Oracle Health Sciences Empirica Signal

Release Notes

Release 9.1.0.8

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Oracle Health Sciences Empirica Signal Release Notes, Release 9.1.0.8

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Preface

This preface contains the following sections:

- Documentation accessibility
- Related resources
- Access to Oracle Support
- Additional copyright information

Documentation accessibility

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- Japanese interface of Oracle Health Sciences Customer Support Portal (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

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1

System requirements

- Client computers
- Application server
- Database server
- Reporting server

Client computers

- Software for client computers

Software for client computers

Component	Requirements
Operating system	Microsoft Windows 10
Internet browsers	Google® Chrome (latest public version) Microsoft® Edge (version 88 or later) Microsoft® Internet Explorer 11
Tools for downloading data	Any or all of the following tools for downloading data: • Adobe Acrobat Reader. • Microsoft Excel, for XLS or XLSX. • Microsoft Word, for RTF files. • SAS System Viewer, for XPT files. • Base SAS, for SAS files. • A ZIP archive manager.

Application server

- Minimum hardware for the application server
- Software for the application server

Minimum hardware for the application server

Component	Description
Processor	64-bit Intel 6-core 2.8 GHz or higher processor. Actual requirements are based on the size of the dataset and the expected number of concurrent users.

Component	Description
Memory	6 GB RAM. Actual requirements are based on the size of the dataset and the expected number of concurrent users.
Disk storage	600 GB for data. Actual requirements are based on the size of your dataset.
Connectivity	1 GB recommended.

Software for the application server

Component	Description
Operating system	Oracle Linux 7.6 or later.
Software	• Oracle Database Client that matches your database version. Select either the developer or the full installation option. The installation must include the SQL*Loader (sqlldr) utility. • WebLogic 12.2.1.3 (includes ADF runtime) with Java 8. • Required only if you plan to use single sign-on: – OAM WebGate, OHS version 12.2.1.3.

Database server

- Minimum hardware for the database server
- Software for the database server

Minimum hardware for the database server

Component	Description
Processor	64-bit Intel 2-core 2.8 GHz or higher processor. Actual requirements are based on the size of the dataset and the expected number of concurrent users.
Memory	16 GB RAM. Actual requirements are based on the size of the dataset and the expected number of concurrent users.
Disk storage	1.2 TB for data. Actual requirements are based on the size of your dataset.
Connectivity	1 GB recommended.

Software for the database server

Component	Description
Operating system	Oracle Linux 7.6 or higher.
Software	Oracle Database 18c, 19c, or Oracle Database 12c These databases are supported with the following installation options: • Block size: 8k • Character set: AL32UTF8 • NLS_LENGTH_SEMANTICS: BYTE • EZ Connect

Reporting server

- Software for the reporting server

Software for the reporting server

A reporting server is required if you plan to use Oracle Business Intelligence Enterprise Edition (OBIEE) with the Oracle Empirica Signal application.

Component	Description
Software	• 64-bit Oracle Business Intelligence Enterprise Edition (OBIEE) release 12c (12.2.1.4). • JDK 8 with Java Cryptography Extension (JCE) Unlimited Strength Jurisdiction Policy Files. • Oracle Business Intelligence Developer Client Tools, 64-bit or 32-bit. The client tools are for use only with Microsoft Windows. To download the tools from your OBIEE instance, click the **Download BI Desktop Tools** link, and then select **Oracle BI Client Installer**, either 64-bit or 32-bit.

2

Changes in the 9.1.0.8 release

This release includes changes to improve security as well as the following bug fixes.

- Issues fixed

Issues fixed

- Download
- Drug profiles

Download

- 35088601 - Downloading case details from the PEC table can take a long time or not work at all

35088601 - Downloading case details from the PEC table can take a long time or not work at all

Before

Downloading case details sometimes was extremely slow or failed with a time-out error.

After

Performance when downloading case details has improved.

Drug profiles

- 34175685 - 2D MGPS runs with RGPS with interactions are listed as 3D runs in DPCs and in Browse

34175685 - 2D MGPS runs with RGPS with interactions are listed as 3D runs in DPCs and in Browse

Before

In drug profile configurations and when browsing data mining runs, 2D MGPS runs with RGPS enabled with interactions were listed as 3D runs.

After

2D MGPS runs with RGPS enabled with interactions are listed as 2D runs.

3

Changes in the 9.1.0.7 release

- 33820060 - Editing topics from the Actions tab saves incorrect topic information

33820060 - Editing topics from the Actions tab saves incorrect topic information

Before

If the topic editor was opened from the Actions tab and there were unsaved edits to the Topic General Information of a different topic, then under certain circumstances the wrong Topic General Information was displayed and could have been saved.

After

When opening the topic editor from the Actions tab, the Topic General Information displays correctly.

4

Changes in the 9.1.0.6 release

- Enhancements
- Issues fixed

Enhancements

- Change RGPS Minimum Lambda parameter from 1.3 to 1.0 for RGPS (33556978)

Change RGPS Minimum Lambda parameter from 1.3 to 1.0 for RGPS (33556978)

Based on feedback from recent collaborative research observing RGPS scores with significant case data changes over time, two advanced modelling parameters can be set in the Signal environment: Minimum and Maximum Lambda. These affect the selection of predictors (i.e., set of contributing drugs) to be included in the regression model.

Lowering the Minimum Lambda parameter causes the algorithm to potentially include more predictors (that are positively correlated with the target event) to the adjustment regression. In this context, the Minimum Lambda parameter default was changed from 1.3 to 1.0; this has been found to increase the stability of RGPS results over time by lessening the chance of omitting an important predictor.

The Maximum Lambda parameter regulates the inclusion of predictors that are negatively correlated with the target event. The default value (unchanged in this release) is 0.3; raising that value would potentially allow more predictors that are negatively correlated with the target event to enter the regression model.

Issues fixed

- Signal management
- Topic management

Signal management

- 33440691 - Data is not refreshed in UI after completion of Scripted Signal Management refresh

33440691 - Data is not refreshed in UI after completion of Scripted Signal Management refresh

Before

After a Scripted Signal Management refresh, the data was not refreshed on the Signal Review page, even after re-login.

After

Data is refreshed in UI after a Scripted Signal Management refresh without re-login.

Topic management

- 33523057 - Topic table attachments cannot be added via Topics API when there are newlines in the XML
- 33596087 - Save on Manage Topic Field Accessibility by State can cause blank screen
- 33647546 - LR run fails with long drug name

33523057 - Topic table attachments cannot be added via Topics API when there are newlines in the XML

Before

Topic Table attachments formatted with newlines in the XML could not be added to a Topic using the Topics API.

After

Topic table attachments formatted with newlines in the XML can now be added to a Topic using the Topics API.

33596087 - Save on Manage Topic Field Accessibility by State can cause blank screen

Before

If a topic workflow configuration had many topic states and many custom fields and changes were made on the Manage Topic Field Accessibility by State page, then a blank screen appeared after clicking Save. Changes were Saved but the application did not return the user to the Manage Fields page as expected.

After

Saving changes on the Manage Topic Field Accessibility by State page returns the user to the Manage Fields page as expected.

33647546 - LR run fails with long drug name

Before

LR data mining runs may have failed if a drug name was longer than 255 characters.

After

LR data mining runs do not fail due to long drug names.

5

Changes in the 9.1.0.5 release

- Enhancements
- Issues fixed

Enhancements

- Handle special characters in topic comments and attachments (28057529)

Handle special characters in topic comments and attachments (28057529)

When a topic is displayed, any invalid characters in its attachments or comments are removed and replaced with the Unicode black square character (■).

Issues fixed

- Case series
- Topic management

Case series

- 33445267 - Case Series report generation is very slow

33445267 - Case Series report generation is very slow

Before

Case series report generation was taking an excessively long time to complete.

After

Case series report generation performance is improved.

Topic management

- 33447352 - Reopen Topic displays the details of the topic previously edited

33447352 - Reopen Topic displays the details of the topic previously edited

Before

When reopening a topic or action, the Reopen window displayed incorrect details if another topic or action was open for edit.

After

When reopening a topic or action, the Reopen window displays the correct details.

6
Changes in the 9.1.0.4 release

- Enhancements
- Issues fixed

Enhancements

- Administration
- Signal management

Administration

- Add Topics Server status information to About page for superusers (32867441)

Add Topics Server status information to About page for superusers (32867441)

If you are a superuser and Oracle Empirica Topics is configured, the About page for Oracle Empirica Signal now includes Topic Server status information.

Signal management

- Add Vigibase Interactive Signal Management (32498046)
- 32872317 - Add Product page is not showing all product fields after SSM to ISM conversion

Add Vigibase Interactive Signal Management (32498046)

Vigibase Interactive Signal Management is being introduced in Oracle Empirica Signal 9.1.0.4. Vigibase Interactive Signal Management requires Vigibase data 2018Q2 or later but can be used with any 9.x release of Oracle Empirica Signal. This patch introduces a configuration script for Vigibase Interactive Signal Management.

Issues fixed

- Signal management
- Signal review
- Subscription data releases in the Oracle Cloud

Signal management

- Add Vigibase Interactive Signal Management (32498046)
- 32872317 - Add Product page is not showing all product fields after SSM to ISM conversion

32872317 - Add Product page is not showing all product fields after SSM to ISM conversion

Before

When a scripted signal configuration was converted to an interactive configuration, the Add Product page did not include the following product fields: Display name, Category, Complexity level, Birthdate, and Organization.

After

All product fields display on the Add Product page after converting a signal configuration from scripted to interactive.

Signal review

- 32543608 - Row Action Menu: View Interactions does not appear when there are two or more interaction runs

32543608 - Row Action Menu: View Interactions does not appear when there are two or more interaction runs

Before

When two or more interaction runs were configured for a Signal Management configuration, the Row Action menu on the Product-Event Combinations page did not include any View Interactions menu items.

After

The Row Action menu on the Product-Event Combinations page now includes View Interactions menu items for each interaction run configured for the selected Signal Management configuration.

Subscription data releases in the Oracle Cloud

- 32626348 - Configuration and report output aliases not getting updated with shared data import

32626348 - Configuration and report output aliases not getting updated with shared data import

Before

When subsequent releases of subscription data were imported into Oracle Empirica Signal, configuration aliases and report output aliases may not have been updated.

After

After subscription data is imported, configuration aliases and report output aliases are targeted to the most recent release of the data.

7

Changes in the 9.1.0.3 release

- Empirica Signal April 2021 CPU Update

Empirica Signal April 2021 CPU Update

This patch addresses the issues described in the April 2021 CPU update.

8
Changes in the 9.1.0.2 release

- Enhancements
- Issues fixed

Enhancements

- Administration
- Subscription data releases in the Oracle Cloud
- User interface

Administration

- Add Topics Service information to About page for superusers (32381005)

Add Topics Service information to About page for superusers (32381005)

If you are a superuser, the About page for Oracle Empirica Signal now includes the Topics Service URL if Topics is configured.

Subscription data releases in the Oracle Cloud

- Remove need to re-login after subscription import (32341196)

Remove need to re-login after subscription import (32341196)

Configurations and, if requested, runs and reports that come with a subscription import are immediately available to logged-in users.

User interface

- Support for Microsoft Edge reflected in Login, Home, and About pages (32442319)

Support for Microsoft Edge reflected in Login, Home, and About pages (32442319)

Oracle Empirica Signal now supports the Microsoft Edge browser.

Issues fixed

- Signal review
- Topic management

Signal review

- 32345352 - Performance issue in Select Topic window when there are a lot of topics (Submit Review)

32345352 - Performance issue in Select Topic window when there are a lot of topics (Submit Review)

Before

The Select Topic window, when accessed from Submit Review, could be slow to display when there were many topics.

After

The performance has improved.

Topic management

- 30897576 - Topic or Action with null Assignee does not appear in some OBIEE reports
- 32345049 - Add Topic Link is incorrectly displaying topics for which the user has View Topic permission
- 32345087 - Add Topic Link page download does not include first column
- 32345100 - Add Topic Link window is blank if the table includes any unassigned topic
- 32471775 - Add Topic Link table may display with already linked topics

30897576 - Topic or Action with null Assignee does not appear in some OBIEE reports

Before

Topics or Actions with no assignment were not included in OBIEE reports that should have included all topics or actions.

After

Topics or Actions with no assignment are now included in OBIEE reports, as expected.

32345049 - Add Topic Link is incorrectly displaying topics for which the user has View Topic permission

Before

In the 9.1.0.1 release, the Add Topic Link window, which required the user to have Edit Topic permission, incorrectly included topics for which the user had only View Topic permission.

After

The Add Topic Link window now correctly displays only topics for which the user has Edit Topic permission.

32345087 - Add Topic Link page download does not include first column

Before

In the 9.1.0.1 release, the downloaded Add Topic Link table excluded the first column.

After

The first column of the Add Topic Link table now downloads.

32345100 - Add Topic Link window is blank if the table includes any unassigned topic

Before

The following issue occurred only in the 9.1.0.1 release when there was a topic with a null Assigned to value.

When the topic workflow configuration was configured such that the topic's Assigned to field was filterable but not required, and the Add Topic Link table would have included an unassigned topic, then the Add Topic Link window was blank.

After

The Add Topic Link window displays correctly.

32471775 - Add Topic Link table may display with already linked topics

Before

In the 9.1.0.1 release, if a topic had links to other topics, those other topics were sometimes included in the Add Topic Link table.

After

A topic's Add Topic Link table does not display topics that are already linked to it.

9

Changes in the 9.1.0.1 release

- Issues fixed

Issues fixed

- Subscription data releases in the Oracle Cloud
- Topic management
- User interface

Subscription data releases in the Oracle Cloud

- 32155623 - Release Notes not accessible

32155623 - Release Notes not accessible

Before

If the Oracle Empirica Signal instance used an Oracle 12.1.0.2 database, then choosing **View Release Notes** from the **Row Action** menu ( ) opened a window with the following message “Release notes not found.”

After

View Release Notes now opens a window with the PDF version of the data period’s Release Notes.

Topic management

- 32217446 - If Topic or Action Name field not visible, topics or actions table does not display
- 32252899 - Performance issue in Add Topic links when there are a lot of topics
- 32267828 - Performance issue in Select Topic window when there are a lot of topics (Save to Topic)

32217446 - If Topic or Action Name field not visible, topics or actions table does not display

Before

If the **Topic Name** field in the topic workflow configuration was not visible and topics were created without topic names, the Topics table on the Topics tab on the Topic Management page did not display.

Similarly, if the **Action Name** field in the topic workflow configuration was not visible and actions were created without action names, the Actions table on the Actions tab on the Topic Management page did not display.

After

Now, tables on the Topics and Actions tabs on the Topic Management page display even when the **Topic Name** or **Action Name** fields are null.

32252899 - Performance issue in Add Topic links when there are a lot of topics

Before

The Add Topic Link page could be slow to display when there were many topics.

After

The performance has improved.

32267828 - Performance issue in Select Topic window when there are a lot of topics (Save to Topic)

Before

The Select Topic window, when accessed from the Save to topic page, could be slow to display when there were many topics.

After

The performance has improved.

User interface

- 32133566 - Topic Management and/or Signal Review pages sometimes do not display
- 32214582 - Improve the performance of building the Project selectors

32133566 - Topic Management and/or Signal Review pages sometimes do not display

Before

Sometimes, when you first navigated to the Signal Review or Topic Management page, the left navigation pane and the right pane did not display. This occurred when you selected **Signal Review** or **Topic Management** from the left navigation pane while on the Home or Feedback page, one of the Settings pages, or one of the Data Analysis pages. This also occurred upon login if your preference **On login, display this page** was set to Signal Review or Topic Management. The problem did not occur when navigating between the Signal Review and Topic Management pages.

After

The left navigation pane and right pane always display when first navigating to the Signal Review or Topic Management page.

32214582 - Improve the performance of building the Project selectors

Before

In certain situations, the page to create or edit a new object loaded slowly. This was due to the system inefficiently generating the list of existing projects presented in the page's **Add to existing project** field. A user with a large number of report definitions, report outputs, queries, case series, saved lists, or topics was more likely to encounter the slow performance.

After

The performance has improved.

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Changes in the 9.1 release

- Enhancements
- Issues fixed

Enhancements

- Administration
- Documentation
- Signal review
- Subscription data releases in Oracle Cloud
- Topic management

Administration

- Database password (25340825)

Database password (25340825)

When the Oracle Empirica Signal Database account password is changed in the credential store, Oracle Empirica Signal automatically retrieves and applies the new password. There is no longer a need to restart the application.

Documentation

- New look and feel for documentation (31241605)

New look and feel for documentation (31241605)

The next time you click the Help link within Oracle Empirica Signal, you might notice a few changes to the help topics and the Oracle Help Center pages, including a new look and feel for the site and many of the guides. It's still the same great content you've come to depend on, just in a new format. And if you like being able to print paper copies, you're in luck: PDFs are now available for most books on the Books page.

Signal review

- Add optional detailed comment column to the Product-Event Combinations table (31170755)

Add optional detailed comment column to the Product-Event Combinations table (31170755)

If you enable the **Allow Free Text Signal Comments** site option, you can include a **Detailed Comment** column in the Product-Event Combinations table.

Subscription data releases in Oracle Cloud

- Enable customers to manage public data subscriptions through the user interface (30874637)

Enable customers to manage public data subscriptions through the user interface (30874637)

Oracle Empirica Signal 9.1 supports access to the Oracle public safety data library. After enabling the feature for a customer Cloud environment, sufficiently privileged users are provided with the new self-service Subscription Data Releases administration page in the Oracle Empirica Signal user interface to manage their data subscriptions. This allows activating access to new data releases as soon as they become available, without the need to wait for data loading or completion of standard runs.

Topic management

- New Topic Management design (30595427)
- Allow user to switch topic workflow configuration without logging out (30595442)
- Allow topic/action assignment to work teams (30874627)

New Topic Management design (30595427)

The Topics page has been redesigned for improved user experience.

- Easily see all topics/actions assigned to you or your work team by using the **View items for** selector.
- View all actions across all topics without having to open each topic.
- View actions that are overdue or upcoming using the Calendar tab.
- View a preview of a topic or action in the Detail panel.
- Quickly view topics that you have recently viewed or edited.
- Filter topics or actions based on any filterable field. Now you can filter by multiple values such as multiple states.
- View the distribution of topics or actions in a graph for any filterable field.
- Edit and view topics and actions in dedicated popup windows.

Allow user to switch topic workflow configuration without logging out (30595442)

Users with access to multiple topic workflow configurations can now change their selected topic workflow configuration using the new drop-down list at the top of the Topic Management page. Users will still be able to change their preferred topic workflow configuration on their Preferences page.

Allow topic/action assignment to work teams (30874627)

You can now assign a topic or action to a work team. This enables users to access a central location to view the topics or actions that require attention from members of the work team. Users can then re-assign the topic or action to an individual user of the work team to process.

To limit work team access to topics and actions, two work team properties have been added:

- **Allow topic visibility:** Controls the availability of the work team in the **Visible to work team(s)** selector when creating and editing topics and topic templates.
- **Allow assignment of topics and actions to work teams:** Controls whether the work team is available in the **Assigned to** field for a topic or action.

Issues fixed

- Administration
- Data mining
- Documentation
- Installation and configuration
- Reporting
- Signal review
- Topic management
- User interface

Administration

- 22493907 - User Profile Preferenced SMC and TMC are not saved
- 30858821 - Restart Listener does not always restart the listener
- 30882210 - Oracle Empirica Signal application heartbeat time not changing

22493907 - User Profile Preferenced SMC and TMC are not saved

Before

User Profile Preference values for Signal Management Configuration and Topic Workflow Configuration fields were not being set when the user profile was applied to a user.

After

User Profile Preference values for Signal Management Configuration and Topic Workflow Configuration fields are being set when applied to a user with access to the configurations and sufficient user permissions.

30858821 - Restart Listener does not always restart the listener

Before

The manual Restart Listener feature did not always restart the listener.

After

Now, it always restarts the listener.

30882210 - Oracle Empirica Signal application heartbeat time not changing

Before

On restart, under some situations data mining runs would not start.

After

On restart, data mining runs start normally.

Data mining

- 26330438 and 26669169- Failure to auto restart listener after listener crash
- 31241293 - Logistic Regression: Select Events text area is not disabled

26330438 and 26669169- Failure to auto restart listener after listener crash

Before

Unexpected error conditions may cause the listener to halt execution and prevent new runs from being picked up for processing.

After

Oracle Empirica Signal restarts the listener after failures.

31241293 - Logistic Regression: Select Events text area is not disabled

Before

When you create a logistic regression data mining run and choose **Select all available values** on the Logistic Regression: Select Events page, the text box would incorrectly become enabled if you navigated back to the page.

After

Now, the text box remains disabled when you choose **Select all available values** on the Logistic Regression: Select Events page.

Documentation

- 31079971 - PRR_CHISQ formula has format issue on PRR_Computations.htm

31079971 - PRR_CHISQ formula has format issue on PRR_Computations.htm

Before

Superscripts for squared values in the PRR_CHISQ formula shown in step 4 and the PRR_CHISQUARE formula in the Yates correction section of the *PRR Computations* topic in the Oracle Empirica Signal *User Guide and Online Help*, were not displayed as superscripts.

After

The PRR_CHISQ and PRR_CHISQUARE formulas presented in the *PRR Computations* topic in the Oracle Empirica Signal *User Guide and Online Help* have been modified to show superscripts as appropriate.

Installation and configuration

- 30467915 - AM 8.2 ETL fails when running Utils.Populate_smqmap_casescore

30467915 - AM 8.2 ETL fails when running Utils.Populate_smqmap_casescore

Before

A character length mismatch between the Oracle Argus Mart Version 8.2 variable *total_dose_unit_ve* and Oracle Empirica Signal 8.1.1.1 caused initial *ETL* failure of *Argus Mart ETL.*

After

The mismatch has been fixed and the *sm_product.total_dose_unit_ve* now allows up to 70 characters.

Reporting

- 31381331 - Report configuration compatibility is broken

31381331 - Report configuration compatibility is broken

Before

In previous releases, the available reports included reports that were not compatible with the variables in the configuration of the selected case series.

After

Now, only compatible reports are displayed.

Signal review

- 30386749 - Some Signal Review windows use Drug instead of Product
- 31316427 - Performance issue in Submit Review when there are a lot of topics

30386749 - Some Signal Review windows use Drug instead of Product

Before

In the Oracle Empirica Signal 9.0 release, the word "Drug" was replaced with the word "Product" in the Signal Review module. However, the replacement was not made on some Signal Review pages.

After

The word "Drug" has been replaced by "Product" on these pages:

- Enter Product Notes
- View Product Notes
- View Event Comments
- Modify Automatic Assignments
- Auto-Assign to Reviewers
- View Source Details
- Audit trail from View a Sector Map from Products page
- Audit trail from Enter Note from Products Page

31316427 - Performance issue in Submit Review when there are a lot of topics

Before

When the user is not a superuser and there are many topics, performance of Submit Review could be slow.

After

Now, the performance has been improved.

Topic management

- 27010239 and 27010306 - Orphan records found after TWC field deletion preventing copy
- 27045275 - Adding/removing a topic link not updating topic's Modified/Modified By fields
- 27045302 - Changes in Action General Information does not update the topic's Modified field
- 27051144 - Topic history in PDF export file is illegible
- 30412363 - Save to Topic can save to wrong topic workflow configuration if user switches preference
- 31591202 - Resolution dates in Oracle Analytics reports included time component

27010239 and 27010306 - Orphan records found after TWC field deletion preventing copy

Before

Under certain conditions, deleting fields from a topic workflow configuration caused issues when the configuration was copied or imported.

After

Topic workflow configurations that have had fields deleted can be copied and imported without issues.

27045275 - Adding/removing a topic link not updating topic's Modified/Modified By fields

Before

Adding and removing a topic link does not update the topic's **Modified** and **Modified By** fields.

After

Now, the **Modified** and **Modified By** fields are updated correctly.

27045302 - Changes in Action General Information does not update the topic's Modified field

Before

Changes on the Action General Information page did not update the topic's **Modified** and **Modified By** fields.

After

Now, when the Action General Information is updated, the topic's **Modified** and **Modified By** fields are updated in the following tables:

- Topics table
- Actions table
- Action History table

27051144 - Topic history in PDF export file is illegible

Before

Starting with the 8.x release, and as an enhancement for 21CFR11 compliance, when exporting a topic to PDF on the Topic Management page, the Topic History section of the Change log contained all topic fields. If the topic workflow configuration defined numerous fields, the information often became illegible.

After

Instead of displaying all the fields, the Topic History table in the PDF file now displays a small set of standard fields and a new column, **Other Changes**, that summarizes other changes to the General Information.

30412363 - Save to Topic can save to wrong topic workflow configuration if user switches preference

Before

If you opened the Save to Topic window and then changed your topic workflow configuration, the attachment may be saved to the new configuration rather than the configuration in use when the Save to Topic window was initially opened.

After

If you select **Save to Topic** and then switch to a different topic workflow configuration, when you click **OK**, an error message is now be displayed. You must close and re-open the Save to Topic window to save to the latest topic workflow configuration.

31591202 - Resolution dates in Oracle Analytics reports included time component

Before

In the Topics by State and Actions by State reports, some date fields also included a non-meaningful time component.

After

Now, only dates and not times are displayed in Oracle Analytics reports.

User interface

- 30192719 - Pages that do not display correctly in IE with Compatibility mode on

30192719 - Pages that do not display correctly in IE with Compatibility mode on

Before

When using IE with compatibility mode on, some pages did not display correctly.

After

Compatibility mode has been turned off for the affected pages. The pages now display correctly.

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Changes in the 9.0 release

- Enhancements
- Issues fixed

Enhancements

- Enhancements in Empirica Signal 9.0
- Signal management
- User interface

Enhancements in Empirica Signal 9.0

Oracle Empirica Signal is now part of the Oracle HSGBU Cloud (SaaS) offering for medical product safety and pharmacovigilance. Oracle Empirica Signal version 9.0 has the following new features and characteristics.

- Browser support has been enhanced. Oracle Empirica Signal now runs in Google Chrome.
- The new user interface for Signal Review has a modern, visual approach that places all features at your fingertips. The Products and Product-Events Combinations pages provide an overview of all signaling activities. Reviewers can immediately assess review completeness for all products or specific product groupings. The new interface includes multiple indicators for items that require personal attention from the user, such as product-event combinations with alerts that require review. Graphical representations help the user visualize and prioritize their activities.
- The existing signal alert concept has been enhanced.
  Graphical and tabular alert information is provided at all levels of the Signal Review page.

  Alert type rules can be defined in one, central place in the application. Alert types can be defined using a logic format similar to that of the view WHERE clause and can be designated as tracked, so they would contribute to the triage process or be purely informational. Each alert type can be triggered based on a drug's review period or complexity level.

  It is now possible to schedule complexity-based alert type rules based on the following data:

  – The granularity of the signal management configuration defined during install.
  – The value of the new product property called **Birthdate**.
  – The **Periodicity** value defined in the alert type rule.
- The existing Signal Review functionality has been improved.
  Oracle Empirica Signal 9.0 improves the selection and filtering of products and events by introducing a new, hierarchical structure. The familiar tabular result display has been augmented with a new card view filtering mechanism that combines numerical, graphical,

and other information in a compact format. The review flow has been enhanced to maintain focus when switching between different pages.

- Auditability has been enhanced.
  The existing Signal audit trail has been augmented with new features such as management of product properties and management of alerts.
- The Add and View/Edit Topic pages have been graphically improved.

Signal management

- Ability to change selected signal management configuration outside Preferences (16379464)
- Enhanced signal alerts (28667141)

Ability to change selected signal management configuration outside Preferences (16379464)

Users with access to multiple Signal Management configurations can now change their selected Signal Management configuration using the new drop-down list at the top of the Signal Review page. Users will still be able to change their preferred Signal Management configuration on their Preferences page.

Enhanced signal alerts (28667141)

Users can now create user-defined configured alert types in Oracle Empirica Signal. A configurable alert type can be informational (informational alert) or part of the signal triage progress (tracked alert). The alert type logic format for these new alert types includes a condition derived from a view WHERE clause.

Standard product properties now include the following: display name, product category, product complexity, birthdate, and organization.

In addition, users can schedule the computation of an alert based on review period or complexity level (periodicity).

User interface

- Simplified navigation (27773661)
- Enhanced signal review (27773776)
- Terminology updated to PRODUCT instead of DRUG (27747895)

Simplified navigation (27773661)

The top-right row of navigation tabs has been replaced by a left-side navigation pane and corresponding menu options.

Enhanced signal review (27773776)

The Signals tab has been replaced with the Signal Review page. The page introduces a hierarchical structure for the selection and filtering of products and events, increases the visibility of alert information on all levels, and monitors the review progress of tracked alerts.

Terminology updated to PRODUCT instead of DRUG (27747895)

Some page titles and options have been updated to reference the term PRODUCT instead of DRUG.

Issues fixed

- Administration
- Case series
- Interactive signal management
- Reporting
- Signal management
- Topics
- User interface

Administration

- 28416178 - Error on selecting signal management configuration not published to your login group
- 28800560 - Cannot edit events for specific drugs and configurations without Manage Signaling Terms permission
- 29351447 - Missing audit record on repointing alias

28416178 - Error on selecting signal management configuration not published to your login group

Before

If you had the Manage Signal Configurations and Manage Signaling Terms permissions, and on the Signal Review page you selected a signal management configuration that wasn’t published to your login group, when you clicked some of the options in the Manage Reference Data menu, an error occurred.

After

Signal management configurations that haven’t been published to your login group are no longer visible on the User Preferences, Signal Review, and Add/Edit Drug Profile Configuration pages.

28800560 - Cannot edit events for specific drugs and configurations without Manage Signaling Terms permission

Before

When you tried to edit the Targeted Medical Events and Listed Events for a drug for which you had been assigned as reviewer, if you didn't have the Manage Signaling Terms permission and the configuration was an interactive signal configuration with the **Allow reviewers to manage their drug's reference data** option enabled, an error occurred.

After

When you try to edit the Targeted Medical Events and Listed Events for a drug for which you have been assigned as reviewer, you no longer get an error if you don't have the Manage Signaling Terms permission and the configuration is an interactive signal configuration with the **Allow reviewers to manage their drug's reference data** option enabled.

29351447 - Missing audit record on repointing alias

Before

If you deleted a data mining run that was the target of an alias, and then repointed the alias to another run, you received an error message and no audit record was created.

After

If you delete a data mining run that is the target of an alias, and then repoint the alias to another run, an audit record is created as expected.

Case series

- 29472762 - Text in Case Details obscured by scroll bar

29472762 - Text in Case Details obscured by scroll bar

Before

Text in the Case Details window was sometimes obscured by the scroll bar.

After

The text in the Case Details window now displays as expected.

Interactive signal management

- 29339103 - DME/TME flags not updated after refresh
- 29475274 - Too many custom terms caused signal refresh to fail

29339103 - DME/TME flags not updated after refresh

Before

When you removed an event term from a Designated Medical Events or Targeted Medical Events list and refreshed, the DME/TME flag for the Drug-Event Combination was still YES instead of NULL.

After

When you remove an event term from a Designated Medical Events or Targeted Medical Events list and refresh, the DME/TME flag for the Product-Event Combination is now NULL.

29475274 - Too many custom terms caused signal refresh to fail

Before

When you tried to refresh a signal configuration with many custom terms, the refresh failed.

After

The presence of many custom terms no longer causes signal refresh to fail.

Reporting

- 29502981 - Custom Interactive Report option in Similar Combinations row action menu not working

29502981 - Custom Interactive Report option in Similar Combinations row action menu not working

Before

When you tried to generate a custom interactive report from the Similar Combinations row action menu, report generation started but no report was made available.

After

The row menu in the Similar Combinations window no longer includes Custom Interactive Reports.

Signal management

- 16378673 - Use current layout as login group default on DEC page doesn't seem right (formerly reported as 15457)
- 16379544 - Selecting SOC value on DEC page removes asterisk in blue bar of modified view (formerly reported as 17447)
- 22249626- Add/Delete Drug does not refresh row count above Drug Overviews page
- 22302588 - In Organize Views popup, view list not initially populated for Category in focus
- 28754044 - Topic association changing in Submit Review window
- 28800560 - Drug reviewer unable to add TME and Listed Events without Manage Signaling Terms permission
- 28931081 - AERS interactive signal management worked only with a review period set to period 1 or disabled
- 29179497 - New alerts displayed using the wrong view
- 29493282 - Error submitting review with more than 1,000 rows selected
- 29522448 - Error viewing a topic attachment containing control characters

16378673 - Use current layout as login group default on DEC page doesn't seem right (formerly reported as 15457)

Before

On the Drug-Event Combinations page, views determine the layout of the table that displays. As a result, the option to **Use current layout as login group default** should not have been

available when users with the Administer Users permission click **Columns** above this table. This option was not intended for use with the table on the Drug-Event Combinations page.

After

Use current layout as login group default is not an option in the Columns dialog for the renamed Product-Event Combinations table in Signal Review.

16379544 - Selecting SOC value on DEC page removes asterisk in blue bar of modified view (formerly reported as 17447)

Before

On the Drug-Event Combinations page, the asterisk that appeared in the blue bar when a user modified a signal view was incorrectly removed when the user selected a value from the SOC drop-down list.

After

On the renamed Product-Event Combinations page, an asterisk appears in a tab when the user modifies the WHERE clause of the tab's view. The asterisk remains until the user either uses **Reset View as Default** or saves the view.

22249626- Add/Delete Drug does not refresh row count above Drug Overviews page

Before

After adding or deleting a drug, the row count that appeared at the top of the Drug Overviews page was not updated.

After

After adding or deleting a product, the row count that appears at the top of the Signal Review Products table is updated.

22302588 - In Organize Views popup, view list not initially populated for Category in focus

Before

When expanding the **Category** list in the Organize Views dialog box, the **Views** list for the first category initially appeared empty.

After

When expanding the **Category** list in the Organize Views dialog box, the **Views** list for the first category is populated.

28754044 - Topic association changing in Submit Review window

Before

In the Document Review window, if you chose **Select a comment** from the **Comment** drop-down and clicked **OK** without typing the comment, the topic association changed from **None** to **Existing**.

After

In the Submit Review window, the topic association no longer changes if you click **OK** without typing a comment.

28800560 - Drug reviewer unable to add TME and Listed Events without Manage Signaling Terms permission

Before

When you tried to edit the TMEs and Listed Events for your drugs, if **Allow reviewers to manage their drug's reference data** was enabled for the interactive signal configuration and you didn't have the Manage Signaling Terms permission in addition to the View Signal Management permission, you received an error message.

After

The Manage Signaling Terms permission is no longer required when reviewers edit the TMEs and Listed Events for their drugs.

28931081 - AERS interactive signal management worked only with a review period set to period 1 or disabled

Before

AERS interactive signal management worked only with review periods disabled, or with review periods enabled and the review period set to **3-Months** for all the drugs.

After

All review periods are now enabled.

29179497 - New alerts displayed using the wrong view

Before

When Argus Interactive Signal Management was enabled, if you clicked the hyperlinked count for the **New** alert on the Drug Overviews page, Oracle Empirica Signal incorrectly displayed drug-event combinations using the **Open/potential signals - new cases** view instead of the **New cases alert** view.

After

Oracle Empirica Signal now displays **New** alerts using the **New cases alert** view.

29493282 - Error submitting review with more than 1,000 rows selected

Before

On the Drug-Event Combinations page, if you selected more than 1,000 rows and clicked **Document Review**, an error message appeared.

After

On the renamed Product-Event Combinations page, an error message no longer appears if you select more than 1,000 rows and click **Submit Review**.

29522448 - Error viewing a topic attachment containing control characters

Before

If you tried to view a topic attachment with control characters in the **Detailed Comments** column, you received an error message.

After

Control characters are automatically removed when you save the **Detailed Comments**, so you no longer receive an error when viewing them.

Topics

- 22449013 - Document Review is allowing new topic in TWC that does not support app data
- 29625359 – Spaces in URLs causing attachments to fail

22449013 - Document Review is allowing new topic in TWC that does not support app data

Before

If you did not set Application Data as a source of attachments for the topic workflow configuration integrated with your signal management configuration, you could not perform Document Review on a drug-event combination with an associated topic.

After

If you set Application Data as a source of attachments for the topic workflow configuration that is integrated with your signal management configuration, you can perform Submit Review on a product-event combination that has an associated topic.

29625359 – Spaces in URLs causing attachments to fail

Before

When you tried to save a URL containing spaces as an attachment to a topic or action, you received an error message.

After

You can now save URLs containing spaces as attachments to topics or actions.

User interface

- 22986249 - IE11: Manage Saved Lists - flashes large headers first before correctly displaying
- 23292989 - Time zone list in User Preferences has changed
- 29159211 - Topic-related message for signal management configuration without topic workflow configuration

22986249 - IE11: Manage Saved Lists - flashes large headers first before correctly displaying

Before

In Internet Explorer 11, after a superuser created or edited a saved list of drugs or event terms, when viewing the list, the headers initially appeared oversized.

After

In Internet Explorer 11, after a superuser creates or edits a saved list of drugs or event terms, when viewing the list, the headers appear as expected.

23292989 - Time zone list in User Preferences has changed

Before

On the User Preferences page, in the **Time Zone** drop-down list, time zones appeared sorted by name

After

On the User Preferences page, in the **Time Zone** drop-down list, time zones appear sorted by offset from UTC (0) and then by name within each offset group.

29159211 - Topic-related message for signal management configuration without topic workflow configuration

Before

On the Drug-Event Combinations page, when you tried to submit a review with comments for a signal management configuration without a topic workflow configuration, you received a topic-related message.

After

On the renamed Product-Event Combination page, when you submit a review with comments for a signal management configuration without a topic workflow configuration, you no longer receive a message.

Change log

Date	Part number	Description
28-Feb-2023	F78221-01	Added release notes for 9.1.0.8 release.
25-Feb-2022	F52986-01	Added release notes for 9.1.0.7 release.
18-Jan-2022	F51307-01	Added release notes for 9.1.0.6 release.
19-Nov-2021	F48846-01	Added release notes for 9.1.0.5 release.
20-May-2021	F42419-01	Added release notes for 9.1.0.4 release.
14-April-21	F41707-01	Added release notes for 9.1.0.3 release.
29-Jan-21	F38490-01	Added release notes for 9.1.0.2 release.
9-Dec-20	F31972-02	Added release notes for 9.1.0.1 release.
2-Sept-20	F31972-01	Original version of this document.