alert type](#)
To create or modify an alert type is a four-step process.
- [Remove alerts in bulk](#)
Superusers or users who have the Manage Signal Configurations permission can remove alerts in bulk.
- [Modify the order in which alert types are displayed](#)
- [Activate and deactivate alert types](#)

About alert types

Creating an alert type involves importing a view for each alert type rule. The view's WHERE clause determines the condition associated with the alert type and the conditions are validated when you save the alert type. One alert type can have several rules; however, there is one rule per review period or per complexity level.

During validation, Oracle Empirica Signal checks the condition's SQL statement and the columns identified in the condition. This controls the rows and columns displayed in the Product-Event Combinations table when the alert type tab is selected. The list of valid columns for the alert type condition is a subset of the list of columns allowed for a view.

Although alert type conditions can contain other alerts, we do not recommend this practice or guarantee the results.

Note

If the alert type is tracked but you did not specify an abbreviation or color, Oracle Empirica Signal uses default values.

Create or edit an alert type

To create or modify an alert type is a four-step process.

1. Create views that reflect the columns and rows desired for the new alert type. Follow the steps in Create a new view in the Add tab menu.
2. Create the alert type and import the views.
3. Activate the alert type.
4. Edit the alert type and make it a tracked alert.

Note

You must have the Manage Signal Configurations permission or be a superuser to access this page. A newly installed Signal Configuration needs to be refreshed once before trying to create views and add alert types.

Create the alert type and import the views

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Click the configuration's **Row Action** menu (⋮), then select **Edit Alert Types**.
4. In the top left corner, click **Add Alert Type** or edit an existing alert type by selecting **Edit** from the alert type's **Row Action** menu (⋮).
5. In the **Label** field, type a unique and descriptive label for the alert type. This will be used as the tab label on the Signal Review Page.
6. In the **Description** field, describe how the alert gets populated. This will become the hover help text for the tab.
7. Oracle recommends that you not select the **Tracked alert** check box at this point.
8. For the **Alert rules based on** field, select the appropriate radio button: **Review period** or **Complexity level / periodicity**.
9. If an alert rule is based on review periods, then note the review period of the first row. If the rule is based on Complexity level / periodicity, note the Complexity level and enter a periodicity value. Open the action menu for this first row and select **Import from View**.

Note

Review Period rules use the product's review period to determine the alert type rule that is used. The rules are evaluated with each refresh. Complexity level / periodicity rules use the product's Complexity level to determine the alert type rule used. The product's birthdate and the alert type rule's periodicity determine if the alert rule should be considered during refresh. For example, if the product birthdate is February and the periodicity is three months, the alert will be triggered in May, August, November, and February. To be considered for complexity-based alert calculations, a product needs both complexity and birthdate values.

10. Select the view to be associated with this alert type rule. Oracle Empirica Signal imports the view and populates the **Condition**, **Selected** columns, and **Sorted by** columns.
11. Repeat steps 9-10 for each Review period or Complexity level / periodicity in the table.
12. Click **Save**.
The alert type appears as the last row of the Edit Alert Types page. The newly added alert type is deactivated by default. This means that **Active in next refresh** is set to **No** for the alert type.

Activate the alert type

1. On the Edit Alert Types page, select **Activate** for the newly created alert type.
2. (Optional) If the new alert type replaces an existing alert type, deactivate the previous alert type.
With the next refresh, the new alert tab will be added.

(Optional) Edit the alert type and make it a tracked alert

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. From the **Configure System** menu, select **Manage Signal Configurations**.

3. Click the configuration's **Row Action menu** (⋮), then select **Edit Alert Types**.
4. To make this a tracked alert, select the **Tracked alert** check box, provide a one-letter abbreviation, and select a color to associate with the alert type. The abbreviation and color appear on the alert tab and cells on the Product-Event Combinations table as the tracked alert's icon.

Changes will take effect in the next refresh.

Remove alerts in bulk

Superusers or users who have the Manage Signal Configurations permission can remove alerts in bulk.

When bulk removal of alerts is in progress the configuration will be marked as Refresh in progress:

- Only one bulk removal can occur for a configuration at a time.
- A bulk removal cannot occur while a refresh is in progress.
- A refresh cannot be submitted if a bulk removal is in progress.
- Completing a Submit Review while bulk removal is in progress will not cause bulk removal to fail but may impact the total number of alerts removed.

Note

This is expected to be an unlikely event, best practice is to unpublish the Signal Configuration before making configuration changes.

1. In the left navigation pane, click the **Settings** icon (



).

2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Click the configuration's **Row Action** menu (Row Action menu icon), then select **Edit Alert Types**.
4. Select **Bulk Remove Alerts**.
5. Select at least one Alert Type and at least one Date.
 - Select Alert Types table contains a row for each tracked alert type that has existing unreviewed alerts. Select individual rows, or use the header row to select/ unselect all.
 - Select from the Dates table containing a row for each alert creation date that has unreviewed alerts. Select individual rows or use the header row to select/ unselect all.

Table 10-1 Alert Types table

Alert type name	Description
Alert Type	Alert type name.
Unreviewed Alerts	Number of unreviewed alerts for the alert type.

Table 10-2 Dates table

Fields	Description
Created Date	Date and time that the alert was created.
Alert Types	List of selected comma-seperated alert types, if they occurred on this date. It updates when the selections in the alert types table change.
Unreviewed alerts	Number of unreviewed alerts on this date for the selected alert types. It updates when the alert type selections change.

6. Click **Save** to proceed with the bulk removal or **Cancel** to go back to the previous state.
7. Once saved, a confirmation message window will appear:
 - Bulk alert removal is in progress. The window is updated with the message *You are requesting to remove unreviewed alerts. This operation cannot be undone. Click **OK** to proceed or **Cancel** to go back to the previous state.* Confirm the bulk removal of alerts by clicking **OK**.
 - The window closes when processing is complete. If the command is successful, the alerts are removed and alert counts on the Signal Review page are updated.

Modify the order in which alert types are displayed

1. In the left navigation pane, click the **Settings** icon (.
2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Find the configuration, click the **Row Action menu** () , then select **Edit Alert Types**.
4. In the top left corner, click **Modify Display Order**.
5. To change the order in which fields display in the Edit Product Fields table and in the Add/Edit Product window, click a field and select one or more fields.
6. When the alert types are in the correct order, click **OK**.
7. Click **OK**.

When the order of the alert types is changed on the Edit Alert Types page, the Products table, the Product-Event Combinations page, and the Tracked and Informational alert graphs displayed in the Detail panel on the right reflect the new order.

Activate and deactivate alert types

1. In the left navigation pane, click the **Settings** icon (.
2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Find the configuration, click the **Row Action menu** () , then select **Edit Alert Types**.
4. Find the alert type to activate or deactivate by looking in the **Active in next refresh** column. Active alert types have the value, **Yes**. Inactive alert types have the value **No**.
5. Click the alert type's **Row Action menu** () and select **Activate** or **Deactivate**.
 - You can only deactivate active alert types that do not have alerts needing review.
 - Changes will not appear in Signal Review until the signal configuration is refreshed.

Manage monitored products

- [Add, edit, or change the name and term of a monitored product](#)
- [Delete a product](#)
- [Edit a product field](#)
- [Add a product field value](#)
- [Delete a product field value](#)
- [Rename a product field value](#)
- [Modify the display order of product fields](#)
- [Modify the display order of a product field's defined values](#)

Add, edit, or change the name and term of a monitored product

Your organization chooses the products to monitor. For non-interactive signal configurations, Oracle creates the list of monitored products during preparation of the signal management data. You can add or edit a product to be monitored and change the names and terms of the monitored product.

In the product-event combinations panel, select a tab to display a specific product-event combinations table determined by the [tab view](#). By default, there is a tab for each active alert type. Also if a default view has been configured this will be the first tab on the left. The first tab on the left displays the default view if a default view has been configured for either the product or the [signal configuration](#). Depending on the setup, the default view is:

- The product default view, if selected.
- The configuration's default view, if no product default view is selected.
- No default view tab, if no product or signal configuration default view is selected.

Note

If you add, edit or change the name of a monitored product and your site uses [multisource signal configurations](#), then all connected configurations are impacted. You cannot add, edit or rename a product from the multisource signal configuration if the lead configuration is undergoing a refresh.

Add or edit a product to monitor

Note

[Product property values](#) must be set up before you add a product. The values available when adding a product are defined when setting up the Signal Configuration.

1. In the left navigation pane, click the **Signal Review** icon ().

2. From the **Manage Reference Data** menu (), in the upper right corner, select **Add Product**.
3. In the **Add/Edit Product** window, fill in the fields according to the table below.
 - Code list values are defined on the [Edit Product Fields](#) page under Manage Signal Configurations. The code list values determine the Category, Complexity level, and Organization values available for selection.
 - To be considered for complexity-based alert type rules, products must have values for both Complexity level and Birthdate.
 - Review period values are used for alert type rules based on review period.
 - Complexity Level, Birthdate, and Review Period values have an impact on alert calculations. Changes made to these properties do not take effect until after the next refresh.
4. Click **Save**.
5. To enable your changes to take effect, refresh the configuration.
If you are changing the product name or product term in a multisource signal configuration:
 - a. Refresh the underlying lead configuration.
 - b. Refresh the multisource signal configuration.

Statistical information and alerts will appear after the next refresh. Customers should contact Oracle for adding products to scripted signal configurations.

Change the name of a monitored product

Before you begin, consider the following:

- You must have the Manage Signaling Terms [user permission](#) to rename a product.
- Product names must be unique within the signal management configuration.
- Product terms must be unique within the signal management configuration.
- Product term must match what's in the data configuration.
- Renames do not take effect until you [refresh](#) the signal configuration.
- Renames in a multisource signal configuration do not take effect until you refresh the underlying lead configuration, and then refresh the multisource signal configuration.
- If you rename a product multiple times between signal management refreshes, the most recent rename is applied during the next refresh.

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **Rename**.
4. To change the product name, in the **New product term** text box, type the term. You can also select a product term from a list using the following links:

- **Select < hierarchy > Term**—Appears if the product is associated with a hierarchy such as the Anatomical Therapeutic Chemical (ATC) Classification System. For more information, see [Select hierarchy terms](#).
- **Select Available Value**—Displays valid product terms. For more information, see [Selecting values from a list](#).

Note

To prevent spelling and capitalization errors, we recommend that you select rather than type values.

5. To change the product name, in the **New product name** text box, type the name.
6. Click **Save**.
7. To enable your changes to take effect, refresh the configuration.

Note

If you are changing the product name or product term in a multisource signal configuration:

- a. Refresh the underlying lead configuration.
- b. Refresh the multisource signal configuration.

Note

If you add a product that was previously [deleted from the signal configuration](#) and the configuration has not been refreshed since the deletion, then the product's tracked alerts appear as reviewed until the next refresh. After the next refresh, the alerts that were removed when the product was deleted no longer appear on the [Signal Review pages](#) or in the [signal history](#).

Field descriptions—Add/Edit Product window

Field	Description
Product term	Unique name of the product. For interactive signal configurations, you can select terms from a list using the following links: • Select < hierarchy > Terms — Appears if the product is associated with a hierarchy such as the Anatomical Therapeutic Chemical (ATC) Classification System. For more information, see Selecting hierarchy terms. • Select Available Value—Displays valid product terms. For more information, see Selecting values from a list. Note: You cannot change the Product term when editing a product.
Product name	Common name of the product that appears by default in the Products table. The value is initially populated from the Product Term value, but can be changed to a unique value when adding or renaming a product. Changes take effect after the next refresh. Note: You cannot change the Product name when editing a product.
Category	One of the categories defined for your signal configuration.
Complexity level	From None to High, or a custom level if defined. This impacts alert calculation. Changes take effect after the next refresh.
Birthdate	Date is used when scheduling complexity alerts, in MM/DD/YYYY format. This impacts alert calculation. Changes made do not take effect until the next refresh.
Organization	Organization associated with this product, as defined for your signal configuration.
Review period	Frequency that evaluations take place for this product; for example, every 3 months, 6 months, or 1 year. This impacts alert calculation. Changes made do not take effect until the next refresh. This field is required if an administrator set up the Review Period feature for the signal configuration.

Field	Description
Default view	Name of the default signal view associated with the product. This view appears as the left-most tab when the product is viewed on the Product-Event Combinations page . This setting is ignored if disabled in the signal configuration . If a different default view is specified in the signal configuration, the product's default view takes precedence and is shown.
Product group	Group associated with the product. - To select an existing group, click Select from existing groups and select from a list of groups. - To add a new group, click Add new group and type in a group name. Note: Products, not reviewers, belong to groups.
Reviewers (optional)	Names of individual reviewers assigned to the product. Click Add Reviewers From List to select reviewers from a list . If the product is marked as participating in automatic assignment of reviewers, you can specify only one reviewer. If there is already a reviewer assigned to the product, you can select no reviewer (--) to remove the assignment. Reviewers available for assignment are users in login groups to which the signal configuration is assigned.
Participates in automatic assignment	Whether the product is eligible for automatic assignment of reviewers. This option is only available if the Allow Automatic Assignment of Reviewers to product site option is enabled.

Delete a product

You cannot delete a product in the following situations:

- There are [notes](#) for the product.
- A refresh is in progress.
- There are [comments](#) for any product-event combinations that include the product.

Note

If you are working from a [multisource signal configuration](#) any changes you make are also made in the underlying lead configuration.

You cannot delete a product from an multisource signal configuration in the following situations:

- The lead configuration or any other [connected configurations](#) are undergoing a [refresh](#).
- The lead configuration or any other connected configurations contain notes for the product.
- The lead configuration or any other connected configurations contain comments for any product-event combinations that include the product.

You must have the Manage Signaling Terms [user permission](#) to delete a product.

1. In the left navigation pane, click the **Signal Review** icon (.
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action Menu** () and select **Delete**.
4. To delete the product, click **OK** on the confirmation message.

On the Signal Review page, alert counts will be updated if the deleted product had unreviewed alerts.

Note

If you delete a product then [add the same product](#) without first refreshing the signal configuration, then the product's tracked alerts appear as reviewed until the next refresh. After the next refresh, the alerts that were removed when the product was deleted no longer appear on the [Signal Review pages](#) or in the [signal history](#).

Edit a product field

1. In the left navigation pane, click the **Settings** icon (.
2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Select the signal configuration and, from its **Row Action menu** () , select **Edit Product Fields**.
4. On the Edit Product Fields page, you can perform the following actions:
 - To [modify the display order of the fields](#), click the **Modify Display Order** link.
 - To [change the columns included](#), click the **Columns** link.
 - To print the product fields, click the **Print** link.
 - To [download the data](#), click the **Download** link.

- To change the number of rows shown, change the number in the **Rows Per page** text box.
 - To [add a field value](#), from the **Row Action menu** () of a selected product field, click **Define Values**.
5. Click **Back**.

Add a product field value

1. In the left navigation pane, click the **Settings** icon ().
2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Select the signal configuration and, from its **Row Action menu** (), select **Edit Product Fields**.
4. To [add a field value](#), from the **Row Action menu** () of a selected product field, click **Define Values**.
5. Click the **Add Value** link, enter the value on the Add Value page, then click **Save**.
6. On the Define Product Fields page, you can also perform the following actions:
 - To [modify the display order of the fields](#), click the **Modify Display Order** link.
 - To [change the columns included](#), click the **Columns** link.
 - To print the product field values, click the **Print** link.
 - To [download the data](#), click the **Download** link.
 - To change the number of rows shown, change the number in the **Rows Per page** text box.
7. Click **Back**.

Delete a product field value

1. In the left navigation pane, click the **Settings** icon ().
2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Select the signal configuration and, from its **Row Action menu** (), select **Edit Product Fields**.
4. From the **Row Action menu** () of the selected product field, click **Define Values**.
5. From the **Row Action menu** () of the selected product field value, click **Delete**.
6. Confirm the deletion by clicking **OK**.

Note

You cannot delete a value which is currently in use by a product.

Rename a product field value

1. In the left navigation pane, click the **Settings** icon (.
2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Select the signal configuration and, from its **Row Action menu** () , select **Edit Product Fields**.
4. From the **Row Action menu** () of the selected product field, click **Define Values**.
5. From the **Row Action menu** () of the selected product field value, click **Rename**.
6. In the **Value** field, type the new name and click **Save**.

Modify the display order of product fields

1. In the left navigation pane, click the **Settings** icon (.
2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Select the signal configuration and, from its **Row Action menu** () , select **Edit Product Fields**.
4. In the top left corner, click **Modify Display Order**.
5. To change the order in which fields display in the Edit Product Fields table and in the Add/Edit Product window, click a field and select one or more fields.
6. When the fields are in the correct order, click **OK**.

Modify the display order of a product field's defined values

1. In the left navigation pane, click the **Settings** icon (.
2. From the **Configure System** menu, select **Manage Signal Configurations**.
3. Select the signal configuration and, from its **Row Action menu** () , select **Edit Product Fields**.
4. From the **Row Action menu** of the selected product field, click **Define values**.
5. In the top left, click **Modify Display Order**.
6. To change the order in which field's defined values display in the Define Product Field Values table and in the Add/Edit Product window, click a field and select one or more fields.
7. When the defined values are in the correct order, click **OK**.

Manage signal configuration refreshes

You can monitor and manage refreshes for interactive signal configurations and [multisource signal configurations](#). You cannot manage scripted signal configuration refreshes. Scripted signal configurations are managed outside of the Oracle Empirica Signal application, based on your organization's requirements. See [About signal configurations](#).

When to consider refreshing a signal configuration?

Typically, you refresh an interactive signal configuration after you perform the following activities (or the underlying data has been refreshed):

- [Rename products.](#)
- [Manage designated medical events.](#)
- [Manage custom terms.](#)
- [Manage targeted medical events.](#)
- [Manage listed events.](#)
- [Edit alert types.](#)

Additional considerations for multisource configurations

In addition to the above criteria, multisource configurations require a refresh in any of the following conditions:

- [Dependent configurations](#) have been refreshed.
- [Secondary configurations have changed.](#)
- Objects [shared with the lead configuration](#) have changed. When shared objects have changed, you must refresh the lead configuration first, then refresh the multisource configuration.

During a refresh, Oracle Empirica Signal incorporates your changes and [validates](#) the signal configuration. If validation errors are found, the refresh fails.

The following topics guide you through the process of managing signal configuration refreshes.

- [About refreshing signal configurations](#)
- [Signal Management Refreshes page](#)
- [Refresh a signal configuration from the Refresh Signal Management page](#)
- [Refresh a signal configuration using a definition file](#)
- [Access signal management refresh details](#)
- [View refresh details for a signal configuration](#)
- [View refresh details for a multisource signal configuration](#)
- [Cancel or delete a signal configuration refresh](#)
- [View jobs for a signal configuration refresh](#)
- [View job details for a signal configuration refresh](#)
- [Validate a signal configuration](#)

About refreshing signal configurations

You can monitor and manage refreshes for interactive signal configurations and [multisource signal configurations](#). You cannot manage scripted signal configuration refreshes. Scripted signal configurations are managed outside of the Oracle Empirica Signal application, based on your organization's requirements. See [About signal configurations](#).

When do configurations require a refresh?

You refresh an interactive signal configuration after you perform the following activities (or the underlying data has been refreshed):

- [Rename products.](#)
- [Manage designated medical events.](#)
- [Manage custom terms.](#)
- [Manage targeted medical events.](#)
- [Manage listed events.](#)
- [Edit alert types.](#)

Additional considerations for multisource configurations

In addition to the above criteria, [multisource signal configurations](#) require a refresh if any of the following conditions are true:

- [Dependent configurations](#) have been refreshed.
- [Secondary configurations have changed.](#)
- Objects [shared with the lead configuration](#) have changed. When shared objects have changed, you must refresh the lead configuration first at least once, then refresh the multisource configuration.

During a refresh, Oracle Empirica Signal incorporates your changes and [validates](#) the signal configuration. If validation errors are found, the refresh fails.

Signal Management Refreshes page

On the Signal Management Refreshes page, you can view refresh runs of signal configurations.

Note

You must have Manage Signal Configurations user permission to perform the following actions.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click **Refresh** in the Row Action menu (Row Action menu icon

⋮

) from the column, if you work with the multi-enterprise enabled Argus configuration.

Note

If the message, *You do not have permission to refresh this configuration*, appears at the top of the page and the **Submit** button is disabled, you don't have the necessary permission to perform a refresh.

4. Click **Manage Refreshes**.

Arrange and extract data

Use the links at the top of the page to configure and download the data appearing in the table.

- [Columns](#)
- [Print](#)
- [Download](#)
- [Back](#)

Select the Signal Management Configuration drop-down menu to filter the table to a specific configuration, if needed.

Row-specific activities

The following options appear in the Row Action menu () for each refresh:

- [View Refresh Details](#)
- [Delete](#)
- [View Jobs for Refresh](#)
- [Create Definitions File](#)

In the new window, you can **Print Help** or **Close** the generated table.

Table 10-3 Field descriptions—Signal Management Refreshes page

Field	Description
ID	Identifier assigned automatically to the refresh when the refresh was created. Each ID is unique and is not re-used if the refresh is deleted.
Signal Management Configuration	Signal configuration name.

Table 10-3 (Cont.) Field descriptions—Signal Management Refreshes page

Field	Description
Data As Of	As of date for the refreshed data, if the data is timestamped .
Created	Date and time when the refresh was created.
Created By	Role or name of the user who created the refresh.
Start date	Date and time that the refresh was executed.
End date	Date and time that the refresh was completed.

Note

When an Argus Mart interactive signal management refresh is initiated, if the user has selected **Latest date at start of refresh** for the **Select As Of Date (unadjusted data time)** option, then the Date As Of on the Manage Refreshes page shows 01-DEC-9999 as a temporary placeholder for Date As Of. This date will be replaced with the actual latest Date As Of from the Argus Mart when the refresh process begins execution. If the refresh is scheduled for a future date/time, the 01-DEC-9999 temporary placeholder is displayed until the refresh begins at the requested future date/time.

Table 10-3 (Cont.) Field descriptions—Signal Management Refreshes page

Field	Description
Status	Status of the refresh run. The column remains empty until the refresh has completed or failed. Statuses include: • Canceled: The refresh was canceled while the job is being performed. • Completed: The refresh completed successfully. • Completed with warnings: The refresh completed but encountered issues. • Error Occurred: The refresh failed. Warnings or errors encountered during a refresh appear on the Jobs for Refresh page.

Refresh a signal configuration from the Refresh Signal Management page

To [refresh a signal configuration](#) for the first time, you must use the Refresh Signal Management page. However, for future refreshes, you can [use a definition file](#).

You must have the Manage Signal Configurations and Create Data Mining Runs [user permissions](#) to initiate a refresh.

After you refresh a signal configuration, you should not edit the signal configuration.

Note

You cannot schedule a refresh if a refresh is in progress.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action menu** () for the signal configuration, and then click **Refresh**.

Note

If you work with the Multi-enterprise enabled Argus configuration and the message, *You do not have permission to refresh this configuration*, appears at the top of the page and the **Submit** button is disabled, you don't have the necessary permission to perform a refresh.

Note

If you work with **Multisource signal configurations**, you must refresh the configuration after you perform [certain activities](#).

4. If your configuration is time-stamped, specify As Of date.

- a. **Latest date at start of refresh**—Use the current data to determine the As Of date of refresh. Selected by default.
 - b. **Specific date**—Select a specific As Of date and time.
5. Specify when to perform the refresh:
 - a. **Run as soon as possible**—The refresh is executed immediately.
 - b. **Do not run until**—The refresh is executed on the date and time that you specify.
6. Check the **Suppress alert calculations** checkbox if you want to prevent automatic calculations.
7. To receive an email notification when the refresh is complete:
 - a. Select the **Email me when complete** check box.
 - b. Type one or more email addresses using a comma to separate each address.

The email addresses associated with your Oracle Empirica Signal user name appear by default. To change these email addresses, contact your site administrator.
8. Click **Submit**.
9. Click **Confirm**, if necessary.
10. Click **Continue**.

Refresh a signal configuration using a definition file

To [refresh an interactive or multisource signal configuration](#) without logging in to the Oracle Empirica Signal application, you can use a definition file. The definition file enables you to refresh a signal configuration that you have refreshed previously.

The following procedure describes how to set up the definition file for the first time.

You must have the Manage Signal Configuration [user permissions](#) to create a definition file.

1. In the left navigation pane, click the **Settings** icon .
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click **Manage Refreshes** at the top of the page.
4. Click the **Row Action menu** () for the refresh to reschedule, and then click **Create Definition File**.
5. Copy the contents of the Input File page into a text editor.
6. Set the **runafter** property.
The format for the date and time is *mm/dd/yyyy hh:mm:ss*.
7. Save the file as *refreshTest.in*.
8. Log in to the Oracle Empirica Signal application server.
9. Save the *refreshTest.in* file in the Signal\Input directory.

Access signal management refresh details

You can view pending or implemented changes to an interactive signal configuration from the following pages:

- **Manage Signal Configurations**—View pending changes before you [refresh](#) the signal configuration.

- **Signal Management Refreshes**—View changes implemented during the refresh.

To view details for refreshes, including refreshes that have already run, that are currently running, or scheduled refreshes:

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Configure System** section, click **Manage Signal Configurations**.
 - To view pending changes to an interactive signal configuration: Click the **Row Action menu** (⋮) for the signal configuration, and then click **View Refresh Details**.
 - To view changes implemented to signal configurations for each refresh:
 - a. On the Manage Signal Configurations page, click the **Manage Refreshes** link at the top of the page.
 - b. From the **Signal Management Configuration** drop-down list, select a configuration.
 - c. To see the details of a refresh listed, click that refresh row's **Row Action menu** (⋮), and then click **View Refresh Details**.

Note

A message stating that details are not available appears if a refresh is running, or scheduled to run, to prevent you from making changes that would impact the refresh.

To learn about the details displayed for interactive signal configuration refreshes, see [View refresh details for a signal configuration](#).

To learn about the details displayed for multisource signal configuration refreshes, see [View refresh details for a multisource signal configuration](#).

View refresh details for a signal configuration

You can [access refresh details](#) for a multisource configuration from the following pages:

- **Manage Signal Configurations**—View pending changes before you [refresh](#) the signal configuration.
- **Manage Refreshes**—View changes implemented during the refresh.

Details for a signal management refresh include monitored products, renamed products, designated medical events, targeted medical events, listed events, custom terms, active alert types, and the signal configuration properties for the refresh.

Field descriptions: Detail for Refresh - Interactive signal configurations

Field	Description
ID	When viewing details of a refresh that has taken place, the ID row displays the identifier assigned to the refresh when the refresh was created. IDs are unique and are not reused.
Monitored products	New and deleted monitored products in alphabetical order.

Field	Description
Renamed products	Renamed monitored products in alphabetical order by current name.
Renamed product terms	Renamed products terms in alphabetical order by product term.
Designated medical events	New and deleted designated medical events in alphabetical order.
Targeted medical events	New and deleted targeted medical events for monitored products in alphabetical order by monitored product.
Listed events	New and deleted listed events for monitored products in alphabetical order by monitored product.
Product custom terms	New, edited, and deleted product custom terms in alphabetical order. The query used to define the custom term is shown.
Event custom terms	New, edited, and deleted event custom terms in alphabetical order. The query used to define the custom term is shown.
Signal configuration properties	Details of the signal configuration .
Calculate Alerts	Shows if alert calculations are enabled or disabled. If the Suppress alert calculations checkbox is selected when submitting the refresh, the value will be No in refresh details page.
Activated alert types: Review period based	Details of the active alert types with review period based alert type rules, including Label, Tracked, Review Period, Condition.
Activated alert types: Complexity level based	Details of the active alert types with complexity level based alert type rules, including Label, Tracked, Complexity, Periodicity, Condition.
Refresh start date	Appears when viewing completed refreshes. Date and time that the refresh was executed.
Refresh created by	Appears when viewing completed refreshes. Name of the user who created the refresh.
Data as of	Appears when viewing completed refreshes. As of date for the refreshed data, if the data is timestamped .
Date	Appears when viewing pending refreshes. Date and time that you accessed the Refresh Details page.

View refresh details for a multisource signal configuration

You can [access refresh details](#) for an interactive or [multisource signal configuration](#) from the following pages:

- **Manage Signal Configurations**—View pending changes before you [refresh](#) the signal configuration.
- **Signal Management Refreshes**—View changes implemented during the refresh.

When viewing refresh details for a multisource signal configuration, you see the following information:

- Information for the lead and secondary configurations, including Name, Label (for secondary configurations), Refresh ID, Refreshed Date and Data As Of.
- Calculate alerts setting.
- Active alert types.
- Refresh date.
- Refresh user.

The details for the lead and secondary configurations may include a Refresh ID link, from which you can open the [details of the last refresh run](#) for the underlying configuration.

If the refresh has been deleted, the run id is not available. If no refresh was run, either because the configuration was not refreshed or the refresh run was deleted, then Refresh ID and Data As Of columns will be empty. The secondary signal configuration section does not appear if no secondary configuration is [specified in the multisource configuration](#).

Field descriptions: Detail for refresh - multisource signal configurations

Field	Description
ID	When viewing details of a refresh that has taken place, the ID row displays the identifier assigned to the refresh when the refresh was created. IDs are unique and are not reused.
Lead signal configuration	Provides the Name, along with details about the last refresh, including Refresh ID, Refreshed Date, and Data As Of. You can click the Refresh ID to view the refresh details for the last refresh of the underlying configuration. If the Refresh ID does not appear, the refresh was either deleted or the configuration was not refreshed.
Secondary signal configuration(s)	Provides the Name and Label of the secondary configuration, along with details about the last refresh, including Refresh ID, Refreshed Date, and Data as of. You can click the Refresh ID to view the refresh details for the last refresh of the underlying configuration. If the Refresh ID does not appear, the refresh was either deleted or the configuration was not refreshed.
Calculate alerts	Indicates whether alerts calculations are included as part of the refresh. If you select the Suppress alert calculations on next refresh check box when adding or editing a multisource signal configuration , the value is NO for the resulting refresh.
Activated alert types: Review period based	Details of the active alert types with review period based alert type rules, including Label, Tracked, Review Period, Condition.
Activated alert types: Complexity level based	Details of the active alert types with complexity level based alert type rules, including Label, Tracked, Complexity, Periodicity, Condition.
Refresh start date	Appears when viewing completed refreshes. Date and time that the refresh was executed.

Field	Description
Refresh created by	Appears when viewing completed refreshes. Name of the user who created the refresh.
Date	Appears when viewing pending refreshes. Displays the date and time that you accessed the Refresh Details page.

Cancel or delete a signal configuration refresh

- You can cancel refreshes that have not started or are in progress.
- You can delete refreshes that have a status of Complete, Error Occurred, or Canceled.

When you delete a refresh, the refresh no longer appears on the Signal Management Refreshes page.

- In the left navigation pane, click the **Settings** icon (.
- In the **Configure System** section, click **Manage Signal Configurations**.
- Click **Manage Refreshes**.
- In the table, locate the refresh to cancel or delete.
- Click the **Row Action menu** () for the refresh, and then click **Cancel** or **Delete**.

Note

If the refresh is canceled, the Signals Review page will remain as it had appeared prior to initiating the refresh. Canceling a refresh also cancels runs that are incomplete or not started.

View jobs for a signal configuration refresh

The **Jobs for Refresh** page shows the progress of the jobs that make up a refresh. Oracle Empirica Signal updates the page automatically until the refresh is successful or an error causes the refresh to fail.

The name and owner of the refresh appear at the top of the page. If a refresh is scheduled for the future, the scheduled date and time also appear.

- In the left navigation pane, click the **Settings** icon (.
- In the **Configure Systems** section, click **Manage Signal Configurations**.
- Click **Manage Refreshes**.
- Click the **Row Action menu** () for the refresh, and then click **View Jobs for Refresh**.

Each refresh run consists of three component jobs: preparation, deployment, and post-processing.

If a refresh fails or completes with warnings, the component job where the error or warning occurred is highlighted and the Status column provides information on the warning or error.

- To view the [changes implemented during the refresh](#), click **View Refresh Details** above the table.

- To view [details about a component job](#) of the refresh, click the job **Name**.

Field descriptions

Column	Description
ID	Automatically assigned unique ID of the refresh. IDs of deleted refreshes are not re-used.
Name	The name of each job that makes up the refresh, for example: - Simgmt_Data_Preparation_ ID - Simgmt_Data_Deployment_ ID - Simgmt_Data_Processing_ ID Click the job name to view job details .
Description	The text, Part of Run , followed by the run ID.
Server	The value, any , appears if the next available listener can perform the job. If multiple listeners are in use, and the refresh is submitted using a definition file , a listener can be specified to perform each job, and the unique ID of the listener appears.
Created	Server date and time when the preparation job was created.
Start Date	Server date and time when the job was started.
End Date	Server date and time when the job ended.
Runnable	The value is NO for a job until the preceding job is complete. After the preceding job is complete, the value is YES.
Status	The column remains empty until the job has completed or failed. If the job completes successfully, the status is Completed. If the run is canceled when the job is being performed, the status is Cancelled. If the job completed with warnings, the status column displays the warning message. If the job failed, an error message appears on a red background .

View job details for a signal configuration refresh

If a [refresh](#) job fails, you can use the Job Detail page to determine the cause of the failure. The Job Detail page displays the status of a component job in a refresh run, any error messages, and a list of input and output files produced by the selected job.

- In the left navigation pane, click the **Settings** icon (.
- In the **Configure System** section, click **Manage Signal Configurations**.
- Click **Manage Refreshes**.
- Click the **Row Action menu** () for the refresh, and then click **View Jobs for Refresh**.
- Click the name of the component job you wish to view.

Field descriptions - Job Detail page

Column	Description
ID	Automatically assigned unique ID of the component job.
Name	The name of the component job.
Description	The text, Part of Run , followed by the run ID.
Server	The value, any , appears if the next available listener can perform the job. If multiple listeners are in use, and the refresh is submitted using a definition file , a listener can be specified to perform each job, and the unique ID of the listener appears.
Created	Server date and time when the preparation job was created.
Start Date	Server date and time when the job was started.
End Date	Server date and time when the job ended.
Runnable	The value is NO for a job until the preceding job is complete. After the preceding job is complete, the value is YES.
Completed	Value is YES or NO, indicating if the job is complete or not.
Cancelled	Value is YES or NO, indicating if the job is cancelled or not.
Status	The column remains empty until the job has completed or failed. If the job completes successfully, the status is Completed. If the run is canceled when the job is being performed, the status is Cancelled. An error message appears on a red background if the job failed.
Error	Value is YES or NO, indicating if the job encountered an error or not.
Error Msg	Displays the error message and Error ID if errors occurred.
Job Parameters	Displays the settings and configuration ID of the component job settings. If files are listed in the Input and Output files rows, you can click to download them.

Validate a signal configuration

Validation criteria

During validation, Oracle Empirica Signal checks the signal configuration to ensure the following:

- Referenced data configurations exist.
- Referenced data configurations are valid.
- Referenced variables exist in each data configuration and are of the correct type.

For example, Oracle Empirica Signal checks whether event variables in the data configuration are of type Event.

- Variables referenced in [custom term](#) queries exist in each data configuration referenced in the signal management configuration.

- Variables referenced in [database restriction](#) queries exist in each data configuration referenced in the signal management configuration.

For a [multisource signal configuration](#), validation ensures the following:

- Alert Type conditions referencing secondary configuration columns are valid.
- Alert Type views referencing secondary configuration columns are valid.
- Lead and Secondary configurations are successfully refreshed.
- Views referencing secondary configuration columns are valid.

Note

When working with multisource signal configurations, you must ensure alert types or views do not include invalid columns from secondary configurations. To enable this, alert calculations are automatically suppressed when [creating a multisource signal configurations](#). You also have the option to suppress alert calculations when [changing a secondary configuration](#).

If a configuration cannot be validated, the refresh will fail.

Validating a configuration

Validation occurs automatically during processes such as a refresh. Additionally, you can manually validate a configuration at any time on the Manage Signal Configurations page.

You must have the Manage Signal Configurations permission to validate a signal configuration.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action menu** () for the signal configuration, and then click **Validate**.
4. Review the list of findings.
5. To return to the Manage Signal Configurations page, click **Continue**.

Manage signal comment types

- [Add a signal comment type](#)
- [Edit a signal comment type](#)
- [Delete a signal comment type](#)
- [Change the sort order of a signal comment type](#)

Add a signal comment type

Signal comment types are comments that you can apply to product-event combinations, for example, *Open Bring to Meeting*.

The application includes some signal comment types by default. If you have the Manage Signal Configurations permission, you can add signal comment types.

Additionally, you can [edit](#) and [delete](#) comment types, and change the sort order of comment types.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action** menu (⋮) for the signal configuration, and then click **Edit Comment Types**.
4. Click **Add Comment Type**.
5. Fill in the fields according to the following table.
6. Click **Save**, and then click **Close**.

Field Descriptions—Add/Edit Comment Type dialog box

Field	Description
Comment text	Comment. When users perform Submit Review, this value appears in the Comment drop-down list.
Abbreviated comment text	Shortened version of the comment. When users select this comment in Submit Review, this value appears in the Comment column on the Product-Event Combinations page.
Is suppress reason?	If you select Yes, the comment is available in the Submit Review dialog box as a reason for suppressing a product-event combination. If this field is not set to Yes for any comments, then Suppress product-event combination does not appear on the Submit Review dialog box.
Is review reason?	If you select Yes, the comment is available to select in the Comment field in the Submit Review dialog box. If private comments are enabled, the comment is available to be added as a private comment.
Requires detailed comment?	If you select Yes , users must enter an additional free-text comment in the Submit Review dialog box when selecting this comment.
Requires associated topic?	If you select Yes , users must associate a topic with the product-event combination in the Submit Review dialog box when selecting this comment.
Review after delta threshold	Enter the number of new cases after which a signal that has been suppressed (on the Submit Review dialog box) becomes unsuppressed.

Note

This feature is only supported in custom signal configurations.

Edit a signal comment type

You can edit signal comment types if you have the Manage Signal Configurations permission.

1. In the left navigation pane, click the **Settings** icon (⚙️).

2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action menu** () for the signal configuration, and then click **Edit Comment Types**.
4. In the table, locate the comment to edit.
5. Click **Edit** for the comment.
6. Modify the fields as needed.
For a description of the fields, see [Add a signal comment type](#).
7. Click **Save**, and then click **Close**.

Delete a signal comment type

You can delete signal comment types if you have the Manage Signal Configurations permission.

If you delete a comment that is applied to a product-event combination, the comment remains visible when you [view the signal history](#).

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action menu** () for the signal configuration, and then click **Edit Comment Types**.
4. In the table, locate the comment to delete.
5. Click **Delete** for the comment, and then click **Close**.

Change the sort order of a signal comment type

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action menu** () for the signal configuration, and then click **Edit Comment Types**.
4. Click **Change Sort Order**.
5. Click a comment, and use the up and down arrows to change the position of the comment.

Assign reviewers to products

- [Automatic assignment of reviewers to products](#)
- [Automatically assign reviewers to products](#)
- [Modify automatic reviewer assignments](#)

Automatic assignment of reviewers to products

Reviewers whose names have been added to the signal management components of the application are eligible for automatic assignment to products. You can either assign reviewers to products when [adding or editing a product](#), or use a process that automatically assigns selected reviewers to products for which there are new cases since an indicated time period.

The automatic assignment process affects only products that have been set up to participate in automatic assignment. (You must have checked **Participates in auto-assignment** when adding or editing the product.) The process looks at products for new cases since the time period you select, and allows you to distribute the products evenly over selected reviewers. Because these products might already have assignments (due to previous cases), the automatic assignment process can result in re-assignments. Products for which there are no new cases (since the last period), but that have been set up to participate in automatic assignment, have their reviewer assignments cleared.

The following table shows how reviewers' product assignments are affected by the automatic assignment process:

Assignment status	Have new cases	Do not have new cases
Already Assigned	Re-assigned if you select them. Retain previous assignments if you do not select them.	Assignments are cleared.
Unassigned	Assigned if you select them. Remain unassigned if you do not select them.	Remain unassigned.

How reviewers are distributed over products

The application does the following during the automatic assignment process:

1. Orders the products in ascending order of the number of new cases.
2. For the first product in the ordered list, assigns the first reviewer in the list of Selected reviewers that you have chosen.
3. For the next product in the ordered list, assigns the next reviewer in the list of Selected reviewers.
4. Continues to assign products until all products have been assigned. When the application reaches the end of the list of Selected reviewers, the application starts again with the first reviewer in the list.

When a product that is already assigned to a reviewer is re-assigned, no attempt is made to retain the currently assigned reviewer. However, it is possible for the product to be re-assigned to the same reviewer coincidentally.

You can force a product that appears in new cases to retain its current assignment by excluding it from the [automatic assignment process](#).

Overriding automatic assignments

At the end of the automatic assignment process, the application displays the automatic assignments that have been made to products and you have the opportunity to override assignments. You can also override the automatic assignment for a product on the [Automatic Assignment page](#) or by editing a product and changing the reviewer.

Automatically assign reviewers to products

You must have the Manage Signaling Terms permission to automatically [assign reviewers](#) to products. Additionally, an administrator must enable the Allow Automatic Assignment of Reviewers to Products [site option](#).

Note

You must refresh signal management before you can use the automatic assignment feature since it uses counts of new cases to evenly distribute product reviews among reviewers.

1. In the left navigation pane, click the **Signal Review** icon ()
2. From the **Manage Reference Data** menu () , on the top right, click **Auto-Assign to Reviewers**.
3. From the **Signal set** drop-down list, select a product criterion.
For a multisource configuration, only signal sets from the Lead configuration are available in the drop-down.
4. From the **Consider drugs with new cases since** drop-down list, select a time period.
Choose a signal set that represents new cases; for example, named "...Nsince" or "...Nnew", and not one that represents a total count (named "...N").
5. Click **Next**.
6. From the **Available reviewers** list, select the reviewers, move them to the **Selected reviewers** list, and click **Next**.
 - Available reviewers for assignment are those in login groups to which the signal configuration is published.

Note

If you are working with a multisource signal configuration, the login groups may differ between the [connected configurations](#). Since the reviewers list is shared between all connected configurations, changes made to one configuration overwrites the data in all on refresh. To prevent losing data, you should assign reviewers from either the multisource signal configuration or the lead configuration, but not both. See [Get started with multisource signal configurations](#).

- An error message appears if there are no drugs that conform to the selected time period.
7. From the **Available drugs** list, select the drugs, move them to the **Selected drugs** list, and click **Next**.
Available drugs are those that are marked as allowing participation in automatic assignment and for which there are new cases since the selected time period.
 8. Click **Next**.
The Automatic Assignments dialog box appears, showing the reviewer assignments that can be made. The number of new cases for each drug is also shown.
 9. Click **Save**.

Modify automatic reviewer assignments

The Automatic Assignments page provides information about drugs that have been assigned automatically to a reviewer. There is one reviewer per drug. This page does not show assignments that were made manually (when the drug was added or edited). You can use this modification procedure to override automatic assignments.

1. In the left navigation pane, click the **Signal Review** icon ()
2. From the **Manage Reference Data** menu () , on the top right, click **Modify Automatic Assignments**.

The Modify Automatic Assignments page appears and provides the following information about each drug that currently has a reviewer (who has been assigned automatically):

Column	Description
Drug	Name of the drug.
Reviewer	Name of the reviewer who has been assigned automatically to the drug.

If rows have been filtered using a SQL WHERE clause in the Column and Rows dialog box, the text, **Rows are filtered**, appears above the table. Rest the cursor on that text to see the SQL WHERE clause that is in effect. For more information, see [Arrange table columns and rows](#).

3. Click the **Row Action** menu () for the drug, and then click **Change**.
4. Select another reviewer from the **Reviewer** drop-down list and click **OK**.

You can also select no reviewer (--) to remove an assignment. Available reviewers for assignment are those in login groups to which the signal configuration is assigned.

Note

If you are working with a multisource signal configuration, be aware that the Drug Reviewer table is shared by all configurations connected as part of an multisource signal configuration. Any changes you make to the reviewers list overwrites the data in all connected configurations. To prevent confusion, you should assign reviewers from either the multisource signal configuration or the lead configuration, but not both. See [Get started with multisource signal configurations](#).

Manage events and custom terms

- [Types of signaling terms](#)
- [Maintain a list of targeted medical events](#)
- [Maintain a list of listed events](#)
- [Add a designated medical event](#)
- [Add, edit, or delete a custom term](#)

Types of signaling terms

For [interactive signal configurations](#), you can manage the following types of signaling terms:

- **Designated medical event (DME)**—Adverse events that your organization wants to monitor closely. DMEs are not associated with a particular product. For more information, see [Add a designated medical event](#).
- **Custom term**—User-specified term used as a pseudo-product or pseudo-event value in data mining. For more information, see [Add, edit, or delete a custom term](#).
- **Targeted medical event (TME)**—Event associated with a product. For more information see, [Maintain a list of targeted medical events](#).
- **Listed event**—Event listed on the label of a product. For more information, see [Maintain a list of listed events](#).

You update DMEs and custom terms from the **Manage Reference Data** menu (), on the top right. You update TMEs and Listed events from the Products table.

Maintain a list of targeted medical events

For [interactive](#) and multisource configurations, you can maintain a list of targeted medical events (TMEs) for each product. A TME is an adverse event that your organization wants to monitor closely for a particular product. For example, you might add Hepatic failure as a TME for Product A.

Before you begin

- You must have the Manage Signaling Terms permission to manage TMEs.
- The Data Configuration for 2D Runs specified for the [signal configuration](#) must be present and valid.
- The Event Variable for 2D Runs and Drug Variable for 2D Runs specified for the signal configuration must exist in the Data Configuration for 2D Runs.
- You define TMEs at the hierarchy level specified in the Event Variable for 2D Runs field for the signal configuration. For example, if the Event Variable for 2D Runs is (Event) PT, you define TMEs using preferred terms.
- You cannot add or delete a targeted medical event while a signal configuration refresh is in progress.
- You must [refresh](#) the signal configuration for your changes to take effect.

If you are working from a [multisource signal configuration](#):

- TMEs are shared between the multisource signal configuration and the lead configuration, as well as any other connected configuration. Modifications made in one configuration will be saved to all.
- You cannot add or delete TMEs in a multisource signal configuration if the lead configuration or any connected configuration is undergoing a refresh.

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.

3. Click the product's **Row Action menu** () and select **Manage Targeted Medical Events**.
4. Add a TME for the product using one of the following methods:
 - [Select < hierarchy > terms](#).
 - [Select available values](#).
 - [Select a saved list of values](#).
 - [Type the values](#).

Note

To prevent spelling and capitalization errors, we recommend that you select rather than type values.

5. (Optional) Select the **Validate list when saving** checkbox.
6. Click **Save**.
 - The TMEs are saved and are applied when you [refresh](#) the signal configuration.
 - If you are working with a [multisource signal configuration](#), you must refresh the underlying lead configuration first, then refresh the multisource signal configuration for changes to take effect.
 - In the Product-Event Combinations page, the TME column identifies product-event combinations that are associated with a TME.

Maintain a list of listed events

For [interactive](#) and multisource configurations, you can maintain a list of listed events for each product. A listed event is an adverse event that is listed on the product label. For example, dizziness is a listed event for Ibuprofen.

Before you begin:

- You must have the Manage Signaling Terms permission to manage listed events.
- The Data Configuration for 2D Runs specified for the [signal configuration](#) must be present and valid.
- The Event Variable for 2D Runs and Drug Variable for 2D Runs specified for the signal configuration must exist in the Data Configuration for 2D Runs.
- You define listed events at the hierarchy level specified in the Event Variable for 2D Runs field for the signal configuration. For example, if the Event Variable for 2D Runs is (Event) PT, you define listed events using preferred terms.
- You cannot add or delete a listed event while a signal configuration refresh is in progress.
- You must [refresh](#) the signal configuration for your changes to take effect.

If you are working from a [multisource signal configuration](#):

- Listed events are shared between the multisource signal configuration and the lead configuration, as well as any other connected configurations. Modifications made in one configuration will be saved to all.
- You cannot add or delete listed events in a multisource signal configuration if the lead configuration or any other connected configurations are undergoing a refresh.

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Click the product's **Row Action menu** () and select **Manage Listed Events**.
4. To add listed events, specify the listed events for the product using one of the following methods:
 - [Select <hierarchy> terms](#).
 - [Select available values](#).
 - [Select a saved list of terms](#).
 - [Type the terms](#).

Note

To prevent spelling and capitalization errors, we recommend that you select rather than type values.

5. (Optional) Select the **Validate list when saving** checkbox.
If you select the checkbox, Oracle Empirica Signal checks whether the terms that you specified are in the source data. If the terms are not in the source data, an error message appears and the invalid terms are moved to the end of the list.
6. Click **Save**.
 - The listed events are saved and are applied when you [refresh](#) the signal configuration.
 - If you are working with a [multisource signal configuration](#), you must refresh the underlying lead configuration first, then refresh the multisource signal configuration for changes to take effect.
 - In the Product-Event Combinations page, the LST column identifies product-event combinations that are associated with a listed event.

Add a designated medical event

You can maintain a list of designated medical events (DMEs) for [interactive and multisource configurations](#). A DME is an adverse event that your organization wants to monitor closely. DMEs are not associated with particular products.

Before you begin

- The Data Configuration for 2D Runs specified for the [signal configuration](#) must be present and valid.
- The Event Variable for 2D Runs and Drug Variable for 2D Runs specified for the signal configuration must exist in the Data Configuration for 2D Runs.
- You define designated medical events (DMEs) at the hierarchy level specified in the Event Variable for 2D Runs field for the signal configuration.
- For example, if the Event Variable for 2D Runs is (Event) PT, you define DMEs using preferred terms.
- You cannot add or delete DMEs while a signal configuration refresh is in progress.

- You can add a maximum of 2000 values as DMEs.
- You must [refresh](#) the signal configuration for your changes to take effect.
- You must have the Manage Signaling Terms permission to manage DMEs.

If you are working from a [multisource signal configuration](#):

- DMEs are shared between the multisource signal configuration and the lead configuration, as well as any other connected configurations. Modifications made in one configuration will be saved to all.
- You cannot add or delete DMEs in a multisource signal configuration if the lead configuration or any other connected configuration are undergoing a refresh.

Adding a designated medical event

1. In the left navigation pane, click the **Signal Review** icon ()
2. From the **Manage Reference Data** menu () , on the top right, click **Manage Designated Medical Events**.
3. Specify the DMEs to add using one of the following methods:
 - [Select <hierarchy> terms](#).
 - [Select available values](#).
 - [Select a saved list of terms](#).
 - [Type the terms](#).

Note

To prevent spelling and capitalization errors, we recommend that you select rather than type values

4. (Optional) Select the **Validate list when saving** checkbox.
If you select the checkbox, Oracle Empirica Signal checks whether the terms that you specified are in the source data. If the terms are not in the source data, an error message appears and the invalid terms are moved to the end of the list.
5. Click **Save**.
 - The DMEs are saved and are applied when you [refresh](#) the signal configuration.
 - If you are working with a [multisource signal configuration](#), you must refresh the underlying lead configuration first, then refresh the multisource signal configuration for changes to take effect.
 - In the [Product-Event Combinations](#) page, the DME column identifies product-event combinations that are associated with a DME.

Add, edit, or delete a custom term

For [interactive and multisource signal configurations](#), you create custom terms to represent a pseudo-value for a product or event. For example, you might create a custom event term called Pain and include the following MedDRA hierarchy terms in the definition of Pain:

- Facial pain

- Lip pain
- Pain in jaw
- Gingival pain

The example is for an event variable. However, you can also create custom terms for product variables.

Custom terms appear as optional values when you define a data mining run. For more information about how custom terms are used in data mining runs, see [What are custom terms?](#)

Before you begin

- The data configurations specified for the [signal configuration](#) must be present and valid.
- The values you use to define each custom term must be present in the data configurations specified for the signal configuration.
- You cannot add, edit, or delete custom terms while a signal configuration refresh is in progress.
- Custom terms must be unique within the signal configuration.
- You must [refresh](#) the signal configuration for your changes to take effect.
- You must have the Manage Signaling Terms permission to manage custom terms.

If you are working from a [multisource signal configuration](#):

- Custom terms are shared between the multisource signal configuration and the lead configuration, as well as any other connected configurations. Modifications made in one configuration will be saved to all.
- You cannot add or delete custom terms in a multisource signal configuration if the lead configuration or any other connected configurations are undergoing a refresh.
- For changes to custom terms to take effect, you must refresh the underlying lead configuration first, then refresh the multisource signal configuration.

Add a custom term

1. In the left navigation pane, click the **Signal Review** icon ()
2. From the **Manage Reference Data** menu () , on the top right, click **Manage Custom Terms**.
3. On the top left, click **Create Custom Term**.
4. In the **Name** field, type a name for the custom term.

If the name includes an invalid character, Oracle Empirica Signal replaces the character with a pound sign (#) and displays an informational message. The following characters are invalid:

- \, /, <, :, >, |, ?, *, ", &, and null
- Control characters
- Non-ASCII characters

Note

If you already added a custom term containing an invalid character, first remove it from the **Manage Custom Terms** section. Second, on the Products page, delete the custom term containing the invalid character and re-add the term without the character.

5. From the **Item variable** drop-down list, select the variable type for the term; for example, Drug or Event.
6. Specify a query to identify the cases for which to include the custom term.
 - [Create Using Query Wizard](#): Create a query from scratch following the steps of the wizard.
 - [Create From Existing Query](#): Choose an existing query. You must have created or published the query. Subsequent changes you make to the query in the library do not affect the custom term.
7. In the **Hierarchy Path** field, click **Select <hierarchy> term**.
8. [Browse the hierarchy](#) to find the hierarchy item with which to associate the custom term.
9. Click **OK**.

Edit a custom term

1. In the table, locate the custom term to edit.
2. Select the custom term's **Row Action menu** () icon, then click **Edit**.
3. Edit the fields as necessary.

Note

We recommend that you do not change the name of the custom term. Changing the name does not actually change the name of the custom term. Rather, it creates a new custom term and removes the old one in the next refresh. Prior comments, topic associations, and unreviewed alerts associated with the prior custom term's product-event combinations will be orphaned.

4. Click **OK**.

Delete a custom term

1. In the table, locate the custom term to delete.
2. Select the custom term's **Row Action menu** () icon, then click **Delete**.
3. Confirm the deletion by clicking **OK**.

Manage signal views

- [Maintain signal views](#)
- [Rename a signal view](#)
- [Organize signal views](#)

Maintain signal views

A signal view specifies the following for the Product-Event Combinations table:

- Which columns are included, and in what order.
- The sort order of columns.
- The SQL WHERE clause that selects product-event combinations (shown on the [Rename Signal View](#) page).

Typically, an organization has predefined standard views. Additional views can be added by the user by the [Save a product-event combinations as a new view](#) option.

A view can be also specified as the [default view for a product](#) or for a [signal configuration](#).

Users with **Manage Signal Views** permission are able to open Manage Signal Views page. They can organize, publish, rename, and delete views created by the user, views created by other users in their login group, as well as views published to their login group.

Users without Manage Signal Views permission are able to open Manage Signal Views page. They can rename and delete views that they created.

1. In the left navigation pane, click the **Signal Review** icon ()
 2. From the **Manage Reference Data** menu () , on the top right, click **Manage Views**.
- The Manage Signal Views page appears and provides the following information about each signal view that you created. If you have the **Manage Signal Views** permission, the page also lists views created by other users in your login group, as well as views published to you.

Column	Description
Name	Name of the signal view. Note If the signal configuration has the review period feature set up, each view name should include the length of the review period, such as New Cases (3 months) and New Cases (6 months).
Description	Description of the signal view.
Category	The grouping for the view, such as Product Alerts or Supplemental. The category defines the view's location in the Add tab menu on the Product-Event Combinations page. View categories are customized for the requirements of each organization.
Modified	Date and time when the signal view was last modified.
Created By	Name of the user who created the signal view.
Created On	Date and time when the signal view was created.

Column	Description
Review Period	The period of time for data in the view, such as the last 3 months, 6 months, or 1 year. Appears if the signal configuration has the review period feature set up.

3. To [organize signal views](#); that is, to specify how they will appear in the **Add tab** menu on the Product-Event Combinations page:

- a. From the **Manage Reference Data** menu (), on the top right, click **Manage Views**.
- b. Click **Organize Views**. (This option is available only if you have the Manage Signal Views permission.)

Rename, publish, or delete a view

If you click the **Row Action menu** () for a signal view, you can do the following:

- To [rename a view](#), click **Rename**.
- To [publish](#) a view, click **Publish**, select the login group(s), then click **Back**.

Note

This option is available only if you have the Manage Signal Views permission.

Prior to publication, signal views are visible to their creator, users with Manage Signal Views permission (in the same login group as the creator) and to superusers. If you are a superuser, you can publish to multiple login groups, including —All—. In the **Publish to Login Groups** list, select one row or hold **Ctrl + left** mouse button click to select more rows. If you publish to —All— and later add a new login group, the object is published automatically to the new login group.

- To delete a view, click **Delete** and then click **OK**.

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

Rename a signal view

1. In the left navigation pane, click the **Signal Review** icon ().
2. From the **Manage Reference Data** menu (), on the top right, click **Manage Views**.
3. Click the **Row Action menu** () for a signal view, and then click **Rename**.

In addition to the information you can change in the steps below, the Rename Signal View page shows the following information about the view:

- The ordered list of columns included on the Product-Event Combinations page.
- The sort order for the Product-Event Combinations table.
- The SQL WHERE clause, if any, that selects the product-event combinations to appear in the Product-Event Combinations table.

4. In the **View name** field, enter a new view name.
5. In the **Description** field, enter an informative description of the view.
6. Optionally, change the **Category** assignment for the view.
 - To add the view to an existing category, select **Add to existing category** and select the view from the drop-down list.
 - To add a new category, select **Add to a new category named** and type the category name in the text box.
7. Optionally, change the **Review period** for the view by selecting it from the **Review period** drop-down list. This option is available if the signal configuration has the review period feature set up.
8. Click **Save**.

Organize signal views

You can define the order of view categories, and the views within each category.

Note

The category, Unassigned, always appears last in the list of categories.

1. In the left navigation pane, click the **Signal Review** icon (.
2. From the **Manage Reference Data** menu () , on the top right, click **Manage Views**.
3. On the top left, click **Organize Views**. (This option is available only if you have the Manage Signal Views permission.)

Select one or more fields in the Category or View list:

- Click



to move the defined value up in the list.

- Click



to move the defined value down in the list.

4. To specify the order in which categories appear, from the **Category** list, click a category name, then click the up and down arrow keys to move the category to the desired position.
5. To specify the order of the views assigned to a category, click a category, then, in the **Views** list, click a view name and move it to the desired position with the up and down arrow keys.
6. To reorder the views, click a view in the **Views** list, then click the up and down arrow keys to move it to the desired position.
7. Click **OK**.

Manage multisource signal configurations

Perform safety surveillance across multiple data sources in one configuration using a multisource signal configuration.

A multisource signal configuration combines the results of multiple underlying signal configurations into a single configuration. You can use this feature to:

- View data and results from multiple safety datasets side-by-side on the Signal Review page.
- View and drill down on data, including scores and case counts, from all sources per product-event combinations.
- Define alerting logic across sources.
- [Get started with multisource signal configurations](#)
- [Add a multisource signal configuration](#)
- [Edit a multisource signal configuration](#)
- [Change a secondary configuration in a multisource signal configuration](#)
- [Review products from a multisource configuration](#)
The Signal Review page combines data from the lead and secondary configurations, prompting you to view the information in the Product Summary sections, System Organ Class (SOC) section, and the detail panel.
- [Delete a multisource signal configuration](#)
- [Multisource signal configuration FAQs](#)

Get started with multisource signal configurations

What is a multisource signal configuration?

A multisource signal configuration enables you to view safety data from multiple data sets side by side in a single configuration. A multisource signal configuration extends an existing interactive signal configuration by adding data from one or more secondary signal configurations, enabling the following capabilities:

- Align data and results from multiple safety datasets in one view on the Signal Review page.
- Use existing view capabilities, display scores, and case counts, and enable drill-down from all sources per Product-Event-Combination (PEC).
- Define Alerting logic across sources.

Understanding the lead and secondary configurations

When planning the setup of your multisource signal configuration, you assign one interactive signal configuration to be the lead configuration with up to two secondary configurations. Your multisource signal configuration only displays the products from the lead with data from the secondary configuration(s) that apply to those products.

When choosing the lead configuration, select the interactive signal configuration that contains all the monitored products you wish to include in your multisource signal configuration. Adding a secondary configuration will combine results from the secondary data set to match across those products.

Understanding shared and independent features

The lead configuration is linked with the multisource signal configuration. When you create a multisource signal configuration, the following information is populated from the lead configuration:

- Current period.
- Alert types with Active in next refresh = Yes.
- Product fields.
- Comment types.
- Default signal view.
- Topic work-flow configuration.
- Topic product field.
- Disable default view.
- Disable private comment.

Some features share information between them, while others are independent.

Shared features

Changes to shared features are synced between the multisource signal configuration and the lead configuration. This means that when you are working in the multisource signal configuration, any changes you make are reflected in the underlying configuration and vice versa.

The following areas share both the multisource signal configuration and the lead configuration:

- TWC and Topic product field assignment.
- Products.
- Product properties.
- Reference data (TME, DME, Listed, Reviewers, Custom Terms).
- Comment types.

Independent features

Changes to independent features only affect the configuration in which they are made.

The following areas are originally copied from the lead configuration but are independent.

- Active Alert Types.
- Views.

Understanding connected configurations

A signal configuration may be included as the lead configuration in multiple multisource signal configurations. The lead configuration and any multisource configurations that refer to the lead are connected configurations. Changes to a shared feature impact all connected configurations.

For example, if you delete a product from a multisource signal configuration, that product is also deleted from the following configurations:

- The lead configuration.
- All other multisource signal configurations referencing the same configuration as the lead.

- Changes are prevented in the configuration if any connected configurations are undergoing a refresh.

Ensuring your products match across lead and secondary configurations

To establish the connection between the configurations, the multisource signal configuration refers to the lead configuration's Product name field. The Product name field is used to join the PEC rows from the underlying configurations.

Review the product names in each configuration and decide which ones you would like to have matched. You may need to rename the product, particularly in the secondary configurations, so that the name matches. If you do rename products, you also need to refresh the configurations before creating your multisource signal configuration in order for the rename to be in effect.

What to expect when creating a multisource signal configuration

Requirements for setting up a multisource signal configuration

- You can only select an interactive signal configuration as the lead configuration in a multisource signal configuration.
- You cannot change the lead configuration once your multisource signal configuration is created.
- You can select interactive or scripted signal configurations as a secondary configuration.
- You can include up to two secondary configurations in a multisource signal configuration.
- You can change the secondary configuration however, doing so changes the structure of the underlying multisource signal configuration tables. Be sure to follow the steps at [Change a secondary configuration in a multisource signal configuration](#) to avoid unexpected results.
- Signal configurations must be refreshed in Oracle Empirica Signal version 9.2.2 before using as the lead configuration in a multisource signal configuration.

Planning your configuration

1. Determine the signal configuration that includes the products you wish to monitor. This configuration will be the lead configuration in the multisource signal configuration.
2. Determine the configuration(s) containing the additional data sources you would like to add for the products in your lead configuration. These configurations will be the secondary configurations in the multisource signal configuration.
3. Review all the configurations. Ensure the **Product name** fields for the products you wish to monitor match. If necessary, rename the products in the secondary configurations and refresh any configurations that required a name change.
4. Plan the alert types and views for the multisource signal configuration. You will set these up after creating the multisource signal configuration.

Best practices for creating and maintaining your multisource configuration

Once you have planned your configuration, follow the steps below to create and maintain your multisource configuration.

- Create the multisource configuration.
- Refresh the multisource configuration, without calculating alerts.
- Set up the alert types and views for the multisource configuration.
- Refresh the multisource configuration, enabling your configured alerts to be calculated.

- Be aware of the refresh cadence of all connected configurations, as you work with the multisource configuration.
 - When you refresh any underlying configurations, no changes get saved.
 - [Refresh the multisource configuration when necessary](#).
 - After making the changes in the multisource configuration, you must often refresh the underlying lead configuration for the changes to take effect in the multisource configuration.

Recommendations

- After creating a multisource configuration, unpublish the lead configuration. Once setting the lead configuration in a multisource configuration, unpublishing the lead will prevent unintended changes to the underlying data.
- Manage the connected configurations. You can include a signal configuration as the lead configuration in multiple multisource signal configurations. Any changes to the underlying lead configuration affect all configurations that refer to it. For example, if you delete a product from a multisource signal configuration, that product is also deleted from the following configurations:
 - The lead configuration.
 - All other multisource signal configurations referencing the same configuration as the lead.

Add a multisource signal configuration

Create a new [multisource signal configuration](#) from the Manage Signal Configurations page. You must have Manage Signal Configurations user permission to perform the following actions.

1. In the left navigation pane, click the **Settings** icon ()
2. In the Configure System section, click **Manage Signal Configurations**.
3. At the top of the page, click the **Add Multisource Signal Configuration**.
4. On the Add Signal Configuration page, enter a name and optional description.
5. From the **Lead Configuration** drop-down menu, select the signal configuration you wish to use as the lead configuration.

Note

The lead configuration must be an interactive signal configuration that has been refreshed after upgrading to 9.2.2.

6. From the **Secondary Configuration** drop-down list, select the signal configuration you wish to use as the secondary configuration. You can select an interactive or scripted signal configuration that has been refreshed as the secondary configuration.
7. In the **Label** field, enter a label for the secondary configuration.

Note

A unique label is required for each secondary configuration. The label you enter will appear as a prefix in table columns and menu options to identify data specific to the secondary configuration.

8. If you are adding an additional secondary configuration, repeat steps 6 and 7, using the additional row provided.

Note

The secondary configurations must be unique.

9. Click **Save**.

Once the multisource signal configuration is saved, the Refresh Signal Management page appears.

Note

The new multisource signal configuration contains a copy of the alert types from the lead configuration. Therefore, once the initial refresh, without alert calculation, has been completed, review and update the multisource configuration's alert types. Consider the following for each alert type:

- [Tracked or informational](#) alert types?
- Should the alert type be Active in the next refresh?
- Consider the rules for each alert type. Should the rules be modified to include secondary configurations?

10. Set your desired options for the refresh and click **Submit**.

The system validates the configuration, and a message confirming that alerts will not be calculated appears.

Click **Submit** to proceed with the refresh without calculating alerts.

11. In the **Refresh Submitted** window, click **Continue**.

The submitted refresh appears on the Signal Management Refreshes page.

Note

Once the initial refresh is completed be sure to review and [update your alert types](#) before generating alerts for the new multisource signal configuration. A newly created multisource signal configuration may contain tracked alerts from the lead configuration, unlike a typical interactive signal configuration, which consists only of [informational alert types](#) after initial installation.

Edit a multisource signal configuration

You must have Manage Signal Configurations permission to edit a multisource signal configuration. The signal configuration must be published to you, individually, or to your login group.

1. In the left navigation pane, click the **Settings** icon ()
2. In the **Configure System** section, click **Manage Signal Configurations**.

3. Click the **Row Action menu** () for the multisource signal configuration, and then click **Edit**.
4. Edit the fields according to the table below.

 Note

Multisource signal configurations require a refresh if dependent configurations have been refreshed, secondary configurations or objects shared with the lead configuration have changed. When shared objects have changed, you must refresh the lead configuration first at least once, then refresh the multisource configuration.

5. Click **Save**.
Oracle Empirica Signal validates the signal configuration, and any errors are displayed at the top of the page.

Field descriptions—Edit Multisource Signal Configurations

Field	Description
Name	Signal configuration name. This name appears on the Signal Review page, above the product-event combinations table.
Description	Description of the configuration.
Lead Configuration (read only)	Identifies the lead configuration in use by the multisource signal configuration. You cannot change the lead configuration.
Secondary Configurations	Identifies the name and label of each secondary configuration in use by the multisource signal configuration. • Use the drop-down menu to select an additional secondary configuration, if available. • Use the Label field to change an existing label or add a label for a secondary configuration. • Click Remove to remove or replace a secondary configuration.

 Note

Changes to secondary configurations, including changing the label, take effect only after refreshing the multisource signal configuration.

Field	Description
Default signal view	Name of the default signal view appearing as the global default for the signal configuration. This view appears as the left-most tab when viewing the Product-Event Combinations page . If a different default view is specified for a specific product , the product's default view takes precedence and is shown when viewing that product.
Suppress alert calculations in next refresh	Select this option if you do not want to calculate any alerts the next time the configuration is refreshed. • When you remove or replace a secondary configuration, this option is selected by default. • You can override this setting if you are sure it will not cause problems with the configuration.

 Note

If you remove or replace a secondary configuration, alert types and views may still point to the previous configuration that is no longer connected to the multisource signal configuration. If this is the case, the refresh fails unless you suppress alert calculations.

See [Change a secondary configuration in a multisource signal configuration](#).

Topic workflow configuration (read only)

Name of the topic workflow configuration that is integrated with the signal management configuration. When this integration exists, users can associate topics with product-event combinations using the Submit Review dialog box, and topics are stored in this topic workflow configuration.

 Note

To change value, edit the lead configuration

Field	Description
Topic product field (read only)	Names of products in product-event combinations associated with topics. You can use the Topic Product Field filter when browsing for existing topics from the Submit Review dialog box.
	Note To change the value, edit the lead configuration.
Disable default view	Select to disable the default view on the Product-Event Combinations page . When disabled, both the default view specified for the signal configuration and the default view specified for a specific product are ignored.
Disable private comment (read only)	Disable private comments setting for product-event combinations.
	Note To change the value, edit the lead configuration.

Change a secondary configuration in a multisource signal configuration

You can change or remove the secondary configuration in a multisource signal configuration. This action results in a reconfiguration of the structure of the underlying tables and requires steps to ensure you achieve the desired results.

Note

You must have Manage Signal Configurations user permission to perform the following actions.

1. (Recommended) [Unpublish](#) the signal configuration.
2. In the left navigation pane, click the **Settings** icon (.
3. In the **Configure System** section, click **Manage Signal Configurations**.
4. Click the **Row Action menu** () for the multisource signal configuration, and then click **Edit**.
5. In the row for the secondary configuration you wish to change or remove, click **Remove**. Click **OK** to confirm your choice.

6. If you are replacing the secondary configuration, select the signal configuration you wish to use from the **Secondary Configuration** drop-down menu.
7. In the **Label** field, enter a label for the secondary configuration.

Note

A unique label is required for each secondary configuration. The label you enter appears as a prefix in table columns and menu options to identify data specific to the secondary configuration.

8. If you are adding an additional secondary configuration, repeat steps 5 through 7, using the additional row provided.

Note

The secondary configurations must be unique.

9. Determine whether you need to suppress alert calculations in the next refresh.
 - **If you do not need to suppress alert calculations:**
 - a. Deselect **Suppress alert calculations in the next refresh**.
 - b. Click **Save**.
 - c. Optionally, modify alert types and views.
 - d. Refresh the multisource signal configuration using the standard refresh procedure, which calculates the alerts.
 - **If you do need to suppress alert calculations (recommended):**
 - a. Ensure the **Suppress alert calculations in the next refresh** checkbox is selected.
 - b. Submit a refresh for the configuration.

Note

The Refresh Signal Management page will contain Warning: *Alerts will not be calculated*.

- c. Modify alert types and views. Remove references to secondary configurations that were removed.
- d. Optionally, set up the [alert types](#) and [views](#) to reference the new secondary configurations.
- e. Refresh the multisource signal configuration using the [standard refresh procedure](#), which calculates the alerts.

Note

If you remove or replace a secondary configuration, alerts types and views may still point to the previous configuration that is no longer connected to the multisource signal configuration. If this is the case, the refresh will fail unless you suppress alert calculations.

Suppressing alert calculations enables you to refresh without calculating any alerts. This initial refresh modifies the structure between the connected configurations. You can then set up the alert types and views to point to the new secondary configurations.

Once you have configured your alerts and views you can refresh the multisource signal configuration again to calculate alerts. Once you remove or replace a secondary configuration, the **Suppress alert calculations in next refresh** option is selected by default. You can override this setting if you are sure it will not cause problems with the configuration.

10. [Republish](#) the multisource signal configuration.

Review products from a multisource configuration

The Signal Review page combines data from the lead and secondary configurations, prompting you to view the information in the Product Summary sections, System Organ Class (SOC) section, and the detail panel.

[Multisource signal configurations](#) appear along with other available configurations in the configuration drop-down menu on the Signal Review page.

As an extension of signal configurations, multisource signal configurations enable you to perform safety surveillance across multiple data sources.

When reviewing statistics from a multisource signal configuration, it helps to understand the source of the data you're viewing and whether your actions affect the multisource signal configuration independently or also impact the underlying configurations.

Viewing aggregate data on products in a multisource signal configuration

The product table displays only products from the lead configuration. The products from any secondary configurations included in the multisource signal configuration do not appear. However, the information you view on the [Signal Review page](#), including the Product Summary sections, System Organ Class (SOC) section, and the Details panel, combines data from the lead and secondary configurations.

- Products and product properties displayed in the table are shared with the lead configuration.
- Alert columns and the counts displayed in the table are specific to the multisource signal configuration.
- Topic workflow configuration and the **Product** field are the same as the lead configuration.

When [selecting columns to view](#) in the Products table, you can add the **Product Term value** for each secondary configuration for reference. Column labels are identified by a prefix matching the secondary configuration label, defined when creating the multisource signal configuration.

Information shared between the lead configuration and the multisource signal configuration

Between the lead signal configuration and multisource signal configuration, the following areas are shared:

- Topic Workflow Configuration and Topic Product field assignment
- Products and Product properties
- Reference data (TME, DME, Listed, Reviewers)
- Comment types
- Case Score tables (when LISM is an Argus configuration)

The following areas are *not* shared:

- Active alert types
- Views

Performing actions on individual products in a multisource signal configuration

Actions you take on individual products from the [Products table Row Action menu](#) may impact the underlying lead configuration.

- [Enter Note](#): When you add a note to a product in the multisource signal configuration, the note is shared with the lead configuration.
- [View Notes](#): Notes are shared with the lead configuration.
- [View Event Comments](#): Event comments are shared with the lead.
- [View Sector Map for All](#): Options for each configuration included in the multisource signal configuration appear in the menu. A prefix matching the secondary configuration label, defined when creating the multisource signal configuration, identifies the secondary configurations.

If you have the appropriate permissions, the following options also appear in the Row Action menu, enabling you to manage aspects of products.

- [Manage Targeted Medical Events](#): Shared with the lead configuration.
- [Manage Listed Events](#): Shared with the lead configuration.
- [Edit](#): Shared with the lead configuration.
- [Rename](#): Shared with the lead configuration.
- [Delete](#): Shared with the lead configuration.

Note

A signal configuration may be included as the lead configuration in multiple multisource signal configurations. Any changes to shared components, regardless of the configuration from which the change was made, affect both the lead configuration and all configurations that refer to it.

For example, if you delete a product from a multisource signal configuration, that product is also deleted from the following configurations:

- The lead configuration
- All other multisource signal configurations referencing the same configuration as the lead

Delete a multisource signal configuration

You cannot delete a multisource signal configuration in the following situations:

- Alerts have been generated.
- A refresh is in progress.

You must have Manage Signal Configurations user permission to perform the following actions.

1. In the left navigation pane, click the **Settings** icon ()
2. In the **Configure System** section, click **Manage Signal Configurations**.
3. Click the **Row Action menu** () for the multisource signal configuration, and then click **Delete**.
4. Click **OK** to confirm your choice.

Multisource signal configuration FAQs

- [How are products matched across configurations in a multisource signal configuration?](#)
- [Which configuration should I choose as the lead configuration in a multisource signal configuration?](#)
- [Can I change the underlying configurations in a multisource configuration?](#)
- [What is a connected configuration?](#)
- [How do I manage refreshes for a multisource configuration?](#)
- [What differences do I see when using Signal Review features with a multisource signal configuration?](#)
- [Why don't I see products from the secondary configurations in a multisource signal configuration?](#)
- [Why can't I modify the column labels for secondary configurations in a multisource configuration?](#)
- [Why do I see warning messages on the Signal Review page when using a multisource configuration?](#)
- [How is auto-assigning to reviewers different for a multisource configuration?](#)
- [How does the Standardized MedDRA Queries \(SMQ\) option work](#)

How are products matched across configurations in a multisource signal configuration?

To establish the connection between the configurations, the multisource signal configuration refers to the lead configuration's Product name field. Every product has Product name and Product term fields. The Product name field is used to connect the Product-Event Combination rows from the underlying configurations.

Review the product names in each configuration and decide which ones you would like to have matched. You may need to rename the product, particularly in the secondary configurations, so that the name matches. If you do rename products, you also need to refresh the configurations before creating your multisource signal configuration in order for the rename to be in effect.

See [Get started with multisource signal configurations](#).

Which configuration should I choose as the lead configuration in a multisource signal configuration?

When choosing the lead configuration, select an interactive signal configuration that contains all the monitored products you wish to include in your multisource signal configuration. Adding a secondary configuration includes results from the secondary data set to match across those products. Your multisource signal configuration only displays the products from the lead, along with data from the secondary configuration(s) that apply to those products.

Signal configurations must be refreshed in Oracle Empirica Signal version 9.2.2 before adding to a multisource signal configuration.

Once your multisource signal configuration is created, you cannot change the lead configuration.

See [Get started with multisource signal configurations](#).

Can I change the underlying configurations in a multisource configuration?

Once your [multisource signal configuration](#) is created, you cannot change the lead configuration.

Although you can change the secondary configuration in a multisource signal configuration, doing so changes the structure of the underlying multisource signal configuration tables. Be sure to follow the steps at [Change a secondary configuration in a multisource signal configuration](#) to avoid unexpected results.

What is a connected configuration?

A signal configuration may be included as the lead configuration in multiple [multisource signal configurations](#). The lead configuration and any multisource configurations that refer to the lead are **connected configurations**.

Note

The secondary configurations included in a multisource configuration are not considered connected configurations.

- Any changes to the underlying lead configuration affect all connected configurations that refer to it.
For example, if you delete a product from a multisource signal configuration, that product is also deleted from the following configurations:

- The lead configuration.
- All other multisource signal configurations referencing the same configuration as the lead.
- Changes are prevented in a configuration if any connected configuration is undergoing a refresh.

See [Get started with multisource signal configurations](#).

How do I manage refreshes for a multisource configuration?

Note

You must refresh the configurations before including them in a [multisource signal configuration](#).

When do I need to refresh a multisource configuration ?

- After initially creating the multisource configuration.
- After you set up the alerts and views for the newly created multisource configuration. This refresh enables your configured alerts to be calculated.
- After any of the [typical activities that would require a refresh for an interactive signal configuration](#).
- In any of the following conditions:
 - [Dependent configurations](#) have been refreshed.
 - [Secondary configurations have changed](#).
 - Objects [shared with the lead configuration](#) have changed. When shared objects have changed, you must refresh the lead configuration first, then refresh the multisource configuration.
- As changes are made while working with the multisource configuration, you must often refresh the underlying lead configuration for the changes to take effect in the multisource configuration.

What happens during the first refresh after creating a multisource configuration?

When you create a multisource signal configuration, the first refresh sets up the structure but does not calculate alerts. This enables you to set up the alert types and views for the multisource signal configuration after creating the multisource signal configuration. After your alert types and views are configured, refresh the multisource signal configuration again, using the standard refresh procedure, which calculates alerts.

How does refreshing affect connected configurations

A signal configuration may be included as the lead configuration in multiple multisource signal configurations. The lead configuration and any multisource configurations that refer to the lead are **connected configurations**.

- Changes are prevented in a configuration if any connected configuration is undergoing a refresh.
- Any changes to the underlying lead configuration affect all connected configurations that refer to it.

For example, if you delete a product from a multisource signal configuration, that product is also deleted from the following configurations:

- The lead configuration
- All other multisource signal configurations referencing the same configuration as the lead
- For some changes to take effect in the multisource signal configuration, you must refresh the lead configuration first, then refresh the multisource configuration.

What differences do I see when using Signal Review features with a multisource signal configuration?

When reviewing products in [multisource signal configurations](#) you see data from the secondary configurations added to the Product and Product-Event Combinations tables. You can add the columns from the secondary configurations by configuring the tables views. Data visualizations, such as sector maps and breakdown graphs, are available for both lead and secondary configurations. You can distinguish columns and menu items that refer to the secondary configurations by the prefix that matches the secondary configuration label [defined in the multisource signal configuration](#).

See [Review products from a multisource configuration](#) and [Review product-event combinations from a multisource configuration](#) for details.

Why don't I see products from the secondary configurations in a multisource signal configuration?

A [multisource signal configurations](#) only displays the products from the lead configuration, along with data from the secondary configuration(s) that apply to those products.

When choosing the lead configuration, select the interactive signal configuration which contains all the monitored products you wish to include in your multisource signal configuration. Adding a secondary configuration includes results from the secondary data set to match across those products.

See [Get started with multisource signal configurations](#)

Why can't I modify the column labels for secondary configurations in a multisource configuration?

When working with a [multisource signal configuration](#), you cannot edit the Product columns originating from a secondary configuration. These columns are recreated with each refresh with a prefix that matches the secondary configuration label [defined in the multisource signal configuration](#).

To change the labels:

1. Change the labels for the secondary configurations as described in [Edit the multisource configuration](#).
2. [Refresh the multisource configuration](#).

Why do I see warning messages on the Signal Review page when using a multisource configuration?

When selecting a [multisource signal configuration](#) on the Signal Review page, you see warning messages if a refresh is in progress or may be needed. Changes are prevented in a configuration if any connected configuration is undergoing a refresh.

Some of the conditions that result in a warning message include:

- A refresh is ongoing for the multisource configuration.
- A refresh is ongoing for the lead or secondary configuration.
- The last refresh was run without calculating alerts.
- The Refreshed date of the lead or secondary configuration is more recent than the multisource configuration.

If the warning indicates a refresh is ongoing, wait for it to complete before proceeding.

If the warning indicates a refresh may be needed, [refresh the multisource configuration](#).

How is auto-assigning to reviewers different for a multisource configuration?

When working with a [multisource signal configurations](#), any changes you make to the reviewers' list overwrite the data in all connected configurations. This includes using the [Auto-Assign to Reviewer](#) function or when [modifying automatic assignments](#).

To prevent confusion, you should assign reviewers from either the multisource signal configuration or the lead configuration, but not both.

How does the Standardized MedDRA Queries (SMQ) option work

The Standardized MedDRA Queries (SMQ) option

In View Similar Combinations the event hierarchy is taken from the lead configuration. No special handling is done when an event only exists in the secondary configuration.

Note

An event may only be in the Secondary Interactive Signal Configurations' MedDRA or the Lead Interactive Signal Configurations and Secondary Interactive Signal Configurations may have different MedDRAs.

Manage topic workflow configurations

This section includes information about topic workflow configuration design and management as well as details and tasks for working with fields, field values, topic states, action states, templates, email notifications, and action types.

- [Topic workflow configuration design](#)
A topic workflow configuration defines how the Topic Management feature works, including the fields that store topic information and the workflow states that you can assign to track progress.
- [Overview of setting up a topic workflow configuration](#)
Oracle Empirica Topics is configured by an administrator who performs several tasks. A sequential outline of those tasks is based on the sample topic workflow configuration delivered with the application.
- [Preconfigured topic workflow configurations](#)
Oracle Empirica Signal provides two sample configurations. The *Sample Topic Workflow Configuration* is a starting point for a basic topic workflow configuration. The *Sample GVP Module IX Topic Workflow configuration* provides general guidance and requirements of signal management in the European Union. You can also copy other configurations that you create or import.

- [Manage Topic Workflow Configurations page](#)
On the Manage Topic Workflow Configurations page, you can list the topic workflow configurations that you created or have been published to your login group.
- [Add a topic workflow configuration](#)
You can add or import a topic workflow configuration.
- [Edit Topic Workflow Configuration page](#)
On the Edit Topic Workflow Configuration page, you can edit workflow details, including fields, topic states, action states, email notifications, topic templates, and action types.
- [Work with topic workflow configurations](#)
You can edit, copy, and delete topic workflow configurations as well as publish them for other users to use. You can also export them for use by another application and download a PDF file that shows all workflow configuration options.
- [Manage fields](#)
These topics apply to fields used to store information for topics, actions, and attachments.
- [Manage field values](#)
You can specify the list of values that appear for a field.
- [Manage topic states](#)
You can view or edit topic states. Specifying topic states in the topic workflow configuration applies a workflow for processing topics. Each topic state may include the next state or state that may be assigned.
- [Manage action states](#)
Each topic workflow configuration defines the workflow states that can be assigned to an action.
- [Manage field access](#)
Once you have defined topic states and fields, you define the level of access that users have to each field
- [Manage topic templates](#)
You can create, edit, and delete topic templates that pre-populate fields and actions in a standardized way.
- [Manage action types](#)
Action types standardize and simplify the creation of topic actions and a topic template actions and can be used to categorize the action's work.
- [Manage email notification rules](#)
You can set up rules to automatically send email notifications based on different changes to actions and topics or create a rule to remind users when an action's completion date is near, due, or overdue.

Topic workflow configuration design

A topic workflow configuration defines how the Topic Management feature works, including the fields that store topic information and the workflow states that you can assign to track progress.

You can set up topic workflow configurations and the [Topic Management](#) feature to accommodate your organization's processes. Users with the Manage Topic Workflow Configurations permission can work with topic workflow configurations.

The following list represents customizable areas of a topic workflow configurations:

- [User settings](#)
- [Topic fields](#)

- [Topic field values](#)
- Workflow states for [topic states](#) and [action states](#)
- [Topic field accessibility](#) and [action field accessibility](#) by states
- [Attachment field accessibility](#) by types
- [Email notification rules](#)
- [Topic templates](#)
- [Action types](#)

These definitions affect the appearance and behavior of the user interface for using topics.

A Sample Topic Workflow Configuration is provided with Oracle Empirica Signal. Use it as a starting point when you design a configuration by copying and editing it. You can also review the [definitions in the Sample Topic Workflow Configuration](#) and base your design on them. The Sample Topic Workflow Configuration itself should not be edited.

Note

Changes to a topic workflow configuration that is already in use are not recommended.

In addition, you can prepare topic features by defining the access permissions to the Oracle Empirica Signal users. For more information, see [Overview of setting up a topic workflow configuration](#).

Overview of setting up a topic workflow configuration

Oracle Empirica Topics is configured by an administrator who performs several tasks. A sequential outline of those tasks is based on the sample topic workflow configuration delivered with the application.

To perform the steps in this outline, an administrator must have been assigned the Manage Topic Workflow Configurations and Administer Users permissions. To add the work team fields, it is also necessary to have Superuser permission.

1. As the basis for a new topic workflow configuration, [add](#) or [copy a topic workflow configuration](#). You can make a copy of the [Sample Topic Workflow Configuration](#) supplied with Oracle Empirica Signal or import the [sample GVP Model IX topic workflow configuration](#).

Note

Do not edit the original Sample Topic Workflow Configuration.

2. Edit the new [topic workflow configuration](#).
3. Publish the new topic workflow configuration to your login group. For more information, see [Publish objects](#).
4. Edit your login group to select the new topic workflow configuration as its Topic Workflow Configuration setting. For more information, see [Edit a login group](#).
5. Create one or more work teams for your login group. A work team can contain all of the users in a given login group, or a specified subset of those users. For more information, see [Add/edit a work team](#).

6. [Assign work team permissions](#) to each work team member.
7. If your topic workflow configuration includes any fields with a context of work team, a Superuser must set the **Topic workflow configuration for work team custom fields** site option.
8. For each of the users in the login group (or work team), including yourself, edit the user account to grant the View Topics permission. For more information, see [Add and edit a user](#) and [User permissions](#).
9. Log out of the application, and then log in again. The Topics page is now available to you.

Users who were already logged in when you granted the View Topics permission must log out of the application and log in again.

If the topic workflow configuration defines application data results as an allowed attachment type, the **Save to Topic** link also appears above tables, graphs, report output, and other Oracle Empirica Signal objects.

Preconfigured topic workflow configurations

Oracle Empirica Signal provides two sample configurations. The *Sample Topic Workflow Configuration* is a starting point for a basic topic workflow configuration. The *Sample GVP Module IX Topic Workflow configuration* provides general guidance and requirements of signal management in the European Union. You can also copy other configurations that you create or import.

- [Sample topic workflow configuration](#)
A sample topic workflow configuration and sample topic are provided with Oracle Empirica Signal.
- [Import the sample GVP Module IX topic workflow configuration](#)
A topic workflow configuration that aligns with GVP module IX is available for import.

Sample topic workflow configuration

A sample topic workflow configuration and sample topic are provided with Oracle Empirica Signal.

To design a new topic workflow configuration, you can [copy the Sample Topic Workflow Configuration](#) and edit it.

Note

The Sample Topic Workflow Configuration itself should not be edited.

Use the information below as a guide when designing a new topic workflow configuration.

In addition to this sample topic workflow configuration, when you install Oracle Empirica Signal, a single topic with an action is also installed. You can see it on the Topic Management page.

Basic configuration options

When you [edit a topic workflow configuration](#) you set these configuration options:

Option	Definition
Name	Sample Topic Workflow Configuration

Option	Definition
Description	Sample Topic Workflow Configuration
Allow topic to be visible to	() One and only one work team (o) Zero, one or more work teams
Allow topic to be linked to	(o) Topics in any state () Topics in final state
Allow addition of comments to	x Topics x Attachments x Actions
Allow sources of attachments	x Application Data x External URL x External Document x Note
Allow topic state closure only when all actions are completed	(cleared)
Allow action state closure only when attachments or comments are provided for action	(cleared)

Field definitions: topics

When you view existing fields, the Context column indicates whether a given field applies to topics, attachments, actions, or possibly to several of these contexts.

The sample topic workflow configuration defines the following fields for topics:

Column Name	Display Name	Format	Filter Field
TOPIC_NAME	Topic name	String	No
TOPIC_DESCRIPTION	Topic description	String	No
CURRENT_STATE_ID	Current state	Integer	Yes
SIGNAL_EVAL_METHOD	Signal evaluation method	String	No
STATE_CHANGE_REASON	Reason for change	String	No
ASSIGNED_TO_USER_ID	Assigned to	Integer	Yes
SEARCH_KEYWORDS	Keywords	String	Yes
RESOLUTION	Resolution	String	No
RESOLUTION_DATE	Resolution date	Date	No

(This table presents a subset of the different attributes that can be set when you add or edit a field.)

Field definitions: actions

The sample topic workflow configuration includes the following fields for actions:

Column Name	Display Name	Format	Filter Field
ACTION_NAME	Action name	String	No
ACTION_DESCRIPTION	Action description	String	No
ACTION_STATE_ID	Action state	Integer	Yes

Column Name	Display Name	Format	Filter Field
ASSIGNED_TO_USER_ID	Assigned to	Integer	Yes
START_DATE_\$ORCL	Start date	Date	No
PLANNED_COMPL_DATE	Planned completion date	Date	No
ACTUAL_COMPL_DATE	Actual completion date	Date	No
ACTION_TYPE_ID_\$ORCL	Action type	Integer	Yes

Field definitions: attachments

The sample topic workflow configuration includes the following fields for attachments:

Column Name	Display Name	Format	Filter Field
NAME	Attachment name	String	No
DESCRIPTION	Attachment description	String	No
URL_ADDRESS	URL address	String	No
FILE_NAME	File name	String	No

Topic states

The sample topic workflow configuration defines the following workflow states for topics:

Name	Description	Initial State	Final State	Next Possible States
Init	Initial state	Yes	No	Assigned, Closed, Escalated
Assigned	Actively being reviewed	No	No	Closed, Escalated
Escalated	Warrants further attention	No	No	Assigned, Closed
Closed	No further action needed or expected	No	Yes	Assigned

Topic field accessibility

The sample topic workflow configuration defines the [level of user access](#) to topic fields for a topic in each workflow state as follows:

Topic Field Column Name	Init	Assigned	Escalated	Closed
TOPIC_NAME	Required	Required	Required	Required
TOPIC_DESCRIPTION	Editable	Editable	Editable	Editable
CURRENT_STATE_ID	Editable	Editable	Editable	Editable
STATE_CHANGE_REASON	-- (Hidden)	Required	Required	Required
ASSIGNED_TO_USER_ID	Editable	Required	Required	Required

Topic Field Column Name	Init	Assigned	Escalated	Closed
SEARCH_KEYWORDS	Editable	Editable	Editable	Editable
RESOLUTION	-- (Hidden)	-- (Hidden)	-- (Hidden)	Required
RESOLUTION_DATE	-- (Hidden)	-- (Hidden)	-- (Hidden)	Required

Action states

The sample topic workflow configuration defines the following workflow states for actions:

Name	Description	Initial State	Final State	Next Possible Action States
Init	Initial state	Yes	No	Closed
Closed	Action completed	No	Yes	
Planned	Planned state	No	No	Init

Action field accessibility

The sample topic workflow configuration defines the [level of user access](#) to action fields for an action in each workflow state as follows:

Action Field Column Name	Planned	Init	Closed
ACTION_TYPE_ID_\$ORCL	Required	Required	Required
ACTION_NAME	Required	Required	Required
ACTION_DESCRIPTION	Editable	Editable	Editable
ACTION_STATE_ID	Editable	Editable	Editable
START_DATE_\$ORCL	Editable	Editable	Editable
ASSIGNED_TO_USER_ID	Editable	Editable	Editable
PLANNED_COMPL_DATE	Editable	Editable	Editable
ACTUAL_COMPL_DATE	Editable	Editable	Editable

Attachment field accessibility

The sample topic workflow configuration defines the [accessibility of attachment fields](#) for each type of attachment as follows:

Field Name	External URL	Oracle Empirica Signal Result	External Document	Note
NAME	Required	Required	Required	Required
DESCRIPTION	Editable	Editable	Editable	Editable
URL_ADDRESS	Required	-- (Hidden)	-- (Hidden)	-- (Hidden)
FILE_NAME	-- (Hidden)	-- (Hidden)	Required	-- (Hidden)

Import the sample GVP Module IX topic workflow configuration

A topic workflow configuration that aligns with GVP module IX is available for import.

Import the sample GVP Module IX topic workflow configuration

Follow these steps to import the sample GVP Module IX topic workflow configuration:

1. In the left navigation pane, click the **Settings** icon ()
2. Click the **About** link.
3. Access the release notes and other system-related documents maintained on the server by clicking the **here** link.
4. Download the `Sample_GVP_Module_IX.dat` file by clicking the file name. The file is downloaded to your Downloads folder.
5. Don't try to open the file. Instead, follow these steps:
 - a. In the left navigation pane, click the **Settings** icon ()
 - b. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
 - c. Click **Import Workflow Configuration File**.
 - d. In the **File to Upload** field, click **Choose File** to locate and select the `Sample_GVP_Module_IX.dat` file from your Downloads folder.
 - e. Click **Upload**.
 - f. In the **Name** field, type a name for the workflow configuration.
 - g. Optionally, in the **Description** field, type a description.
 - h. Click **Save**.

View the sample GVP Module IX topic workflow configuration options

You can download a PDF file that includes all the configuration options for the sample GVP Model IX topic workflow configuration.

1. In the left navigation pane, click the **Settings** icon ()
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Select the sample GVP Module IX configuration's **Row Action** menu () , and then select **Create PDF**.
4. Follow the directions for your browser.
5. Click **Save**.

Manage Topic Workflow Configurations page

On the Manage Topic Workflow Configurations page, you can list the topic workflow configurations that you created or have been published to your login group.

General activities

The following links appear at the top of the page and affect the entire page:

- [Add Workflow Configuration](#) to add a blank topic workflow configuration or define the fields, workflow states, user access levels, e-mail notification rules, and templates.
- [Import Workflow Configuration Account](#) to import files from this and previous releases.
- [Import Workflow Configuration File](#) to import a previously exported topic workflow.
- Back to return to the Settings page.
- [Columns](#) to select the columns to include in a table, specify the order in which they appear in a table, specify the sort order within columns, and make your layout the default for users in your login group.
- [Print](#) the content of the topic workflow configuration.
- [Download](#) the topic workflow configuration in a selected format.

Row-specific activities

The following menu options are available from the Row Action menu (, located in the first column of the table, and affect an individual row in the table:

- [Edit](#) to edit workflow details, including fields, topic states, action states, email notifications, topic templates, and action types.
- [Copy](#) to duplicate an existing topic workflow configuration and use it to create a customized configuration.
- [Delete](#) to delete the configuration from the database, along with all topics, including all comments and attachments associated with them. You can also remove references to the configuration without deleting it from the database; it will no longer be accessible from the application.
- [Publish](#) to make a topic workflow configuration available to other users.
- [Export](#) to allow another application instance with the same or greater topic schema version to import it.
- [Create PDF](#) to create a downloadable file that includes all the workflow configuration options; site options; topic, action, attachment, and work team fields; topic and action states; action types; topic templates and actions; and email notification rules defined for the topic workflow configuration.

Field descriptions—Manage Topic Workflow Configurations page

In this section, you can view the information for each topic workflow configuration.

Field	Description
ID	Identifier assigned to the configuration. Each topic workflow configuration ID is unique and is not re-used if the configuration is deleted.
Name	Name of the topic workflow configuration.
Description	Description of the topic workflow configuration.
Account Name	Name of the Oracle database account that contains topic workflow configuration data.
Owner	Name of the user who created the topic workflow configuration.

Add a topic workflow configuration

You can add or import a topic workflow configuration.

- [Add a topic workflow configuration](#)
Some organizations use only one topic workflow configuration. Others work with multiple topic workflow configurations.
- [Import a workflow configuration account](#)
You can import everything from a previous workflow configuration account.
- [Import a workflow configuration file](#)
You can import a previously exported topic workflow configuration using the **Import Workflow Configuration File** link on the Manage Topic Workflow Configurations page.
- [About importing a workflow configuration file](#)
You can import topic workflow configurations that were exported from any current or previous Topic schema version.

Add a topic workflow configuration

Some organizations use only one topic workflow configuration. Others work with multiple topic workflow configurations.

Note

If you use multiple topic workflow configurations, you can report on each of them in a separate subject area using Oracle Analytics Server. If you use Oracle Empirica Signal on premise, see the *Oracle Analytics Configuration Guide for Empirica Reporting* for more information about setting up the multiple topic workflow configuration Add multiple Topic Workflow Configurations option. If you use Oracle Empirica Topics, and you are a cloud customer, contact your Oracle representative to add them for you.

You can add a blank topic workflow configuration that includes a minimal design for topic workflow. Or, you can define the fields, workflow states, user access levels, e-mail notification rules, and templates.

Alternatively, Oracle Empirica Signal provides a [Sample Topic Workflow Configuration](#) which you can use as a starting point for a new topic workflow configuration.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click **Add Workflow Configuration**.
4. Enter a name and a description for the topic workflow configuration.
 - You cannot create a new configuration with the same name as a topic workflow configuration that was [deleted by reference only](#).
 - The description for the topic workflow configuration can be up to 1,000 characters.
5. Click **Save**.
6. (Recommended) Test the topic workflow configuration before you publish it to a [login group](#). To test, do the following:
 - a. Log out and log back in as the user who created the configuration.

- b. Click the Topic Management page and select the new configuration.
- c. When you are finished, publish the topic workflow configuration to the login group.

Import a workflow configuration account

You can import everything from a previous workflow configuration account.

Note

This option is used when installing or upgrading the Oracle Empirica Signal application. Typically, you do not need to perform this process during regular system use.

When you import topic workflow configurations from an Oracle account, the application does the following:

- Adds any new topic workflow configurations found in the Oracle account.
- Re-imports any topic workflow configurations found in the Oracle account that have been deleted from the application by having references removed. Any topics (and comments associated with them) that existed at the time of the deletion are also restored.

Note

If a topic workflow configuration has been deleted permanently, it cannot be re-imported.

A confirmation dialog box displays after topic workflow configurations are imported successfully. The import does not affect your current or existing topic workflow configurations.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the **Import Workflow Configuration Account** link.
A confirmation dialog box appears.
4. Click **OK**.
5. (Recommended) Test the topic workflow configurations before you publish them to a [login group](#). For each configuration, do the following:
 - a. Log out and log back in as the user who created the configuration.
 - b. Click the Topic Management page and select the new configuration.
 - c. When you are finished, publish the topic workflow configuration to the login group.

Import a workflow configuration file

You can import a previously exported topic workflow configuration using the **Import Workflow Configuration File** link on the Manage Topic Workflow Configurations page.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.

3. Click **Import Workflow Configuration File**.
4. In the **File to Upload** field, click **Choose File** to locate and select the export file on the local computer.
5. Click **Upload**.
6. In the **Name** field, type a name for the workflow configuration.
7. Optionally, in the **Description** field, type a description.
8. Click **Save**.

About importing a workflow configuration file

You can import topic workflow configurations that were exported from any current or previous Topic schema version.

To import the topic workflow configuration, you must have the Manage Topic Workflow Configurations permission. During the import, you can name and describe the topic workflow configuration.

The imported topic workflow configuration contains the following information from the exported configuration:

- Topic schema version
- Export format version
- Exported timestamp
- Exported user information

Note

Fields with a work team context are not included in the export and import of topic workflow configurations. Therefore, Topic Field Modified and Action Field Modified email notification rules that reference fields with a work team context are not included. Topic templates that contain populated topic or action fields with a work team context are also not included. If these exist in the original topic workflow configuration, they must be added to the imported topic workflow configuration.

Fields that reference users are not included in the export and import of topics, such as Topic Template, Topic Template Action, and Action Type assignments.

Edit Topic Workflow Configuration page

On the Edit Topic Workflow Configuration page, you can edit workflow details, including fields, topic states, action states, email notifications, topic templates, and action types.

Sample GVP Module IX Overview

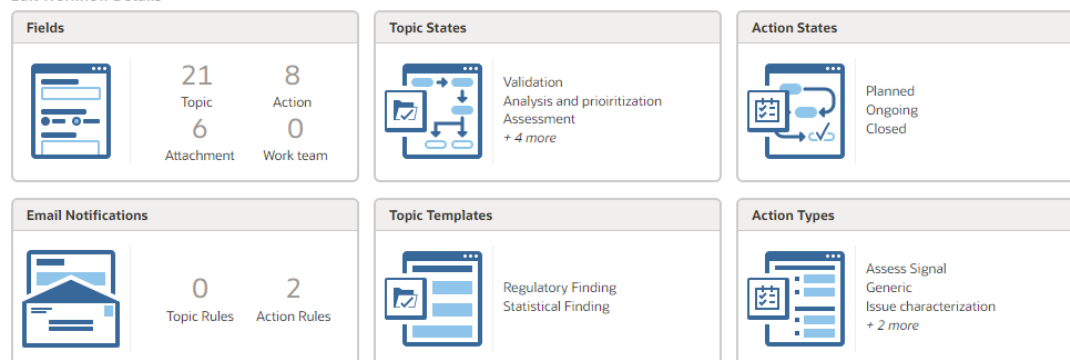
Sample GVP Module IX Topic Workflow Configuration

Allow topic to be visible to:

One and only one work team

[Edit Workflow Configuration Options](#)

Edit Workflow Details



Workflow options

At the top of the page is the name of the topic workflow configuration and some options that have been selected for the topic workflow configuration. To view and edit these options, click the [Edit Workflow Configuration Options](#) link.

Workflow Details

Each card shown is a link to its management page. You can edit all topic workflow details from this page. Each card displays summary information about the topic workflow configuration. Select a card to view or edit all topic workflow configuration details for each of the following areas:

- **Fields**—Define fields to store information for topics, actions, and attachments. Every topic workflow configuration includes a set of standard fields and custom fields to store information related to topics that your organization finds useful. The Fields card shows how many topic, action, attachment, and work team fields have been defined for the topic workflow configuration.
- **Topic States**—Specify the workflow states that can be assigned to a topic. For each workflow state, you can also define the next possible state or states that can be assigned. The card shows a summary of the topic states that have been defined for the topic workflow configuration.
- **Action States**—Specify the workflow states that can be assigned to an action. For each workflow state, you can also define the next possible state or states that can be assigned. The card shows a summary of the action states that have been defined for the topic workflow configuration.
- **Email Notifications**—Add, modify, and delete email notification rules for topics and actions. The card shows the number of topic rules and action rules states that have been defined for the topic workflow configuration.

- **Topic Templates**—Topic templates can serve as the starting point for creating new topics. View and edit topic template information, including their actions and history. The card shows a summary of the topic templates that have been defined for the topic workflow configuration.
- **Action Types**—Modify the generic action type or create a new action type and define its features. The card shows a summary of the action types that have been defined for the topic workflow configuration.

Work with topic workflow configurations

You can edit, copy, and delete topic workflow configurations as well as publish them for other users to use. You can also export them for use by another application and download a PDF file that shows all workflow configuration options.

- [Edit topic workflow configuration options](#)
The topic workflow configuration options determine how users can work with topics that are created using the topic workflow configuration.
- [Copy a topic workflow configuration](#)
You can copy either sample topic workflow configuration as well as other configurations that you create or import.
- [Delete a topic workflow configuration](#)
There are two deletion options: Make the topic workflow configuration inaccessible from the application and permanent deletions from the database.
- [Publish a workflow configuration](#)
Publishing the topic workflow configuration makes it available to other users. By default, the publication level of every newly created object is Private.
- [About exporting a topic workflow configuration](#)
You can export a topic workflow configuration to a file. The exported topic workflow configuration can be imported into another application instance.
- [Export a topic workflow configuration](#)
You can export a topic workflow configuration to allow another application instance with the same or greater topic schema version to import it.
- [Create a PDF for a topic workflow configuration](#)
You can download a PDF file that includes all the workflow configuration options.

Edit topic workflow configuration options

The topic workflow configuration options determine how users can work with topics that are created using the topic workflow configuration.

Note

Editing a topic workflow configuration that is already in use is not recommended.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action** menu () , and then click **Edit**.

4. On the Edit Topic Workflow Configuration page, click the **Edit Workflow Configuration Options** link.
5. Update the values in the **Name** and **Description** fields as needed.
6. To customize the topic workflow configuration, edit the fields according to the table below.
7. Click **Save**.
8. Log out and log in again to see the changes in the application.

Field descriptions—Edit Workflow Configuration page

Field	Description
Allow topic to be visible to	Defines the level of cross-team interaction enabled for topics. You can choose one of the following: • One and only one work team—Topics can be reviewed by, and assigned to, the members of the work team selected in the Visible to work team field of a specific topic. For configurations that select this option, it may be useful to give one or more administrative users the View Topics across Work Teams user permission. • Zero, one or more work teams—Topics can be reviewed by, and assigned to, the members of all work teams selected in the Visible to work team field of a specific topic. Topics visible to zero work teams are accessible only to the user who created them.

Note

For a user to view or act on topics that have been made visible to a work team, appropriate [work team permissions](#) must be assigned to that user.

Field	Description
Allow topic to be linked to	Defines how the topic linking feature functions. You can choose one of the following: • Topics in any state—Users can add a reference link from one topic to another topic regardless of workflow state. • Topics in final state—Users can add a reference link from one topic to another topic that is in a final state. Note For a user to link two topics, both topics must be visible to the user's work team with the Edit Topics or Edit Topic Actions work team permission.
Allow addition of comments to	Select one or more of these check boxes to enable the comment feature, which allows users to add free-text comments. You can enable the comment feature for: • Topics—Comments can be added and appear in the Topic Comments section of the Topic page. • Attachments—Comments can be added for attachments to a topic in the Topic Attachments section of the Topic page and for attachments to an action in the Action Attachments section of the Topic Action page. • Actions—Comments can be added and appear in the Action Comments section of the Topic Action page. Comments cannot be edited or deleted after entry. Note To add comments, users need the Edit Topics/Actions work team permission.

Field	Description
Allow sources of attachments	Select one or more of these check boxes to enable the attachment feature, which allows users to add supporting information to a topic or action. You can clear a check box to prevent attachments in that format from being added. • Application Data—A Save to Topic link is added to pages throughout Oracle Empirica Signal to allow the currently displayed object to be saved as an attachment to a topic or action. A site option can be set to limit the number of rows in table displays that can be saved with topics. • External URL—Add attachments in the form of a URL. • External document—Add files, including documents, spreadsheets, and images, to the topic. A site option can be set to limit the size of files saved with topics. • Note—Users can enter text to provide an overall description of several other attachments that are added Attachments of the selected types can be added to a topic or to individual actions, and can be edited or deleted. Attachments to a topic appear in the Topic Attachments section of the Topic page and attachments to an action appear in the Action Attachments section of the Topic Action page. Note To add attachments, users must have the Add/Edit/Delete Attachments in Open Topics/Actions or the Edit Attachments in Closed Topics/Actions work team permission.
Allow topic state closure only when all actions are completed	If selected, users can assign a final workflow state to a topic only when all of that topic's actions are in a final state. If cleared, users can assign a final state to a topic regardless of the workflow state of that topic's actions.
Warn on action state closure if no attachments or comments are provided for action	If selected, users who assign a final workflow state to an action that does not have any associated comments or attachments receive a warning message. If cleared, users can assign a final state to an action at any time without a warning.

Copy a topic workflow configuration

You can copy either sample topic workflow configuration as well as other configurations that you create or import.

You need the Manage Topic Workflow Configurations permission to copy an existing configuration and modify it.

Note

When you copy a topic workflow configuration, the latest versions of templates are also copied. However, any existing topics that are based on the configuration are *not* copied.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Copy**.
4. Type a unique name for the topic workflow configuration.
5. Optionally, modify the description of the topic workflow configuration.
6. Click **Save**.
7. (Recommended) Test the topic workflow configuration before you publish it to a [login group](#). To test, do the following:
 - a. Log out and log back in as the user who created the configuration.
 - b. Click the Topic Management page and select the new configuration.
 - c. When you are finished, publish the topic workflow configuration to the login group.

Delete a topic workflow configuration

There are two deletion options: Make the topic workflow configuration inaccessible from the application and permanent deletions from the database.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Delete**.
4. On the Delete Workflow configuration page, choose:
 - **Remove Reference only**—Deletes the configuration by reference. The configuration and any existing topics, including all comments and the associated attachments, are no longer accessible from the application. However, all of the data remains in the database and can be [re-imported](#) if necessary.
 - **Delete permanently**—Deletes the configuration from the database, along with all topics, including all comments and attachments associated with them. You must be a superuser to delete a topic workflow configuration permanently. A message informs you that for 21 CFR Part 11 compliance, you must print each topic for the topic workflow configuration and export tables from the Oracle account. Before you print the topics, verify that the [topic workflow configuration options](#) that allow

addition of comments to topics, actions, and attachments are all checked. This assures all comments are included, even if these settings were changed in the topic workflow configuration over time.

Tables that store topic data and workflow configurations

The tables shown below store data for topics and topic workflow configurations. The `_x` suffix represents the unique identifier in the `TM_CONFIG_LOCAL` table for a topic workflow configuration.

Topic tables	Topic workflow configurations tables
TM_TOPIC_x	TM_CONFIG_LOCAL
TM_TOPIC_COMMENT_x	TM_STATE_x
TM_ATTACHMENT_x	TM_STATE_TOPICAATTRIBUTE_x
TM_ATTACHMENT_CONTENT_x	TM_STATE_TRANSITIONS_x
TM_ATTACHMENT_COMMENT_x	TM_TOPIC_FIELD_x
TM_TOPICWORKTEAM_x	TM_TOPIC_CODEVALUES_x
TM_TOPICLINKS_x	TM_EMAIL_NOTIFN_RULES_x
TM_TOPIC_ACTION_x	TM_ATTACH_ATTR_x
TM_ACTION_COMMENT_x	TM_ATTACH_TYPE_x
TM_ACTION_ATTACHMENT_x	TM_ACTIONSTATE_x
TA_ATTACH_CONTENT_x	TM_ACTIONSTATE_ATTR_x
TA_ATTACH_COMMENT_x	TM_ACTIONSTATE_TRANS_x
TM_ACTION_ACTIVATIONSTATE_x	NY_ACTIONSTATE_RULE_MAP_x
TM_ACTIONWORKTEAM_x	TM_ACTION_TYPE_x
--	NY_REASON_CATEGORY
--	NY_RULES_x
--	NY_MESSAGE_x
--	NY_DESTINATION_x
--	NY_STATE_RULE_MAP_x
--	NY_ACTION_RULE_MAP_x
--	NY_FIELD_MODIFY_MAP_x
--	NY_CATEGORY_MAP_x
--	NY_REMIND_x
--	NY_HISTORY_x
--	NY_ACTION_REMIND_MAP_x

Publish a workflow configuration

Publishing the topic workflow configuration makes it available to other users. By default, the publication level of every newly created object is Private.

Note

Users without Administer Users permission can only publish objects they have created. Users with the Administer Users permission can publish objects that they or any users in their login group created.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Publish**.

The Publish Workflow Configuration page appears and includes publication status information such as who owns it and the publication level.

Note

If no publication status appears, the object has been published to a different login group than yours by a superuser.

4. If you are a superuser, you can publish an object to multiple login groups. In the **Publish to Login Groups** drop-down list, **click** or **Ctrl+click** to select login groups.

If you publish to –All– and later add a new login group, the object is published automatically to the new login group.

5. Click **Publish**.

The object is published to all of the users who are in your login group.

6. Click **Back** to return to the Manage Topic Workflow Configurations page.

About exporting a topic workflow configuration

You can export a topic workflow configuration to a file. The exported topic workflow configuration can be imported into another application instance.

Exporting a topic workflow configuration can be useful when developing the topic workflow configuration in a test environment and then loading it into a production environment. You can import the topic workflow configuration into Oracle Empirica Signal if its topic schema version is less than or equal to the Oracle Empirica Signal topic schema version.

You must have the Manage Topic Workflow Configurations permission to export the topic workflow configuration.

When you click **Export**, the selected topic workflow configuration is exported into a .dat file in XML format, which you can save on your local computer. By default, the file name is *<Topic Workflow Configuration name>.dat*.

The exported .dat file contains the following data:

- Topic schema version
- Topic workflow configuration metadata (such as, Name, Description, and ID)
- Fields
Fields that include work team contexts are not exported.
- Up to 5000 defined values for fields
A warning message appears if more than 5000 values have been defined for a field. If you proceed, the first 5000 values are exported based on their display order.
- Topic states and state information
- Topic field accessibility by state
- Action states and action state information
- Action field accessibility by state
- Attachment field accessibility by type
- Email notification rules
Recipient values that are exported can include New Assignee, Previous Assignee, and Visible to Work Team Members. Individual usernames are not included in the export.

The Topic Field Modified or Action Field Modified notification reasons that reference fields that include work team contexts are not exported. These fields can exist in the Message Subject and Message Text; however, because they will not be exported, they will not be populated when the email is sent on the imported side.
- Topic templates
If a topic template contains populated topic or action fields and these fields have a work team context, then the topic template is not exported. The history of the topic template is not exported. The Assigned to field for the Template and Template Actions are not exported.
- Action types
The Assigned To field is not exported.

Export a topic workflow configuration

You can export a topic workflow configuration to allow another application instance with the same or greater topic schema version to import it.

To export a topic workflow configuration:

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action** menu () , and then click **Export**.
4. Follow the directions for your browser.
5. Click **Save**.

Create a PDF for a topic workflow configuration

You can download a PDF file that includes all the workflow configuration options.

The PDF file includes all the workflow configuration options; site options; topic, action, attachment, and work team fields; defined values; topic and action states and accessibility by state and type; action types; topic templates and actions; and email notification rules defined for the topic workflow configuration.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Select the configuration's **Row Action menu** (⋮), and then select **Create PDF**.
4. Follow the directions for your browser.
5. Click **Save**.

Manage fields

These topics apply to fields used to store information for topics, actions, and attachments.

- [About fields](#)
In a topic workflow configuration, you can define fields to store information for topics, actions, and attachments.
- [Manage Fields page](#)
On the Manage Fields page, you can view all defined fields, including fields that apply only to specific states in the topic or action workflow, or to certain types of attachments. You can add, modify, and delete these fields.
- [View a field](#)
You can view basic information about all the fields defined for the topic workflow configuration.
- [About managing the display order for fields and field values](#)
You can reorder standard and custom fields in addition to reordering lists of field values.
- [Add a field](#)
You can add a custom field to a topic workflow configuration.
- [Add a multi-selection list field](#)
When you add a field to a topic workflow configuration, it appears by default as a single value-entry field and accepts any alphanumeric value that a user enters. Alternatives to single value-entry include Append-Only and Multiple Values.
- [Add a drop-down list field](#)
When you add a field to a topic workflow configuration, it appears by default as a value-entry field and accepts any alphanumeric value a user enters. An alternative is to provide a limited set of entries for a field to display a drop-down list with those values.
- [Add linked fields](#)
In cases where user interaction with a pair of fields, which are related and requires a selection of one field before presenting the values that are valid for another, you can include a linked pair of drop-down lists in your topic workflow configuration.
- [Constrain field values by work team](#)
You can limit the values that users can select for a field based on the user's work team membership.
- [Identify a field as a filter field](#)
Any field in a topic workflow configuration can be identified as a filter field. A filter field appears in the **Select Filter** drop-down list on the Filter bar of the Topics and Actions tables.
- [Edit a field](#)
You can edit all defined fields, including general field information as well as the values defined for the fields.

- [Delete a field](#)
Only custom fields can be deleted.
- [Modify the display order for a field](#)
A field can only have one display order, even if it appears in more than one context. You can set the display order of the standard and custom fields.

About fields

In a topic workflow configuration, you can define fields to store information for topics, actions, and attachments.

Every topic workflow configuration includes a set of standard fields, and custom fields to store information related to topics that your organization finds useful.

To define whether or not a field appears for topics or actions in a given workflow state or for attachments of a certain type, you also specify the [topic field accessibility by state](#), [action field accessibility by state](#), and [attachment field accessibility by type](#).

Manage Fields page

On the Manage Fields page, you can view all defined fields, including fields that apply only to specific states in the topic or action workflow, or to certain types of attachments. You can add, modify, and delete these fields.

General activities

The following links appear at the top of the page and affect the entire page:

- [Add Field](#) adds a custom field to the topic workflow configuration.
- [Modify Display Order](#) gives you control over the order in which the fields are displayed on the Manage Fields page.
- Manage Accessibility includes three options:
 - [Topic Fields by State](#) defines the level of access that users have to each field when a topic is in each of the workflow states.
 - [Action Fields by State](#) defines the level of access that users have to each field when an action is in each of those states.
 - [Attachment Fields by Type](#) defines the level of access that users have to each field based on the type of attachment.
- Back returns you to the Edit Topic Workflow Configuration page.
- [Columns](#) allows you to select the columns and sort order for the Manage Fields page.
- [Print](#) sends a PDF version of the Manage Fields table to your printer.
- [Download](#) sends the Manage Fields table to your PC in the format you specify.

Row-specific activities

The following menu options are available from the **Row Action menu** (), located in the left most column of the table, and affect an individual row in the table:

- [Edit](#) basic field information.
- [Define Values](#) specifies one or more valid values for a field that affect selections made across the application.

- [Delete](#) a field that isn't used by any topics or work teams. If you are a superuser, you can delete any field.

Field descriptions—Manage Fields page

Field	Description
Name	Oracle database column name for the field.
Format	One of the following values: • String—Alphanumeric text value for the field. • Integer—Positive integer value for the field. • Date—Date in mm/dd/yyyy format in the field.
Filter	• Yes if the field acts as a display filter, appearing above tables of topic-related data as a drop-down list populated by all stored values. See Identifying a field as a filter field. • Select No for fields that are not used to filter displayed data.
Custom/Standard	One of the following values: • Standard—A field included in all topic workflow configurations. • Custom—A field added to the topic workflow configuration by your organization.
Display Name	Name of the field as it appears in the user interface.
Order	Position of the field within the workflow. The number indicates the place in the workflow of the field. The context determines where the Oracle Empirica Signal application uses the order: • For a topic—In the Add Topic or Topic General Information section of the Topic. • For an action—In the Add Action or Action General Information section of the Topic Action page. • For an attachment—On the Add Attachment page. You can modify the order of both standard and custom fields.
Context	Oracle Empirica Signal element to which the field is applied. One or more of the following values: • Topic • Action • Attachments • Work teams

Note

The order applies to all fields with a given context. You can assign a single order value for the field.

Field	Description
Field Type	One of the following field type options: • Single value—A single value field type. This is the default field type. • Append-only—A multiple values field type in which a previously selected value cannot be removed. See Adding a multi-selection list field. • Multiple values—A multiple values field type that supports adding and removing values. • Append-only and constrained—An append-only field whose values are restricted based on work team. See Constraining field values by work team. • Linked—The subsidiary field in a linked pair. See Adding linked fields.
Field Values	Defined values for the field: • A field with defined values appears with a list selection control in the user interface. See Adding a drop-down list field or Adding a multi-selection list field. • A field without defined values appears as a value-entry field.

View a field

You can view basic information about all the fields defined for the topic workflow configuration.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Fields** card.

On the Manage Fields page, you can see [information about each field](#) defined.

About managing the display order for fields and field values

You can reorder standard and custom fields in addition to reordering lists of field values.

 Tip

Select one or more fields in the Category or View list:

- Click



to move the defined value up in the list.

- Click



to move the defined value down in the list.

Standard fields appear in the following order:

1. Topic fields
2. Action fields
3. Attachment fields

The custom fields appear after the standard fields in the order you added them. You can modify the default sequence:

- For a topic—On the [Add Topic page](#) or Topic General Information section of the Topic page.
- For an action—On the [Add Topic Action page](#) or Action General Information section of the Topic Action page.
- For a document-style attachment—On the [Add Attachment page](#).
- For a work team—On the [Edit Work Team page](#).

 Note

A field can only have one display order, even if it appears in more than one context. You can prevent a field from appearing when the topic or action is in a given state by assigning a field access level of **hidden** to the field for that state. This also applies to attachments of different types.

Add a field

You can add a custom field to a topic workflow configuration.

Adding a field adds a column to an Oracle database table, so you must specify the data type (for example, string, integer, or date). You can also make selections that affect how users interact with the field in the user interface, including the field label displayed, how users select values for the field, and whether the field applies to topics, actions, or attachments, or any combination of these contexts.

1. In the left navigation pane, click the **Settings** icon (.

2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.

3. Click the configuration's **Row Action menu** (), and then click **Edit**.

4. On the Edit Topic Workflow Configuration page, click the **Fields** card.

5. To add a field, click the **Add Field** link.

6. In the **Column name** field, type the field name to appear in the Oracle database.

The name must begin with a letter. It must be up to 30 characters in length, and consist of uppercase letters, numbers, and the special characters \$, _, and # only.

7. In the **Display name** field, type the field name to appear in the user interface.

The display name appears as the label for the field and as a column header, as the hover help text, and as a label above the field information in the Details panel.

8. From the **Format** drop-down list, select the type of data to be collected: string, integer, or date.

Note

The options described in the steps below do not apply to date fields.

9. For string fields only, in the **Length** field, specify the maximum length.

10. Specify a type for the field. The type determines how you specify values for the field:

- **Single Value:** This is the default field type.
- **Append-only:** A multiple values field type in which a previously selected value cannot be removed (string fields only).
- **Multiple Values:** A multiple values field type that supports adding and removing values (string fields only).
- **Linked:** The subsidiary field in a linked pair.
- **Constrained values based on work team:** An append-only field restricted to the work team context.

11. Select a context for the field. The field can appear as and store values for topics, topic actions, topic attachments, or work teams, or any combination of these contexts.

12. To limit the values that can be selected for a field based on the work team membership of the current user, select **Work teams** in addition to one of the other contexts. See [Constrain field values by work team](#).

Note

A superuser must set the **Topic workflow configuration for work team custom fields** site option to this configuration and the configuration must be published. If your organization uses more than one topic workflow configuration, you must define custom fields with the work team context identically in each topic workflow configuration.

13. Select **Display as filter field** to make the field available as a filter on the Topics and Actions tabs on the Topic Management page. See [Identify a field as a filter field](#).

14. Click **Save**.

Fields appear in the user interface as value-entry fields unless you explicitly define a valid set of values for them. For example, description fields are typically value-entry fields that allow users the flexibility to enter any value.

You can [define valid values](#) for custom fields that have a format of string or integer, and for certain standard fields. Fields with defined values appear in the user interface as drop-down lists or, if you define a field as Append-only, as a multi-selection list. See [Add a drop-down list field](#) and [Add a multi-selection list field](#).

Add a multi-selection list field

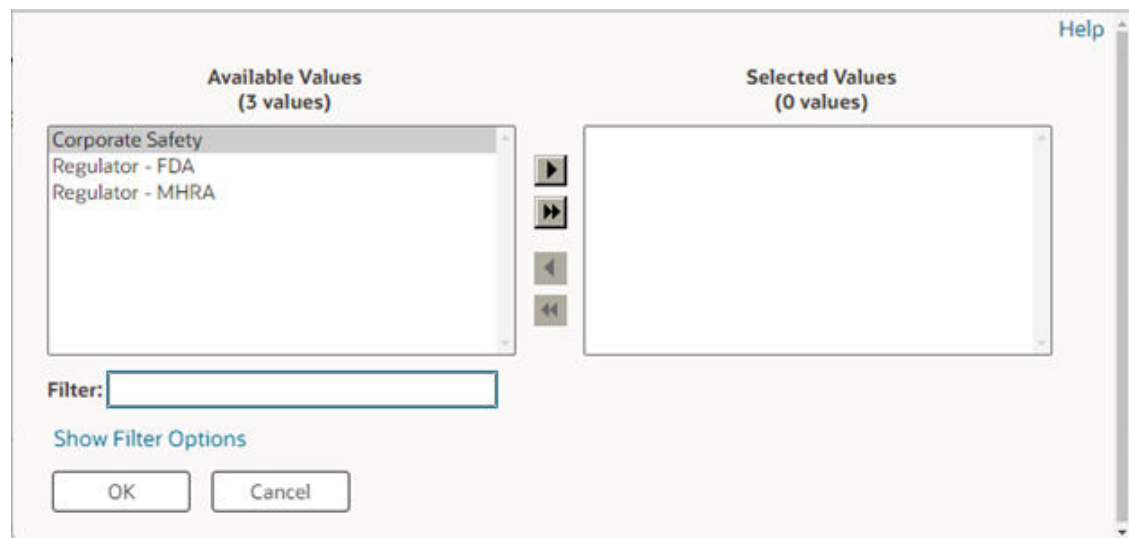
When you add a field to a topic workflow configuration, it appears by default as a single value-entry field and accepts any alphanumeric value that a user enters. Alternatives to single value-entry include Append-Only and Multiple Values.

Both of these multi-selection list fields provide a limited set of possible values and both appear in the user interface with a link to a multi-selection list.

Figure 10-2 Edit reports column



Figure 10-3 Select available values



Like a [drop-down list field](#), a multi-selection list field limits the number of possible entries that users can make and enforces consistency. Append-only fields also ensure that any value selected at one point in time cannot be deleted or replaced. Users cannot later edit this type of field to remove or replace a value. Multiple Values fields do allow users to edit the field and remove or replace values.

Note

You can further reduce the possibility of user error when entering field values by setting up a multi-selection field, and then specifying the work team or teams that can select each of its valid values. See [Constrain field values by work team](#).

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Fields** card.
5. To add a field, click the **Add Field** link.
6. In the **Column Name** field, enter a column name.
7. In the **Display name** field, type a name to display in the user interface.
8. From the **Format** drop-down list, select either string or integer as the format.
9. For a string field, in the **Length** field, specify a maximum field length.
10. In the **Type** section, check **Append-only** or **Multiple Values**.
11. In the **Context** section, select the field context. The field can be used to collect information for a topic, action, attachment, or work team.
12. To use the field as a filter, check **Display as filter field**. See [Identify a field as a filter field](#).
13. Click **Save**.
14. Click the **Row Action menu** () for the field you added, and then click **Define Values**.
The [Define Valid Field Values page](#) appears.
15. Click **Add Value**.
16. On the [Add Value page](#), supply a field value for users to select.
17. Click **Save**.
18. Repeat steps 15 through 17 to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file and then upload it. See [Upload a table of valid values](#).
19. Click **Back** to return to the Manage Fields page.

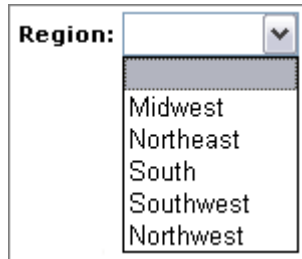
By default, the new field appears with a **Select Available Values** link next to it for a topic or action that is in any workflow state, for any type of document-style attachment, or for a work team. The field is editable: that is, users can select values for it or leave it blank.

You can make this field required (users must select at least one value before saving). See [Manage topic field accessibility by state](#), [Manage action field accessibility by state](#), or [Manage attachment field accessibility by type](#).

Add a drop-down list field

When you add a field to a topic workflow configuration, it appears by default as a value-entry field and accepts any alphanumeric value a user enters. An alternative is to provide a limited set of entries for a field to display a drop-down list with those values.

For example:



Users can select a single value from a drop-down list, and can change the selected value for the field at any time (if permitted for a given workflow state by the topic or action field access level). Drop-down lists structure data entry by limiting the number of possible entries. They also assure that the values stored for a field are consistent.

Note

An alternative is to add a field that appears with a multi-selection list control in the user interface. There are two field types that support this: Append-only and Multiple Values. If the field is Append Only, users can select one or more values, but cannot remove any previously selected and saved values. If the field is Multiple Values, users can select one or more values, and can remove previously saved values. See [Add a multi-selection list field](#).

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (⋮) for a configuration, and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Fields** card.
5. To add a field, click the **Add Field** link.
6. In the **Column name** field, enter a column name.
7. In the **Display name** field, enter a name to appear in the user interface.
8. From the **Format** drop-down list, select the format of the field: String, Integer, or Date.
9. If you specified a **String** format, in the **Length** field, enter the maximum field length.
10. In the **Type** section, select **Single Value**.
11. In the **Context** section, select the field context. The field can be used to collect information for a topic, action, attachment, or work team.
12. Optionally, specify the field to be used for filtering by checking **Display as filter field**. See [Identify a field as a filter field](#).
13. Click **Save**.

Note

You can design a pair of drop-down list fields that are linked. Selections available for the second field in the pair are dependent on the selection for the first in the pair. See [Adding linked fields](#).

14. Click the **Row Action menu** () for the field you added, and then click **Define Values**.
15. Click **Add Value**.
16. In the **Value** field, enter a field value for users to select.
17. Click **Save**.
18. Repeat steps 15 - 17 to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file, and then upload it. See [Upload a table of valid values](#).
19. [Modify the display order](#) of the valid values as needed. Click **Modify Display Order**.
 - a. From the **Values for Dropdown** list, select a value.
 - b. To change the order of the value in the list, use the up-arrow and down-arrow buttons.

By default, the new field appears as a drop-down list for a topic or action that is in any workflow state, for any type of document-style attachment, or for a work team. The field is editable; that is, users can select a value from the list or select " " (blank).

You can make this field required (the blank value is not offered, and users must select one of the defined values before saving).

Add linked fields

In cases where user interaction with a pair of fields, which are related and requires a selection of one field before presenting the values that are valid for another, you can include a linked pair of drop-down lists in your topic workflow configuration.

In the following example, the user interface presents linked fields for selecting a MedDRA SOC and MedDRA HLGT:



Users must select a value for the parent field, MedDRA SOC, first. The list of values for the subsidiary field, MedDRA HLGT, is then populated with values that are valid given that initial selection.

MedDRA SOCD: Metab

MedDRA HLGT:

- Acid-base disorders
- Metabolism disorders NEC
- Appetite and general nutritional disord
- Bone, calcium, magnesium and phosphorus
- Diabetic complications**
- Electrolyte and fluid balance conditions
- Food intolerance syndromes
- Glucose metabolism disorders (incl diabe

- You must define valid values for both of the fields in a linked pair. Both fields appear as drop-down lists in the user interface.
- Both of the fields in a linked pair must be custom fields that you add to the topic workflow configuration.
- You must define two different fields as the linked pair. A field cannot be selected as its own link to parent field.

Add the parent field

The first field you add is the parent field.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (⋮), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Fields** card.
5. Click **Add Field**.
6. In the **Column Name** field, enter a column name.
7. In the **Display name** field, type a name to display in the user interface.
8. From the **Format** drop-down list, select either string or integer as the format.
9. For a string field, in the **Length** field, specify a maximum field length.
10. In the **Type** section, do not check any options.
11. In the **Context** section, select the field context. The field can be used to collect information for a topic, action, attachment, or work team.
12. To use the field as a filter, check **Display as filter** field. See [Identify a field as a filter field](#).
13. Click **Save**, and then click **Back**.
14. On the Manage Fields page, click the **Row Action menu** (⋮) for the parent field, and then click **Define Values**.
15. Click **Add Value**.
16. In the **Value** field, enter a value for users to select, and then click **Save**.
17. Repeat steps 14 - 15 to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file, and then upload it. See [Upload a table of valid values](#).

18. [Modify the display order](#) of the valid values as needed. For more information, see [Modify the display order for the values](#).

Add the child field

On the **Add field** page, enter a second, subsidiary, field.

1. In the **Column Name** field, enter a column name.
2. In the **Display name** field, type a name to display in the user interface.
3. From the **Format** drop-down list, select either string or integer as the format.
4. For a string field, in the **Length** field, specify a maximum field length.
5. In the **Type** section, check **Linked** and, from the **Link to parent field** drop-down list, select the field you added as the parent field.
6. In the **Context** section, select the same field context(s) as for the parent field.
7. Optionally, specify the field to be used for filtering by checking **Display as filter field**. See [Identify a field as a filter field](#).
8. Click **Save**.

Define the parent-child values

1. On the Manage Fields page, click the **Row Action menu** () for the subsidiary field, and then click **Define Values**.
2. Click **Add Value**.
3. On the [Add Value page](#), supply the values for users to select. For each value that you add, from the **Link to parent value** drop-down list, identify the value for the parent field that must be selected for this value to be available.
4. Click **Save**.
5. Repeat Step 4 to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file, and then upload it. See [Upload a table of valid values](#).
6. [Modify the display order](#) of the valid values, as needed. For more information, see [Modify the display order for the values](#).

By default, both new fields will be editable for a topic or action in any workflow state, or for any type of document-style attachment. Users can select a value or select " " (blank).

7. Alternatively, you can make one or both of these fields required (the blank value is not offered, and users must select one of the defined values before saving). Generally, you should apply the same access level to both of the fields in the linked pair. See [Manage topic field accessibility by state](#), [Manage action field accessibility by state](#), or [Manage attachment field accessibility by type](#).

Constrain field values by work team

You can limit the values that users can select for a field based on the user's work team membership.

You can further limit the values that users can select for a multi-selection field by specifying the values that the members of a work team are able to select; that is, to constrain the field's valid values based on work team. This feature can reduce the possibility of user error when entering data and prevent the loss of information collected over time.

Note

If your organization uses more than one topic workflow configuration, any custom fields for the work team context must be defined identically in each topic workflow configuration.

Add the field to a topic workflow configuration

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Fields** card.
5. To add a field, click the **Add Field** link.
6. In the **Column Name** field, enter a column name.
7. In the **Display name** field, type a name to display in the user interface.
8. From the **Format** drop-down list, select either string or integer as the format.
9. For a string field, in the **Length** field, specify a maximum field length.
10. In the **Type** section, check **Append-only** or **Multiple Values**.
11. In the **Type** section, check **Constrained values based on work team**.
12. In the **Context** section, select the field context. You must check at least one of these options. The field can be used to collect information for a topic, action, attachment, or work team.
13. In the **Context** section, check **Work Team**.
14. To use the field as a filter, check **Display as filter** field. See [Identify a field as a filter field](#).
15. Click **Save**.

Define the values

1. On the Manage Fields page, click the field's **Row Action menu** () , and then click **Define Values**.
2. Click **Add Value**.
3. On the [Add Value page](#), supply a value for users to select.
4. Click **Save**.
5. Repeat steps 2 - 4 to add all possible values for the field. Alternatively, you can store all field values in a .csv (comma-separated value) file, and then upload it. See [Upload a table of valid values](#).
6. Click **Back**.

By default, the new field will be editable for a topic or action that is in any workflow state or for every type of document-style attachment. You can make this field required (users must select at least one value before saving), hidden, or visible in certain states or for certain attachment types. See [Manage topic field accessibility by state](#), [Manage action field accessibility by state](#), or [Manage attachment field accessibility by type](#).

Set site options

You can perform the following steps only if you are a superuser.

1. In the left navigation pane, click the **Settings** icon () .
2. In the **Administer System** section, click **Set Site Options**.
3. At the bottom of the page, from the **Topic workflow configuration for work team custom fields** drop-down list, select the topic workflow configuration that has the constrained value field.
Custom work team fields appear when you add and edit work teams only after your topic workflow configuration has been published and this site option has been set.
4. Click **Save**.
5. In the left navigation pane, click the **Settings** icon () .
6. In the **Manage Users** section, click **Edit Work teams**.
7. Click the work team's **Row Action menu** () , and then click **Edit**.
The [Edit Work Team page](#) appears. Your new field appears as a multi-selection list field.
8. To specify values for members of this work team to select for this field in the user interface, next to the multi-selection list field, click **Select Available Values**.
9. To define the values to present to each set of users, repeat this step for each work team.
10. Log out, then log back in.
11. To test your new field, in the left navigation pane, click the **Topic Management** icon () , and then add or edit a topic, action, or attachment. The values available for selection in this field reflect your membership in one or more work teams.

Identify a field as a filter field

Any field in a topic workflow configuration can be identified as a filter field. A filter field appears in the **Select Filter** drop-down list on the Filter bar of the Topics and Actions tables.

Using filter fields, you can limit the number of rows that appear in the Topics and Actions tables to only those that match the value selected for this field.

Note

- Only fields that store a limited number of values (no more than 50 but, typically, less) should be identified as filter fields, as longer lists can become difficult for users to navigate effectively.
- The first 30 characters of each field value are shown in the drop-down list. Longer values are shortened to 30 characters.

1. In the left navigation pane, click the **Settings** icon () .
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Fields** card.

5. On the Manage Fields page, click the field's **Row Action menu** (), and then click **Edit**.
6. On the Edit Field page, select **Display as filter field**.
7. Click **Save**.

Edit a field

You can edit all defined fields, including general field information as well as the values defined for the fields.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Fields** card.
5. Click the field's **Row Action menu** (), and then click **Edit**.
6. Modify the fields as described below:

Field	Description
Column name	Not editable. The name of the field as it appears in the Oracle database.
Display name	The label that appears when adding or editing a topic or action.
Format	Not editable. Type of data to be collected: Date, String, or Integer.
Length	For a string format field, the Length field is editable. If you provide a new length that is less than or equal to an existing value, the page displays an error message.
Type	The type determines how users can specify values: • Single Value—A single value field type. This is the default field type. • Append-only—A multiple values field type in which a previously selected value cannot be removed. • Multiple Values—A multiple values field type that supports adding and removing values. • Linked—The subsidiary field in a linked pair. • Constrained values based on work team—An append-only field restricted to the work team context.
Context	Oracle Empirica Signal element to which the field is applied. One or more of the following values: • Topics • Actions • Attachments • Work teams

Field	Description
Filter	Make this a filterable field that appears in the Select Filter drop-down list on the Topics and Actions tabs on the Topic Management page.

- Click **Save**.

Delete a field

Only custom fields can be deleted.

- If you are not a superuser, you can delete a field only if no values are present for that field in any existing topics or work teams. To prevent a field from appearing for the topics feature, you can assign an access level of -- (Hidden) to the field for all topic states, all action states, or all attachment types.
 - If you are a superuser, you can delete a field for which a value is present in an existing topic. A warning message informs you that for 21 CFR Part 11 compliance, you must print each topic for the topic workflow configuration, and export tables from the Oracle account for the topic workflow configuration. For a complete list of topic and topic workflow configuration tables, see [Delete a Topic Workflow Configuration](#).
- In the left navigation pane, click the **Settings** icon (.
 - In the **Configure System** section, click **Manage Topic Workflow Configurations**.
 - Click the configuration's **Row Action menu** () , and then click **Edit**.
 - Click the **Fields** card.
 - Click the custom field's **Row Action menu** () , and then click **Delete**.

Note

If the field is referenced in any Topic Field Modified or Action Field Modified email notification rules, you must [edit the email notification rule](#) before the field is deleted. A dialog box appears with a list of the relevant notification rules.

Or, if you attempt to delete the field which has a value defined in an existing topic template or action type, the application prompts you to first remove the field value from the topic templates or action types, and then delete the field.

Modify the display order for a field

A field can only have one display order, even if it appears in more than one context. You can set the display order of the standard and custom fields.

- In the left navigation pane, click the **Settings** icon (.
- In the **Configure System** section, click **Manage Topic Workflow Configurations**.
- Click the configuration's **Row Action menu** () , and then click **Edit**.
- On the Edit Topic Workflow Configuration page, click the **Fields** card.
- Click the **Modify Display Order** link.

6. The dialog box lists every field in the currently assigned display order. For each field, the identifying information appears as **Display name [COLUMN_NAME] (ID=#)**.
7. Select one or more fields.

✓ **Tip**

- Use the  and  keys to move the field up or down in the list.

8. Click **OK**.

Manage field values

You can specify the list of values that appear for a field.

- [View valid values for a field](#)
To present a list of values for a field, instead of a value-entry field, you supply one or more valid values for that field.
- [Add or edit field values](#)
Use this process to define or edit all values for a field.
- [Delete a field value](#)
Only field values you have defined for custom fields can be deleted.
- [Upload a table of valid values](#)
To add a large number of field values, define a file with a table of values, then upload them.
- [Modify the display order for field values](#)
You can specify the order in which valid field values appears in the drop-down list for that field.

View valid values for a field

To present a list of values for a field, instead of a value-entry field, you supply one or more valid values for that field.

You can define values for:

- Standard string fields.
- Custom string fields.
- Custom integer fields.

You must define values for custom fields that have one of these types:

- Linked

 Note

You must define values for both the controlling parent field and its subsidiary field. Typically, all values for the parent field are defined before the values for the subsidiary field are defined.

- Append-only
- Constrained and Append-only

- Multiple Values
- Constrained and Multiple Values

You can also specify the order in which the values appear in the list. If the field is not required, users can select " " (blank) to leave the field empty.

To define field values:

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configuration**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. Click the **Fields** card.
5. Click the field's **Row Action menu** () , and then click **Define Values**.

The Define Valid Field Values page provides the following information about the field values that have been defined.

Column	Description
Value	Value that is available for selection in the topic field.
Link to Parent	Value that must be selected for the parent field for this value to be available. Applies to the subsidiary field in a linked pair only.
Order	Number indicating the display order for the value.

Add or edit field values

Use this process to define or edit all values for a field.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. Click the **Fields** card.
5. Click the field's **Row Action menu** () , and then click **Define Values**.
6. Choose one of the following:
 - To add a value, click the **Add Value** link.
 - To edit a value, click the value's **Row Action menu** () , and then click **Edit**.
7. In the **Value** field, enter a value.

If the field you are adding is the subsidiary field in a linked pair, select the value that this value is subsidiary to in the **Link to the parent value** field.

For example, if a MedDRA SOC field and a MedDRA HLGT field are linked, you select an SOC value, and then a list of relevant HLGT values is made available for selection.

8. Click **Save**.

9. Repeat this process as needed to define or edit all valid values for the field. Alternatively, you can save all values in a .csv file and [upload the table of values](#).

Delete a field value

Only field values you have defined for custom fields can be deleted.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. Click the **Fields** card.
5. Click the field's **Row Action menu** () , and then click **Define Values**.
6. Click the field value's **Row Action menu** () , and then click **Delete**.

If you attempt to delete a field value that is referenced in existing topic templates, the application prompts you to first remove the field value from the topic templates or action types.

7. Click **OK**.

If the field value isn't in an existing topic template, Oracle Empirica Signal deletes the field value. If not, no change is made to the Define Valid Field Values page.

Note

If you delete or change a value that is already in use in a topic, the original value remains in any topics that have used that value; however, the value is no longer available for selection in that, or any other, topic.

Upload a table of valid values

To add a large number of field values, define a file with a table of values, then upload them.

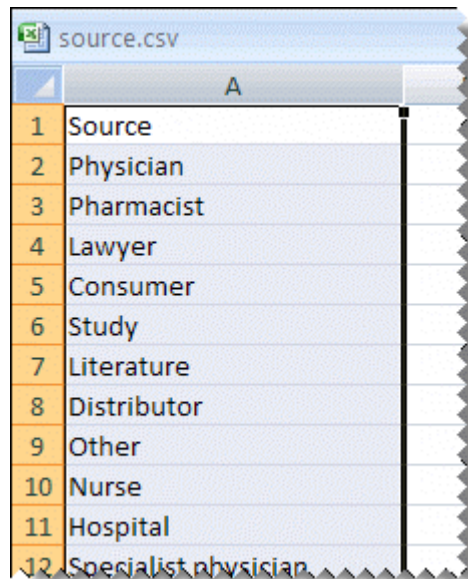
Create the table of values

1. Determine the valid values for the field.
2. Prepare a comma-separated value (.csv) file with a single column and with a column heading in the first row. Enter a single value of u to 100 characters in each subsequent row.

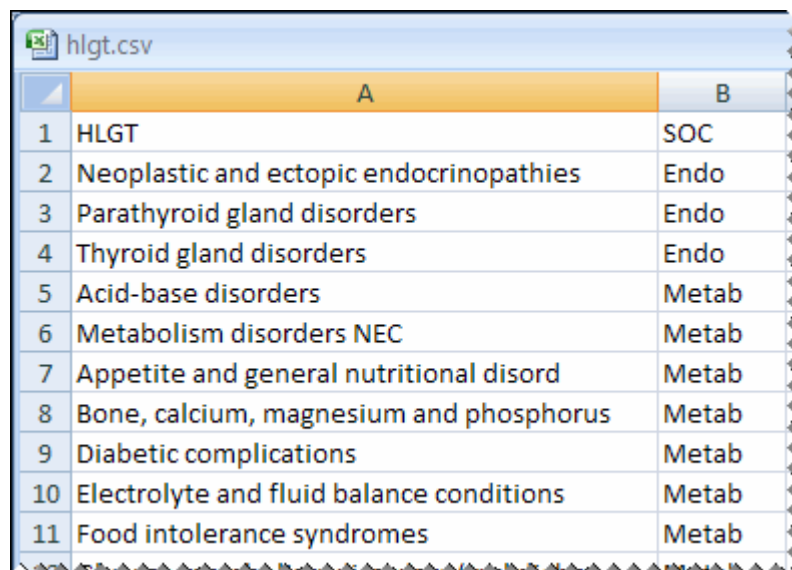
Note

For a field that is the subsidiary field in a [linked pair](#), the table that you upload should contain two columns. The first column should contain the values for that field, and the second column should contain the values that are valid for the controlling, parent field.

For example:

Typical format:


	A
1	Source
2	Physician
3	Pharmacist
4	Lawyer
5	Consumer
6	Study
7	Literature
8	Distributor
9	Other
10	Nurse
11	Hospital
12	Specialist physician

Format for subsidiary linked fields only:


	A	B
1	HLGT	SOC
2	Neoplastic and ectopic endocrinopathies	Endo
3	Parathyroid gland disorders	Endo
4	Thyroid gland disorders	Endo
5	Acid-base disorders	Metab
6	Metabolism disorders NEC	Metab
7	Appetite and general nutritional disord	Metab
8	Bone, calcium, magnesium and phosphorus	Metab
9	Diabetic complications	Metab
10	Electrolyte and fluid balance conditions	Metab
11	Food intolerance syndromes	Metab

3. Save the file with the .csv (comma-separated value) file extension.

Upload the table of valid values

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (⋮), and then click **Edit**.
4. Click the **Fields** card.
5. Click the field's **Row Action menu** (⋮), and then click **Define Values**.
6. On the Define Valid Field Values page, click the **Upload Table** link.

7. Make sure that the .csv file you want to upload is in the format shown and that the first row contains a column header.
8. In the **File to upload** field, click **Choose File** to locate the file on your computer, then click **Open**.
9. Click **Upload**.
10. If necessary, you can [edit the values](#) or [change the display order](#) for the values.

Modify the display order for field values

You can specify the order in which valid field values appears in the drop-down list for that field.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () for a configuration, and then click **Edit**.
4. Click the **Fields** card.
5. Click the field's **Row Action menu** () , and then click **Define Values**.
6. Click the **Modify Display Order** link and select one or more fields.

Tip

-  and  keys to move values up and down in the list.

7. Click **OK**.

Manage topic states

You can view or edit topic states. Specifying topic states in the topic workflow configuration applies a workflow for processing topics. Each topic state may include the next state or state that may be assigned.

- [About topic states](#)
To create a structured workflow for processing topics, define the states that a topic goes through.
- [Manage Topic States page](#)
On the Manage Topic States page, you can view the defined topic states, add states, and edit or delete states.
- [View a topic state](#)
You can view each topic state to process topics through the workflow. Each topic state may define subsequent states that can be assigned to the topic.
- [Add a topic state](#)
When you add a topic state, you can define its workflow state transitions: the path used to move a topic from one state to another in the workflow.
- [Edit a topic state](#)
You can edit the name, description, and possible next states for a topic state, as well as specify possible next states that require approval.

- [Delete a topic state](#)

You can delete topic states; however, you cannot delete the Init state and topic states in use.

About topic states

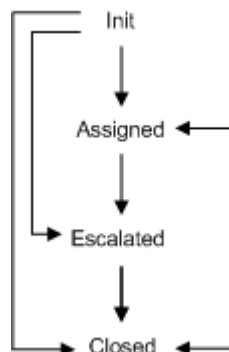
To create a structured workflow for processing topics, define the states that a topic goes through.

Each [topic workflow configuration](#) defines the workflow states that can be assigned to a topic. Every topic has a state that provides the status of the topic within the workflow. When you add a topic workflow configuration, Oracle Empirica Topics automatically creates a limited set of states: Init and Closed. You can add states and customize the transitions permitted between states. For example, you can specify the next possible state or states that can be assigned to the topic. You can also configure these transitions so that they require approval before application to the topic. Transitions that require approval are marked with the **Requires Approval** icon (🔒).

If Signal Management is integrated with Topics, you can include **Topic Name** and **Topic State** columns on the Product-Event Combinations table and in Signal Management views. You can also change the topic state to move the topic through your organization's workflow.

For example, the sample topic workflow configuration includes workflow states of Init (Initial), Assigned, Escalated, and Closed for topics. When a topic is in the Init state, it can move to any of the other three states. When it is in the Assigned state, the next possible states are Escalated or Closed.

The illustration shows the workflow supported by these states.



Note

Each topic workflow configuration also defines a separate set of workflow states that can be assigned to the actions for a topic. See [About action states](#) for more information. The illustration shows the workflow supported by these states.

Manage Topic States page

On the Manage Topic States page, you can view the defined topic states, add states, and edit or delete states.

General activities

The following links appear at the top of the page and affect the entire page:

- [Add State](#) adds another topic state to the topic workflow configuration.
- [Back](#) returns you to the Edit Topic Workflow Configuration page.
- [Columns](#) allows you to select the columns and sort order for the Manage Topic States page.
- [Print](#) sends a PDF version of the Manage Topic States table to your printer.
- [Download](#) sends the Manage Topic States table to your PC in the format you specify.

Row-specific activities

The following options are available from the Row Action menu (), and affect an individual row in the table:

- [Edit](#) topic state information, possible next states, approval requirements, and whether this is a final state.
- [Delete](#) a topic state that isn't used by any topics or work teams. If you are a superuser, you can delete any topic state.

Field descriptions—Manage Topic State page

In this section, you can view the information for each topic workflow state.

Field	Description
Name	Name of the topic workflow state.
Description	Description of the topic workflow state.
Initial State	Select Yes for a workflow state assigned automatically to a new topic when it is added. Select No for a state to indicate the topic is in progress or closed.

 **Note**

When you add a topic workflow state, the **Init** topic workflow state is supplied with the value set to **Yes**. You cannot add or change this setting for any other topic workflow state.

Field	Description
Final State	Select Yes for a workflow state to indicate no further information is expected to be gathered for a topic. Select No for a state to indicate the topic is new (initial state) or in progress. Topics in a final state can be reopened if the next defined possible state is not in the Final State, and if the topic is visible to work teams and the user has the Reopen Topics/Actions work team permission.
ⓘ Note You can set a topic workflow configuration option to require that all actions be in a final state before the topic itself can be moved to a final state. See Edit Workflow Configuration Options.	
Next Possible States	States a user can assign to a topic that is in this state. Determines the transitions that are possible from one state to another. If the transition requires approval, the Requires Approval icon () appears next to the state.

View a topic state

- You can view each topic state to process topics through the workflow. Each topic state may define subsequent states that can be assigned to the topic.
1. In the left navigation pane, click the **Settings** icon ().
 2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
 3. Click the configuration's **Row Action menu** (), and then click **Edit**.
 4. On the Edit Topic Workflow Configuration page, click the **Topic States** card.

On the Manage Topic States page, the defined topic states appear in a table and include the name, description, whether the state is initial or final, and possible next states that you can assign.
 5. To return to the Edit Topic Workflow Configuration page, click the **Back** link.

Add a topic state

When you add a topic state, you can define its workflow state transitions: the path used to move a topic from one state to another in the workflow.

You can select one or more states as the **Possible next states** and you can specify which transitions require approval.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Topic States** card.
5. Click the **Add State** link.
6. Enter the **Name** of the topic workflow state.
7. Enter the **Description** of the topic workflow state.
8. In the **Possible next states** field, specify the states that users are able to assign to a topic in this state.
 - a. To select a state, click **Select States**, then select one or more available values and move them to the **Selected Values** list.
 - b. (Optional) Add a filter by clicking the **Show Filter Options** link and [choosing filter options](#).
 - c. Click **OK**.
9. If the user must have Approval permission to transition the topic to this state, select the **Requires Approval** check box. The user must have [Approve Topic State Changes permission](#).
10. To indicate that a state closes a topic when it is assigned, select **This is a final state**.
 To work with a topic that is in a final state and visible to any work team, you must have the Reopen Topic [work team permission](#), and a non-final state, such as Reopened, must be defined as a possible next state. You can then reopen the topic and change its current state to a non-final state before editing it further.

Note

The topic workflow configuration may also require that all of a topic's actions be in a final state before the topic itself can be assigned a final state. See [Edit Workflow Configuration Options](#).

11. Click **OK**.

After you define the workflow states for topics and define the fields that store topic information, you should review the [level of access](#) assigned to each field and state. When you add a new state, by default every topic field is editable when the topic is in that state. You can modify the level of access for each field to hidden, visible, editable, or required for the new state.

Edit a topic state

You can edit the name, description, and possible next states for a topic state, as well as specify possible next states that require approval.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () for a configuration, and then click **Edit**.

4. On the Edit Topic Workflow Configuration page, click the **Topic States** card.
5. Click the topic state's **Row Action menu** (⋮), and then click **Edit**.
6. Modify the **Name** of the topic workflow state.

If you modify a state name, any topics currently in that state are updated automatically.

① Note

You can rename the state named Init. However, it is always considered to be the initial state for a topic and is assigned automatically to every new topic created.

7. Modify the **Description** of the topic workflow state.
8. In the **Possible next states** field, specify the states that users can assign to a topic in this state.

① Note

If state transitions are changed and these transitions are referenced in Topic State Changed email notification rules, you need to first [edit the notification rule](#). A list of the affected email notification rules is displayed.

- a. To select a state, click **Select States**.
- b. To require that the transition to a new state must be approved by the work team member who has been assigned, select the **Requires Approval** check box.
9. To indicate that a state closes a topic when it is assigned, select **This is a final state**. To work with a topic that is in a final state and visible to all work teams, a user must have the Reopen Topic [work team permission](#), and a state other than Final must be defined as a possible next state. This allows the user to reopen the topic and change its current state to that non-final state before editing it further.
10. Click **OK**.

Delete a topic state

You can delete topic states; however, you cannot delete the Init state and topic states in use.

Before you delete a topic state, determine how it is used.

- You cannot delete the Init (Initial) state.
- You cannot delete a topic state that is being used by:
 - A topic.
 - An action type (active or deactivated).
 - A topic template action.
 - A planned action.

To determine which topics are in a given state, in the left navigation pane, click the **Topic Management** icon (📁), and then sort the table using the Current state column.

To delete the state:

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (⋮), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Topic States** card.
5. On the Manage Topic States page, click the topic state's **Row Action menu** (⋮), and then click **Delete**.
Oracle Empirica Signal asks you to confirm the deletion.
6. To delete the topic state, click **OK**. Otherwise, click **Cancel**.

❗ Note

When you delete a topic state, it is removed automatically as one of the next possible states for any other state. You may need to [adjust the email notification rules](#) and the assignment of next possible states for the remaining states.

Manage action states

Each topic workflow configuration defines the workflow states that can be assigned to an action.

- [About action states](#)
To create a structured workflow for completing actions, each topic workflow configuration defines the workflow states that can be assigned to an action.
- [Manage Action States page](#)
On the Manage Action State page, you can add, modify, and delete the action states.
- [View an action state](#)
You can view action states in the topic workflow configurations.
- [Add an action state](#)
You can add an action state to a topic workflow configuration.
- [Edit an action state](#)
You can edit the name, description, and possible next states for an action state.
- [Delete an action state](#)
You can delete action states; however, you cannot delete the Planned and Init states and action states in use.

About action states

To create a structured workflow for completing actions, each topic workflow configuration defines the workflow states that can be assigned to an action.

Each [topic workflow configuration](#) defines the workflow states that can trigger a planned action to move to the initial state. When you add a topic workflow configuration, Oracle Empirica Topics automatically creates a limited set of action states: Planned, Init, and Closed.

- Actions in the Planned state are dormant. These *planned* actions remain dormant until they are transitioned from the Planned state into the Init state.

- Open actions include actions designated as the Initial state and actions in any other state that is not the Planned state or designated as a *final* state. These *open* actions are the actions actively being worked on.
 - Closed actions include actions in any state designated as a *final* state. Closed actions are actions whose work has been completed.
- A topic workflow configuration will always have one planned state and one initial state.

You can add states and customize the transitions permitted between states. For each workflow state, you can define the next possible state or states that can be assigned. For example, you can set up a [topic workflow configuration](#) so that an action passes through the workflow states: Planned, Initial, Assigned, and Closed.

Once you have defined action states and the fields that store action information, you define the [level of access](#) that users have to each field when an action is in each of the states. You specify whether each field is visible, editable, or required when the action is in each state.

Note

Each topic workflow configuration also defines a separate set of workflow states that can be assigned to a topic as a whole. See [About topic states](#) for more information.

Manage Action States page

On the Manage Action State page, you can add, modify, and delete the action states.

General activities

The following links appear at the top of the page and affect the entire page:

- [Add Action State](#) adds another action state to the topic workflow configuration.
- [Back](#) returns you to the Edit Topic Workflow Configuration page.
- [Columns](#) allows you to select the columns and sort order for the Manage Action States page.
- [Print](#) sends a PDF version of the Manage Action States table to your printer.
- [Download](#) sends the Manage Action States table to your PC in the format you specify.

Row-specific activities

The following options are available from the Row Action menu (), and affect an individual row in the table:

- [Edit](#) action state information, possible next states, and whether this is a final state. No action state can specify Planned as the next action state.
- [Delete](#) an action state that isn't used by any topics or work teams. You cannot delete the Planned or Init action state.

Field descriptions—Manage Action States page

In this section, you can view the information for each action state.

Field	Description
Name	Name of the action state.

Field	Description
Description	Description of the action state.
Planned State	Make the Planned and Initial State field accessibility settings the same. Yes indicates that the action is planned, but not initialized. No indicates the action is in progress or closed.
Initial State	Yes for the workflow state to be assigned automatically to a new action when it is added. No for a state to indicate the action is in progress or closed.
Final State	Yes for a workflow state to indicate no further information is expected to be gathered for an action. No for a state to indicate an action is new (initial state) or in progress.

Note

You can set a topic workflow configuration option to require an action to have an associated comment or attachment before a final state can be assigned to it. See [Edit Workflow Configuration Options](#) for more information.

Next Possible Action States	States that a user can assign to an action that is in this state. Determines the transitions that are possible from one state to another.

View an action state

You can view action states in the topic workflow configurations.

Each action state can include the initial, final, and next possible action states. You can also specify a Planned action state, whose next action state is initial.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action States** card.

On the Manage Action States page, the defined action states appear in a table and include the name, description, planned, initial, and final states as well as possible next states that you can assign.

- To return to the Edit Topic Workflow Configuration page, click the **Back** link.

Add an action state

You can add an action state to a topic workflow configuration.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action States** card.
5. Click the **Add State** link.
6. Enter the **Name** of the action state.
7. Enter the **Description** of the action state.
8. In the **Possible next states field**, specify the states that users are able to assign to an action in this state.

Note

No action state can specify Planned as the next action state.

- a. To select a state, click **Select Action States**, then select one or more available values and move them to the **Selected Values** list.
 - b. (Optional) Add a filter by clicking the **Show Filter Options** link and [choosing filter options](#).
 - c. Click **OK**.
9. To indicate this state closes an action when assigned, select the **This is a final State** check box.

Note

The topic workflow configuration may also require all of a topic's actions be in a final state before the topic itself can be assigned a final state. See [Edit Workflow Configuration Options](#).

10. Click **OK**.

When a new action state is added, the **Action type** field's accessibility is set to **Required** by default.

Edit an action state

You can edit the name, description, and possible next states for an action state.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action States** card.

5. Click the **Row Action menu** () for an action state, and then click **Edit**.
6. Modify the **Name** of the action state.

If you modify a state name, any actions currently in that state are updated automatically.

 Note

You can rename the state named Init. However, it is always considered to be the initial state for an action and is automatically assigned to every new open action created.

7. Modify the **Description** of the action state.
8. In the **Possible next action states** field, specify the states that users can assign to an action that is in this state. No action state can specify Planned as the next action state.

 Note

If state transitions are changed and these transitions are referenced in Action State Changed email notification rules, you need to first edit the notification rule. A list of the affected email notification rules is displayed.

- a. To select a state, click **Select Action States**, then select one or more available values and move them to the **Selected Values** list.
 - b. (Optional) Add a filter by clicking the **Show Filter Options** link and [choosing filter options](#).
 - c. Click **OK**.
9. To indicate that this state will close an action when it is assigned, select **This is a final state**.
10. Click **OK**.

 Note

The topic workflow configuration may also require all of a topic's actions be in a final state before the topic itself can be assigned a final state. See [Edit Workflow Configuration Options](#).

Delete an action state

You can delete action states; however, you cannot delete the Planned and Init states and action states in use.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action States** card.

5. Click the action state's **Row Action menu** (), and then click **Delete**.
6. To delete the topic state, click **OK**. Otherwise, click **Cancel**

You cannot delete the **Planned** or **Init** (Initial) states, and you cannot delete a state that is currently assigned to any action.

Note

When you delete a state, it is removed automatically as one of the possible next states for any other action states. You may need to adjust the email notification rules and the assignment of next possible states for the remaining action states.

Manage field access

Once you have defined topic states and fields, you define the level of access that users have to each field

- [Manage topic field accessibility by state](#)
Once you have defined topic states and fields, define the level of access that users have to each field when a topic is in each of the workflow states.
- [Manage action field accessibility by state](#)
Once you have defined action states and fields, you define the level of access that users have to each field when an action is in each of those states.
- [Manage attachment field accessibility by type](#)
Once you have edited a topic workflow configuration's options to select the types of attachments that can be added to a topic (or action), and defined fields for attachments, you specify the level of access that users have to each field based on the type of attachment.

Manage topic field accessibility by state

Once you have defined topic states and fields, define the level of access that users have to each field when a topic is in each of the workflow states.

Specify whether each field is required, editable (but not required), visible (but not editable), or hidden in each state. If you make a field required for a state, a topic cannot be saved in that state until the user provides a value for the field.

The access levels that you define are enforced when:

- A user edits a topic that is currently in that state.
- A user assigns that state to the topic. For example, suppose that the RESOLUTION field is editable in the Reviewed state and required in the Closed state. While the topic state is Reviewed, users can leave the RESOLUTION field empty. However, the user who changes the topic's state to Closed is required to provide a resolution.
- In addition, when a topic is created during the process of [saving an attachment to a topic](#) from another page in the application (if enabled as an attachment type for the topic workflow configuration), the TOPIC_NAME is required but no other requirements for the Initial state are enforced until the first time that topic is edited.

Note

Do not assign a non-editable access level (visible or hidden) to fields that store process-related data for the topic. For example, the `CURRENT_STATE_ID` field should always be editable in any state. For more information about the `CURRENT_STATE_ID` see Topic workflow configuration design.

Access levels apply only when a topic is edited. When a topic is viewed, all non-hidden fields are display-only.

1. In the left navigation pane, click the **Settings** icon (.
2. Click **Manage Topic Workflow Configurations** at the base of the Configure System section.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Configuration page, click the **Fields** card.
5. On the Manage Fields page, click the **Manage Accessibility** link.
6. From the menu, select **Topic Fields by State**.

The Manage Topic Field Accessibility by State page presents a table with a **Field Name**, a **Display Name** column, a column for each topic state and a row for each topic field. The column heading and columns **Field Name** and **Display Name** are always visible when you scroll through the table.

For reference, you can review the field access levels for topic workflow states [defined in the Sample Topic Workflow Configuration](#).

7. From the drop-down lists in the access level cells, select an access level for each field when a topic is in that state. The access levels are:

Access Level	Description
--	Hidden. Does not appear on the Topic page. For example, you assign this access level to the <code>RESOLUTION</code> and <code>RESOLUTION_DATE</code> fields for topics that are in any state other than Closed. Note: This access level should only be assigned to fields that store informational, rather than process-related, data for the topic. For example, this access level is not recommended for the <code>CURRENT_STATE_ID</code> field in any state, since a topic's current state should always be editable (or required).
Visible	Appears on the Topic page as informational text. Values cannot be entered or modified. Note: This access level should only be assigned to fields that store informational, rather than process-related, data for the topic. For example, this access level is not recommended for the <code>CURRENT_STATE_ID</code> field in any state, since a topic's current state should always be editable (or required).

Access Level	Description
Editable	Appears on the Topic page and entries are allowed. For example, you assign this access level to the TOPIC_DESCRIPTION field for topics that are in any state.
Required	Appears on the Topic page and an entry must be made. If you leave this field blank, topic information cannot be saved. For example, you assign this access level to the STATE_CHANGE_REASON field when topics are in any state other than Initial to assure that a meaningful log of the changes made to a topic kept.

8. Select a link at the top of the page to perform additional actions:
 - Click the [Print](#) link to print the table or only the currently displayed page of a table.
 - Click the [Download](#) link to download the table.
 - Click [Columns](#) to arrange the table columns and rows.
 - Click Back to return to the Manage Fields page.

Manage action field accessibility by state

Once you have defined action states and fields, you define the level of access that users have to each field when an action is in each of those states.

You specify whether each field is required, editable (but not required), visible (but not editable), or hidden in each state. If you make a field required for a state, an action cannot be saved in that state until the user provides a value for the field.

The access levels that you define are enforced when:

- A user edits an action that is in that state.
- A user assigns that state to the action.

Access levels apply only when an action is edited. When an action is viewed, all non-hidden fields are display-only.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Configuration page, click the **Fields** card.
5. On the Manage Fields page, click the **Manage Accessibility** link.
6. From the menu, select **Action Fields by State**.

The Manage Topic Field Accessibility by State page presents a table with a Field Name, a Display Name column, a column for each topic state and a row for each topic field. The column heading and columns Field Name and Display Name are always visible when you scroll through the table.

For reference, you can review the field access levels for action workflow states [defined in the Sample Topic Workflow Configuration](#).

7. From the drop-down lists in the action state cells, select an access level for each field when an action is in that state. The access levels are:

Access Level	Description
--	Hidden. Does not appear on the Topic Action page. For example, you assign this access level to the ACTUAL_COMPL_DATE field for actions that are in the Initial state.
Visible	Appears on the Topic Action page as informational text. Values cannot be entered or modified.
Note This access level should only be assigned to fields that store informational, rather than process-related, data for the action. For example, this access level is not recommended for the ACTION_STATE_ID field in any state, since an action's current state should always be editable (or required).	
Editable	Appears on the Topic Action page and entries are allowed. Typically, this access level is used for most action fields in most states.
Required	Appears on the Topic Action page and an entry must be made. If you leave the field blank, the action cannot be saved. For example, you assign this access level to the ACTUAL_COMPL_DATE field when actions are in the Closed state.

8. Select a link at the top of the page to perform additional actions:
- Click the [Print](#) link to print the table or only the currently displayed page of a table.
 - Click the [Download](#) link to download the table.
 - Click [Columns](#) to arrange the table columns and rows.
 - Click **Back** to return to the Manage Fields page.

Manage attachment field accessibility by type

Once you have edited a topic workflow configuration's options to select the types of attachments that can be added to a topic (or action), and defined fields for attachments, you specify the level of access that users have to each field based on the type of attachment.

You specify whether each field is hidden, visible, editable, or required for an external document such as a URL, file, or note, or for an Oracle Empirica Signal object. If you make a field required for an attachment type, an attachment of that type cannot be added or edited until the user provides a value for the field.

Note

Specifications made for Oracle Empirica Signal objects apply only when the attachment is edited. When an Oracle Empirica Signal object is [saved as an attachment to a topic](#), the Name field is required, the Description field is optional, and all other fields are hidden.

1. In the left navigation pane, click the **Settings** icon (.
2. In the configuration's **Configure System** section, click **Manage Topic Workflow Configurations**.
3. On the Edit Topic Workflow Configuration page, click the **Fields** card.
4. On the Manage Fields page, click the **Manage Accessibility** link.
5. From the menu, select **Attachment Fields by Type**.

The Manage Attachment Field Accessibility by Type page presents a table with a column for attachment type and a row for each attachment field.

For reference, you can review the field access levels for attachment fields [defined in the Sample Topic Workflow Configuration](#).

6. From the drop-down lists in the attachment type cells, select an access level for each field when an attachment is of that type. The access levels are:

Access Level	Description
--	Hidden. Does not appear when users add or edit an attachment. For example, you assign this access level to the URL_ADDRESS field for every type of attachment, except for URL, and to the FILE_NAME field for every type of attachment, except for external documents.
Visible	Appears when users add or edit an attachment as informational text. Values cannot be entered or modified.
Editable	Appears when users add or edit an attachment and entries are allowed. For example, you assign this access level to the DESCRIPTION field for all attachment types.
Required	Appears when users add or edit an attachment and an entry must be made. If the field is left blank, the attachment cannot be saved. For example, you might assign this access level to the URL_ADDRESS field for the URL attachment type, and to the FILE_NAME field for the external document attachment type.

Note

Required is the only value you can assign to the Init and Planned action states. For all other action states, you must assign Hidden, Visible, or Required.

7. Click **Save**.

Manage topic templates

You can create, edit, and delete topic templates that pre-populate fields and actions in a standardized way.

- [Manage Topic Templates page](#)
Topic templates can serve as the starting point for creating new topics. You can create, edit, and delete topic templates that can be used by designated work team members to pre-populate fields and actions in a standardized way.
- [View existing topic templates](#)
You can view the topic templates defined for the topic workflow configuration.
- [View a specific topic template](#)
You can view the details of a specific topic template.
- [Topic Template page](#)
On the Topic Template page, you can view and edit topic template information, including their actions and history.
- [Add a topic template](#)
Topic templates standardize and simplify the creation of topics and their associated actions. When creating a new topic, users in those work teams to which the template is visible can select the template to populate the initial topic and action field values.
- [Make a topic template visible to a work team](#)
To allow users to use the topic template when creating a new topic, the template must be made visible to a work team in which the users belong.
- [Edit a topic template](#)
When you edit a topic template, you can perform all the actions of managing a topic template.
- [Copy a topic template](#)
On the Manage Topic Templates page, you can copy an existing topic template using the **Copy** option in the Row Action menu.
- [Delete a topic template](#)
On the Manage Topic Template page, you can delete a topic template using **Delete** in the Row Action menu.
- [Topic template actions](#)
Topic templates contain topic template actions that define actions that are created when you add a topic using that topic template. The topic template actions define the topic state when these actions become active in the topic.

Manage Topic Templates page

Topic templates can serve as the starting point for creating new topics. You can create, edit, and delete topic templates that can be used by designated work team members to pre-populate fields and actions in a standardized way.

If you have the Manage Topic Workflow Configurations permission, you can add and manage topic templates for a particular topic workflow configuration that is published to your login group.

General activities

The following links and filters appear at the top of the page and affect the entire page.

- [Add Topic Template](#) adds another topic template to the topic workflow configuration.
- Back returns you to the Edit Topic Workflow Configuration page.
- [Columns](#) allows you to select the columns and sort order for the Manage Topic Templates page.
- [Print](#) prints the Manage Topic Templates table or saves the table as a PDF version.
- [Download](#) sends the Manage Topic Templates table to your PC in the format you specify.

Row-specific activities

The following menu options are available from the Row Action menu (), and affect an individual row in the table:

- [View](#) to display the Topic Template General Information, Template Actions, and History of Topic Template General Information section of the selected topic template.
- [Edit](#) to change the topic template's Topic Template General Information, Template Actions, and format of the History of Topic Template General Information section.
- [Copy](#) an existing topic template using the **Copy** link in the Row Action menu. Template topic actions are included in the copy.
- [Delete](#) a topic template without affecting topics created previously with that template.

Field descriptions—Manage Topic Templates page

This table describes the default fields displayed on the Manage Topic Templates page. To add columns, click the **Columns** link.

Field	Description
ID	Identifier that was assigned automatically when the topic template was created. Each topic template ID is unique and is not re-used if the template is deleted.
Name	Name of the topic template.
Description	Description of the topic template.
Work Teams	Work teams whose members can use the topic template. If your topic workflow configuration is in zero, one, or more mode, the selected work teams value will be used as the default value when the topic is created.
Created By	Name of the user who created the topic template.
Assigned to	User or work team to whom the action is assigned, by default. By default, this field is set to (No Value). Available users and work teams are determined by the Visible to work team selection. • Users: Members of the Visible to work team selection with Edit Topic/Action work team permission. • Work teams: All work teams with the Assign to work team property enabled and at least one active member in the Users list.
Created	Date and time when the topic template was created.

Field	Description
Modified By	Name of the user who last modified the topic template.
Modified	Date and time when the topic template was last modified.

View existing topic templates

You can view the topic templates defined for the topic workflow configuration.

1. In the left navigation pane, click the **Settings** icon ()
 2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
 3. Click the configuration's **Row Action menu** () , and then click **Edit**.
 4. On the Edit Topic Workflow Configuration page, click the **Topic Templates** card.
- Oracle Empirica Signal displays the [Manage Topic Templates page](#) listing the existing topic templates.

View a specific topic template

You can view the details of a specific topic template.

1. In the left navigation pane, click the **Settings** icon ()
 2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
 3. Click the configuration's **Row Action menu** () , and then click **Edit**.
 4. On the Edit Topic Workflow Configuration page, click the **Topic Templates** card.
- Oracle Empirica Signal displays the [Manage Topic Templates page](#) listing the existing topic templates.
5. From the topic template's **Row Action menu** () , select **View**.

Topic Template page

On the Topic Template page, you can view and edit topic template information, including their actions and history.

The Topic Template page includes several links and filters that apply to the page as a whole as well as three information sections:

- **Topic Template General Information:** You can edit the values in this section.
- **Template Actions:** You can add template actions as well as view, edit, and delete template actions.
- **History of Topic Template General Information:** You can view the history of changes to the topic template general information.

General activities

The following links and filters appear at the top of the page or section and affect the entire page or section.

- [Print](#) sends the page or section you select to your printer.
- **Show All** and **Hide All** expands and collapses the sections on the page.
- To expand or collapse section details, click  for a single section. To hide section details, click  for the section.
- Back returns you to the Manage Topic Templates page.
- [Add Template Action](#) adds an action of the selected **Action type** to the topic template.
- [Columns](#) allows you to select the columns and sort order for the Template Actions and History of Topic Template General Information sections.
- [Download](#) sends the content of the Topic Template table to your PC in the format you specify.

Section details

Section	Description	Available actions
Topic Template General Information	Displays the current field values that describe a topic template: • Includes all standard and custom fields accessible in the initial state, except the following: – Topic State – Project – Keywords • A date field appears as offsets expressed in days. When the template is used, the date field in the topic is computed based on topic creation date plus topic template offset. • Arrow icons may appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for Country () and State () appear, the arrows indicate that you must select a value for the Country field first and then select a value for the State field. You cannot select a State value first: the values available for State depend on the Country you select. • The Visible to work team field displays a comma separated list of work teams whose members will be able to use the topic template. When the page is in edit mode, it appears as a list.	In Edit mode: • Each field accepts text, numeric, or pre-defined values that you can select. A field that accepts text may also offer a Select Available Values link so you can select one or more values from a list. • To save changes to the Topic Template General Information section, click Save. Saved changes are shown as entries in the History of Topic Template General Information section. Note: The Save button affects only the Topic Template General Information section of the topic template. You do not need to click Save after you work with template actions.

Section	Description	Available actions
Template Actions	Displays a list of each specific activity identified for the topic template. Actions may reflect research activities, such as literature searches, scheduled meetings, or any other activity you wish to track for the topic template. For field descriptions, see Topic Template Action page.	When in Edit mode, you can click Add Topic Template Action to add an action, or click an action's Row Action menu to view, edit, or delete an action.
History of Topic Template General Information	Displays information on changes that have taken place for the topic template.	A new row is added to the table each time you click Save in the Topic Template General Information section.

Field descriptions—Topic Template General Information

Depending on your organization's workflow configuration, the following fields appear in this section. You may see additional fields.

Field	Description
Visible to work team	The work team or teams whose members can view or act on the topic template. You can click Browse to view a descriptive list of work teams. If your topic workflow is in zero, one, or more mode, the Visible to work team setting in the topic template is used as the default when the topic is created using the template.
Name	Name of the topic template.
Description	Description of the topic template.
Assigned to	Allows you to preset this field with users, work teams, or no value. When you save the page, the Assigned to value is verified. Users must be enabled users from the selected Visible to work teams entry that have edit permission. Work teams are those with Allow assignment of topics and actions enabled and at least one user in the Assigned to list.

Add a topic template

Topic templates standardize and simplify the creation of topics and their associated actions. When creating a new topic, users in those work teams to which the template is visible can select the template to populate the initial topic and action field values.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Topic Templates** card.
5. On the Manage Topic Templates page, click the **Add Topic Template** link.

The Add Topic Template page displays the fields in the Topic Template General Information section that are available in the Initial state, determined by the selected topic workflow configuration. It does not include the Topic state, Keywords, Reason for change, or Project fields.

6. From the **Visible to work team** list, select which users and work teams can use the template.

Note

To select multiple work teams, hold down the **Ctrl** key and click each work team. Deselect a work team by holding down the **Ctrl** key and clicking the work team. You can click **Browse** to view a descriptive list of work teams.

7. In the **Name** and **Description** fields, type a template name and a description for the topic template.
8. From the **Assigned to** list, select a work team or user from the **Visible to work team** list to preassign to the topic created from this template. You can also select **(No Value)**.
9. For the other fields on the page, specify values for any other Topic fields to include in the template.

Date fields are specified as offsets. Date offsets specified in the topic template are inherited by topics as actual dates, offset from the time of topic creation.

10. Click **Save** or, if you want to add template actions to the newly created topic template from the Add Topic Template page, click **Save & Edit**.

You can then perform further editing and [add actions to the template](#).

Make a topic template visible to a work team

To allow users to use the topic template when creating a new topic, the template must be made visible to a work team in which the users belong.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Manage Topic Templates**.
4. On the Edit Topic Workflow Configuration page, click the **Topic Templates** card.
5. On the Manage Topic Templates page, click the topic template's **Row Action menu** () , and then click **Edit**.

The specific fields that appear on the Edit Topic Template page depend on your topic workflow configuration.

6. Use the **Visible to work team** field to control who will have access to the template. Your selection also acts as the default setting for the topic's **Visible to work team** field when the topic workflow configuration is configured to be visible to zero, one, or more work teams. You can select multiple work teams even if the topic workflow configuration is configured for only one work team. Only work teams for your login group are available for selection.

Note

To select multiple work teams, hold down the **Ctrl** key and click each work team. Deselect a work team by holding down the **Ctrl** key and clicking the work team.

You can click **Browse** to the right of the **Visible to work team** field to view a descriptive list of work teams.

Column	Description
ID	Unique identifier of the work team.
Name	Name of the work team.
Description	Description text about the work team.
Login Group	Name of the login group. Each work team is a subset of a login group.
All Users	Yes, if all users in the login group are members of the work team. No, if users have been individually added to the work team.
Users	The full name and Oracle Empirica Signal username of each member of the work team. Blank, if all users in the login group are members of the work team.
Topic Visibility	Work team property that determines whether or not the work team is available for visibility.
Topic/Action Assignment	Work team property that determines whether or not the work team is available for topic/action assignment.
Created By	Name of the user who created the work team.
Created	Date and time when the work team was created.
Modified By	Name of the user who last modified the work team.
Modified	Date and time when the work team was last modified.

For information about viewing, printing, or downloading tables or changing the way data displays in the table, see [About tables](#).

Edit a topic template

When you edit a topic template, you can perform all the actions of managing a topic template.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Topic Templates** card.
5. Click the topic template's **Row Action menu** () , and then click **Edit**.
6. In the Topic General Information section, specify values.

7. Click **Save**.
8. In the Template Actions section, do any of the following:
 - Click the **Add Template Action** link to add an action.
 - Click the template action's **Row Action menu** (), and then click **View**.
 - Click the template action's **Row Action menu** (), and then click **Edit**.
 - Click the template action's **Row Action menu** (), and then click **Delete**.

Copy a topic template

On the Manage Topic Templates page, you can copy an existing topic template using the **Copy** option in the Row Action menu.

Template topic actions are included in the copy.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (), and then click **Edit**.
4. On the Edit Topic workflow Configuration page, click the **Topic Templates** card.
5. Click the topic template's **Row Action menu** (), and then click **Copy**.
6. In the **Name** field, leave the default name or type a different template name.
7. In the **Description** field, type a description of the topic template.
8. Click **Save**.

Delete a topic template

On the Manage Topic Template page, you can delete a topic template using **Delete** in the Row Action menu.

When a topic template is deleted, any topics created previously with that template are not affected.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Topic Templates** card.
5. Click the topic template's **Row Action menu** (), and then click **Delete**.
6. Confirm the deletion by clicking **OK**.

Topic template actions

Topic templates contain topic template actions that define actions that are created when you add a topic using that topic template. The topic template actions define the topic state when these actions become active in the topic.

- [About topic template actions](#)
You can add actions to topic templates.
- [View a topic template action](#)
You can view the template actions that have been added to a topic template.
- [Add a topic template action](#)
When you create a topic template and save it, you can then edit it and add template actions.
- [Topic Template Action page](#)
You can view, edit, and see the history of the topic template action information.
- [Edit a topic template action](#)
When you edit a topic template action, you can perform all operations of managing a topic template action, including deletion.

About topic template actions

You can add actions to topic templates.

Every topic template action must have an action type. When you select the action type, the values for the **Action** fields are populated per the selected action type. You can modify the preassigned **Assigned To** value. You can also override the other predefined values by selecting the **Override defaults** check box. For more information, see [Add a topic template action](#).

View a topic template action

You can view the template actions that have been added to a topic template.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Topic Templates** card.
5. Click the topic template's **Row Action menu** (), and then click **View**.
6. The Template Actions section shows the template actions associated with the topic template and information about each action as specified when the action was added.
7. To view the general information and history of the template action general information, in the **Template Actions** section, click the action's **Row Action menu** () , and then click **View**.

The [Topic Template Action page](#) appears and shows general information and the history of the selected topic template action.

Add a topic template action

When you create a topic template and save it, you can then edit it and add template actions.

To add an action to the topic template as you create it: After you have entered the general information for the topic template, click **Save & Edit** to open the Topic Template Action page.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**. Start with Step 6, below.
3. Click the configuration's **Row Action menu** (⋮), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Topic Templates** card.
5. Click the topic template's **Row Action menu** (⋮), and then click **Edit**.
6. On the Topic Template page in the **Template Actions** section, click the **Add Template Action** link.
7. On the Add Topic Template Action page, from the **Action type** drop-down list, choose an action type. This is a required field. When you select an action type, the action type's predefined values are displayed for the template action.
 - If you select the Generic action type, the **Override defaults** check box is selected and disabled.
 - If you select an action type other than Generic, then the **Override defaults** check box is deselected. All fields other than **Action type** and **Assigned to** are disabled. This means values for the field are always displayed from the action type. If the action type changes, the template action automatically updates. When you select **Override defaults**, the template action fields display in their configured state of *visible* or *editable*.
 - You can change the value in the **Assigned to** field without overriding the defaults.
8. Enter values for the action **Name** and **Description**.
9. Use the **Activate on topic states** field to schedule when an action will be activated (move from the *Planned* to the *Initial* state). In the **Activate on topic states** field, select:
 - **All** to create actions in the initial state by default.
 - **Select states** to specify the topic state or states that will activate the action; for example, move the action from the *Planned* to the *Initial* state. To create the action in the *Planned* state, do not choose the *Initial* topic state.
10. Enter values for any other [fields to be included in the template action](#).
11. Click **Save**.

Topic Template Action page

You can view, edit, and see the history of the topic template action information.

In edit mode, you can also perform activities based on your permissions and topic workflow configuration.

To expand the sections on this page, click **Show All**, or click  for a single section. To hide section details, click  for the section or click **Hide All**.

Sections of the Topic Template Action page

Section	Description	Available actions
Template Action General Information	Displays the current values in the standard or custom fields that describe the template action: - The fields can be display-only, editable, or required. If a field is required, an asterisk (*) appears next to it and the action cannot be saved until you provide a value for the field. - Date fields appear as offsets expressed in days. When the template is used, the date the action becomes activated is computed based on the topic creation date plus the template offset. - Arrow icons may appear after the names of a pair of fields to show that they are a linked pair. For example, if fields for Country (📍) and State (📍) appear, the arrows indicate that you must select a value for the Country field first and then select a value for the State field. You cannot select a State value first: the values available for State depend on the Country you select.	In Edit mode, each field accepts text, numeric, and date values, or provides a list of predefined values that you can select. If a value is not required in the field, you can select (a blank value) to indicate no value for the field. A field that accepts text may also offer a Select Available Values link so you can select one or more values from a list. To save changes in the Template Action General Information section, click Save. Note: The Save button affects only the Template Action General Information section of the topic template. You do not need to click Save after you work with other sections of this page.
History of Template Action General Information	Displays information on changes made to the template action.	A new row is added to the table each time you click Save in the Template Action General Information section.

Field descriptions—Template Action General Information

Depending on your organization's workflow configuration, the following fields appear in this section.

Field	Description
Action type	Required. Every topic template action must have an Action type. Available values include all activated action types for the login group, but defaults to Generic or first type in the list. The selected action type populates the values in the other General Information fields.

Field	Description
Override defaults	If not selected, all fields, except Assigned to, are disabled. When selected, you can override the selected action type's predefined values. For the Generic action type, the Override defaults feature is disabled.
Action name	Required. Name for the action.
Action description	Description of the action.
Activate on topic states	All means that the action will, by default, be created in the initial state. Use Select states when moving the topic to the Assigned state. At least one topic state should be selected. If the initial topic state is not selected, the action is created in the Planned state.
Assigned to	Specify users or work teams. Oracle Empirica Topics verifies the Assigned to value. Users include enabled users from the saved topic template's Visible to work teams field that have edit permission. Work teams include all work teams with the Allow assignment of topics and actions work team property enabled and at least one user in the Assigned to list.
Start date	Anticipated start date for the action.
Planned completion date	Planned date for the completion of the action.
Actual completion date	Date the action was completed.

If another user edits the same topic template action at the same time, the first one to save the action will have their changes saved. The second user gets an error message indicating the action has been changed since the edit session began. The General Information section of the page becomes visible, allowing the user to print or take a screen shot, so that the information can be reentered.

Edit a topic template action

When you edit a topic template action, you can perform all operations of managing a topic template action, including deletion.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Topic Templates** card.
5. Click the topic template's **Row Action menu** () , and then click **Edit**.
6. On the Topic Template page in the **Topic Template Action** section, click the action's **Row Action menu** () , and then click **Edit**

7. Edit the values in the [Template Action General Information section](#) as necessary.
8. Click **Save**.

The History of Template Action General Information section updates.

Manage action types

Action types standardize and simplify the creation of topic actions and a topic template actions and can be used to categorize the action's work.

- [About action types](#)
Action types serve as templates for actions and to categorize actions. Use them for repetitive actions that must be performed on all topics.
- [Manage Action Types page](#)
The Topic Workflow Configuration administrator creates action types and makes them visible to work teams. On the Manage Action Types page, you can add, modify, and delete the action types shown in the table.
- [View the action types](#)
You can view the defined action types on the Manage Action Types page.
- [Action Type page](#)
On the Action Type page, you can view and edit action types, including their general information and history.
- [View a specific action type](#)
You can view the general information for and history of a specific action type.
- [Add an action type](#)
You can add an action type to a topic workflow configuration.
- [Activate or deactivate an action type](#)
Action types are activated by default. To discontinue use of an action type, the action type can be deactivated.
- [Copy an action type](#)
You can copy action types.
- [Edit an action type](#)
You can edit the general information about an action type.
- [Delete an action type](#)
You can delete action types other than the Generic action type and those that have never been used by a topic action or topic template action.

About action types

Action types serve as templates for actions and to categorize actions. Use them for repetitive actions that must be performed on all topics.

Once the action is created, the action type serves as a way of categorizing the action's work. For example, you might create a literature search action type because you always check to see if the event has already been documented. Or, if you find a signal, you often have to put together all the information and prepare a presentation for another team.

To use action types, you:

- Create the action type. Define default values to be used every time the action type is used in a topic template action or in an action.

- Create a topic template action using the action type. You can define multiple action types and at what point they transition from a planned action to an active action. For example, you might only prepare a presentation when the topic itself activates the action. Move this action from a planned state into an initial state by transitioning the topic state to the Analysis and Prioritization state.
- Create a topic using the template. This can happen from Submit Review, Save to topic, or when adding a topic. All the actions will either be planned or they will be initialized, depending on how you configured the topic template actions.
- Add an action to an existing topic. The action type selected determines whether the action will be activated based on the current state of the topic.

When working with actions, use the action type filter to filter the action table or calendar to include actions of a certain type or graph actions by action type to see a distribution of actions by action type.

Manage Action Types page

The Topic Workflow Configuration administrator creates action types and makes them visible to work teams. On the Manage Action Types page, you can add, modify, and delete the action types shown in the table.

General activities

The following options are available from the Header Row Action menu (), and affect the table:

- [Columns](#) allows you to select the columns and sort order for the Manage Action Types page.
- [Download](#) sends the Manage Action Types table to your PC in the format you specify.
- [Add Action Type](#) adds another action type to the topic workflow configuration.
- Back returns you to the Edit Topic Workflow Configuration page.

Row-specific activities

The following options are available from the Row Action menus (), and affect an individual row in the table:

- [View](#) to display the Action Type General Information and History of Action Type General Information.
- [Edit](#) to change the action type's Action Type General Information and format of the History of Action Type General Information section.
- [Copy](#) to duplicate an action type, including the general information about the selected action type, thereby creating a new action type.
- [Delete](#) to delete action types other than the Generic action type and that have never been used by used by a topic action or topic template action.
- [Deactivate](#) or **Activate** any action type, including the Generic action type. You must activate action types to apply them to your topics or topic templates. If you deactivate an action type, it is no longer available for selection for new templates and actions.

Field descriptions—Manage Action Types page default fields

In this section, you can view the information for and status of each action type defined.

Field	Description
Action type	Name of the action type.
Action type description	Description of the action type.
Color	Optionally, assign a color to the action type to identify the action type associated with a topic or topic template at a glance.
Active	Status of the action type. Yes means it has been activated. No means the action type has not been activated or has been deactivated.
Activate on topic states	Use this field to identify topic states that will cause an action of this type to be activated; for example, move from the planned state to the initial state. Use the All states option to indicate that all topic states should activate actions with this action type or use the Selected states option to identify specific topic states.
Start date	Offset value. When the action moves to the initial state, the value is calculated from the current date plus the offset days.
Created By	User who created the action type.
Created	Date and time the action type was created.
Modified By	User who modified the action type.
Modified	Date and time the action type was modified.

Field descriptions—Manage Action Types page standard fields

In this section, you can view the information for and status of each action type defined.

Field	Description
ID	Identifier that was assigned automatically when the action type was created. Each action type ID is unique and is not re-used if the action type is deleted.
Work teams	Work teams whose members can use the action type.
Action description	Default value to be used for the action's description.
Action name	Default value to be used for the action's name.
Actual completion date	Offset value, when action move to initial state actual date will be calculated and used as the default value.
Assigned to	Default value to be used for the action's assigned to field.
Planned completion date	Offset value, when action move to initial state actual date will be calculated and used as the default value.

Additional columns may be available depending on you topic workflow configuration.

View the action types

You can view the defined action types on the Manage Action Types page.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.

3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action Types** card.

On the Manage Action Types page, the defined action types appear in a table. The Generic action type is a special action type. It cannot be deleted and it is always available to all work teams.

5. To return to the Edit Topic Workflow Configuration page, from the Header Row Action menu () , click **Back**.

Action Type page

On the Action Type page, you can view and edit action types, including their general information and history.

The Action Type page includes several links and filters that apply to the page as a whole as well as two information sections:

- **Action Type General Information:** You can edit the values in this section.
- **History of Action Type General Information:** Each row documents the changes made to the action type.

General activities

The following links and filters appear at the top of the page or section and affect the entire page or section.

- [Print](#) prints the Action Type page.
- **Show All** and **Hide All** expands and collapses the sections on the page. To expand or collapse section details, click  for a single section. To hide section details, click .
- **Back** returns you to the Manage Action Types page.
- [Columns](#) allows you to select the columns and sort order for the History of Action Type General Information section.
- [Download](#) sends the content of the History of Action Type General Information section of the Action Type page to your PC in the format you specify.

Section details

Section	Description	Available actions
Action Type General Information	Displays the current field values that define the properties of an action type and defines values that impact actions created with the action type. Action type properties: • Status. • Visible to work teams. • Action type. • Action type description (used as hover help). • Color. Fields that impact actions: • Action name. • Action description. • Activate on topic states. • Assigned to. • All standard and custom action fields accessible in the initial state. Date fields appear as offsets.	In Edit mode: • Each field accepts text, numeric, or pre-defined values that you can select. A field that accepts text may also offer a Select Available Values link so you can select one or more values from a list. • To save changes to the Action Type General Information section, click Save. Saved changes are shown as entries in the History of Action Type General Information section.
History of Action Type General Information	Displays information on changes that have taken place for the action type.	A new row is added to the table each time you click Save in the Action Type General Information section.

View a specific action type

You can view the general information for and history of a specific action type.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action Types** card.
5. From the Action Types page, click the action type's **Row Action menu** () , and then click **View**.

The Action Type page includes several links and filters that apply to the page as a whole as well as two information sections:

- **Action Type General Information:** Displays the current field values that define the properties of an action type:
 - Status.
 - Visible to work teams.
 - Action type name.
 - Action type description.

- Color associated with the action type.
 - Topic state that activates the action type.
 - Date fields as offsets expressed in days.
 - **History of Action Type General Information:** You can sort the information by the columns shown; for example, by status or assignment.
6. To return to the Manage Action Types page, click the **Back** link.

Add an action type

You can add an action type to a topic workflow configuration.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action Types** card.

By default, the built-in Generic action type appears at the top of the Manage Action Types table. It is both active and visible to all work teams. You can edit it and rename it, but you can't delete it.
5. From the Header Row Action menu, click **Add Action Type** or click the plus sign (+) on the far right side above the table.
6. On the Add Action Type page, from the **Visible to work teams** drop-down menu, choose one or more work teams or click **Browse** to view the information about the work teams. Users in the selected work teams can see the action type.
7. In the **Action type** field, enter a category that describes the action type; for example, create `slideshow`. The name must be unique; however, you can reuse the name of a deleted action type.
8. Enter the **Action type description**. This description is used in the application as hover text when the user is adding an action and inspecting the **Action type** drop-down list.
9. To assign a color to the action type, select the **Color** check box and click a color. Remove the assignment to a color by deselecting the **Color** check box.
10. In the **Action name** field, enter the default value to be used for the action's name; for example, `Slideapp`.
11. In the **Action description** field, enter the default value to be used for the action's description.
12. In the **Activate on topic states** field, choose which topic states will, by default, activate actions with this action type.
 - Click **All States**. By default, the action created with this action type will be created in the initial state.
 - Click **Select states**, then use the **Select states** link to choose topic states that, by default, will activate actions with this action type. When an action is created, if the topic is currently in one of the selected states, the action is created in the initial state. If the topic is not currently in one of the selected states, the action is created in the planned state and will move to the initial state when the topic transitions into one of the selected states.
You should select at least one topic state, or the action is created in the Planned state and requires manual activation.

13. From the **Assigned to** drop-down menu, select an individual or work team to be used as the default value for the actions **Assigned to** field. The users must be members of a **Visible to work team** selection.
14. In the **Start date** field, enter a default offset value. A date value will be computed based on the date the action is activated plus the offset.
15. In the **Planned completion date** field, enter a default offset value. A date value will be computed based on the date the action is activated plus the offset. If an action does not have a planned completion date, it will not be visible on the Calendar tab.

Note

When editing actions, the application maintains the delta between the Start date and Planned completion date.

16. Custom action fields available in the action's initial state will also be listed on the page. For each field, enter the default values.
17. Click **Save**.

The action type is added to the table on the Manage Action Types page.

Activate or deactivate an action type

Action types are activated by default. To discontinue use of an action type, the action type can be deactivated.

All action types can be activated or deactivated, including the Generic action type.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action Types** card.
5. Click the action type's **Row Action menu** () , and then click **Activate** or **Deactivate**.

The value in the Active column in the Action Types table changes to Yes or No.

Copy an action type

You can copy action types.

You can also [edit the copied action type](#) to customize it. This may be more efficient than creating an entirely new action type.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () for a configuration, and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action Types** card.
5. Click the action type's Row Action menu () , and then click **Copy**.

6. On the Copy Action Type page, in the **Name** field, enter a different action type name.
7. In the **Description** field, type a description of the action type.
8. Click **Save**.

Edit an action type

You can edit the general information about an action type.

1. In the left navigation pane, click the **Settings** icon () .
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action Types** card.

5. Click the action type's **Row Action menu** (), and then click **Edit**.
6. Modify the fields in the Action Type General Information section.

You cannot change the status of the action type. To do this, select Activate or Deactivate from the action type's **Row Action menu** ().

7. Click **Save**.

The changes you made in the Action Type General Information section appear as a new row in table in the History of Action Type General Information section.

Delete an action type

You can delete action types other than the Generic action type and those that have never been used by a topic action or topic template action.

1. In the left navigation pane, click the **Settings** icon () .
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Action Types** card.
5. Click the action type's **Row Action menu** (), and then click **Delete**.

Note

You cannot delete the Generic action type. You can rename it, edit it, or deactivate it.

6. Respond to the confirmation message by clicking **OK** or **Cancel** to stop the deletion. If the action type is in use by an action or topic template action, you will not be able to delete it.

The action type is removed from the table on the Manage Action Types page.

Manage email notification rules

You can set up rules to automatically send email notifications based on different changes to actions and topics or create a rule to remind users when an action's completion date is near, due, or overdue.

- [About email notification rules](#)
You can set up rules to automatically send email notifications based on different changes to actions and topics.
- [View existing email notification rules](#)
From the Manage Email Notification Rules page, you can view the rules in effect and then edit or delete them.
- [Manage Email Notification Rules page](#)
You can set up rules to automatically send email notifications based on different changes to actions and topics or create a rule to remind users when an action's completion date is near, due, or overdue.
- [Add or edit an email notification rule](#)
You can set up rules to automatically send email notifications based on different changes to actions and topics or create a rule to remind users when an action's completion date is near, due, or overdue.
- [Insert a field variable into email message text](#)
To provide contextual information in an email message, you can include topic and action field variables in the message subject and text. When the message is generated, field variables are replaced by the current values.
- [Delete an email notification rule](#)
You can delete an email notification rule.

About email notification rules

You can set up rules to automatically send email notifications based on different changes to actions and topics.

The fields you enter to define email notifications vary depending on the type of rule—Topic or Action—and the notification reason.

Topic-based rules

Topic-based email notification rules include these basic fields: Notification rule name, Notification reason, Send to, Message Subject, and Message text.

The topic-based notification reasons include:

- A topic has been added.
- A topic has been deleted.
- A topic has been modified.
- A particular topic field has been modified.
- A topic's state has changed.
- A topic assignment has changed.
- A topic assignment has changed to a user.
- A topic assignment has changed to a work team.

Action-based rules

Action-based email notification rules have the same basic fields plus an **Applicable states** field. The Applicable states field allows you to further refine the rule. When the Notification reason is **Action Added**, the only applicable states will be **Planned** and **Init**.

The action-based notification reasons include:

- A new action has been added.
- An action has been deleted.
- An action has been modified.
- A particular action field has been modified.
- The action's state has changed.
- An action assignment has changed.
- An action assignment has changed to a user.
- An action assignment has changed to a work team.
- An email reminder is needed.

View existing email notification rules

From the Manage Email Notification Rules page, you can view the rules in effect and then edit or delete them.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Email Notifications** card.

Oracle Empirica Signal displays the email notification rules that have been defined for the topic workflow configuration.

For each rule, You can see the unique system-assigned ID, Rule Name, Notification Reason, Message Subject, Message Text, and who the email will be sent to.

5. To only view rules pertaining to a specific notification reason, select it from the **Notification Reason** drop-down list at the top of the page.

Manage Email Notification Rules page

You can set up rules to automatically send email notifications based on different changes to actions and topics or create a rule to remind users when an action's completion date is near, due, or overdue.

General activities

The Manage Email Notification Rules page shows all the defined email notification rules and allows you to add, edit, and delete rules.

The following links appear at the top of the page and affect the entire page:

- [Add Email Notification Rule](#) to define a new rule.
- Back to return to the Edit Topic Workflow Configuration page.

- [Columns](#) to select the columns and sort order for the Manage Email Notification Rules page.
- [Print](#) to send a PDF version of the Manage Email Notification Rules table to your printer.
- [Download](#) to send the Manage Email Notification Rules table to your PC in the format you specify.

The **Notification Reason** filter appears at the top of the page and limits the email notification rules table to rules that have been added for the selected notification reason.

Row-specific activities

The following menu options are available from the Row Action menu (), and affect an individual row in the table:

- [Edit](#) to modify the email notification rule.
- [Delete](#) to delete the email notification rule.

Field descriptions—Manage Email Notification Rules page

Field	Description
ID	Email notification rule identifier.
Rule Name	Email notification rule name.
Notification Reason	The activity selected to initiate an automated email notification. You can define multiple rules for each email notification reason.
Message Subject	Email subject line.
Message Text	Email text.
Send To	Message recipients: Note: Users must have an email address associated with their username to receive emails.

Add or edit an email notification rule

You can set up rules to automatically send email notifications based on different changes to actions and topics or create a rule to remind users when an action's completion date is near, due, or overdue.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** (), and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Email Notifications** card.
5. Add or edit an email notification rule:
 - To add a rule, click the **Add Email Notification Rule** link.
 - To edit a rule, click the notification rule's **Row Action menu** (), and then click **Edit**.

 Note

You can edit any email notification rule, even one you didn't define.

- 6. See the table below for details on defining the email notification rule.
- 7. Click **OK**.

Table 10-4 Fields dependent on Notification Reason

Additional Field	Description
Notification rule name	Email notification rule name.
• Topic-based • Action-based	

Table 10-4 (Cont.) Fields dependent on Notification Reason

Additional Field	Description
Notification reason • Topic-based • Action-based	The activity selected to initiate an automated email notification. You can define multiple rules for each email notification reason. Note: In Edit mode, the Notification reason field is disabled and cannot be modified. Activities include: • Topic Added—A new topic is created. • Topic Deleted—A topic is deleted. • Topic Modified—A topic is modified. • Topic Field Modified—A topic field is modified. • Topic State Changed—The workflow state of a topic changes. • Topic Assignment Changed—A topic assignment changes. • Topic Assignment Changed (to User)—New rule, only triggered when the new assignee is a user. • Topic Assignment Changed (to Work Team)—New rule, only triggered when the new assignee is a work team. • Action Added—An action is added to a topic. By default, the Planned state check box is not selected. An initial state is selected. You must select at least one check box. • Action Deleted—An action is deleted. By default, the Planned state check box is not selected. All other states are checked with individual states disabled and checked. You must select at least one check box. • Action Modified—An action is modified. By default, the Planned state check box is not selected. All other states are checked with individual states disabled and checked. You must select at least one check box. • Action Field Modified—An action field is modified. By default, the Planned state check box is not selected. All other states are checked with individual states disabled and checked. You must select at least one check box. • Action State Changed—The workflow state of an action changes. • Action Assignment Changed—An action assignment changes. By default, the Planned state check box is not selected. All other states are checked with individual states disabled and checked. You must select at least one check box. • Action Assignment Changed (to User)—New rule, only triggered when the new assignee is a user. By default, the Planned state check box is not selected. All other states are checked with individual states disabled and

Table 10-4 (Cont.) Fields dependent on Notification Reason

Additional Field	Description
	checked. You must select at least one check box. • Action Assignment Changed (to Work Team)—New rule, only triggered when the new assignee is a work team. By default, the Planned state check box is not selected. All other states are checked with individual states disabled and checked. You must select at least one check box. • Email Reminder—Daily, at a time specified in Site Options. The Planned check box doesn't appear as an applicable state.
Send to • Topic-based • Action-based	Click Select Recipients to display the Select Recipients page and select recipients from the Available Values list, then click OK. Message recipients: • Visible to Work Team Members—All members of the work team, or teams that can view the topic. • New Assignee—User or work team currently assigned to the topic or action. If the New Assignee is a work team, notifications will be sent only to work team members who can view the topic. • Previous Assignee—User or work team previously assigned to the topic. If the Previous Assignee is a work team, notifications will be sent only to work team members who can currently view the topic. • Individual users—Enabled users in the login group, regardless of topic visibility. • Approvers—Enabled users with edit access to the topic and approval work team permission. Note: Users must have an email address associated with their username to receive emails. A single email will be sent to an individual only once, even if, for example, a particular user is in multiple work teams or both the Assigned To user AND in a work team to which the topic was visible. Disabled or deleted users will not receive email notifications.
Message subject • Topic-based • Action-based	Enter the Email subject you want to use for email messages generated for the selected reason. Click the Show Fields link to select items from a list of field variables. When the message is generated, the current values replace the field variables you selected. Note: You must provide a message subject to save the email notification rule. Before including fields in the subject, ensure that the resulting emails will not contain sensitive or confidential information.

Table 10-4 (Cont.) Fields dependent on Notification Reason

Additional Field	Description
Message text • Topic-based • Action-based	Enter the body of the message in the Message text field. Click the Show Fields link to select items from a list of field variables. When the message is generated, the current values replace the field variables you selected. Field variables appear as <<topic.FieldName>> or <<action.FieldName>>. Note: Before including fields in the message, ensure that the resulting emails will not contain sensitive or confidential information.
Applicable states • Action-based	Select action states to further refine the notification rule. The action states available for selection depend on the notification reason. • Action Added—Planned and Init. • Email Reminder—All active states and individual active (non-Planned) states. • All other action-based notification reasons—Planned, All active states, and individual active (non-Planned) states. Selecting the All active states check box selects and disables the individual active states. If All active states is selected and an active action state is added or removed from the configuration, the rule's Applicable states field is automatically updated. Deselecting the All active states check box enables individual active states, allowing you to select specific states.
Component modified • Topic-based • Action-based	For the Topic Modified notification reason, the Component modified field appears as a multiple selection list that includes: • Link Added • Link Removed • Topic Comments Added • Topic Attachment Added • Topic Attachment Deleted • Topic Attachment Modified • Topic Attachment Comments Added • Topic Field Values Changed For the Action Modified notification reason, the Component modified field appears as a multiple selection list that includes: • Action Comments Added • Action Attachment Added • Action Attachment Deleted • Action Attachment Modified • Action Attachment Comments Added • Action Field Values Changed

Table 10-4 (Cont.) Fields dependent on Notification Reason

Additional Field	Description
Modified field • Topic-based • Action-based	For the Topic Field Modified notification reason, the values include the display names of all fields where Context is Topic , or for Action Field Modified notification reason, the list includes all fields where Context is Action
Email Notification State changes • Topic-based • Action-based	For Topic State Changed and Action State Changed notification reasons, the Notification state changes field appears as a matrix of check boxes with Current State as the rows and Transitioned State as the columns. • Only valid transitions are enabled. • Select specific transitions, or use the top row of check boxes to select or clear all valid transitions to the respective transitioned state. • To require approval when the state changes, select the Requires Approval check box.
Send reminder • Action-based	For Email Reminder reasons, only, use the date to monitor Send reminder days and on , after , or before selection fields to control when an email reminder will be sent. Email reminders can be sent daily based on time specified in the Time to send topic email reminder notifications field on the Site Options page. • Date to monitor is set to the Planned Completion date field and cannot be changed. • In the Date to Monitor field, specify the number of days before, after, or on that the message is to be sent. Note: The days field is disabled when on is selected and enabled when before or after is selected.

Insert a field variable into email message text

To provide contextual information in an email message, you can include topic and action field variables in the message subject and text. When the message is generated, field variables are replaced by the current values.

For example, an email notification rule that includes field variables in the message text appears as follows:

```
The state for the <<topic.TOPIC_NAME>> topic has been changed to
<<topic.CURRENT_STATE_ID>>. The following reason for this change was provided:
<<topic.STATE_CHANGE_REASON>>.
```

When an email message is generated based on this rule, the body of the actual message might read:

The state for the Acetaminophen and Alcohol Use topic has been changed to Closed. The following reason for this change was provided: **This is a known, labeled risk.**

Note

Before including fields in the message subject or message text, ensure that the resulting emails will not contain sensitive or confidential information.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Email Notifications** card.
5. Add or edit the email notification rule:
 - To add a rule, click the **Add Email Notification Rule** link.
 - To edit a rule, click the notification rule's **Row Action menu** () , and then click **Edit**.

Note

You can edit any email notification rule, even one you didn't define.

6. In the **Message text** field on the Add Email Notification Rule or Edit Email Notification Rule page, click **Show Fields**.

For a topic-related email notification reason, a page lists all topic fields. For an action-related reason, the page lists all topic fields and all action fields.
7. Highlight a field to insert a variable for it into the message text.

The field variable is inserted at the location of the cursor.
8. Click **OK**.

Note

Action emails trigger when you click **Save** on the Topic Action page. Any topic field included in an Action email message reflects the last saved General Information value.

Delete an email notification rule

You can delete an email notification rule.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Topic Workflow Configurations**.
3. Click the configuration's **Row Action menu** () , and then click **Edit**.
4. On the Edit Topic Workflow Configuration page, click the **Email Notifications** card.
5. Click the notification rule's **Row Action menu** () , and then click **Delete**.
6. Confirm the deletion by clicking **OK**.

Manage subscription data releases

- [View the Oracle public safety data library](#)
For Cloud environments, Oracle Empirica Signal supports access to the Oracle public safety data library.
- [Import a subscription data release](#)
Use the Subscription Data Releases administration page to view available data releases, review their release notes, and import the releases of your choice into Oracle Empirica Signal.
- [View the Import Log](#)
Each time you import a subscription data release, Oracle Empirica Signal generates an Import Log ...

View the Oracle public safety data library

For Cloud environments, Oracle Empirica Signal supports access to the Oracle public safety data library.

If you subscribe to public safety data and Oracle has enabled the data library access for your environment, then users with Manage Configurations permission can access the Manage Subscription Data Releases page. From this page, users can view available data releases and associated release notes and import releases into Oracle Empirica Signal.

If your Oracle Empirica Signal instance is connected to a dedicated Argus Mart server in the Cloud, the Manage Subscription Data Releases page also shows a row listing *Argus* as a data offering. The import date reflects when the initial connection was established. Data updates happen automatically through the Argus Mart ETL.

1. Log into the Oracle Empirica Signal application as a user with the Manage Configurations user permission.
2. In the left navigation pane, click the **Settings** icon () .
3. In the **Configure System** section, click **Manage Subscription Data Releases**.
4. (Optional) Filter the list of subscription data releases shown.
 - From the **Status** drop-down list, select a status value or - - to include all statuses.
 - From the **Data Offering** drop-down list, select a data offering name or - - to include all data offerings.

The Manage Subscription Data Releases table contains a row for each shared data release you have access to and provides the following information about each release:

Column	Description
Data Offering	One of the following values: AERS, Argus, JADER, VAERS, VIGIBASE, or WVAERS.

Column	Description
Release Name	The name of the release.
 Note If an Argus Mart release is a multi-enterprise data offering, appended to the release name are the letters ME.	
Description	Basic information about the data release.
Release Date	Date and time that release was available on the shared data server.
Status	One of the following values: Available, Cancelled, Error Occurred, In Queue, Loaded, Local, Running, Suspended.
Product Dictionaries	If the data configuration specifies product dictionaries, the names and versions of the product dictionaries used by this release.
Event Dictionaries	If the data configuration specifies event dictionaries, the names and versions of the event dictionaries used by this release.
Requested	Date and time when import of the data release was requested.
Requested by	Name of the user who requested the data release be imported.
Imported	Date and time when the data release was imported.

Manage Subscription Data Releases page options

- To manage the columns in the table, click **Columns**. For more information, see [Arrange table columns](#).
- To download the table, click **Download**. For more information, see [Download data](#).

Row Action menu options

Note

Options available in the Row Action menu vary depending on the data release and status of the row you select.

If you click a data release's **Row Action menu** () , you can do the following:

- To view a PDF version of the *Release Notes* about a data offering release, click **View Release Notes**.
- To retrieve a log of the details of the latest import, click **View Log**. You can print the log.
- To [import an available data release](#), click **Import**.

- To cancel an import while its status is **In Queue** or **Running**, click **Cancel**. The status changes to **Cancelled**.
- If the import fails, the status changes to **Error Occurred**. You can perform the import again by clicking **Retry Import**.
- To republish a loaded data offering and give all current login groups Read access to the configurations associated with the data release, click **Republish**.
- For an Argus Mart Data Release, you can refresh dictionaries for all configurations by selecting **Refresh Dictionaries**.

Import a subscription data release

Use the Subscription Data Releases administration page to view available data releases, review their release notes, and import the releases of your choice into Oracle Empirica Signal.

To import a data release that is available to you, perform the following steps.

1. In the left navigation pane, click the **Settings** icon ()
2. In the **Configure System** section, click **Manage Subscription Data Releases**.
3. Click a data offering's **Row Action menu** () , and click **Import**.

Note

If the status of the data release is Local, it exists locally and you cannot import it. You can view the release notes.
If the status of the data release is Suspended, your subscription is no longer active and you cannot import it. You can view the release notes.

4. Choose whether you want to create Standard Runs and Report Outputs. You may receive one or more choices depending on the data offering. See the *Release Notes* for the particular data release for more details.

Note

The report outputs that can be created along with the data release import are summary reports for use by [Drug Profiles](#).

5. Choose whether to notify **All users** or **Selected users** when the release is available. If you chose **Selected users**, choose them from a list of available users. Then click **OK**.

Note

When notifying all users, the users cannot see the list of other recipients.

6. Specify whether to add the data mining run to an existing or new project.
 - If you choose **Existing**, select the project from the **Project Name** drop-down list.
 - If you choose **New**, enter the **Project name**.

7. In the **License Agreements** section, select and confirm all of the statements associated with the licenses and dictionaries you are importing.
8. Click **Submit**.

- Oracle Empirica Signal runs the import job in the background.
- You can track the progress of the import by hovering on the background processing indicator ().
- The **Status** column on the Manage Subscription Data Releases table updates to **Running** or **In Queue**.
- If an issue is encountered during the import, the **Status** column displays **Error Occurred**.

 Note

If you cancel an import while another import is in the queue, the second import run may fail.

If you encounter this error, re-import the data release run that failed.

To avoid this error, submit only one subscription data import run at a time. Wait until the initial import run's status changes to **Loaded** before submitting another import request.

9. When the import completes, view the objects associated with the imported data release.
 - The Status of the data release is updated to **Loaded**.
 - The **Imported** column updates with the date and time of the import.
 - Configurations for the imported data release are available on the Manage Configurations page. The imported configurations will be of Type **Managed**. You may need to [add the Type column](#) to the Manage Configuration page.

 Note

After import, if the **Enable multi-enterprise support** checkbox was selected, then the imported Argus configurations will be listed on the Manage Configurations page as *Type Argus ME*.

- Standard runs, if requested, will be available immediately on the Data Mining Runs page. The runs will be published to all login groups and have a size of 0B.
 - If report outputs were requested, then the jobs for the summary reports are submitted. Once finished, the report outputs will be published to all currently available login groups.
 - If the data release specifies aliases and aliases did not already exist, then aliases are created. Existing aliases are updated only if the data offering is for a later date than the current alias.
 - Email notifications are sent to users as requested in the import request. The recipient list is not visible to individual recipients.
10. To examine the import details, click the data release's **Row Action menu** () , and click **View Log**.

View the Import Log

Each time you import a subscription data release, Oracle Empirica Signal generates an Import Log ...

1. In the left navigation pane, click the **Settings** icon ()
2. In the **Configure System** section, click **Manage Subscription Data Releases**.
3. Click a data offering's **Row Action menu** () , and click **View Log**.
Oracle Empirica Signal displays import details for the selected subscription data release.
4. To print a copy of the log, click the **Print** link at the top of the page.
5. Click **Close**.

Manage drug profile configurations

- [About drug profile configurations](#)
- [Set up the Drug Profiles feature](#)
- [View existing drug profile configurations](#)
- [Add or edit a drug profile configuration](#)
- [Save a drug profile configuration](#)
- [View a drug profile configuration](#)
- [Rename a drug profile configuration](#)

About drug profile configurations

A drug profile configuration is the specification of which data mining runs and which report outputs are the source of charts that users can add to a drug profile layout (on the Drug Profile page). To access the Drug Profile page, a user must set a drug profile configuration as a [user preference](#).

For example, a drug profile configuration specifies that for generic drugs, the MGPS 2D run is 2019Q4: Generic (S + C). In a drug profile, users who have that configuration set as a user preference can add charts for a generic drug based on the results of the 2019Q4: Generic (S + C) run.

Note

Drug profile configurations are separate from drug profile layouts. Drug profile layouts, which are saved collections of charts as well as their placement and display options, can be used with various drug profile configurations. For example, if you are using the layout, Generic + trade comparators, and you change your user preference to a different drug profile configuration, the Generic + trade comparators layout is still available.

Only report outputs from an [all cases summary report](#) can be used in a drug profile configuration. This is a special type of interactive report that must meet certain criteria.

In the drug profile configuration, you can specify data mining runs and report outputs for generic names, trade names, and ingredients. To specify a run or report output, you can select either the run name or an [alias](#) that has been set up for the run or report output.

You might want to create multiple drug profile configurations for different purposes. For example, you can set up one drug profile configuration for AERS data and another drug profile configuration for proprietary data. For information on setting up the drug profiles feature, see [Set up a drug profile](#).

Set up the Drug Profiles feature

To implement the features of the Drug Profile page for your organization, an administrator must complete some configuration steps.

Required permissions

To set up the Drug Profiles feature, an administrator must have the following permissions:

- View Data Mining Results
- Create Data Mining Run
- View Drug Profiles
- Create Drug Profile Layouts
- Create Report Definitions
- Administer Users
- Administer Drug Profiles
- Manage Aliases

Follow the steps below to set up the Drug Profiles feature. These steps include an example of a single initial drug profile layout that presents source data and data mining results from the frequently used standard AERS+SRS (S) data configuration.

Create an All Cases Summary report

For a drug profile layout to include distribution tables or graphs of source data, you create an [all cases summary report](#) for the Generic drug subtype.

1. In the left navigation pane, hover over the **Data Analysis** icon () and then click **Interactive Reports**.
2. Click **Create Definition**.
3. Create an all cases summary report. See [Create or edit an interactive report definition](#).
 - a. From the **Configuration** drop-down list, select the configuration.
 - b. In the **Name** and **Description** fields, type a name for the report and a description.
 - c. Perform one of the following:
 - i. To add the report definition to an existing project, select it from the **Add to existing project** drop-down list.
 - ii. To add it to a new project, specify the project name in the **Add to a new project named** field.
 - d. From the **Type** drop-down list, select **Summary of all Cases**

This report type contains a single row variable for a drug subtype (such as Generic) and includes columns that show the distribution of cases by such variables as Gender, Age Group, and Report Received Year. You then run the report on the current AERS+SRS (S) configuration. (The report collects data across the entire configuration and can take some time to run.)

4. When the report output for the All Cases Summary report is complete, add an alias for the report output. (This step also is optional, but recommended.)

Create an alias

To streamline the process of keeping drug profile layouts that include data mining run results current over time, add an [alias](#) for each of those data mining runs.

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Aliases**.
3. On the **Manage Aliases** page, click **Add Alias**. For information on adding an alias, see [Add or edit an alias](#).
4. Add a **Latest <run type> alias** for each of these runs, such as Latest Generic (S), and associate each alias with the most recent run of that type.

This step is optional, but recommended. For example, each quarterly AERS data release includes a standard set of MGPS data mining runs that are based on the current AERS+SRS (S) configuration. When each subsequent AERS data release is received, you update the aliases to reference the newest available run, which has the effect of keeping all of the drug profile configurations that use those aliases up to date without requiring individual edits to every drug profile configuration.

Add a drug profile configuration

For each drug subtype (Generic, Trade, or Ingredient), you specify a report output (to supply source data) and data mining runs of different types (to supply run results). Oracle recommends that you supply the aliases you set up for the report output and data mining runs, rather than the actual names. See [Add or edit a drug profile configuration](#).

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Drug Profile Configurations**.
3. On the **Manage Drug Profile Configurations** page, click **Add Drug Profile Configuration**.

Note

The report output for the All Cases Summary report you created is available for selection in the Generic section, but not in the Trade or Ingredient sections of the page. Later, you can create and run an all cases summary report for each drug subtype, set up aliases, and edit the drug profile configuration to reference them.

4. Publish the drug profile configuration. See [Publish an object](#).

Set your user preference

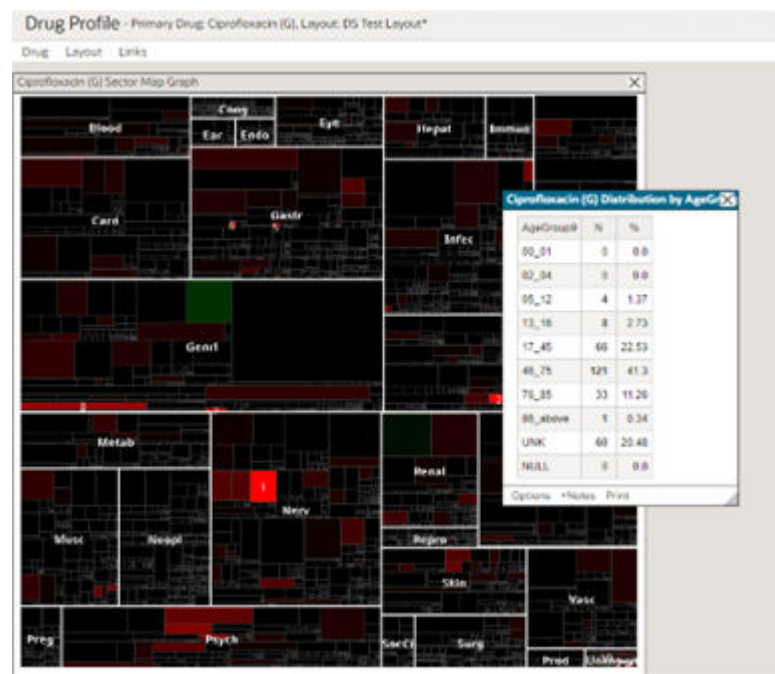
1. Set your user preference, **Drug Profile Configuration**, to the drug profile configuration you created as an alias. See [Set user preferences](#).
2. Log out of the Oracle Empirica Signal application, then log back in.
The Drug Profile page should now be available to you.

Create a drug profile layout

For more information, see [View a drug profile](#).

1. In the left navigation pane, hover on the **Data Analysis** icon () , then click **Drug Profiles**.
2. From the **Layout** menu, select **Create**.
3. Select at least one chart to include in the layout; for example, a graph of data from one of the data mining runs you defined for the drug profile configuration, or a graph or table of source data from the report output. For more information, see [Adding a chart to a drug profile layout](#).
4. Add more charts and arrange them as desired.

Figure 10-4 Drug profile Ciprofloxacin (G) Sector Map Graph



5. Publish the drug profile layout. See [Publish a drug profile layout](#).
6. Set your user preference, **Drug Profile Layout**, to the drug profile layout you created.

Grant users View Drug Profiles permission

1. For each of the users who will use drug profiles, [edit the user account](#) to grant the **View Drug Profiles** permission.
2. Optionally, grant the **Create Drug Profile Layouts** permission, as well. See [Adding or editing a user](#) and [User permissions](#).

Note

Of the users who will use drug profiles, any who were logged in when you granted the drug profiles permission(s) must log out of the application and log back in.

3. The users who will use drug profiles can now set their [user preferences](#), **Drug Profile Configuration** and **Drug Profile Layout**, to the objects you created (alias and drug profile

layout). After the users log out and log back in, the Drug Profile page is visible and the drug profile layout provided by default.

Refine the drug profile configuration and layout

You can now repeat steps of this process as needed to refine the drug profile configuration and drug profile layout. For example, you might create and run an additional all cases summary report for each of the other drug subtypes, Trade and Ingredient, add an aliases for them, edit the drug profile configuration to include them, and modify or add other drug profile layouts.

Refresh data for a drug profile

When a data update is available, such as when new AERS+SRS (S) data is released each quarter, you refresh the data used by the drug profiles:

1. Rerun each all cases summary report referenced by the drug profiles configuration on the new AERS+SRS (S) data configuration and save the output.
2. Rerun each data mining run referenced by the drug profiles configuration. (The standard AERS+SRS (S) data mining runs may already have been rerun at release installation.)
3. Update all aliases, for both report outputs and data mining runs, that are in use by the drug profiles configuration. If you chose not to use aliases, update each drug profile configuration to supply the new report output and data mining run names.

Note

Run definition files and Report definition files can update existing aliases automatically.

View existing drug profile configurations

The Manage Drug Profile Configurations page lists [drug profile configurations](#) that you created or that are published to you. If you have the Administer Users permission, the page also lists unpublished configurations created by any user in your login group.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Drug Profile Configurations**.

The Manage Drug Profile Configurations page provides the following information about each profile configuration:

Column	Description
ID	Automatically assigned unique identifier of the configuration.
Name	Name of the configuration.
Description	Description of the configuration.
Created By	Name of the user who created the configuration.
Created	Date and time when the configuration was created.
Modified	Date and time when the configuration was last modified.
Modified By	Name of the user who last modified the configuration.

View, edit, rename, publish, and delete drug profile configurations

If you click the **Row Action menu** () for a drug profile configuration that you created, you can also do the following:

- To [view a drug profile configuration](#), click **View**.
- To [edit a drug profile configuration](#), click **Edit**.
- To [rename a drug profile configuration](#), click **Rename**. If any users have the configuration set as a user preference, that setting is changed automatically to the new name.
- To publish a drug profile configuration, click **Publish**, select the login group(s), then click **Back**. (If you have the Administer Users permission, you can publish configurations created by any user in your login group.)

If you are a superuser, you can publish to multiple login groups, including —All—. In the **Publish to Login Groups** drop-down list, **click** or **Ctrl+click** to select login groups. If you publish to —All— and later add a new login group, the object is published automatically to the new login group.

- To delete a drug profile configuration, click **Delete**.

Add or edit a drug profile configuration

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Drug Profile Configurations**.
3. Perform one of the following:
 - To add a new configuration, click **Add Drug Profile Configuration**.
 - To edit a configuration, click the **Row Action menu** () for the configuration, and then click **Edit**.
4. If your organization uses [signal management](#), from the **Signal Management Configuration** drop-down list, select a [signal configuration](#).

When the drug profile configuration and the specified signal configuration are both in use by a user and that user has a drug layout set as a user preference, then the Products table on the Signal Review page will have the Drug Profile menu option, which points to the Drug Profile page.

Note

Regardless of the drug type on the Signal Review page, the drug is considered by the Drug Profile page to be a generic name. Thus, only the generic name settings in the drug profile configuration are used.

5. For each section on the page, you can specify report outputs and runs that you created or that are published to you. (If you have the Administer Users permission, you can also specify unpublished report outputs and runs created by any users in your login group.) For any report outputs and runs that you can specify, you can also specify any existing aliases for them.
6. Click **Next**.
7. To save the configuration, enter or edit the name and description of the drug profile configuration, and then [save the drug profile configuration](#).

If you created a drug profile configuration, it appears as the bottom row of the Manage Drug Profile Configurations page.

Reference data mining runs and aliases

The data mining runs that you reference in a drug profile configuration must have an item variable with the [subtype](#) Generic, Trade, or Ingredient (depending on the section of the [drug profile configuration](#)) in the data configuration.

Lists of available report outputs and data mining runs also include aliases for those objects. If the drug profile configuration refers to an alias, the alias is resolved each time a user goes to the Drug Profile page. This is useful if updates of data and new data mining runs are expected, and you want charts for those new runs to be available on the Drug Profile page. For example, the drug profile configuration refers to an alias named, Latest 2D Generic. The alias can be updated to point to new data mining runs, but the drug profile configuration does not need to be updated, and users do not need to set their user preference to a new drug profile configuration.

Note

Users of the Drug Profile Page can view charts for all report outputs and data mining runs that are referenced by their current drug profile configuration, regardless of whether or not they can view the report outputs or runs elsewhere in the application.

When defining a drug profile configuration, consider which data configurations the data mining runs and report outputs that you reference are based on.

Available drugs list

Another consideration is that when users select drugs when adding a chart (on the Drug Profile page), the list of available drugs can differ depending on the type of chart. For example, suppose that the 2D run results, but not the 3D run results, include custom terms. When selecting drugs for an EBGM graph, but not for a nested confidence interval graph, users are able to select custom terms (the nested interval graph applies only to results for the 3D run). For consistency of available drugs that can be selected for various chart types, the drug profile configuration should reference similarly constructed data mining runs. Users can also select drugs from the Drug menu. In constructing the list of available drugs that can be selected from the Drug menu, the application uses the following objects, in order of precedence:

- MGPS 2D Run
- MGPS 2D by Year Run
- Report Output
- MGPS 3D Run
- LR 2D Run

Save a drug profile configuration

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Drug Profile Configurations**.
3. Perform one of the following:
 - To add a new configuration, click **Add Drug Profile Configuration**.

- To edit a configuration, click the **Rows Action menu** () for the configuration, and then click **Edit**.
- 4. If your organization uses [signal management](#), from the **Signal Management Configuration** drop-down list, select a [signal configuration](#).
- 5. For each section on the page, you can specify report outputs and runs that you created or that are published to you. (If you have the Administer Users permission, you can also specify unpublished report outputs and runs created by any users in your login group.) For any report outputs and runs that you can specify, you can also specify any existing aliases for them.
- 6. Click **Next**.
- 7. To save the configuration, in the **Name** field, enter a name for the drug profile configuration.

Note

If you are editing an existing drug profile configuration and you change its name, the existing configuration is renamed.

- 8. Optionally, in the **Description** field, enter a description of the drug profile configuration. If you created a drug profile configuration, it appears as the bottom row of the Manage Drug Profile Configurations page.

Note

Oracle recommends that you test the drug profile configuration before publishing it. To do so, you can set your [user preference](#), Drug Profile Configuration, to the new drug profile configuration and go to the Drug Profile page.

View a drug profile configuration

- 1. In the left navigation pane, click the **Settings** icon ().
- 2. In the **Configure System** section, click **Manage Drug Profile Configurations**.

- 3. Click the **Row Action menu** () for a configuration, and then click **View**.

The Drug Profile Configuration Description dialog box provides the following information. Many of these fields are specific separately based on Drug Subtype (Generic Name, Ingredient Name, Trade Name) as defined in the data configuration variable:

Field	Description
Drug Profile Configuration Name	Name of the drug profile configuration.
ID	Automatically assigned identifier of the drug profile configuration.
Description	Description of the drug profile configuration.

Field	Description
Signal Configuration	Name and ID of the signal configuration (if any) associated with the drug profile configuration. When the drug profile configuration and the specified signal configuration are both in use by a user and that user has a drug layout set as a user preference, then the Products table on the Signal Review page will have the Drug Profiles menu option, which points to the Drug Profile page.
Report Output ID	Name and ID of (or alias for) an all cases summary report , which is a specific type of interactive report.
MGPS 2D ID	Name and ID of (or alias for) a completed two-dimensional MGPS data mining run for which charts can be added on the Drugs page. This can also be a run that uses cumulative subsetting. In this case, only the subset that is the accumulation of all the other subsets is used.
MGPS 2D by Year ID	Name and ID of (or alias for) a completed two-dimensional MGPS data mining run that uses cumulative subsetting by year, for which charts can be added on the Drugs page.
MGPS 3D ID	Name and ID of (or alias for) a completed three-dimensional MGPS data mining run for which charts can be added on the Drugs page. Subsetted three-dimensional runs are not available to select.
LR 2D ID	Name and ID of (or alias for) a completed logistic regression data mining run for which charts can be added on the Drugs page. The set of drugs included in logistic regression results is typically smaller than the set of drugs in MGPS results. On the Drugs page, graphs for logistic regression results are available only if the selected drug was included in the model or added explicitly during creation of the run.

Note

Regardless of the drug type on the Signal Review page, the drug is considered by the Drug Profile page to be a generic name. Thus, only the generic name settings in the drug profile configuration are used.

Rename a drug profile configuration

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Drug Profile Configurations**.

3. Click the **Row Action menu** () for a drug profile configuration, and then click **Rename**.
4. In the **Name** field, enter a new name for the drug profile configuration.
5. Optionally, in the **Description** field, modify the description of the drug profile configuration.

Note

If any users have the drug profile configuration set as a [user preference](#), that setting is changed automatically to the new name.

Manage aliases

- [What is an alias?](#)
- [Manage aliases](#)
- [Add or edit an alias](#)
- [View product-event combinations for a card or tab](#)
Use cards and tabs to choose the specific data to display on the product-event combinations table.

What is an alias?

An [alias](#) is a named reference to a data mining run, report output, or data configuration.

Currently, aliases can be used in setting up a [drug profile configuration](#), [interactive signal management](#), and [run definition files](#) (managed by Oracle).

Interactive signal management configurations can reference configuration aliases for all reports, 2D runs and 3D runs. When the signal management configuration is refreshed, any aliases referenced by the signal management configuration are resolved.

A drug profile configuration can reference aliases for data mining runs or report outputs. When a user navigates to the Drugs page, any aliases referenced by the drug profile configuration are resolved. When source data is updated and new runs and report outputs are created, you can modify the aliases to point to different runs and report outputs, rather than modifying the drug profile configuration.

Manage aliases

An alias is a named reference to a data mining run, report output, or data configuration.

If you have permission to view the target of an [alias](#), the alias is listed on the Manage Aliases page.

1. Log into the Oracle Empirica Signal application as a user with the Manage Aliases permission.
2. In the left navigation pane, click the **Settings** icon (.
3. In the **Configure System** section, click **Manage Aliases**.
4. From the **Target Type** drop-down list, select the target type for which you want to view aliases, or--to include all types (optional).

Column	Description
Name	Name of the alias. The name must be unique among other aliases for the same target type.
Target Type	One of the following values: • Configuration—The target is a data configuration. • Data Mining Run—The target is a completed data mining run (MGPS or logistic regression). • Report Output—The target is a report output.
Target	Name and/or identifier of the specific data configuration, data mining run, or report output with which the alias is associated.
Note If you change the name of a data mining run, report output, or data configuration that is the target of an existing alias, this field is updated automatically for that alias.	
Report output and data mining run alias names distinguish between S (Standard) and S+C. This only impacts users of drug profiles whose existing aliases have (S+C) data mining runs or report outputs as their target. • If your aliases have Suspect-only targets (targets that use the (S) configuration), you do not need to change anything in your drug profile configurations; the aliases will update to the new data release as they always have and will point to their Suspect-only targets. • If your data mining run and report output aliases in drug profiles currently point to (S + C) runs or report outputs, you must change your drug profile configurations to use the new alias names to point to the (S + C) targets. As with the Suspect-only aliases, these new aliases will be updated with each succeeding data release. Note that the alias for the 3D data mining run needs no such distinction, as it only ever uses the (S + C) configuration.	
Target Status	One of the following values: • Valid—The alias target exists and, in the case of a data configuration, is valid. • Broken—The alias target has been deleted. In the case of a data configuration, the target status also becomes Broken if the data configuration becomes invalid.
Created By	Name of the user who created the alias.
Created	Date and time when the alias was created.
Modified By	Name of the user who last modified the alias.
Modified	Date and time when the alias was last modified.

Manage Aliases page options

- To add an alias, click **Add Alias**. For more information, see [Add or edit an alias](#).
- To edit an alias that you created, click the **Row Action menu** () for an alias, and then click **Edit**.

Row Action menu options

If you click the Row Action menu () for an alias, you can do the following:

- To view an alias, click **View**.
- To edit an alias that you created, click **Edit**.
- To delete an alias that you created, click **Delete**. If you delete an alias that is referenced by a drug profile configuration, that reference is removed from the drug profile configuration.

Note

If you have the Administer Users permission, you can edit or delete aliases created by other users in your login group.

Add or edit an alias

1. In the left navigation pane, click the **Settings** icon ().
2. In the **Configure System** section, click **Manage Aliases**.
3. From the **Target Type** drop-down list, select the target type for which you want to view aliases, or--to include all types (optional).
4. Perform one of the following:
 - To add a new alias, click **Add Alias**.
 - To edit an alias, click the **Row Action menu** () for the alias, and then click **Edit**. You can edit only aliases that you have created, except that if you have the Administer Users permission, you can edit aliases created by any user in your login group.
5. In the **Alias Name** field, enter an alias name.
6. From the **Target Type** drop-down list, select the target type. For more information, see [Manage aliases](#).
7. From the **Target** drop-down list, select the target. For more information, see [Manage aliases](#).
8. Click **OK**.

View product-event combinations for a card or tab

Use cards and tabs to choose the specific data to display on the product-event combinations table.

You can filter the product-event combinations panel to a specific System Organ Class by selecting a System Organ Class card. The Product-Event Combinations tables only include events for the selected System Organ class.

In the product-event combinations panel, select a tab to display a specific product-event combinations table determined by the [tab view](#).

To add tabs to the product-event combinations panel for views [created by](#) or made public to you, click the **Add Tab** (+) icon to the right of the tabs.

Some of the values in the table are links to a menu for [drilling down to case detail and reports](#).

1. In the left navigation pane, click the **Signal Review** icon ().
2. (Optional) From the **Products By** drop-down list, select a product grouping, then select a card to filter the Products table.
3. Select the product, click the **Row Action menu** (⋮) icon, and select **View Product-Event Combinations**, or click the product name or total count.
4. View the product-event combinations for a tab by selecting the **All** SOC card or filter the product-event combination tables by selecting a specific SOC card. For example, to view only product-event combinations for blood and lymphatic symptom disorders, click the Blood card. The Product-Event Combinations panel refreshes to include only the combinations for that SOC.
 - The number of combinations, the sort order, the rows per page, and the number of pages in the table appear under the row of tabs.
 - By default, the table contains Status and Alerts columns. These columns show the review status and alerts associated with the product-event combination.
5. Click a tab to display the product-event combinations for that tab.
 - The default view tab, if available, includes the view's name only.
 - Tracked alert tabs include an alert icon (letter and color as defined by the alert type definition), an alert name and a count.
 - Informational alert tabs include the alert name and a count.
 - Alerts in scripted signal configurations show the alert name only.
 - Added tabs show the view name only.
 - Hover on the tab to show details. If the tab is for a configured alert, then the hover text includes "Alert based on review period or complexity level."
 - The Status column shows whether the product-event combination needs to be reviewed or has been reviewed. If Topics has been integrated with this configuration, the Status column indicates whether a topic has been associated with the combination, by the presence of the () icon.
 - The Alerts column contains an icon for each tracked alert type that was raised in the most recent refresh or any unreviewed tracked alert from a previous refresh.
6. [Drill down on the case details](#) for any product-event combination by clicking the case total in any column and selecting an item from the drop-down menu.
7. [Rearrange the columns](#), [download](#) the table, perform [operations on multiple rows](#) in the table, and save the table as a view from the **Header Action menu** (⋮).

Transform data

- [About data transformations](#)

- [Map text values](#)
- [Custom terms and mapped text values](#)
- [Define variable cutpoints](#)
- [Convert dates](#)
- [Exclude synthetic values](#)

About data transformations

A data transformation is a means of mapping text values to new values, converting date values, or organizing numeric or date values into groups. The source data remains unchanged, and the transformed values are available for selection when you create data mining runs.

You specify data transformations for individual variables within a [data configuration](#). The results of the transformation do not affect the actual source data.

For example, suppose that the source data contains a date variable RCVD_DATE. You want to allow run creators to select half-years as subset categories. You can use a data transformation to convert the date values for the RCVD_DATE variable to new half-year values, such as 2019H1 and 2019H2. A data mining run creator can then use the half-year variable for subsetting, and select different half-year values as subset categories. The source safety data continues to store only date values, but the run results refer to the half-year values instead of the full-date values.

Transformation options

To transform data in a data configuration, you can do the following:

- [Map text values](#).
- [Define variable cutpoints](#).
- [Convert date values](#).

When you define data transformations, it is preferable to include a new data configuration variable for the transformed data. For example, if the RCVD_DATE variable exists, and you want to transform its data, keep the RCVD_DATE variable as is in the data configuration and add a new variable, such as RCVD_HALFYR, to store the transformed data.

An additional transformation option allows you to upload a list of [synthetic values](#) that are in the source data. For example, you could upload the names of Standardized MedDRA Queries (SMQs) to be ignored by [MGPS](#) when estimating the shrinkage parameters for EBGM scores. Note that custom terms are ignored automatically for the estimation of shrinkage parameters.

Note

The raw RR scores for combinations involving custom terms and the excluded synthetic values are shrunk by the Bayesian formula, but they do not participate in the determination of the formula itself.

For any one data configuration variable, you can only specify one data transformation type. However, you can add variables that reference the same column in the source database. You can also specify a different transformation for each of those variables. For example, suppose that the source database has a RCVD_DATE column. You could create a RCVD_HALFYR variable to convert date values and a RCVD_RANGE variable that groups received dates according to date cutpoints.

Transformation results

When you define data transformations that map text values, define variable cutpoints, or convert date values, note that:

- Variables that transform data are not available for creating [queries](#) or defining [reports](#).
- Variables that map text values are available for creating [saved lists](#). The mapped values, however, do not match the source data. As a result, the saved list does not pass validation. You can save and use the saved list, even though it does not pass validation.
- Transformed variables are not available as the drug variable, event variable, or as additional covariates in a logistic regression run.
- If included in the drilldown map table, a variable that transforms data shows the source data, rather than the transformed data, when users [drill down to a list of cases](#) or to [view case details](#).
- If you define a data transformation for a variable in a data configuration, for which there are existing runs that use the variable, users cannot drill down correctly in the run results until the runs are re-executed.

Note

These restrictions do not apply to a synthetic values transformation.

Map text values

Mapping text values from the [source data](#) to specified text values or to a different hierarchy of terms involves a [data transformation](#). For example, you can use mapping to do the following:

- Combine multiple adverse events from the source data into a single combined event.
- Specify that PTs from the source data should use a non-primary path for hierarchy values assigned by the application.
- Recode drug names from the source data.

The mapped values can be selected for use in an MGPS data mining run.

Note

See [Defining custom terms](#) for another way of mapping values to a term that you specify for a data mining run. See [Comparing custom terms and mapped text values](#) for information on the differences between these features.

To map text values, you use a text editor to create a file that contains the mappings and then you upload the file to a mapped variable in the configuration. To view the current mappings for a variable, edit the configuration, and for the mapped variable click **View Current Mapping**.

Note

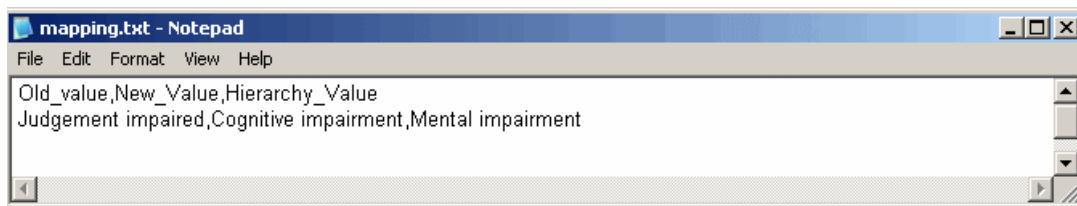
If you modify a mapping file, your changes are not applied automatically to the mapped variable. You must edit the configuration and upload the modified mapping file for the mapped variable.

Text mapping process

1. Determine how you want to map values. This example maps several PTs to the term, Cognitive impairment, and specifies that the term Cognitive impairment will use hierarchy values for the PT, Mental impairment.
2. In Microsoft Notepad or another text editor, create a mapping file and type the following column headings on the first line of the document:

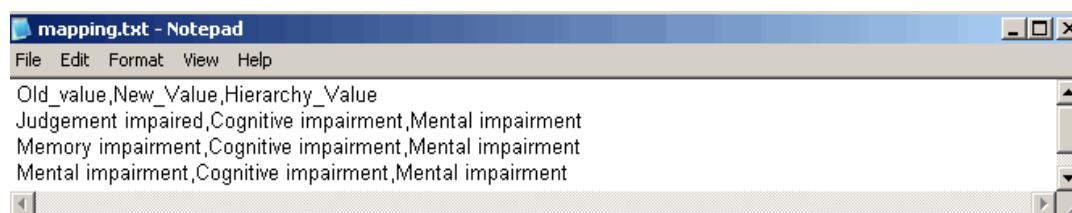


3. On the second line, type in the first old value (as it appears in the data, including capitalization), a comma, and then the new value. The new value does not need to exist in the source data. You must specify both an old value and new value. If you do not specify both values, values might be omitted from run results.
4. Type in the value that uses the hierarchy that you want to use for the new value. The hierarchy value is used only if the mapped variable is set up with a hierarchy. An exact match (including capitalization) of the hierarchy value must exist in the hierarchy, although it does not need to exist in the source data. If the mapped variable is set up to use a hierarchy, you must specify a hierarchy value.
5. You must separate each term with a comma. Do not include extra spaces or any extra carriage returns.

**Note**

If a term includes a comma, enclose the term in double quotation marks (for example, "Gastric ulcer, perforated"). If a term includes a double quotation mark, enter a backslash before the double quotation mark (for example, "Gastric ulcer, \"perforated\""). When you view the current mapping on the Edit Variable page, the double quotation marks and/or backslashes do not appear.

6. Repeat this process for each value that you want to map. This example maps several PTs to the same new value and hierarchy value. This is not a requirement for the mapping file. In the same mapping file, you can map different PTs to different new values and hierarchy values.



Note

You can perform only one level of mapping. In the above example, if you also map Cognitive impairment to Cognitive decline, none of the old values are mapped to Cognitive decline.

In the last line of the above example, the old value is mapped to a new value but continues to use the hierarchy of the old value. If the new value already exists in the source data, the hierarchy value applies to the existing value, as well. In this example, if Cognitive impairment is in the source data, the hierarchy for Mental impairment is used for it.

7. Make sure that there are no extra carriage returns or spaces in the file. The mapping does not work properly if there are extra carriage returns or spaces.
8. Save the file with the extension .csv.

Changing only the hierarchy

If you want to change only the hierarchy used for the old value, enter the same old and new value, and then the hierarchy value:



Generating results for mapped values

When creating a data mining run, choose the new variable. (Because you did not modify the original variable, that variable is also still available for selection.) Results are generated for combinations including the new value, as in the following example:

	Generic_Name	PT	HLT	HLGT	SOC	N ▼	EBGM ▼	EB05	EB95	RR
⋮	Insulin	Cognitive disorder	Mental impairment (excl dementia and memory loss)	Mental impairment disorders	Nerv	16	0.891	0.626	1.24	0.944

Note

There might be more results for Insulin and the pre-mapped terms than for Insulin and the new mapping term because cases that include multiple pre-mapped terms are counted only once for the new mapping term.

Custom terms and mapped text values

The Oracle Empirica Signal application offers two options for grouping values, such as a list of drugs or a list of events, together for use in a data mining run without affecting source data. These features are:

- **Custom Terms**—see [Define custom terms](#).
- **Mapped Text Values**—see [Map text values](#).

While these options are similar, each has different advantages and limitations. The differences between these features are as follows.

Options	Custom Terms	Mapped Text Values
MGPS runs can include:	X	X
Logistic regression runs can include:	X	--
Set up using query logic:	X	--
Set up once, then reusable: (Manage Configurations permission)	--	X
Set up for each run: (Create Data Mining Run permission)	X	--
Can be set up for variables configured to use a hierarchy table:	--	X
Can be set up for variables configured to use a hierarchy account:	X	X

When a custom term is added to a data mining run, that custom term cannot include a variable with mapped text values. Oracle recommends that when mapping text values, instead of applying this data transformation directly to a configuration variable, set up a new configuration variable based on the same table and column specifically to incorporate the mapping. When two different variables are offered in this way, the values of the original variable remain available for inclusion in a custom term. See [About data transformations](#).

Define variable cutpoints

Categorization based on cutpoints is a type of [data transformation](#). If the source data for the [data configuration](#) does not contain a variable that categorizes values in a way that is needed for stratification or subsetting during a data mining run, you can create categories by defining cutpoints for the variable. You can define categories for only a continuous variable; that is, numeric or date variables.

For example, the source data contains Age, but not Age Group. The data miner wants to subset data by the following groups: 18 or younger, 19-65, and over 65. You can define a variable based on Age, and then categorize those age values into groups by specifying cutpoint values that indicate the range of each category.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click the **Row Action menu** () for the data configuration, and then click **Edit**.
4. To add a variable to represent the cutpoints, click the **Add New Variable** link. For more information, see [Add or edit a data configuration variable](#).

5. In the **Name** field, enter the name of the variable.

Variable names display throughout the application, including when users select criteria for viewing data mining results, defining queries, or creating report definitions. For example, a column might be named SYMPTOM in the Oracle table, but renamed to appear as Event in the application.
6. In the **Description** field, type a description of the variable.
7. Next to the **Table** field, click **Select Table/Column**.
8. As the **Column** of source data, select the variable containing values that you want to map. The source column must contain numeric or date values.
9. Set **Hide From Query Wizard** to **Yes**. (Even if this setting is set to **No**, the mapped variable is not available in the Query Wizard.)
10. In the **Data Transformation** section, click **User-defined cutpoints**, and then click **View/Edit**.
11. To assist you in determining which categories to define, you can [view column statistics](#) about the distribution of values for the field in the entire source database.
12. In the first row, which starts with **VALUE <=**, in the **Value** column, enter the last value in the first category.
13. In the **Label** column, enter a label for the first category. For a date value, use the format, mm/dd/yyyy. For example, 12/14/2019.
14. In the next row, enter the last, or highest, value and a label for the second category. (You must enter the cutpoint values in ascending order.)
15. Continue defining categories until you are ready to define the last category.
16. For the last category, enter only a label. There is no need to enter a value. For example:

Define Cutpoints for Variable Age (yrs)

	Value	Label
VALUE <=	18	18 or younger
18 < VALUE <=	65	19 through 65
65 < VALUE		Over 65

View Column Statistics

☐ Add additional cutpoints upon saving

Minimum Value:

Maximum Value:

- 17. If you need to add more categories than you can currently fit on this page, check **Add additional cutpoints upon saving**. When you click **Save**, you can add more categories.
- 18. Optionally, enter values into the **Minimum Value** field and the **Maximum Value** field.

The minimum and maximum apply to the source values, not the transformed values. This option is useful if you want to exclude extreme values from inclusion in a data mining run. The excluded values are considered missing. They are assigned the value that the user sets for the [user preference](#), **Replace Missing Values with**.

When specifying a minimum and maximum value for a date value, use the format mm/dd/yyyy, for example, 12/14/2019.

19. Click **Save**.

If you checked **Add additional cutpoints upon saving**, another row is added.

20. When you are finished specifying categories, clear **Add additional cutpoints upon saving**, and click **Save**.

The cutpoints for the variable are created. If you define cutpoints for a variable in a configuration for which there are existing runs that use the variable, users cannot [drill down](#) correctly in the run results until the runs are re-executed.

Convert dates

A date conversion is a [data transformation](#). For a variable that is based on a date value in the source data, you can convert the date value to a year, a half year, or a quarter year.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Configure System** section, click **Manage Configurations**.
3. Click the **Row Action menu** () for the data configuration, and then click **Edit**.
4. To add a variable to represent the converted data values, click the **Add New Variable** link. For more information, see [Add or edit a data configuration variable](#).
5. In the **Name** field, enter the name of the variable.

Variable names display throughout the application, including when users select criteria for viewing data mining results, defining queries, or creating report definitions. For example, a column might be named SYMPTOM in the Oracle table, but renamed to appear as Event in the application.

6. In the **Description** field, type a description of the variable.
7. Next to the **Table** field, click **Select Table/Column**.
8. As the **Column** of source data, select the variable containing values that you want to convert. The source column must contain date values.
9. Set **Hide From Query Wizard** to **Yes**. (Even if this setting is set to **No**, the mapped variable is not available in the Query Wizard.)
10. In the **Data Transformation** section, click **Date function**, and then click **Select Function**.
11. Select one of the following functions:
 - **QUARTER**—Convert the date to a quarter year formatted as the four-digit year followed by the quarter (for example, 2006Q1, 2006Q2, 2006Q3, and 2006Q4).
 - **YEAR**—Convert the date to a four-digit year.
 - **HALF**—Convert the date to a half-year formatted as the four-digit year followed by the half year (for example, 2006H1 and 2006H2).
12. Enter a minimum or maximum value (optional). The minimum and maximum apply to the source values, not the transformed values.

This option is useful if you want to exclude extreme values from inclusion in a run. The excluded values are considered missing. The application assigns the value that the user sets for the [user preference](#), **Replace Missing Values with**.

When specifying a minimum and maximum value, use the format mm/dd/yyyy, for example, 12/14/2006.

13. Click **Save**.

Note

If you convert a date variable in a configuration for which there are existing runs that use the variable, users cannot [drill down](#) correctly in the run results until the runs are re-executed.

Exclude synthetic values

When estimating shrinkage parameters for EBGM scores generated by a data mining run, [MGPS](#) does not consider custom terms. If source data includes other synthetic values, such as standardized MedDRA queries, you must exclude those values for the appropriate [data configuration variable](#). Once synthetic values have been excluded, MGPS does not consider them when estimating shrinkage parameters for EBGM scores.

Note

AERS data releases provided to you by Oracle are already configured to exclude SMQs as synthetic values.

1. In Microsoft Notepad, or another text editor, create a file containing the synthetic values.
 - The file must have only one column of up to 200 characters.
 - The first row in the file must be the header, Value.
2. Make sure that there are no extra carriage returns or spaces in the file.
3. Save the file with the extension, .csv.
4. In the left navigation pane, click the **Settings** icon (.
5. In the **Configure System** section, click **Manage Configurations**.
6. Click the **Row Action menu** () for the data configuration, then click **Edit**.
7. Click the **Row Action menu** () for a configuration variable, and then click **Edit**.
8. In the **Data Transformation** section, click **Synthetic values**.
9. Click **Upload Table**.
10. Click **Browse**.
11. Select the file of synthetic values and click **Open**, and then click **Upload**.
12. To make sure the values are correct, in the **Data Transformation** section, select **Synthetic values** and click **View Current Values**.
13. Click **Close**, and then click **Save**.

14. [Validate](#) the data configuration.

Note

When you have excluded synthetic values, users creating a data mining run do not need to take any additional steps to exclude them.

Administer the system

- [Set site options](#)
- [Send a message to all users](#)
- [Manually restart the listener process](#)
- [Manage run storage](#)
- [Change user default data mining runs](#)

Set site options

A site option is a setting that customizes an aspect of the Oracle Empirica Signal application. Setting site options requires the superuser permission.

Note

The site options in the Password Restrictions section are not applicable to single sign-on or LDAP passwords. You can set password restrictions for single sign-on users in Oracle Access Manager.

1. In the left navigation pane, click the **Settings** icon (.
2. From the **Administrator System** section, select **Set Site Options**.
3. Edit the fields as necessary.
4. Click **Save**.
5. Optionally, you can do one of the following:
 - To review your changes, select **Review Changes**.
 - To continue to work on the application, select **Continue**.

Field descriptions—Site Options page

Note

Password-related options do not apply to SSO or LDAP authentication.

Field	Description
Expiration	Enter the number of days until user passwords expire. This optional setting affects passwords for all users. The expiration period is counted from when the user was created or when the password was last changed. The default value is 90 days. Note: Individual users can be configured so their password never expires. Also, when a user password has expired, the user can create a new password.
Expiration Warning	Enter the number of days prior to password expiration that a warning message begins to display when users log in. This optional setting affects passwords for all users. The default value is 15 days. The expiration warning period is counted from when the user is created or when the user's password is last changed.
Minimum Length	Enter the minimum length of new passwords. Passwords can be up to 64 characters long. Existing passwords are not affected by this value. The default value is 8.
Number of Attempts Allowed	Select the number of times users can attempt to log in with an incorrect or missing password before the account is locked. The default value is 3. When this limit is reached, an email message is sent to all superusers and to all user names with the Administer Users permission in the same login group as the locked account. Note: When a user account is locked, the Account locked check box is checked automatically for the user. To unlock the user account, edit the user and clear the check box.
Number of Passwords Retained	Indicate the number of unique passwords that are retained in the history of the user. Passwords retained in a user's history cannot be re-used. For example, suppose that you set this field to 100. Each time the user changes the password, the old password is retained (up to 100) and when a new password is selected, it cannot match any of those in the history. If you want to allow password re-use, set this value to 0. If you want to prevent password re-use, set this value to a high number such as 1000. The default value is 8.
Alphabetic Numeric Non-alphanumeric Lower case Upper case	Enter a number in each field to define how many of each character must be present when new passwords are set. The default value for each character is one.
SMTP Server	Enter the name of the SMTP server to use for email notification of run completion, feedback email, and error email. This field must be filled in correctly for these email functions to work.
From Email Address	Enter the email address from which topic email notifications and run completion notifications will be sent. The default value is <code>empiricasignalnoreply_ww@oracle.com</code> .

Field	Description
Error Email	Enter the email address for notification of system errors. You can enter one address or multiple addresses separated by commas. Note: System errors are also recorded in the User Activity Audit Trail.
Date Format, Time Format	Select the date format and time format to use for server date/times that are displayed in Oracle Empirica Signal application. Note: UTC is Coordinated Universal Time (abbreviated as UTC).
Auto-Start Local Listener	If Yes , the listener process starts automatically when a batch run is submitted. This option needs to be set to Yes unless the listener process does not run on the Web server.
Log Level	Select the type of information to be included in the weberror.log file on the Oracle Empirica Signal server.
Max Memory Per Report	Enter the maximum amount (MB) of memory that a single report is allowed to use when executing. It is recommended you consult with Oracle support before changing this value. Note: To decrease the amount of memory used by reports, set the Generate drill-down Information option to No while editing report attributes. Additionally, if memory issues cause a large report to fail or take a long time, increase this site option.
Max number of rows per table allowed in topic attachments	Maximum number (n) of rows of tabular data that can be saved as an attachment to a topic. Only the first rows of the displayed tabular data are saved as the attachment. A message informs you that not all rows are being saved
Max number of rows allowed for the total of all topic attachments per accessible topic PDF	Maximum number of rows that can be added in all selected topic attachments when you create an accessible topic PDF or accessible topic zip archive.
Max number of bytes per file allowed in topic attachments	Maximum size (MB) of files that can be added as an attachment to a topic. If you try to add a larger file as an attachment, an error message appears.
Time to send topic email reminder notifications	Hour of the day when Email Reminders for Email Notification Rules are sent.
Max cache size for LR index tables and data files	Maximum size (MB) of Oracle index tables or files saved during execution of a logistic regression run.
Show menu items: Signal Review	Select to show the Signal Review menu item to users with appropriate permissions.
Data Mining Runs	Select to show the Data Mining Runs menu item in the Data Analysis  section of the left navigation pane to users with appropriate permissions.
Data Mining Results	Select to show the Data Mining Results menu item in the Data Analysis  section of the left navigation pane to users with appropriate permissions .
Queries	Select to show the Queries menu item in the Data Analysis  section of the left navigation pane.

Field	Description
Case Series	Select to show the Case Series menu item in the Data Analysis  section of the left navigation pane.
Reports	Select to show the Reports menu item in the Data Analysis  section of the left navigation pane.
Drug Profiles	Select to show the Drug Profiles menu item in the Data Analysis  section of the left navigation pane to users with appropriate permissions.
Allow Case Comment/Review/Exclusion	Select to include the Reviewer Input section on the Case Details page, or clear to prevent the Reviewer Input section from appearing. This only affects the Case Details page that you access on the Case Series page.
Allow Free Text Signal Comments	Select to allow users to enter free text comments when, on the Signal Review page, they filter a product-event combination or add a comment when reviewing a signal summary. Regardless of the setting of this option, users can select from a list of predefined comments.
Allow Automatic Assignment of Reviewers to Products	Select to allow users with appropriate permissions to assign reviewers to products automatically.
Enable Interactive Reports	Select to show the Interactive Reports link on the Reports page.
Enable Query Wizard	Select to enable use of the Query Wizard to define queries.
Allow Case Count on Query Preview Page	Select to show the Show case count by default on preview page check box on the Set User Preferences page.
Enable Second Level drill-down on Cases Page	Select to allow users to drill down to view case details for a particular case when they are viewing a list of cases. This option does not apply to the Case Series page or to a case ID hyperlink in a report; you can always drill down to case details from these locations.
Enable Download Case Details	Select to allow users to download case details.
Enable LDAP	Select to enable the creating, updating, and authentication of users via an LDAP directory.
Enable Oracle Analytics Reporting	Select to allow users to view or generate Oracle Analytics reports.
Enable RGPS Option in MGPS Data Mining Runs	Select to allow users to include RGPS computations in data mining runs. Note: This option is enabled only if R and RGPS are installed.
Limit User Provisioning (Oracle-hosted installations only)	Select to disallow the following activities by users with the Administer Users user permission: • Adding a new user on the Users page. • Deleting users on the Users page. • Editing the Authentication, Username, First Name, Last Name, and Email fields on the Edit User page. This option does not affect superusers.
Add message to Notes for Results (Table and Graphs)	Enter text to display below tables or graphs of data mining results. For example, the message might read "These data do not, by themselves, demonstrate causal associations; they may serve as an impetus for further investigation."

Field	Description
Notes for Signal Management Interactions Graph	Enter text to display at the bottom of the Interactions page for a product-event combination on the Signal Review page.
Product-event combination comment length	Maximum length of detailed comments for product-event combinations on the Signals Review page.
Default User Profile	For organizations provisioning users via identity management service (IAMS or IDCS), indicates the profile applied by default to new users.
Topic workflow configuration for work team custom fields	For organizations using the topics feature, indicates the topic workflow configuration that implements custom fields for work teams. The selected configuration also must be published to the login group for the fields to be visible when a work team is added or edited for that login group. See Add or edit a work team and Constrain field values by work team .

Send a message to all users

If you have the Administer Users permission, you can send an email message to all Oracle Empirica Signal users who:

- Have an email address associated with their username.
- Are in your login group.
- Have an active user account (that is, the Account disabled check box is cleared on the [Add/Edit User](#) page).

For example, you might want to send a message announcing an upgrade or scheduling server maintenance.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Administer System** section, click **Send Message to All Users**.
3. In the **Subject** field, enter the subject of your message.
4. In the **Comments** field, enter the text of your message.
5. Click **Send**.

The application sends the message to users, regardless of whether or not they are currently logged in, and displays a confirmation for each message sent.

In the email message:

- The date and time of the message is the date and time at which you clicked **Send**.
 - The **From** line shows the email address associated with your username. If there is no email address associated with your username, the **From** line shows the email address associated with the **FromEmailAddress** field on the [Set Site Options page](#).
 - The **Subject** line shows the text you entered in the subject line.
6. Click **Continue**.

Manually restart the listener process

The Oracle Empirica Signal listener process is responsible for identifying background work and assigning it to processes for execution. The listener process starts when the application starts

up, and updates an associated heartbeat date and time value every 2-30 seconds while the application is running.

Occasionally, the listener process terminates unexpectedly (either because it encounters an error or because it is stopped by a system operator).

When a run is submitted, the application checks the heartbeat value to determine if the listener process is still running. If the listener process is not running, the application restarts it automatically, if the Auto-Start Local Listener site option is set to Yes. You can also restart the listener process manually from within the application at any time.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Administer System** section, click **Restart Listener**.

Note

You can restart the listener process only if the listener is running as part of the Oracle Empirica Signal website. If the listener is running outside of the Oracle Empirica Signal website, clicking **Restart Listener** has no effect.

Manage run storage

- [Manage data mining run storage](#)
- [Export data mining run data](#)
- [Import data mining run data](#)
- [Mark a data mining run as archived](#)
- [Move a data mining run with a Move script](#)
- [Create a run definition file](#)

Manage data mining run storage

The Oracle Empirica Signal tools for managing data mining run storage are intended for the use of an Oracle Database Administrator who is responsible for the Oracle Empirica Signal database.

To archive a run, you export the run data and set the archived flag to **Yes**. To de-archive a run, you import the run data and clear the Archived flag.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Administer System** section, click **Manage Run Storage**.

Row Action menu options

Click the **Row Action menu** () for a run to do the following:

- To [export the run data](#), click **Export Run Data**.
- To [import the run data](#), click **Import Run Data**.
- To mark a run as archived, click **Set Archived Flag**. The value in the Archived column changes to Yes.
- To clear the Archived flag, click **Clear Archived Flag**.

- To move the run to a different tablespace, click **Create Move Script**.

On the Data Mining Runs page, you can include an Archived column showing the setting of the Archive flag. If the Archived flag for a run is set to **Yes**, the run description on the Data Mining Runs page starts with **Archived**. If the Archived flag is **Yes** for a run, you cannot view run results.

Export data mining run data

- In the left navigation pane, click the **Settings** icon (.
- In the **Administer System** section, click **Manage Run Storage**.
- Click the **Row Action** menu () for the run, and then click **Export Run Data**.
- Follow instructions on the Export Run Data page, as shown in the following example:

```
--
-- To successfully archive run data, you may need DBA privileges for your database.
--

-- Step 1: Export the Run Data
-- Export the oracle data for the following tables: WEBVDM70.OutputData_379, WEBVDM70.DRUG_INDEX_379, WEBVDM70.EVENT_INDEX_379
-- This can be done using an Oracle EXPORT command similar to the one below:

EXP WEBVDM70/ <password>@<tns_name> log=run_379.log file=run_379_out.dmp tables=(OutputData_379, DRUG_INDEX_379, EVENT_INDEX_379)

-- Step 2: Mark the Run as "Archived"
-- Mark the Run as Archived from the Manage Run Storage page

-- Step 3: Truncate the data in the following tables: WEBVDM70.OutputData_379, WEBVDM70.DRUG_INDEX_379, WEBVDM70.EVENT_INDEX_379
-- NOTE: Do NOT use the DROP TABLE command. The empty tables need to exist for the application to work properly
-- The truncation can be done using the oracle TRUNCATE or DELETE FROM commands:

TRUNCATE TABLE WEBVDM70.OutputData_379;
TRUNCATE TABLE WEBVDM70.DRUG_INDEX_379;
TRUNCATE TABLE WEBVDM70.EVENT_INDEX_379;

DELETE FROM WEBVDM70.OutputData_379;
DELETE FROM WEBVDM70.DRUG_INDEX_379;
DELETE FROM WEBVDM70.EVENT_INDEX_379;
```

Import data mining run data

- In the left navigation pane, click the **Settings** icon (.
- In the **Administer System** section, click **Manage Run Storage**.
- Click the **Row Action** menu () for the run, and then click **Import Run Data**.
- Follow instructions on the Import Run Data page, as shown in the following example:

```
--
-- To successfully de-archive run data, you may need DBA privileges for your database.
--

-- Step 1: Make sure the following tables current contain 0 rows:
-- WEBVDMESHTEST.OutputData_337, WEBVDMESHTEST.DRUG_INDEX_337, WEBVDMESHTEST.EVENT_INDEX_337

-- Step 2: Import the Run Data into empty run tables
-- Import the oracle data for the following tables: WEBVDMESHTEST.OutputData_337, WEBVDMESHTEST.DRUG_INDEX_337, WEBVDMESHTEST.EVENT_INDEX_337
-- This can be done using an Oracle IMPORT command similar to the one below:

IMP WEBVDMESHTEST/ <password>@<tns_name> ignore=y log=run_337_in.log file=run_337.dmp tables=(OutputData_337, DRUG_INDEX_337, EVENT_INDEX_337)

-- Step 3: Verify Row Counts for tables
-- Compare the row counts listed in the export and import logs.

-- Step 4: Clear the "Archived" flag for the Run
-- Clear the Archived flag for the Run from the Manage Run Storage page
```

Mark a data mining run as archived

On the [Data Mining Runs page](#), you can include an Archived column showing the setting of the Archive flag. You set the Archived flag on the Manage Run Storage page.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Administer System** section, click **Manage Run Storage**.
3. To set the Archive flag to **Yes**, click the **Row Action menu** () for the run, and then click **Set Archived Flag**. You can now import this run data.
4. To clear the Archive flag, click the **Row Action menu** () for a run with the Archived value of Yes, and then click **Clear Archived Flag**. You can now export this run data.

 Note

If the Archived flag for a run is set to Yes, the run description on the Data Mining Runs page starts with Archived. If the Archived flag is Yes for a run, you cannot view run results (except that you can view the complete results table on the [Data sources page](#)).

Move a data mining run with a Move script

Oracle Empirica Signal provides a SQL script that you can run to transfer the tables and indexes for a data mining run to a different tablespace. For example, you might want to move a frequently used run to its own tablespace to improve performance, or move a run to a different tablespace to facilitate archiving of the run at the tablespace level.

1. In the left navigation pane, click the **Settings** icon (.
2. In the **Administer System** section, click **Manage Run Storage**.
3. Click the **Row Action menu** () for the run, and then click **Create Move Script**.
The Move Run Script page now displays an SQL script.
4. Copy the SQL script and paste it into an ASCII text editor, such as Notepad.
5. Edit the script to define the destination tablespace for the run.
6. Save the script in a text file and execute it using Oracle tools.

Create a run definition file

A run definition file is an input file that can be used to execute MGPS and logistic regression data mining runs externally. The runs and results then appear in the Oracle Empirica Signal application. Only the execution of the runs occurs outside of the application. For more information about executing data mining runs externally, contact Oracle.

1. Perform one of the following: In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
 - In the left navigation pane, hover on the **Data Analysis** icon () , then click **Data Mining Runs**.
 - In the left navigation pane, click the **Settings** icon () , select **Manage signal Configurations**, then click **Manage Refreshes**.
2. Click the **Row Action menu** () for the run, and then click **Create Definition File**.

The definition input file appears.

Change user default data mining runs

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Administer System** section, click **Change User Default Runs**.
3. From the **Change the Default Run for users with a current Default Run** of drop-down list, select the default run to replace for all users. Click **Browse** to [find and select a run](#).
4. From the **to the following run** drop-down list, select the name of the run to replace the existing default run.
5. Click **Replace Default Run**.
6. Click **Continue**.

 Note

This option affects only current settings of user preferences.

Monitor the system

- [View currently logged in users](#)
- [View the user activity audit trail](#)
- [About auditing](#)
- [View the server status](#)
- [View free disk space](#)
- [View the batch report queue](#)
- [Truncate a report batch run](#)

View currently logged in users

The Current Users page provides the information about users in your login group who are currently logged into Oracle Empirica Signal.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Monitor System** section, click **View Currently Logged In Users**.

The Current Users page displays the following information about the currently logged in users:

Column	Description
User Name	Full name followed by the username in brackets.
Login Date	Date and time when the user logged in. The date and time format is set by the site administrator.
Session ID	Automatically assigned identifier for the user's Oracle Empirica Signal session.

Column	Description
IP	IP address of the computer from which the user connected to the application.

View the user activity audit trail

Administrators use the User Activity Audit Trail to view actions performed by users in their login group. You can filter this activity by username, activity, date, or any combination. The User Activity Audit Trail also includes the activities of deleted users.

1. In the left navigation pane, click the **Settings** icon (.
2. From the **Monitor System** section, click **View User Activity Audit Trail**.
3. From the **User** drop-down list, select a user, or to view activities for all users, select --.
Deleted users are denoted in the drop-down list with the (deleted) status appended to their usernames.
4. In the **Start Date** and **End Date** fields, specify a time period for which to include user activities, or before or after a specific date. Enter dates in the format MM/DD/YYYY, or click the **Calendar** icon () to select dates.
To include all activity for all users and activities, leave these fields blank.
5. Select the activities that you want to include in the report.
 - To include or exclude specific activities, select or clear activity check boxes (such as Login Failed).
 - To include or exclude all activities listed for the category, select or clear category check boxes (such as Authentication).
 - To include all activities, click **Check All**.
 - To clear all check boxes, click **Clear All**.

Note

To include Publish, Rename, and Copy activities, select the appropriate Edit activity.

6. Click **View User Activity**.

The User Activity Audit Trail provides the following information:

Column	Description
ID	Unique activity identifier.
Username	Username of the user who performed the activity.

Note

The report denotes deleted users by appending (deleted) to the username.

Column	Description
Session	Unique identifier for the user's Oracle Empirica Signal session.
IP Address	IP address of the computer used to connect to the application. In cases where the connected user is a system user, the IP address displays ::1 (local).
Activity Name	Category and name of the activity.
Activity Date	Date and time when the user activity occurred. The date and time format is determined by a site option , and by your time zone preference.
Additional Information	Details about the activity that was performed. This might include the name and unique identifier of an object where the identifier is in parentheses, such as CaseSeries=My Case Series(533). For system errors, an error ID appears. The Signal server log file contains the same error identifier and more details about the error. Note: The Additional Information field of an audit record may include more text than will fit in a single row of the table. In this case, the record will overflow across multiple rows, creating additional entries in the table as needed to show the complete record. Each entry will have a unique ID. The Additional Information cell will begin with the text "Part [x] of [total]" to indicate the total number of rows showing the complete record.

For information about viewing, printing, or downloading tables or changing the way data displays in the User Activity Audit Trail, see [About tables](#).

About auditing

The Oracle Empirica Signal Auditing feature tracks user activity that occurs in the application. Auditing captures detailed information about user actions, such as data run creation, that provides you with an easily accessible, historical account of user activity occurring in the following signal categories:

- Authentication
- Errors
- Administration
- Login Groups
- Users
- Aliases
- Case Series, Queries
- Configurations
- Data Mining Runs
- Reports
- Saved Lists

- Subscription Data Releases (only used by Oracle Empirica Signal Cloud Service)
- View Results
- Drug Profiles
- Signals
- Signal Administration
- Signal Reviewer
- Topics
- Topic Administration

Note

Auditing occurs automatically. You do not need to install or enable the auditing feature.

An administrator can access audited user activity by viewing the User Activity Audit Trail and use the information to:

- Trace actions by one or more users over time.
- Monitor configuration modifications.
- Monitor permission or authentication issues.
- Monitor administration changes.
- Troubleshoot errors.
- Identify suspicious activity or security incidents.
- Identify any violations in policies and procedures.

Using the User Activity Audit Trail, you can better enforce your company's security policy and assist users with errors or issues.

Oracle Empirica Signal maintains audited user activity indefinitely. You cannot modify or delete user activity through Oracle Empirica Signal.

View the server status

Within the Oracle Empirica Signal application, two types of computer processing occur:

- Foreground or interactive processing, such as the specification of runs.
- Background or batch processing, such as the execution of runs.

If you are running on a single-processor server, that processor must perform both types of processing. If you are running on a multi-processor server, you can control how the available processors are used to perform foreground or background processing.

On the Server Status page, you to set the maximum number of processors to use for background processing; that is, the number of concurrent runs that can be performed. For a dedicated server, Oracle recommends that you set the maximum to one less than the number of processors that are on the server. For a shared server, Oracle recommends a smaller number of maximum processors.

For example, if there are three processors on a dedicated Oracle Empirica Signal server, and you set the maximum number of processors to 2, then two runs can run at the same time.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Monitor System** section, click **View Server Status**.
3. In the **Maximum Processors** field, type the maximum number of processors for the server listed.
4. Click **Save**.
5. Click **Continue**.

View free disk space

The option to view free disk space is intended for users who are familiar with Oracle storage mechanisms.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Monitor System** section, click **View Free Space**.
3. From the **Tablespace** drop-down list, select an Oracle tablespace.

View the batch report queue

The Report Batch Runs page provides information about reports that are run in batch mode. It is intended for troubleshooting any problems related to batch reports in conjunction with Oracle.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Monitor System** section, click **View Batch Report Queue**.

From this page, you can [truncate report batch runs](#), delete the report batch run, and view the jobs for a run. When viewing the jobs for a report batch run, you can also view detailed information, including log files, for the job.

Truncate a report batch run

This feature is intended for use in conjunction with Oracle.

1. In the left navigation pane, click the **Settings** icon (⚙️).
2. In the **Monitor System** section, click **View Batch Report Queue**.
3. In the top left corner, click **Truncate**.
4. In the **Truncate Runs completed before** field, select the date before which completed runs should be truncated.
5. Click **Truncate**.

Set up saved lists

- [About saved lists](#)
- [Saved Lists page](#)
- [Create or edit a saved list](#)
- [Add saved lists in bulk](#)
- [View or print a saved list](#)

- [Set permissions for a saved list](#)

About saved lists

A saved list is a list of up to 1,000 drug or event terms that have been grouped together and saved. Once you have created a saved list, you can refer to the list instead of specifying the individual terms. For example, if you have saved antipsychotic drugs in a list, you can refer to that list elsewhere when you need a list of antipsychotic drugs.

In most places where you can select values for a drug or event variable (for example, when selecting criteria to view data mining run results), you can create a saved list from the values that you have selected. You can also create or edit saved lists by clicking the **Settings** icon () in the left navigation pane, and then clicking **Manage Saved Lists**.

Saved Lists page

On the Saved Lists page, you can view saved lists that you have created or for which you have the edit permission. The page displays saved lists created by all users in your login group if you have the Administer Users permission.

General activities

The following links appear at the top of the page and affect the entire page:

- [Create Saved List](#)
- [Add Lists In Bulk](#)
- [Back](#)
- [Columns](#)
- [Print](#)
- [Download](#)

The following filters appear at the top of the page and affect the rows displayed in the table:

- [Project](#)
- [Configuration](#)

Row-specific activities

The following menu options are available from the **Row Action menu** () , and affect an individual row in the table:

- [View](#)
- [Edit](#)
- [Set Permissions](#)
- [Delete](#)

Field descriptions—Saved List page

Field	Description
Name	Name of the saved list.
Description	Description of the saved list.

Field	Description
Project	Name of the project to which the saved list is assigned.
Configuration	Name of the data configuration on which the saved list is based. If the saved list is based on a run, the name of the data configuration used by the run appears.
Created By	Name of the user who created the saved list.
Created On	Date and time the saved list was created.
# of Terms	Number of terms included in the saved list.
ID	Identifier the application automatically assigns when the saved list is created. Each saved list ID is unique and is not re-used if you delete the saved list.
List Type	Type of variable to which the saved list is attached. Possible values are Drug, Event, and Item.
Modified	Date and time when the saved list was last modified.
Modified By	Name of the user who last modified the saved list.
Variable	Name of the variable for which the saved list contains terms.

Create or edit a saved list

Most dialog boxes from which you can select values for drug or event variables, such as when browsing and selecting terms from a [hierarchy](#), include a **Save As List** button to create a saved list from the values that you have selected.

You can also create a saved list from scratch and edit a saved list.

1. In the left navigation pane, click the **Settings** icon (.
2. Click **Manage Saved Lists**.
3. Perform one of the following:
 - To create a saved list, click **Create Saved List**.
 - To edit a saved list, click the **Row Action menu** () for a saved list, and then click **Edit**.
4. In the **Name** field, enter the name for the list.
5. In the **Description** field, enter a description of the list.
6. Assign the saved list to a [project](#).
 - To assign the saved list to an existing project, click **Add to existing project** and select a project from the drop-down list of projects associated with objects that you created or that are published to you.
 - To create a new project and assign the saved list to it, click **Add to a new project named** and enter a project name.
7. From the **Configuration** drop-down list, select a configuration, or click **Browse** to browse for a configuration.

8. From the **Associated Variable** drop-down list, select a variable to associate with the saved list. The list includes variables that have a Variable Type of Drug, Event, or Generalized Item in the data configuration.
9. Enter values for the saved list.
 - Click **Select Available Values**. For more information, see [Select values from the list](#).
 - Click **Select ATC Terms** or **Select MedDRA Terms** (if the selected variable has an associated hierarchy). See [Select hierarchy terms](#).
 - [Type the values](#) (or copy them from elsewhere and paste them in). For example, you can include custom terms that were used in a data mining run.

Note

To prevent spelling and capitalization errors, Oracle recommends that you select rather than type values.

10. To verify that the specified values match values in the source data, check the Validate list when saving. If any of the terms do not have a matching value in the source data, a warning message appears and the unmatched values appear at the end of the list. You can save all values, even if discrepancies are found, except for duplicates that get removed.

Note

If you create a saved list by saving values during viewing of data mining results, the list might include custom terms. For the custom terms, no matches are found in the source data. However, matches are found when the saved list is used to select drugs or events to view data mining results that include those custom terms.

11. Click **Save**.

The saved list is available when you [select results criteria](#) for a run that is based on the same data configuration or create a query using the variable with which the saved list is associated. To make your list available to other users, [set permissions](#) for it.

Add saved lists in bulk

On the [Saved Lists page](#), the **Add Lists in Bulk** option enables you to add multiple saved lists at the same time. You can use this feature only if you are a superuser. If you are interested in using this feature, contact Oracle.

1. In the left navigation pane, click the **Settings** icon (.
2. Click **Manage Saved Lists**.
3. Click **Add Lists in Bulk**.
4. On the **Saved List Bulk Entry** page, enter the configuration or click **Browse** to select a configuration.
5. From the **Variable** drop-down list, select a variable.
6. In the **List_Name List_Value** text box, enter the contents of one or more saved lists.
Each line must contain a List_name and List_value, separated by a tab.
7. Click **Save**.

Note

The content you entered is not validated.

View or print a saved list

You can view or print the variables and terms included in a saved list. For more information about saved lists, see [About saved lists](#).

1. In the left navigation pane, click the **Settings** icon (.
2. Click **Manage Saved Lists**.
3. Click the **Row Action menu** () of the saved list.
4. To view the list, click **View**.
5. (Optional) To print the terms and other information for the saved list, click **Print** to access the Windows Print Window.

Set permissions for a saved list

Users with the Read permission can [select a saved list](#) for use during certain activities. Users with the Edit permission can select the saved list, as well as edit, modify permissions for, or delete the saved list on the Saved Lists page.

1. In the left navigation pane, click the **Settings** icon (.
2. Click **Manage Saved Lists**.
3. Click the **Row Action menu** () of the saved list, and then click **Set Permissions**.
The Saved Lists Permissions dialog box has two sections. The Group Permissions applies to your login group. The Individual Permissions section includes individual users in your login group. Superusers see all login groups.
The permissions you can select are No Access, Read, or Edit.
4. To grant permissions to a [login group](#), click **No Access**, **Read**, or **Edit**. The selected permission applies to all members of the login group.
5. To grant permissions to individual users in your login group, in the **Individual Permissions** section, click **No Access**, **Read**, or **Edit** next to each username.
User permissions for a saved list are determined by settings for both the individual user and the user's login group. For example, if the individual user has Read access but that user's login group has Edit access, the user has Edit access.
6. Click **Save**.

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Change log

Date	Part number	Description
October 2025	G38256-03	Updated some backend structural elements that don't impact the information in this publication.

Date	Part number	Description
October 2025	G38256-02	Fixed the following bugs: 33636305, for more information see the updated topic Set your user preferences. 32568734, for more information see the updated topic Make a topic template visible to a work team. Documented the following enhancements: 37308880, for more information see the updated topic View details of a data mining run. 33910100, for more information see the updated topics Overview of setting up a topic workflow configuration, Import the sample GVP Module IX topic workflow configuration, Preconfigured topic workflow configurations, Sample topic workflow configuration. 34707490, for more information see the updated topic Delete a login group. 36054788, for more information see the updated topics Edit a signal configuration, Generate a predefined topic report in Oracle Analytics, Predefined Oracle Analytics topic reports. 35407129, for more information see the new topics Your Home page is your starting point, The Tasks section shows signal management and topics tasks assigned to you, The Source Data section summarizes the recency of both data sources and signal management configurations, Configure your Home page. 35393343, for more information see the updated topic Edit a signal configuration. 23214915, for more information see the updated topic Edit a signal configuration. 20402302, for more information see the updated

Date	Part number	Description
		topics Enter a note about a product, Add a comment, Submit a review for a product-event combination, Add a signal comment type, Add annotations to a specific case in a case series. Documented the following documentation bugs: • 37169373 and 37169359, for more information see the updated topic View annotations for a case series. • 36540108, for more information see the updated topic Create or edit an alert type. • 37994387, for more information see the updated topic Edit a signal configuration. • 37976462, for more information see the updated topics Sections of the Topic Management page, Define the set of topics to work with, View actions on the calendar.