Oracle® Argus Analytics User's Guide





Oracle Argus Analytics User's Guide, Release 8.2.1

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Preface

This preface contains the following sections:

- Documentation accessibility
- · Related resources
- Access to Oracle Support
 To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc.

Related resources

All documentation and other supporting materials are available on the Oracle Help Center.

Access to Oracle Support

To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.

Cloud customers receive support assistance through Support Cloud

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

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



On-premises customers receive support assistance through My Oracle Support

Oracle customers that have purchased support have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.



Part I

Using Oracle Argus Analytics

This part of the Oracle Argus Analytics User's Guide describes how to use this product.

Part I contains the following chapters:

- Getting Started with Oracle Argus Analytics
- Using Oracle Argus Analytics
- Working with Reports



1

Getting Started with Oracle Argus Analytics

This chapter contains the following topics:

- Overview
- Architecture
- Reporting
- Regulatory Compliance

Overview

Business Intelligence has become a very important analytical tool for the pharmaceutical and related industries as more business operations are run globally in today's electronically wired world. By using the Oracle Argus Analytics software tool, pharmaceutical companies and contract research organizations (CRO) can keep tab on how efficiently case processing is performed, their overall safety compliance with regulatory authorities, and a day to day assessment of drug safety personnel required to maintain a smooth operation of the drug safety department.

Oracle Argus Analytics is an analytical and transactional reporting application based on a predefined set of key performance indicators (KPIs), facts, and dimensions with support for predefined and custom reporting. Oracle Argus Analytics also functions as a decision support system to monitor process bottlenecks and compliance deviations. With the use of this analytical tool, it will be possible for the drug safety management to generate out-of-the-box set of compliance metrics reports via Oracle Business Intelligence Enterprise Edition (OBIEE) that can be integrated with existing Oracle Argus Safety application. The interactive OBIEE dashboard will provide solutions to business questions and present data in charts, pivot tables, and reports. The results could be further enhanced through charting, result layout and drill-down features.

Pharmacovigilance Organizations require insights into the following key drug safety business process areas that impact the performance of drug safety operation within a case processing site/multiple case processing sites:

- Case Receipt Compliance: Adverse event reports must be received by the drug safety department within the time frame as defined by the business in its Standard Operating Procedure (SOP) from internal as well as external sources.
- Case Volume: In order to assess the balance of required drug safety personnel
 versus the number of cases received on a daily basis, the drug Safety
 management needs to view the overall volume of cases including but not limited
 to subsets of serious vs. non-serious, case type, product type, pregnancy and
 lactation exposure cases (with/without adverse events) etc.
- Case Processing Time: Drug Safety management continually needs to determine
 if the cases are processed in an efficient and timely manner and ideally without
 needing re-work, in order to meet the regulatory submission deadlines.
- Cases Processed by a User/User Group: Drug Safety management requires the ability to determine if the workload is balanced. The number of cases processed

- by each user enables management to review how the work is being accomplished and understand how many cases a person can handle.
- Workload Allocation for Open/Current Cases: Drug safety management needs the
 ability to view real-time open work, the associated status, its due date, and the
 amount of time it has been in a given status so workload can be proactively
 managed and continue to be balanced and re-balanced in the cases of personnel
 absence, vacations or over allocation.
- Compliance Maintenance: Drug safety departments need to process their expedited cases in a time-critical manner since the expedited reporting due date begins incrementing after the first employee or an agent of the company first learns about the adverse event associated with a company product.
- Pregnancy Case Tracking: Pregnancy case tracking includes counting pregnancy cases with and without adverse events. This information is typically needed for PSUR pregnancy section preparation and/or maintaining pregnancy registries.
- Root Cause Analysis: Regulatory submissions are late for a reason and a case
 may have a global and/or a local root cause for being late. The reason each
 submission is late needs be determined and tracked since the ability to categorize
 the root cause enables the company to take the necessary corrective and
 preventive measures.

For more information, see:

What Can I Do Using Oracle Argus Analytics?

What Can I Do Using Oracle Argus Analytics?

Oracle Argus Analytics integrates data from Oracle Argus Safety and additional sources, where appropriate, into a predefined data mart schema and generates both predefined and custom reports of key metrics across the pharmacovigilance spectrum. Oracle Argus Analytics allows you to perform the following functions:

- Extract all necessary drug safety data from Oracle Argus Safety into a predefined data mart, for viewing through the rich dashboard and report interface of Oracle Business Intelligence Enterprise Edition Plus (OBIEE).
- Extract such data from other database sources as well, subject to the development of separate Extract Transform Load (ETL) programs for each database source.
- View predefined analytical reports delivered with the application.
- Rapidly create new reports using the extensive predefined cycle time, quality and volume based metrics across data management and drug safety operations processes.



Architecture

Oracle supplied source-independent ETL - Scheduled by ODI Oracle supplied source-dependent ETL Argus Safety Database - Scheduled by ODI PVA Schema OPVA DWH Star Schema Stage Tables Tables Current Views in OPVA schema on Argus Safety DB Application Server Machine OBIEE Presentation BI Server Server OBIEE Session in a Browser Presentation Repository Catalog

Figure 1-1 The Oracle Argus Analytics Architecture

The Oracle Argus Analytics architecture includes the following principal components:

A predefined Intelligence application, based on Oracle Business Intelligence Enterprise Edition Plus (OBIEE), including Oracle BI Presentation Services, and a predefined set of Oracle BI reports, accessible through prebuilt interactive dashboards.

Reporting

Oracle Argus Analytics provides reports for the two key drug safety functional areas - Retrospective Workflow Metrics and Current Metrics.

Retrospective Workflow Metrics Reports further include the following types of reports:

- Case Version Metrics Report answers questions related to the volume of cases, and the time taken to complete a case, at case version level.
- Case Routing History Report answers questions about how long it took to complete a workflow state (step) before transitioning to the next workflow state in a case. It will represent a log of all the workflow states an individual case safety report (ICSR) went through (routed to) in its workflow lifecycle.



- Case Workflow State History Report answers questions about all the workflow states that a case has been through and the number of times each workflow state was repeated in that case.
- Case Work History Report answers questions related to the details of the
 workflow states a case version went through in its workflow lifecycle. It can be
 used to derive the actual work time spent in each workflow state per user or the
 version or at the case level.
- User Case Work History Report answers questions related to the total time a
 user spends in working on a case version, total actual work time spent in each
 workflow state, average time spent in working on one case version by one user in
 one workflow state.
- Expedited Report History Report answers questions related to the timeliness
 and volume of single case report submissions, which includes expedited reports
 and reports sent to a business partner for submission, in relation to the regulatory
 due date.
- Report Routing History Report answers questions related to the details of the workflow states an expedited report went through (routed to) in its workflow lifecycle.

Current Metrics Reports include the following types of reports:

- Pending Cases Report answers questions related to pending on-time, due soon and overdue cases.
- **Pending Report** answers questions related to pending, due soon, and overdue single case report submissions, which includes expedited reports and reports sent to a business partner for submission, in relation to the regulatory due date.

See Also:

- Using Oracle Argus Analytics
- Working with Reports
- Dashboards and Reports

Regulatory Compliance

Oracle Argus Analytics is designed as a single data-warehousing platform that facilitates integration of both non-regulated and regulated data. This single platform provides secure access to authorized users. It provides reduced total cost of ownership through reduced data integration costs and infrastructure maintenance costs, compared with multiple warehousing solutions.

The primary regulatory requirements include: (i) data tracking and (ii) Extract Transform Load (ETL) Version Management.

For more information, see:

- Tracking Data
- Managing ETL Versions
- Executing the ETLs
- Security



Tracking Data

The origin of any data displayed in a report must be traceable to its source, and all transformations applied to the data must be accessible. Data sourced from Oracle Argus Safety is traced by the following criteria and rules:

- Load: When the data was loaded from the source database into the staging tables.
- Staging Mapping: The version of ETL mapping used to transform the data from source to staging table, and when it was executed.
- Target Mapping: The version of ETL mapping used to transform the data from the staging table to target tables, and when it was executed.
- Transformations and calculations performed on the data within the Oracle
 Business Intelligence Enterprise Edition Repository can be versioned and saved
 permanently in a third-party versioning tool.
- Calculations can also be performed in reports managed through Oracle Business Intelligence Enterprise Edition Analytics. The Oracle Business Intelligence Enterprise Edition Analytics Administrator is responsible for controlling what calculations are performed, and who can perform them.

Managing ETL Versions

You can use a third-party versioning tool or in-built functionality of ODI to manage ETL versions.

Executing the ETLs

In case of ODI, the execution of the ETLs is controlled by ODI Studio. You can create users and set the for various types of accessibility in ODI Studio. Please refer to the ODI documentation for more information.

Security

Data within the data mart is secure from updates by unauthorized personnel, and can only be updated through controlled execution of ETL mappings.

The ability to modify ETL routines is restricted to a user group or role of ETL developers. Access to execute ETL routines is restricted to a specific privilege, which can be granted to a user group or role.

In addition, access to data is available for authorized personnel only constrained through user groups or roles.

See Also:

Implementing Security



2

Using Oracle Argus Analytics



The appearance of the user interface that you see in the application may vary from the figures displayed in the subsequent sections.

See Also:

Oracle Business Intelligence Administrator Guide and User Guide

This chapter contains the following topics:

- Overview
- Accessing Oracle Argus Analytics
- Using Oracle Business Intelligence
- Performing Common Tasks in Oracle Business Intelligence
- Navigating in Oracle Business Intelligence

Overview

Oracle Argus Analytics includes dashboards, reports, and metrics that let you view relevant, interactive information—current as at the last date the data mart was refreshed. It also includes dashboards and reports to access the run-time data.

Dashboards are access points for information. Each dashboard is designed for a specific job responsibility.

When you access a dashboard, the information displayed changes based on your security privileges. For example, a user with BIConsumer application role may not be able to see the same data as the user with BIAuthor role.

A dashboard contains one or more related dashboard *pages*. A dashboard page contains a series of related *reports* (also called *requests*). A report can contain a tabular report, pivot table, or graph. You can drill down to detailed report by clicking the linked data. You can also filter the data that you see in reports using a set of *parameters* (called *filters*). Figure 2-1 displays the report hierarchy.



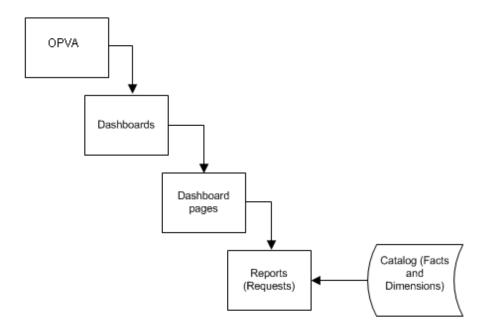


Figure 2-1 The Report Hierarchy

In addition to the dashboards and reports that are packaged with Oracle Argus Analytics, you can also create and manage reports or dashboards if you have appropriate permissions. Use Oracle BI Analysis to manage reports.

Oracle Business Intelligence Enterprise Edition includes additional applications that are not directly used by Oracle Argus Analytics. These include Oracle Business Intelligence Agents and Oracle Business Intelligence Publisher. These applications extend the usefulness of the information provided by Oracle Argus Analytics.

Use Oracle Business Intelligence Agents to detect specific analytic results and notify appropriate user or group about the result. Use Oracle Business Intelligence Publisher to create formatted and printable reports.

See Also:

- Working with Reports for more information about creating and managing reports.
- Oracle Argus Analytics Presentation Catalog for more information about the columns in Oracle Argus Analytics that you can use to create and modify reports.
- Oracle Business Intelligence Administrator Guide and User Guide.

Accessing Oracle Argus Analytics

Your security privileges determine what reports you can see and what you can do in Oracle Argus Analytics.

For more information, see:

Viewing a Dashboard



Viewing a Dashboard

Perform the following steps to view a dashboard:

- Log in to Oracle Argus Analytics.
- 2. Click the Dashboard drop-down menu and select the relevant dashboard.

Note:

You might get the following errors while accessing reports if there is no data in Oracle Argus Safety:

```
Error Codes: OPR4ONWY:U9IM8TAC:OI2DL65P

State: HY000. Code: 10058. [NQODBC] [SQL_STATE: HY000]
[nQSError: 10058] A general error has occurred.
[nQSError: 43113] Message returned from OBIS.

[nQSError: 23006] The session variable,
NQ_SESSION.USER_LN, has no value definition. (HY000)
```

Conditions that will produce this error:

- 1. The connection pool in the RPD is not set to the correct credentials to point to the RPD schema that was created during the install. a. To verify this we can open the RPD in online mode via the BI Administration Tool and check the DB connection details in the RPD, Physical Layer -> OPVA_DWH -> OPVA_CP and OPVA_CP_Initblocks connection pools.
- 2. The PVA row level security is inherited from the Argus Safety Instance that it is linked to. The user names that one creates in Oracle Business Intelligence Enterprise Edition (if using the built-in LDAP of WLS or external LDAP) should be the same as that in the Oracle Argus Safety system. For example, if 'admin' is the login for the Oracle Business Intelligence Enterprise Edition user that has been created, then the same login should have been present in the Oracle Argus Safety Instance as well. The OPVA ETLs when run would have already picked up the relevant Enterprise, Case Processing Site, Study, and Product accesses that the user 'admin' has in the Oracle Argus Safety Instance and the OPVA RPD applies the same in the PVA requests created via Answers or in the Dashboards.
- 3. There is no data in Oracle Argus Safety at the time you are trying to access these reports.

Using Oracle Business Intelligence

Oracle Business Intelligence helps end-users obtain, view, and analyze the data. After the data has been organized and analyzed, it can provide an organization with the metrics to measure the state of Oracle Argus Safety data. These capabilities enable the pharmaceutical organization to make better decisions, take informed action, and implement more efficient business processes.



For more information, see:

- Logging In
- Working with Oracle Business Intelligence

Logging In

To log in to Oracle Argus Analytics, you must have a browser on your computer and a URL, username, and password provided by your company. For the list of supported browsers, versions, and platforms, refer to the Oracle Argus Analytics Installation Guide.

1. Open your browser and enter the URL provided by your company.

Typically, the URL to access the dashboards will be

http://<system_name_or_ip_address>:<port_number>/analytics/saw.dll? Dashboard

Figure 2-2 Oracle Argus Analytics Login Page



- 2. Enter your user ID and password.
- 3. Click Login.

After your login credentials are authenticated, your default dashboard page is displayed.



Working with Oracle Business Intelligence

In the Oracle Business Intelligence Enterprise Edition (OBIEE), you can work with:

Analysis

This area of Oracle Business Intelligence is also known as Answers. Analysis are queries against an organization's data that provide answers to business questions. Analysis allows you to explore and interact with information by visually presenting data in easy-to-understand formats (such as tables and graphs). You can save, organize, and share the results of analysis. Your organization might also have purchased prebuilt analysis specific to your industry. Pre-built analysis can be used as purchased or modified to suit the information needs of your business.

Dashboards

This area of Oracle Business Intelligence is also known as Interactive Dashboards. Dashboards provide personalized views of corporate and external information. A dashboard consists of one or more pages that contain content, such as analysis, links to Web sites, Oracle Business Intelligence Publisher reports, and so on. Dashboards allow you to provide end users with access to analytics information. Your organization might also have purchased preconfigured dashboards that contain prebuilt analysis specific to your industry.

Filters, Selection Steps, and Prompts

Filters, selection steps, and prompts allow you to limit or specify the data that is displayed in dashboards and analysis.

Agents

This area of Oracle Business Intelligence is also known as Delivers. Agents enable you to automate your business processes. You can use agents to provide event-driven alerting, scheduled content publishing, and conditional event-driven action execution. Agents can be scheduled or can be triggered by a specific condition, which enables you to deliver timely information to users.

Conditions

Conditions are objects that return a single Boolean value that is based on the evaluation of an analysis or of a Key Performance Indicator (KPI). You use conditions to determine whether something is to be done, for example whether an agent is to deliver its content.

Actions

Actions provide functionality to navigate to related content or to invoke operations, functions, or processes in external systems. You can include actions in various objects, such as analysis and dashboard pages. Actions allow users to take the proper action based on the business insight that they gained from the data that they received.

Scorecards

This area of Oracle Business Intelligence is known as Oracle Scorecard and Strategy Management. Scorecards allow you to model the objectives and initiatives that comprise your corporate strategy, evaluate their performance by assigning KPIs, and determine and display overall performance.

Other Products



Oracle Business Intelligence interacts in various ways with other products. For example, with the Oracle Business Intelligence Add-in for Microsoft Office, you can access and run analysis from Oracle Business Intelligence directly within your Microsoft Office workspace.

For more information, see:

- Oracle Business Intelligence Interactive Dashboards
- Oracle Business Intelligence Analysis
- Oracle Business Intelligence Agents

Oracle Business Intelligence Interactive Dashboards

Dashboards provide personalized views of corporate and external information. A dashboard consists of one or more pages. Pages can display anything that you can access or open with a Web browser, including the following:

- The results of analysis The result of an analysis is the output returned from the
 Oracle BI Server that matches the analysis criteria. It can be shown in various
 views, such as a table, graph, and gauge. Users can examine and analyze results,
 print as PDF or HTML, save as PDF, or export them to a spreadsheet.
- Alerts from agents
- Action links and action link menus
- Images
- Text
- Views of folders in the Oracle Business Intelligence Presentation Catalog
- · Links to websites
- Links to documents
- Embedded content (such as Web pages or documents)
- Oracle Business Intelligence Publisher Reports
- When you open a dashboard, the content of the dashboard is displayed in one or more dashboard pages. Dashboard pages are identified by tabs across the top of the dashboard. A toolbar at the top right contains buttons that let you:
- Edit the dashboard, if you have the appropriate permissions and privileges
- Display various options for working with a Dashboard Page, such as printing the current page

Oracle Business Intelligence Analysis

An analysis is a query against an organization's data that provides answers to business questions. A query contains the underlying SQL statements that are issued to the Oracle Business Intelligence Server.

Analysis let you explore and interact with information by visually presenting data in tables, graphs, pivot tables, and so on. You can save, organize, and share the results of analysis.

Analysis that you create can be saved in the Oracle Business Intelligence Presentation Catalog and integrated into any Oracle Business Intelligence Enterprise Edition



dashboard. Analysis can be enhanced through features such as graphs, result layout, calculated items, and drilling.

Oracle Business Intelligence Agents

Agents enable you to automate your business processes. You can use them to provide event-driven alerting, scheduled content publishing, and conditional event-driven action execution.

You can choose:

- · A schedule that the Agent runs on
- A data condition that determines what the Agent does
- An analysis that can be distributed
- Actions that can be automatically executed depending on whether the data condition is met
- Agents can dynamically detect information-based problems and opportunities, determine the appropriate individuals to notify, and deliver information to them through a wide range of devices such as e-mail, phones, etc.

Performing Common Tasks in Oracle Business Intelligence

This section explains how to perform the following common tasks in Oracle Business Intelligence:

- Signing Out of Oracle Business Intelligence Enterprise Edition
- Using Online Help

Signing Out of Oracle Business Intelligence Enterprise Edition



Do not close the browser window to sign out of Oracle Business Intelligence Enterprise Edition.

To sign out of Oracle Business Intelligence Enterprise Edition:

• In the global header, click **Sign Out**.

Using Online Help

Oracle Business Intelligence includes Oracle Argus Analytics-specific online help for both dashboards and reports.

The following image provides a sample view of the Help links (highlighted in yellow) that exist on each page.



Figure 2-3 Using The Help Links

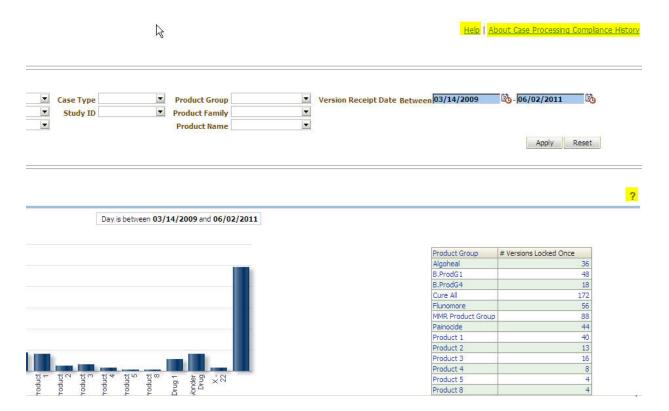


Table 2-1 Accessing Online Help

| Name of Help Link | Clicking on this link |
|---|---|
| Help | Opens the entire Help system, in an online book format. |
| <name dashboard="" of="" page-<br="">specific Help></name> | Re-directs to the description about the specific <dashboard page="">.</dashboard> |
| ? | Pops up the description about the specific report. |

Online help opens in a new browser window. You can scroll down the help page or use hyperlinks to navigate to other topics.

Navigating in Oracle Business Intelligence

This section explains basic navigation within Oracle Business Intelligence.

- What is Available to You After Accessing Oracle Business Intelligence?
- What is the Oracle Business Intelligence Enterprise Edition Home Page?
- What is the Oracle Business Intelligence Enterprise Edition Global Header?
- Setting Preferences
- Drilling In Results
- Printing an Oracle Business Intelligence Dashboard or Saved Request
- Emailing an Oracle Business Intelligence Dashboard Page or Request



What is Available to You After Accessing Oracle Business Intelligence?

After signing in to Oracle Business Intelligence Enterprise Edition, you are presented with one of the following pages, depending on what has been configured for you:

- Your personal dashboard, named My Dashboard
- A Home page
- A dashboard that is specific to your job function

This page is your starting point for working in Oracle Business Intelligence Enterprise Edition. As you work, you can use the global header and the Home page as the primary ways to navigate Oracle Business Intelligence Enterprise Edition.

The Global Header:

The global header is displayed at the top of the Oracle Business Intelligence Enterprise Edition interface and is always available as you work. It enables you to easily access the functionality that Oracle Business Intelligence Enterprise Edition provides. For example, you can access the Home page, access dashboards, open objects (such as analysis and dashboard prompts), Create new objects, and so on.

The Home Page

From the Home page, you can learn how to get started with Oracle Business Intelligence Enterprise Edition, create and modify objects, and browse and manage objects in the catalog. After you have accessed the starting point of a task, the interface then presents you with the page, dialog, or editor that you use to perform the task.

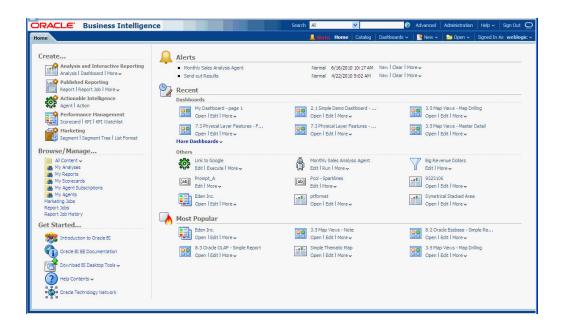
What is the Oracle Business Intelligence Enterprise Edition Home Page?

The Home page provides a starting point for performing tasks in Oracle Business Intelligence Enterprise Edition. The Home page is divided into sections that allow you to quickly begin a specific task, locate an object, or access technical documentation. It also includes sections that allow you to quickly access objects that you have recently viewed, created, or updated, and objects that are accessed the most often by the users assigned to the groups to which you belong.

Depending on what has been configured as your starting page, you might be presented with the Home page when you sign in to Oracle Business Intelligence Enterprise Edition.

Alternatively, you can always navigate to the Home page by clicking the Home page link in the global header.





What is the Oracle Business Intelligence Enterprise Edition Global Header?

The global header provides quick access to commonly used functions and is always available from the user interface.

For example, you can use the global header to begin a new task, search the Oracle Business Intelligence Presentation Catalog, access the product documentation, or view a different object, without having to return to the Home page. The global header also includes the Home page link so that you can quickly access the Home page from other pages.

Figure 2-4 The Global Header



The Global Header includes the following components:

- Search Enables you to search the catalog.
- Advanced Displays the Catalog page in search mode, where you can search for objects in the catalog. In search mode, the Search pane is displayed rather than the Folders pane within the page.
- Administration Available only if you are logged in as an administrator. Displays
 the Administration page, where you can perform administration tasks such as
 managing privileges and metadata for maps.
- Help Displays the following options:



- xxx Help (where xxx is the name of the page, editor, or tab) Dynamically changes to display the Help topic for the current page, editor, or tab.
- Help Contents Displays a cascading menu that provides options that link to the tables of contents for Oracle Business Intelligence Enterprise Edition, Oracle Business Intelligence Publisher, and Marketing.
- Documentation Displays the documentation library for Oracle Business Intelligence Enterprise Edition.
- OTN Displays the Business Intelligence and Data Warehousing Technology Center page on the Oracle Technology Network (OTN).
- About OBIEE Displays a dialog identifying the Oracle Business Intelligence Enterprise Edition version and copyright information.
- Sign Out Signs you out of Oracle Business Intelligence Enterprise Edition.
- Alerts Available only if one or more alerts have been generated for you. Displays
 the Alerts dialog, where you can manage your alerts. An alert is a notification
 that is generated by an agent that delivers personalized and actionable content to
 specified recipients and to subscribers to the agent.
- Home Displays the Home page.
- Catalog Displays the Catalog page, where you can locate objects in the catalog and perform tasks specific to those objects.
- Dashboards Contains links to all dashboards that are stored within the
 Dashboards sub-folder of the user's folder or any shared folder (note that
 dashboards not saved to the Dashboards sub-folders are not displayed from the
 global header's Dashboard list).
- New Displays a list of the objects that you can create. To create an object, select
 it from the list. The appropriate dialog or editor is displayed for you to create the
 object.
- Open Displays the following options:
 - Open Displays the Open dialog, where you can select the object with which you want to work.
 - Recent Objects Displays a list of the objects that you have recently viewed, created, or updated. You can use this list to select an object with which you want to work.
 - Most Popular Objects Displays a list of the objects that are accessed the
 most often by the users that are assigned to the groups to which you belong.
 You can use this list to select an object with which you want to work.
- **Signed In As username** (where username is the user name that your current session is using) Displays the following options:
 - My Account Displays the My Account dialog, where you can specify your preferences, such as time zone, delivery devices, and delivery profile.
 - Act As Available only if your organization has enabled this functionality and you have been granted the appropriate permissions. Enables you to act as another user.



Setting Preferences

You and end-users can set personal preferences for OBIEE. By using the My Account dialog (depending on your privileges), you can:

- · View general account information, such as your display name and user ID
- View and modify your preferences, such as language, time zone, and currency
- View and modify your preferences for BI Publisher, such as location and time zone
- View and modify your delivery options for agents
- View the roles and groups to which you belong

For more information, see:

- Steps to Set Preferences
- Exporting the Oracle Business Intelligence Results
- Sorting Options Menu and Buttons

Steps to Set Preferences

Execute the following steps to set preferences:

- In the global header, click Signed In As <username> and select My Account.
 The My Account dialog is displayed.
- 2. Complete the appropriate settings.
- Click OK to save your changes.

Exporting the Oracle Business Intelligence Results

Oracle Business Intelligence provides options for exporting results into different formats. This is done using the Export link available in each report and dashboard. The different export options are listed as follows:

- Adobe PDF
- Microsoft Excel 2003+
- Microsoft Powerpoint (Powerpoint 2003, Powerpoint 2007+)
- WebArchive (mht)
- Data (CSV Format, Tab delimited format, and XML)

The following steps assume that you are already on a result page:

Exporting into a PDF

The result can be exported in PDF format with the following steps:

- 1. Click Export.
- 2. Select the PDF option.
- The File Download dialog opens. Click Open or Save in the File Download dialog.
- Based on the user action, the result would either open in PDF format (if Adobe Reader is available in the machine) or will proceed with the Save.



- Exporting to Microsoft Excel 2003+The result can be stored in Excel format with the following steps:
 - Click Export.
 - Select the Excel 2003+ option.
 - 3. The File Download dialog opens. Click **Open** or **Save** in the File Download dialog.
 - 4. Based on the user action, the result would either open as an Excel sheet (if Microsoft Excel is available in the machine) or will proceed with the Save.

Exporting to Microsoft Powerpoint

The result can be stored in Powerpoint slides with this option. This option also has two sub-options: Powerpoint 2003 and Powerpoint 2007+.

Execute the following steps:

- 1. Click Export.
- 2. Select the Powerpoint option.
- 3. Select from one of the secondary options: Powerpoint 2003 or Powerpoint 2007+.
- **4.** The File Download dialog opens. Click **Open** or **Save** in the File Download dialog.
- Based on the user action, the result would either open in Powerpoint (if Microsoft Powerpoint is available in the machine) or will proceed with the Save.

Exporting to Web Archive (mht)

Execute the following steps:

- Click Export.
- 2. Select the WebArchive (mht) option.
- 3. The **File Download** dialog opens. Click **Open** or **Save** in the File Download dialog.
- 4. Based on the user action, the result would either open as an MHT file or will proceed with the Save.

Exporting the results in Data Format

The results can be exported in CSV format, tab delimited format, and XML format.

Execute the following steps:

- Click Export.
- 2. Select the Data option.
- 3. Select the CSV sub-option.
- **4.** The File Download dialog opens. Click **Open** or **Save** in the File Download dialog.
- Based on the user action, the result would either open as a CSV formatted file with the application for which CSV format is configured or will proceed with the Save.

Add to Briefing Book

This section explains briefing books and the steps to add content to briefing books.



About Briefing Books

A briefing book is a collection of static or updatable snapshots of dashboard pages, individual analysis, and BI Publisher reports. If your organization is licensed for Oracle BI Briefing Books, you can work with briefing books. A briefing book allows you to perform the following tasks:

- Add the content of dashboard pages (including pages that contain BI Publisher reports) or individual analysis to new or existing briefing books.
- Edit briefing books to reorder content, delete content, and change the content type, navigation link properties, and content description.
- Download briefing books in PDF or MHTML format for printing and viewing.
- Add a list of briefing books to a dashboard page.
- Update, schedule, and deliver briefing books using agents, if your organization is licensed to Oracle Business Intelligence Delivers.

Adding Content to Briefing Books

Execute the following steps to add content to a briefing book:

- Navigate to the page to add or to the page that contains the analysis to be added.
- Perform one of the following actions:
 To add the contents of the dashboard page to a briefing book, click the Page
 Options toolbar button on the Dashboard page and select Add To Briefing Book.

To add the results of an individual analysis to a briefing book, locate the analysis on the dashboard and click the **Add to Briefing Book** link.

- 3. The Save Briefing Book Content dialog is displayed.
- 4. Click **Browse** to display the Save As dialog.
- 5. In the Save As dialog:

To save the contents to a new briefing book, specify the location in which to save the briefing book in the **Save In** field. Enter a name for the briefing book in the **Name** field. You can also enter a description in the **Description** field (optional), and click **OK**.

To save the contents to an existing briefing book, select the briefing book and click \mathbf{OK} .

- 6. In the Save Briefing Book Content dialog, complete the remaining fields as appropriate.
- 7. Click OK.
- 8. The content is now added to the briefing book.

For more information about the briefing book, please refer to the Oracle Business Intelligence Enterprise Edition *Administration and User Guide* or Help files.

Sorting Options Menu and Buttons

This section explains about sorting values in columns.

Sorting Mechanisms

You can use one of the following mechanisms to sort values in columns:



- Right-click in the column header of pivot tables and tables to display the following list of options for sorting the columns. In the Selected Columns pane, click the Options button. You can also right-click to display the Right-Click Menu for Tables and Pivot Tables, where you can select options for sorting.
- Sort Ascending Sorts the values in the column by ascending order, as a first-level sort. For example, string values sort alphabetically A through Z, numbers sort lowest to highest, and dates sort earliest to latest. In the Selected Columns pane, when you select this option as the first sort, a Sort button is displayed to the left of the column name in the Selected Columns pane. If you later add another sort, then the Sort button includes the number 1.
- Sort Descending Sorts the values in the column by descending order, as a first-level sort. In the Selected Columns pane, when you select this option as the first sort, a Sort button is displayed to the left of the column name in the Selected Columns pane. If you later add another sort, then the Sort button includes the number 1.
- Add Ascending Sort Specifies that an ascending sort for this column is added
 as another sort for the analysis. In the Selected Columns pane, when you select
 this option, a Sort button with a number such as 2 or 3 is displayed to the left of
 the column name in the Selected Columns pane.
- Add Descending Sort Specifies that an descending sort for this column is added as another sort for the analysis. In the Selected Columns pane, when you select this option, a Sort button with a number such as 2 or 3 is displayed to the left of the column name in the Selected Columns pane.
- Clear Sort Removes the sort specification for the specified column. This option
 works differently in the Selected Columns pane than in other places. If you make
 sort specifications in both the Selected Columns pane and in the view itself, then
 you return to the Selected Columns pane and click Clear Sort, only the sort that
 you specified in the Selected Columns pane is removed. A sort that you specified
 in the view remains.
- Clear Sorts in All Columns or Clear All Sorts in View Removes all sort specifications that you have made. The Clear Sorts in All Columns option works differently in the Selected Columns pane than in other places. If you make sort specifications in both the Selected Columns pane and in the view itself, then you return to the Selected Columns pane and click Clear Sorts for All Columns, only the sorts that you specified in the Selected Columns pane are removed. Sorts that you specified in the view remain.
- Hover the mouse pointer over the area to the right of the column name in the header of a pivot table or table and click either the upward facing triangle (Sort Ascending) or the downward facing triangle (Sort Descending) for that column. These sort specifications override those that you make with the right-click menu. Hovering is not available in the Selected Columns pane.

If you see a shaded-in sort button in the column header or the row header, then you know that the column contains a primary sort. You can add a second-level or third-level sort by hovering over another innermost column header or row header and clicking the appropriate sort button.

These options are also available in the Results tab: Data View editor, the Results tab: Table editor, and in views on dashboards. The Sort Ascending and Sort Descending triangles are not available in the Selected Columns pane or the Layout pane.



Drilling In Results

Many of the results that are displayed in views represent hierarchical data structures. The metadata specifies these hierarchies, and this enables you to access the different levels of detail within them. For example, information in a sales graph might be categorized by region. Clicking a specific region in the graph might display each country within that region, if the country is the next level within the hierarchy of the metadata. Such clicking is referred to as drilling.

If the content designer has set up views for drilling, then you can drill in them on dashboards.

For more information, see:

- What Is Drilling?
- Where Can I Drill?

What Is Drilling?

Drilling is a way to navigate through data in views quickly and easily.

- You drill down to display data in more detail, which displays more members.
 You can drill down to an actual item in the database. For example, if you work in sales, you can drill down to the city level within a sales analysis, and observe that there is a large sale pending in Paris.
- You drill up to display data in less detail, in hierarchical columns.
 For example, you might drill up from a month value to see a summary for the whole year. You can drill up in the current hierarchy, either for the entire column at the header level or for individual members. You can drill up from District to Region. Drilling up hides the current level (such as District) and retains the higher level (such as Region).

Where Can I Drill?

You can drill in the following types of views:

- Table and Pivot Table
- Graphs
- Maps
- Drilling in Tables and Pivot Tables

When you drill down in a table or a pivot table, the detail level data is added to the current data. For example, when you drill from a continent, the table displays data for the continent and for the countries in that continent. For an attribute column, the list of members in the header is expanded, and it includes the original member.

The way that you drill in tables and pivot tables depends on the column type, as described in the following sections:

Drilling in Attribute Columns

To drill in an attribute column, click the heading or member in which you want to drill. When you hover over the value before clicking, an underline is displayed below the value to indicate that you can click to drill.



When you drill in an attribute column, you add the lower level to the view. All views are affected by drilling in an attribute column, which is equivalent to a filter drill. After you click the value, a column is added to the analysis and a filter is automatically created and listed in the Criteria tab.

You cannot drill on groups for attribute columns. To see the definition of a group for an attribute column, edit the corresponding step in the Selection Steps pane.

Drilling in Hierarchical Columns

To drill in a hierarchical column, click the Expand and Collapse icons beside the members. Click to expand or collapse one level. For example, expanding from Total Products to Products inserts the Product members while retaining the value for Total Products.

When you drill in a hierarchical column, you expand and collapse the nodes of data that are in the view. Drilling in a hierarchical column affects only that particular view. No other views are affected.

Drilling in level-based hierarchies and value-based hierarchies works the same. Each time you drill in a hierarchy, you expand or collapse one level. For example, if the hierarchy has a level for continents, regions, and cities, and the view shows continent data, you can expand from Australia down one level to display regions in Australia. From there, you can expand one level from a region, to cities in that region, or you can collapse one level, back to continents.

When you drill, the drill state is preserved. If you collapse at a higher level and re-expand, then the members are re-displayed at the same drill point.

When you click the Collapse icon, you collapse back to the current level any levels in the hierarchy that are present in the analysis, regardless of whether they were added by drilling down or by adding the levels from the Subject Areas pane.

You can perform asymmetric drilling, which enables you to drill various members to different levels. For example, if you expand World, then you might see Americas, Asia, and Australia at the same second-level for continents. You can then drill Americas to expand it and see its regions, while Asia and Australia are not expanded.

You can expand and collapse the members of a group for hierarchical columns. For example, if you have a group that includes cities and the group is included in a view, then you see the cities when you click the group name.

Drilling in Graphs

When you drill down in a graph, the detail level data replaces the current data. For example, when you drill down from a continent, the graph displays data for the countries in that continent, but not for the continent itself.

You can drill down in the following ways:

- You can click a label (for which drilling is available) on any axis or in the legend to drill down. A change in the mouse pointer indicates that drilling is available.
- If the graph contains only attribute columns and measure columns, then you can click a data point to drill all columns.
- If the graph contains multiple columns including at least one hierarchical column, then when you click a label or a data point, you see a menu from which you can select which columns to drill down. If there are action links available, then the menu also displays those links.



You do not drill up in a graph. Click the **Back** button on the browser to return to a previous graph.



The time series line graph does not support drill down on a time column where data types other than data or date-time are used.

Printing an Oracle Business Intelligence Dashboard or Saved Request

You can display printer-friendly versions of existing dashboards and requests. A printer-friendly version does not contain any extraneous links or other hypertext items.

You can print using HTML or Adobe PDF (Portable Document Format). Adobe PDF is the only print option available for Oracle BI Publisher reports. Adobe Reader 6.0 or greater is required to print using Adobe PDF.



The HTML method of printing relies on the print handling capabilities of your browser. If you do not get the results you want, choose PDF to open, and then print the dashboard or request.

To print a dashboard or a request:

- 1. Navigate to an existing dashboard or request.
- 2. To print a request, click the **Print** link, and then choose **HTML** or **PDF**.

To print a dashboard page, click the following icon at the bottom of the dashboard, and choose HTML or PDF:



- For HTML, a new window shows the selected item without the extraneous links. Choose File > Print on the browser menu.
- For PDF, use the options available in the Adobe PDF window to save or print the file.

Emailing an Oracle Business Intelligence Dashboard Page or Request

You can email a dashboard page or a request as an attachment. The format you use depends on your browser, such as Web Archive, Single File (.mht) in Internet Explorer or Mozilla Archive Format (.maf) in Mozilla and Firefox.



The Mozilla Archive Format capability is available as a separately downloaded plug-in.



In any browser, you can also save a dashboard page or request as a collection of HTML files. You can then zip and email the corresponding directory of associated files.

To email a dashboard page or request:

- 1. Navigate to the dashboard page or request that you want to send.
- To email a request, click the Print link, and then choose HTML or PDF. To email a dashboard page, locate and click the Print icon at the bottom of the dashboard, and then choose HTML or PDF.

A new browser window opens that contains the dashboard page or the request.

- 3. From the browser's toolbar, choose **File > Save As**.
- **4.** Save the file to the desired location, with the appropriate file type for your browser.
- 5. Send the saved attachment using an email application.



The saved attachments can also be used as a means to archive and restore requests as they exist at a particular point in time.



Working with Reports

Using Oracle Business Intelligence Analysis, you can run or display predefined reports (delivered with Oracle Argus Analytics), and you can also create or modify custom reports.

This chapter contains the following topics:

- Pre-defined Reports
- Custom Reports
- Viewing Reports With Your Apple iPhone

Pre-defined Reports

Oracle Argus Analytics is delivered with a bunch of pre-defined reports. A subset of these reports is displayed on your dashboard pages, based on the user group you are assigned to.

A report can contain data in a tabular format, pivot table, or graph. You can filter the data visible on the report based on certain criteria such as Program, Study, Users, User Group, etc. These filters are called *prompts*. Some reports let you drill down to a more detailed report.

The following is a list of some report-related tasks that you can perform:

- Create and modify reports
- Refresh the results
- Print and Save reports
- Add reports to the briefing book
- Copy reports

See Also:

- Using Oracle Argus Analytics for more information about report-related tasks.
- Dashboards and Reports for more information about predefined reports.
- Oracle Argus Analytics Installation Guide for instructions on installing Oracle Argus Analytics.

Go to:

· Opening and Using Dashboards

Opening and Using Dashboards

Perform the following steps to open and use dashboards:

1. In the global header, click **Catalog** to view the Catalog page.



- Navigate to the dashboard and click the Open link. The dashboard is opened to the first Dashboard Page. If no content has been added, an Empty Dashboard Page notification message is displayed.
- **3.** This is an optional step You may choose to perform any of the following tasks:
 - Display the dashboard in the Dashboard Builder for editing.
 - Navigate among dashboard page by clicking the page tabs.
 - Print a page.
 - Refresh a page.

Perform this to ensure that the refresh operation bypasses saved information in the Oracle BI Presentation Services cache and is issued to the Oracle BI Server for processing.

When you select a specific dashboard or analysis, Presentation Services checks its cache to determine if the identical results have recently been requested. If so, Presentation Services returns the most recent results, thereby avoiding unnecessary processing by the BI Server and the back-end database. If not, the analysis is issued to the BI Server for processing. You cannot force the analysis past the BI Server's cache.

Administrators can configure cache settings that control what is cached and for how long. For information, refer to *Managing Performance Tuning and Query Caching* in the *Oracle Fusion Middleware System Administrator's Guide for Oracle Business Intelligence Enterprise Edition*.

Custom Reports

You can create a custom report if you have been assigned the required permissions and responsibilities. If you prefer, you can copy a pre-defined report and use it as a template for the new report.

Use the Oracle Business Intelligence Answers user interface to create your own report. But before you proceed, consider the following points:

- Do not modify a pre-defined report. If you do, your changes will be overwritten
 when a new release of Oracle Argus Analytics is installed. Alternatively, you can
 make a copy, and modify the copy.
- Define a Catalog Folder hierarchy that gives each Answers user, a unique folder tree. Limit the right to move requests into public folders to members of the Oracle Argus Analytics Administrators group.
- Limit the right to place requests onto shared dashboards to members of the Oracle Argus Analytics Administrators group.

Viewing Reports With Your Apple iPhone

To download Oracle Business Intelligence Mobile, tap the App Store icon on the Home screen of your iPad or iPhone.

Alternatively, you can download the application from your computer through iTunes and then synchronize your iPad or iPhone.

Performs the following steps to download and install Oracle Business Intelligence Mobile:



- On your device, go to iTunes, and search the App Store for Oracle.
- From the displayed search results, select the Oracle Business Intelligence Mobile application, and tap the **Install** button.



Part II

Administration

This part of the Guide discusses topics and tasks related to administration of Oracle Argus Analytics.

Part II contains the following chapters:

- Extract Transform Load Programs
- Maintaining the Repository and Data Mart
- Performance Considerations
- Implementing Security



4

Extract Transform Load Programs

To load data from the source systems to the data mart, Oracle Argus Analytics uses Extract Transform and Load (ETL) programs that

- Identify and read desired data from different data source systems,
- Clean and format data uniformly, and
- Write it to the target data mart.

In Oracle Argus Analytics, Oracle Argus Safety is the source system for which Oracle provides pre-defined ETL.

This chapter contains the following topics:

- ETL Architecture
- Executing the ETL Load Plans in ODI
- Customizing an ETL Execution Plan/Load Plan (ODI)
- Creating an ETL Load Plan (ODI Only)
- Modifying an ETL Load Plan (ODI Only)
- Scheduling an ETL Load Plan (ODI Only)
- Customizable User Exits in Oracle Argus Analytics ETLs

ETL Architecture

Figure 4-1 displays the ETL process delivered with Oracle Argus Analytics.

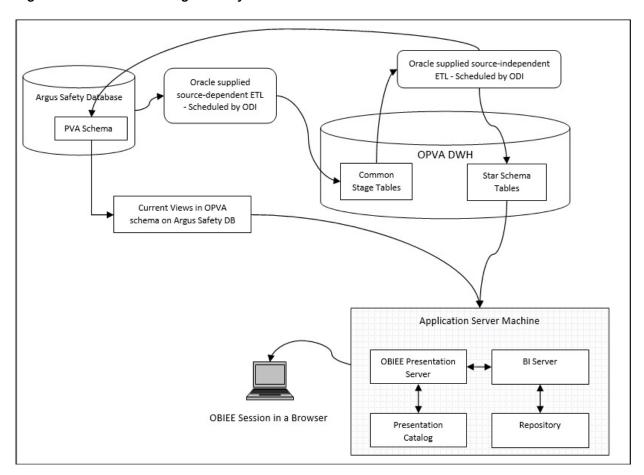


Figure 4-1 The Oracle Argus Analytics ETL Architecture

Oracle Argus Analytics has ETLs defined in the Oracle Data Integrator (ODI).

Set up as a recurring job in ODI, the Extraction, Transformation, and Load process (ETL) is designed to periodically capture targeted metrics (dimension and fact data) from multiple Safety databases, transform and organize them for efficient query, and populate the star-schema tables.

While the Oracle Argus Analytics data model supports data extraction from multiple sources, Oracle Argus Analytics includes only source-dependent extract (SDE) mappings/ODI for the Oracle Argus Safety database. However, you can also define SDE mappings from additional external sources that write to the appropriate staging tables. Note that you are responsible for resolving any duplicate records that may be created as a consequence.

The SDE programs map the transactional data to staging tables, in which the data must conform to a standardized format, effectively merging the data from multiple, disparate database sources. This is the architectural feature that accommodates external database sourcing.

The staged data is transformed using the source-independent loads (SILs) to starschema tables, where such data are organized for efficient query by the Oracle BI Server. There is one SDE mapping for each target table, which extracts data from the source system and loads it to the staging tables. SDEs have the following features:

- Incremental Submission Mode: Oracle Argus Analytics-supplied ETL uses timestamps and journal tables in the source transactional system to optimize periodic loads.
- Normal load writes one record at a time. It is intended to be used for updates to
 the data mart, once population has been completed. Normal load is faster, if data
 volume is sufficiently small. You can also restart load if the load is interrupted.

There is one SIL mapping/interface for each target table. The SIL extracts the normalized data from the staging table and inserts it into the data mart star-schema target table. SILs have the following attributes:

- Concerning changes to dimension values over time, Oracle Argus Analytics overwrites old values with new ones. This strategy is termed as Slowly Changing Dimension approach 1.
- Oracle Argus Analytics's data model includes aggregate tables and a number of indexes, designed to minimize query time.
- The results of each ETL execution is logged by ODI. The logs hold information about errors encountered, during execution.
 - For ODI, the EL\$_<TABLE_NAME> will store the erroneous data rows per table. Example: For W PRODUCT D ETL the error table is EL\$ W PRODUCT D.
 - During ETL execution, records which fail to be inserted in the target table (for example, some records violate a constraint) are placed in the ODI error tables, as mentioned above. You can review which records did not make it into the data mart, and decide on appropriate action with respect to them.

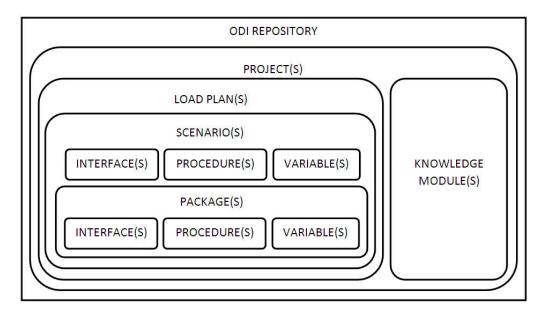
For more information, see:

Oracle Argus Analytics Hierarchy



Oracle Argus Analytics Hierarchy

Figure 4-2 Oracle Argus Analytics Hierarchy for ODI



Oracle Argus Analytics follows the hierarchy for ODI, as listed below:

- ODI REPOSITORY ODI Master and Work repository, which holds all the ODI objects for Oracle Argus Analytics ETL.
- PROJECT A collection of all Oracle Argus Analytics-related ODI ETL objects.
- KNOWLEDGE MODULE Templates of PLSQL code used in Interfaces/Mappings to achieve a specific ETL flow.
- LOAD PLAN ETL execution plan, which holds a pre-defined ordered set of scenarios to load the warehouse appropriately.
- SCENARIO The generated executable (and uneditable) code of the objects in ODI like Package, Procedure, Interfaces/Mappings, and Variables. Scenarios can be considered as frozen versions of the code at the time of generation, with subsequent updates of the relevant unit of code not affecting it.
- PACKAGE An ordered set of Interfaces/Mappings, Procedures, variables and packages as well to be executed in a defined manner.
- INTERFACE/MAPPING Executable ETL code for loading the target tables.
- PROCEDURE Modularized executable code for loading the target tables.
- VARIABLE Used for making code path decisions based on the user input provided while executing Load Plans.

Executing the ETL Load Plans in ODI

To load data from the source to their target tables in the data mart, run the Load Plan packaged with Oracle Argus Analytics ODI.

Perform the following tasks in ODI Studio:

- 1. Navigate to the Operator tab.
- In the Load Plans and Scenarios sections, right-click Load Plan: LP_FL_AN for full loads or LP_IL_AN for Incremental Loads option and select Execute/Run.
- 3. Provide the values for the Load Plan variables, as mentioned in the table below.

Table 4-1 ODI Parameters

| Parameters | Load Type | Description | Allowed Values |
|------------------------------|-----------|--|---|
| VAR_ALN_PERIOD_F ROM_DATE | Full Load | The start date of the days to populate from in the W_DAY_D/PVA_DAY table. It should be in the format: MM/DD/RRRR | Date values such as: 01/01/1980 Recommended value: 01/01/1980 |
| VAR_ALN_PERIOD_T O_DATE | Full Load | The end date of the days to populate till in the W_DAY_D/PVA_DAY table. It should be in the format: MM/DD/RRRR | Date values such as: 12/31/2019 Recommended Value: 12/31/2019 |
| VAR_INT_TRUNCATE _STAGE | Both | This variable is used to decide whether to truncate the stage table or not and is useful in multiple Argus Safety DB support | Valid values:0: Does not truncate Stage table1: Truncate Stage table Should be specified as 1 always in case of Single Argus Safety Instance as source information Recommended Value: |
| VAR_INT_COLLECT_S TATISTICS | Both | This variable is used to decide whether the statistics of the target tables need to be collected or not. | Default Value: 1 Values Accepted: 0,1 0: Load Plans will not collect statistics 1: Load Plans will collect statistics after loading data |
| VAR_ALN_ENTERPRI SE | Both | The specific Enterprise ID to run the ETL for. | -1: Runs the ETL for the entire Warehouse0: Runs the ETL for all the enterprises the user (\$\$p_user_name) has access toInteger Value [1,2,3, etc]: Runs the Incremental ETL for the specified Enterprise only. Note: For Full Load, this value has to be -1. |



Table 4-1 (Cont.) ODI Parameters

| Parameters | Load Type | Description | Allowed Values |
|--------------------------------|---------------------|--|---|
| VAR_ALN_ERROR_R EJECT_LIMIT | Both | This variable is used to set the number of rows that will be tracked in the respective error tables prior to aborting the ETL in case of errors. | Valid Values:Positive Integer numbers: (E.g. 0, 100, 1000, etc.)UNLIMITED: All the error records are logged Recommended Value: UNLIMITED |
| VAR_ALN_USER_NA ME | Both | The user name for which the ETL shall use to set the VPD Context for the specified enterprise in the parameter: VAR_ALN_ENTERPRI SE. This value should be passed inside single quotes: such as 'username'. | Default value: 'admin' |
| VAR_INT_RAISE_ERR OR | Both | Setting this variable to 0 or 1 will appropriately either stop a Load Plan/ Interfaces/Mappings or continue the same when data errors are encountered during the load. | 0: Do not raise data error when encountered during ETLs1: Raise data error when encountered during ETLs Recommended Value: |
| VAR_INT_CONFIG_DA YS | Incremental Load | Reduces the incremental extract window by the specified number of days. Example: Extract all changed rows between LAST_EXTRACT_DAT E and (SYSDATE - \$\$p_config_days) | Integers Recommended Value: 0 |
| VAR_INT_REKEY_FAC T | Incremental Load | To rekey fact tables in case data in the W_HS_MAPPING_S defined for match and merge has changed | 0: Will not rekey the Fact tables 1: Will rekey the Fact tables Recommended Value: 0 |



| Parameters | Load Type | Description | Allowed Values |
|--|---------------------|--|---|
| VAR_INT_OVERRIDE_ LAST_EXTRACT_DAT E | Incremental Load | Specify a Date value in the format MM/DD/RRRR if you want to override the last extract date for the Incremental Data for the specific ETL run. This will cause reload of data in the warehouse that are present in the given incremental extract window. | Date values such as:01/01/1900 or 12/23/2012 Recommended Value: NULL (Change this with discretion) |
| VAR_INT_INCLUDE_P SEUDO_ST_CODE_F LG | Both | The parameter defines whether to include the workflow states present between the Locking record and the Unlocking record of a case in the Case Workflow State Fact table. | Date values is 1.1: Include the Workflow States between Locking and Unlocking records of the case.0: Exclude the Workflow States between Locking and Unlocking records of the case. |

Table 4-1 (Cont.) ODI Parameters

4. Click OK to run the Load Plan.

Customizing an ETL Execution Plan/Load Plan (ODI)

When you customize an ETL Execution Plan/Load Plan (ODI), it is your responsibility to maintain version control over changes to ETL mappings/interfaces.

Oracle recommends that you carefully track the changes you make to Oracle-supplied ETL so that you can re-apply these changes in subsequent releases.

Note:

The ETL Execution Plans that extract data for the data mart fact tables assume that the dimensions to which each fact is related are up-to-date at the time the fact ETL Execution Plans are executed. This assumption is the basis for certain fact calculations that would provide erroneous results if the assumption were not true.

As shipped, Oracle Argus Analytics ETL workflows ensure this interlock by executing the ETL for related dimensions immediately before running the ETL for a fact.

This is standard data mart management practice, but especially important, given the interdependence of the dimensions and the fact. The need to execute dimension ETL immediately before corresponding fact ETL, and the danger of not doing it, is emphasized here because it is possible (though discouraged) to modify these shipped workflows.



Creating an ETL Load Plan (ODI Only)

Though Oracle Argus Analytics includes ETL Load Plans for extracting data from Oracle Argus Safety to Oracle Argus Analytics data mart, you may want to create your own ETL Interfaces/Mappings to extract data from other data sources.

Note:

The value of DATASOURCE_NUM_ID is set to 1 for Oracle Argus Safety and is taken from the view VW_DATASOURCE present in the Oracle Argus Analytics Source Schema (AN_SRC). Update this view to change the DATASOURCE_NUM_ID number, only if desired.

Also, ensure that this change (if needed) is done prior to running the Full Load for Oracle Argus Analytics. By default, we advise not to change this value (view).

See Also:

Oracle ® Fusion Middleware Developer's Guide for Oracle Data Integrator 11g/12c

To add one or more tables or columns along with the associated ETL Load Plans to populate data into these tables, perform the following tasks:

- Create the new Datastore for source and target table metadata inside the appropriate ODI Models.
- 2. Work in ODI Studio and create the ETL components (Interface/Mapping and its Scenario) for this program to populate the table or column appropriately.
- 3. Edit or create an existing Load Plan.
- 4. Add the scenario generated at the appropriate hierarchical level and position where it needs to be executed, in the Load Plan.
- 5. Save the Load Plan.

Modifying an ETL Load Plan (ODI Only)

You may also want to modify an existing ETL to meet your reporting requirements.

See Also:

• Oracle ® Fusion Middleware Developer's Guide for Oracle Data Integrator 11g/12c

To modify an ETL Load Plan without any changes to the associated tables or columns, perform the following tasks:

- Identify the Load Plan that needs to be modified in the repository.
- Identify the Interface/Mapping or Package in the Load Plan that you intend to modify.
- 3. Open and modify the ETLs (Interface/Mapping/Procedure) in ODI Studio under the Project ArgusAnalytics111.



- 4. Test and save the changes in ODI Studio.
- 5. Verify that the changes made have been applied successfully.
- 6. Regenerate the associated scenario with the Interface/Mapping/Procedure.

To modify one or more tables or columns without any changes to the associated ETL programs (typically to widen a column):

- 1. Change the table/view properties, as required.
- 2. Save the Interface/Mapping and regenerate the associated scenario in ODI Studio.

Scheduling an ETL Load Plan (ODI Only)

To schedule a Load Plan, perform the following tasks:

- In the ODI Studio, navigate to the Load Plans and Scenarios section in the Operator tab.
- 2. Expand the Load Plan that you wish to schedule.
- 3. Right-click on the **Scheduling** tree node and select **New Scheduling**.
- Enter the required details and click Save.
- 5. Restart the associated Physical Agent with the Load Plan (default value: PA AN).

Customizable User Exits in Oracle Argus Analytics ETLs

The VW_CONFIGURABLE_TARGET_DAYS view, and the VW_CONFIGURABLE_DUESOON_DAYS view can be used to customize some of the attribute values used in Oracle Argus Analytics as per organization requirements.

The views VW_CONFIGURABLE_TARGET_DAYS and VW_CONFIGURABLE_DUESOON_DAYS are used in the source code for the views Pending Cases Fact and Pending Reports Fact present in the Current Metrics of Oracle Argus Analytics and in the ETL SDE views.

These objects are available in the AN_SRC schema created on the Argus Safety DB Instance, specified during Oracle Argus Analytics Installation.

For more information, see:

- VW CONFIGURABLE TARGET DAYS
- VW CONFIGURABLE DUESOON DAYS

VW_CONFIGURABLE_TARGET_DAYS

The VW_CONFIGURABLE_TARGET_DAYS view is similar to this function. This view, by default, returns 10 days for a serious case and 30 days if the case is not serious, as per the enterprise present. It can be modified accordingly, as per organizational requirements.



Table 4-2 Oracle Argus Analytics Presentation Catalog Attributes Affected - Lock Target Days

| ID | Fact | Column | |
|---------|---------------|------------------|--|
| M-CVH01 | Case Version | Lock Target Days | |
| M-PC04 | Pending Cases | Lock Target Days | |



Refer to the Facts and Sources in Oracle Argus Analytics Presentation Catalog for the other attributes that are dependent on the attributes mentioned in the above table.

VW_CONFIGURABLE_DUESOON_DAYS

The VW_CONFIGURABLE_DUESOON_DAYS view is similar to this function. This view is used in the Pending Cases Fact and Pending Reports Fact views present in the Current Metrics. It can be modified accordingly, as per organizational requirements.

Table 4-3 Oracle Business Intelligence Presentation Catalog Attributes Affected - Due Soon Days

| ID | Fact | Column |
|--------|---------------|---|
| M-PC06 | | Lock Due Soon Date |
| M-PC02 | Pending Cases | Earliest Exp Report Due Soon Date |
| M-PC06 | Pending Cases | Lock Due Soon Date |
| M-PC09 | Pending Cases | State Due Soon Date - I |
| M-PC12 | Pending Cases | State Due Soon Date - II |
| M-PC16 | Pending Cases | # Unlocked Cases w Expedited Report Due Soon |
| M-PC19 | Pending Cases | # Unlocked Cases Due Soon |
| M-PC22 | Pending Cases | # Unlocked Cases w State Due Soon - I |
| M-PC25 | Pending Cases | # Unlocked Cases w State Due Soon - II |

Note:

Refer to the Facts and Sources in Oracle Argus Analytics Presentation Catalog for the other attributes that are dependent on the attributes mentioned in the above table.



5

Maintaining the Repository and Data Mart

This chapter contains the following topics:

- Maintaining the Oracle Argus Analytics Repository
- Maintaining the Oracle Argus Analytics Data Mart

Maintaining the Oracle Argus Analytics Repository

Each release of Oracle Argus Analytics contains a Repository (RPD) file. The Repository is the data store for the Oracle BI Server. It maintains the mapping of the physical tables comprising the data mart to the Presentation Layer, which holds the columns and tables available for use in OBIEE Requests. As shipped, the RPD corresponds to the Oracle Argus Analytics data mart, and can be used without any modification.

However, you might find it desirable to modify the Oracle-supplied Oracle Argus Analytics Repository file (RPD), for any of the following reasons:

- You want to add a column or table to the data mart, and propagate that addition into the layers of the repository.
- You want to add a calculated column in the Presentation Layer as a function of some set of physical layer columns.
- You want to modify a repository variable value, or add a new repository variable, for use in some Presentation Catalog calculation.
- You want to modify a group, an account, or a privilege maintained through the repository.

This section describes the procedures you must follow to carry out these types of modifications.

You should be aware that, once you have modified the Oracle-supplied Repository, it is your responsibility to merge these modifications into Repositories supplied by Oracle in patches and releases of Oracle Argus Analytics. Details on how to re-apply your modifications are provided below.



Caution:

Changes to the Repository should be made with care.

Privileges to make changes in the Oracle Argus Analytics Repository should be granted only to a limited set of users who need to make such changes and also know how to make them correctly.

Changes should be tested on a side copy of the Repository before being released for production use.

For more information, see:

Modifying the Repository

Modifying the Repository

The Oracle Argus Analytics Repository is maintained as a versioned object in a version controlling software. A copy of that Repository is deployed to the application server file system. This *deployed* Repository is the one that the Oracle BI Server uses. All changes to the Repository, however, must be made through a two-step process:

- Modify the versioned Repository object.
- Deploy the latest version of the Repository object.

Therefore, Oracle requires that you do not modify the deployed Oracle Argus Analytics Repository directly.

If you do need to modify the Repository, perform the following tasks:

- 1. Open RPD using the Administration tool and make the desired modifications.
- Launch the Oracle BI Presentation Server to verify the changes.

Maintaining the Oracle Argus Analytics Data Mart

You may need to modify the Oracle Argus Analytics data mart, typically for one of the following reasons:

- Derivation: Calculation of a new measure as a function of some supplied measures.
- Extension: Adding data that was not delivered with Oracle Argus Analytics.
- Substitution: Swapping data from a different source for a column that was delivered with Oracle Argus Analytics.



Caution:

Exercise caution when you modify the data mart. Please conform to the recommendations mentioned in the subsequent sections.

For more information, see:

- Derivations
- Substitutions
- Modifying Data Mart Tables

Derivations

A *derivation* is a calculation of a new measure as a function of some supplied measures. Oracle Argus Analytics displays all derivations as a column in Answers. You can use any of the following approaches to calculate derivations:

Calculate the derivation as part of the creation of a request.



- In this approach, only the Web Catalog is modified. However, you must specify the calculation for each request, and the calculation is executed every time the request is executed.
- Calculate the derivation in the physical or business layer of the RPD file; it
 is propagated to the presentation layer. This makes the derivation you created
 appear in Answers as a column.
 Using this approach, you can specify the calculation once and use it for multiple
 requests. The derived value looks the same as any other Answers column.
- Calculate the derivation in the data mart.
 The calculation is run at ETL execution time and not at query time. The derived value looks the same as any other Answers column. In this approach, you must add the result column to the staging and target tables, modify the ETL procedures (both Source Dependent Extract (SDE) and Source Independent Load (SIL)), and then add the column to all the layers of the RPD.

Substitutions

A substitution occurs if you have a preferred alternative source of data for a column that Oracle Argus Analytics populates from Oracle Argus Safety. For example, you may want to load the W_RXI_STUDY_D.STUDY_SPONSOR other than what Oracle Argus Analytics is loading. You will have to perform the following tasks:

- 1. Create a table at database containing the locally-sourced values of the column, and also add whatever keys are needed to join to the Oracle-supplied view.
- 2. Create a program that joins the two tables and creates a new table, in which the locally-sourced values replace the Oracle-supplied values for the column of interest. Call this the Substitution Table.
- 3. Modify the SDE to read from the Substitution Table, rather than the Oracle-supplied table or view.

If you make changes to a source table, you must propagate that change forward as far as necessary. Some of the scenarios and the related necessary adjustments are described in the Table 4-1:

Table 5-1 Scenarios Requiring Necessary Adjustments

| Scenario | Adjustments Required | |
|---|--|--|
| New table has the same layout as the old table, but is passed through from a different source | Change the SDE that reads the old table to instead read the new table. | |
| Modified table has modified layout | Modify the SDE to read the modified layout. | |
| | 2. Modify the staging table populated by the SDE to include the modified layout. | |
| | 3. Modify the SIL to read the modified layout. | |
| | 4. Modify the target table to include the modified layout. | |
| | 5. Modify the RPD to accept the changed data mart table. | |



Table 5-1 (Cont.) Scenarios Requiring Necessary Adjustments

| Scenario | Adjustments Required |
|-----------|--|
| New table | Add a staging table to accept the new input. |
| | Add an SDE to read from the new table and write to the staging table. |
| | Add a data mart table to make the new data available to the BI Server. |
| | Add an SIL to populate the new data mart table from the new staging table. |
| | 5. Modify the RPD to accept the new data mart table. |

Modifying Data Mart Tables

Depending on what changes are required to the data mart, it is necessary to modify the source, staging, and target tables.

For more information, see:

Managing Indexes

Managing Indexes

Oracle Argus Analytics is delivered with a set of indexes. If you wish, you can create additional indexes to meet your query requirements.



Oracle recommends that you Drop and re-create all indexes only for full load. This should be disabled for incremental load.

It is useful to drop all indexes on the data mart tables before loading large volumes of data, and to recreate them afterward. ODI can automate this process for you.

To drop indexes per table, use the procedure call opvautilcommon.p Drop Indexes(pTableName in varchar2).

To create indexes per table, use the procedure call opvautilcommon.p_Create_Indexes(pTableName in varchar2).



The P_DROP_INDEXES procedure stores the index metadata information in the table W_PVA_INDEX_S OR PVA_INDEX_S. This information is later used by the procedure P_CREATE_INDEXES to re-create the dropped indexes on the given table.



6

Performance Considerations

This chapter lists the performance considerations that should be adhered to, while creating requests or dashboards.

This chapter contains the following topics:

- · Conformed Dimensions in Oracle Argus Analytics
- Aggregate Facts in Oracle Argus Analytics
- Creation of Prompts and Filters
- Oracle Business Intelligence Enterprise Edition Caching and Cache Seeding

Conformed Dimensions in Oracle Argus Analytics

A conformed dimension is a set of data attributes that have been physically implemented in multiple database tables using the same structure, attributes, values, definitions and concepts in each implementation. It is always a good practice to use Conformed Dimension columns along with the Facts when we create any Requests. By using the conformed dimensions, OBIEE forms select statements that choose the correct Fact table to display accurate data.

Non-conformed dimensions imply the existence of logical and/or physical inconsistencies that should be avoided. Using Non-conformed Dimensions with the Fact leads to unwanted Table selection in the Query formation which results the Report to display null values (in case of Aggregates values) and might degrade the Performance of the Request or Report.

For example: If the user selects some of the aggregate measures from Case Version Fact along with the Routing user from User Dimension and Workflow State from State Dimension, the Report does not display the aggregate measures values as both the selected Dimension attributes are Non-conformed Dimensions for the Case Version Fact.

The following table contains the details of the conformed Dimensions for the Facts we have used in Oracle Argus Analytics.

Table 6-1 Retrospective Facts and their Conformed Dimensions

| Retrospective Facts | Conformed Dimensions |
|---------------------|-------------------------------|
| Case Fact | Enterprise |
| Case Fact | Case Processing Site |
| Case Fact | Product |
| Case Fact | Study |
| Case Fact | Period - Clock Start Date |
| Case Fact | Period - Initial Receipt Date |



Table 6-1 (Cont.) Retrospective Facts and their Conformed Dimensions

| Case Version Fact Case Routing Fact Case Workflow State Fact Case Work User Fact Cas | Detwo anactive Facto | Cantagonal Disconsions |
|--|--------------------------|-------------------------------|
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| Expedited Submission Enterprise | Case Work Fact | Period - Version Receipt Date |
| | Expedited Submission | · |
| | <u> </u> | · |



Table 6-1 (Cont.) Retrospective Facts and their Conformed Dimensions

| Retrospective Facts | Conformed Dimensions |
|----------------------|---|
| Expedited Submission | Product |
| Expedited Submission | Study |
| Expedited Submission | Period - Clock Start Date |
| Expedited Submission | Period - Initial Receipt Date |
| Expedited Submission | Period - Version Receipt Date |
| Expedited Submission | Expedited Submission Dimensions - Report Generation Date |
| Expedited Submission | Expedited Submission Dimensions - Report Submission Or MDN Date |
| Expedited Submission | Expedited Submission Dimensions - License |
| Expedited Submission | Expedited Submission Dimensions - Report Destination |
| Report Routing | Enterprise |
| Report Routing | Case Processing Site |
| Report Routing | Product |
| Report Routing | Study |

Table 6-2 Current Facts and their Conformed Dimensions

| Current Facts | Conformed Dimensions |
|-----------------|--|
| Pending Cases | Enterprise |
| Pending Cases | Case Processing Site |
| Pending Cases | Product |
| Pending Cases | Study |
| Pending Cases | Period - Initial Receipt Date |
| Pending Reports | Enterprise |
| Pending Reports | Case Processing Site |
| Pending Reports | Product |
| Pending Reports | Study |
| Pending Reports | Period - Initial Receipt Date |
| Pending Reports | Pending Report Dimensions - License |
| Pending Reports | Pending Report Dimensions - Report Destination |

Aggregate Facts in Oracle Argus Analytics

Most of the requests that we tend to include in Dashboards are Summary Reports, where in data from the fact table is used to roll up to the appropriate level against a dimension. Instead, we can create aggregate tables that contain pre-computed sums, averages and so on for a fact table at a specific hierarchical level in the dimension (e.g. Month for a Period Dimension).



This, in essence, means that we compress specific data from the base Fact into the derived Aggregate Fact for the agreed dimensions levels. We can then make use of this Aggregate Fact table to derive these Summary Reports which will be much faster (as it will contain much lesser data to process) when compared to rolling up the same data from the detail-level base Fact table thus improving the response times of the requests.

Aggregate fact tables contain same measure data like in the lowest granularity fact table but summarized on certain levels of the dimensions that we plan to use.

In Oracle Argus Analytics, we have introduced the following Aggregate Facts to increase the performance of the Dashboard Reports:

W_PVA_CASE_MN_A

This is an Aggregate Fact table for the Base Fact W_PVA_CASE_VERSION_F and contains the same aggregate measures like the Base Fact, but aggregated at the Version Receipt Month level from the Period Dimension, along with the Enterprise, Product, Study, Case Processing Site, Case Type, Case Seriousness, and Case Deletion Indicator dimensions. Whereas, in the Base Fact W_PVA_CASE_VERSION_F, the granularity is at the Case ID, Version ID level for all the measures which is in turn at the Version Receipt Date level for each version of the case.

So, if we select the Month attribute from the "Period" Presentation Folder (Period -> "Case Version - Version Receipt Date" -> Month) along with the Case Version Aggregates, the data will be selected from the Aggregate table and not from the Base Fact table. The same is true even when attributes from Enterprise, Product, Study or Case Processing Site Presentation Folders are selected or the attributes Case Type, Case Seriousness, and Case Deletion Indicator.

Whereas, If we select attribute Date from the "Period" Presentation Folder (Period -> "Case Version - Version Receipt Date" -> Day) along with the Case Version Aggregates, the data will be selected from the Base fact table, which might take longer to retrieve the results of the request.

Table 6-3 Aggregate Case Version Fact - Conformed Dimensions

| Retrospective Facts | Conformed Dimensions |
|--|--|
| Aggregate Case Version Fact - Version Receipt Month | Enterprise |
| Aggregate Case Version Fact - Version Receipt Month | Case Processing Site |
| Aggregate Case Version Fact - Version Receipt Month | Product |
| Aggregate Case Version Fact - Version Receipt Month | Study |
| Aggregate Case Version Fact - Version Receipt Month | Period - Version Receipt Date (at the hierarchical level of Month in the Period dimension) |
| Aggregate Case Version Fact - Version Receipt Month | Case Type |
| Aggregate Case Version Fact - Version Receipt Month | Case Seriousness |



Table 6-3 (Cont.) Aggregate Case Version Fact - Conformed Dimensions

| Retrospective Facts | Conformed Dimensions |
|---|-------------------------|
| Aggregate Case Version Fact - Version Receipt Month | Case Deletion Indicator |

W PVA WORKFLOW ST A (Case Workflow State Fact)

This is a dual purpose Fact table that serves as an Aggregate Fact (not explicitly called so due to its implementation in the Oracle Argus Analytics RPD), and, it is also used as a Fact table. What this means is that, on one hand it provides meaningful aggregate metrics on the operational effectiveness on routing of cases across workflow states and on the other hand it also serves as an aggregate fact on top of the Case Routing Fact.

In terms of Aggregate Fact usage, this is a compressed form of the Case Routing Fact table and is compressed to provide aggregate metrics at the level of Enterprise ID, Case ID, Version ID and Workflow State. In the RPD this Fact table is exposed as a Presentation Folder "Case Workflow State" and can be directly used with the dimensions as mentioned in the above table, listing conformed dimensions.

W PVA CASE PROCESSING MN A

This is an Aggregate Fact table for the Base Fact W_PVA_CASE_F and contains the same aggregate measures like the Base Fact, but aggregated at the Initial Receipt Month level from the Period Dimension, along with the Enterprise, Product, Study, Case Processing Site, Case Type, Case Seriousness and Case Deletion Indicator dimensions. Whereas, in the Base Fact W_PVA_CASE_F, the granularity is at the Case ID level for all the measures which is in turn at the Initial Receipt Date level for each case.

Table 6-4 Aggregate Case Version Fact - Conformed Dimensions

| Retrospective Facts | Conformed Dimensions |
|---|--|
| Aggregate Case Fact - Initial Receipt Month | Enterprise |
| Aggregate Case Fact - Initial Receipt Month | Case Processing Site |
| Aggregate Case Fact - Initial Receipt Month | Product |
| Aggregate Case Fact - Initial Receipt Month | Study |
| Aggregate Case Fact - Initial Receipt Month | Period - Initial Receipt Date (at the hierarchical level of Month in the Period dimension) |
| Aggregate Case Fact - Initial Receipt Month | Case Type |
| Aggregate Case Fact - Initial Receipt Month | Case Seriousness |
| Aggregate Case Fact - Initial Receipt Month | Case Deletion Indicator |



W_PVA_REPORT_SUBMSN_MN_A

This is an Aggregate Fact table for the Base Fact W_PVA_CASE_RPT_SUBMSN_F and contains the same aggregate measures like the Base Fact, but aggregated at the Report Submission or MDN Month level from the Period Dimension, along with the Enterprise, Product, Study, Case Processing Site, Report Destination, Report Assigned User Group and Report Completion Type dimensions. Whereas, in the Base Fact W_PVA_CASE_RPT_SUBMSN_F, the granularity is at the Case ID, Version ID & Report ID level for all the measures which is in turn at the Report Submission Or MDN Date level for each case.

Table 6-5 Aggregate Case Version Fact - Conformed Dimensions

| Retrospective Facts | Conformed Dimensions |
|---|--|
| Aggregate Report Submission Fact - Report Submission Or MDN Month | Enterprise |
| Aggregate Report Submission Fact - Report Submission Or MDN Month | Case Processing Site |
| Aggregate Report Submission Fact - Report Submission Or MDN Month | Product |
| Aggregate Report Submission Fact - Report Submission Or MDN Month | Study |
| Aggregate Report Submission Fact - Report Submission Or MDN Month | Expedited Submission Dimensions - Report Submission Or MDN Date (at the hierarchical level of Month in the Period dimension) |
| Aggregate Report Submission Fact - Report Submission Or MDN Month | Report Destination |
| Aggregate Report Submission Fact - Report Submission Or MDN Month | Report Assigned User Group |
| Aggregate Report Submission Fact - Report Submission Or MDN Month | Report Completion Type |

Creation of Prompts and Filters

When we create Prompts and Filters, it is better to avoid using functions to get or modify the Prompt or Filter values such as Substring, IfNull, Cast, ValueOf and so on. Inclusion of such prompts in the dashboard pages or as filters in Requests might degrade the performance of the Requests/Dashboards associated with it. It is advisable to use the direct column values for creating Prompts and Filters.

It is a best practice to enforce the Dashboard Prompts to have default values associated with it, so that the Dashboard Requests (which have filters on the same columns) can benefit from the default values, as it will result in analyzing the request on a much smaller subset of the Fact/Aggregate Fact data.

For more information, see:



Mandatory Prompts

Mandatory Prompts

The prompts that are present in the dashboard can be made mandatory. By making a prompt mandatory, the particular report can be forced to use the aggregate facts, thereby improving performance significantly.

For more information, see:

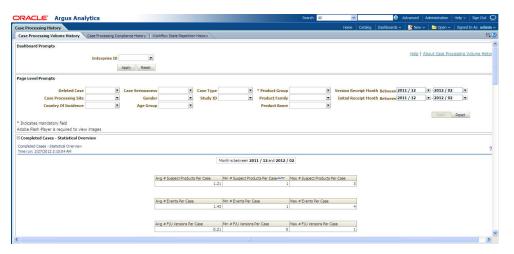
- Creating a mandatory field in page-level prompts
- · Setting up default values

Creating a mandatory field in page-level prompts

The following example lists the steps required to make the Product Group prompt as a mandatory prompt:

 Login to the Oracle Business Intelligence Enterprise Edition application as a user with administrative rights and access to edit the dashboards. Typically, this would be the administrator.

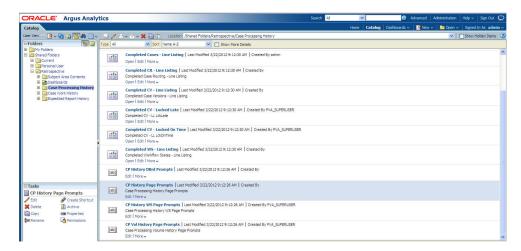
Figure 6-1 Dashboard Reports



- Navigate to the folder in the catalog where prompts are saved. Example: Catalog
 Shared folders > Retrospective > Case Processing History.
- 3. Click the **Edit** link to make the change. Example: CP History Page Prompts.

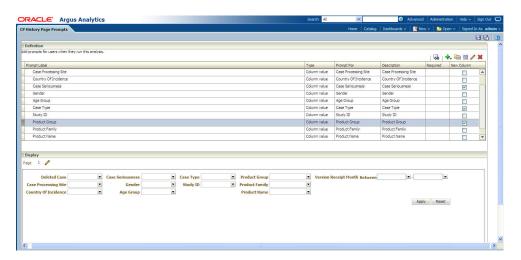


Figure 6-2 Oracle Business Intelligence Enterprise Edition Objects in Catalog Folders



4. Select the field which is to be made mandatory and click the Edit icon (present on the top right of the opened screen), such as the Product Group field selected below.

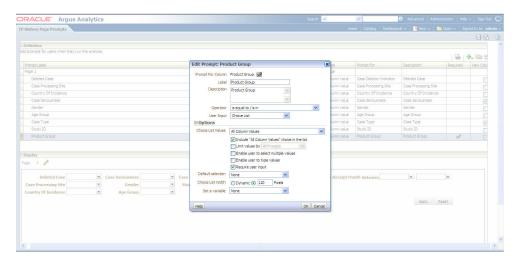
Figure 6-3 Catalog Prompt Edit Page



5. An **Edit Prompt** dialog appears, with options to customize the prompt. To make the field mandatory, check the **Require user input** checkbox and click **OK**.

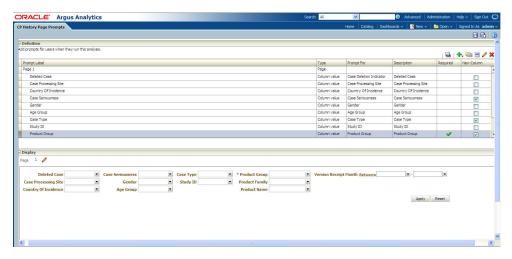


Figure 6-4 Edit Prompt Dialog



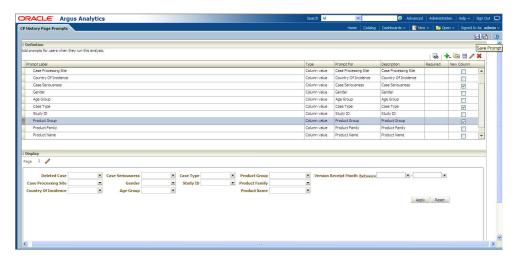
6. You can verify the change by checking the Required column of the field (**Product Group** below). Mandatory fields have a tick mark displayed against them. In the Preview window, an asterisk (*) appears before the name of the mandatory field.

Figure 6-5 Preview Changes in Dashboard Prompts



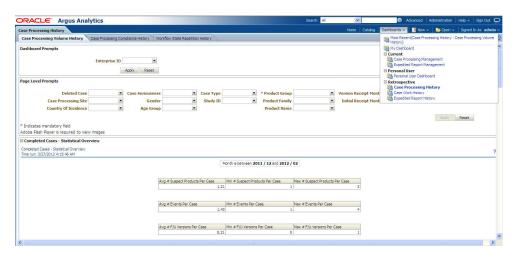
7. Save the prompt by selecting the **Save** icon (highlighted below), present on the top right side of the screen.

Figure 6-6 Saving Dashboard Prompts



8. The column configured for mandatory input is now reflected in the page-level prompt of the respective reports.

Figure 6-7 Mandatory Prompts Marked with * in Report Page



Note:

The **Apply** button is disabled. This button will get enabled only after values for all the mandatory prompts present in a page have been entered. The text * Indicates mandatory field is displayed next to the mandatory prompts present in a page.

Setting up default values

Prompts can be set with default preferred values, based on the logged-in user. This would be very useful when the same value is supplied to a prompt by a user most of the time. Further, it can also be helpful by setting up a default value for the mandatory prompts.

The following example lists the steps required to set up the default value for the mandatory parameter called **Product Group**:

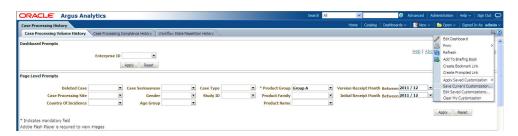
1. Navigate to the report where the default prompt value is to be saved. Go to the prompt, select the value, and click **Apply**.

Figure 6-8 Default Value Selection for Mandatory Prompts



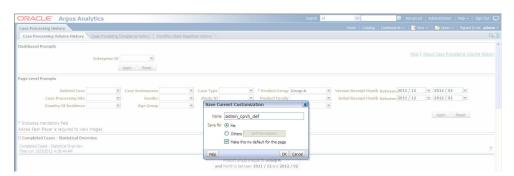
To save the current selection, click the Page Option icon present on the top right corner of the opened report. Select Save Current Customization from the drop-down menu.

Figure 6-9 Save Default Customization



3. In the Save Current Customization dialog that appears, enter the customization name in the Name field and select the Make this my default for this page checkbox. Click OK to save your customized changes.

Figure 6-10 Name the Default Customization Before Saving





Oracle Business Intelligence Enterprise Edition Caching and Cache Seeding

Cache is a component that improves performance by transparently storing data such that future requests for the same criteria can be served much faster. Like other application cache is not virtual memory in Oracle Business Intelligence Enterprise Edition. In Oracle Business Intelligence Enterprise Edition cache will be stored as files on the Hard Disk of the Oracle Business Intelligence Enterprise Edition Server in the form of files. By Default caching is enabled in the Oracle Business Intelligence Enterprise Edition server configuration.

For time-consuming Dashboard Pages, we can use the concept of cache seeding in Oracle Business Intelligence Enterprise Edition, this can be configured as a scheduled job that will ensure that the data is cached and readily available as and when the user runs the dashboard.



7

Implementing Security

This chapter contains the following topics:

- About Security in Oracle Argus Analytics
- Setting Up User Authentication

About Security in Oracle Argus Analytics

Oracle Argus Analytics spans several applications:

Oracle Argus Safety is the data source.

ODI ETL Execution plans and transforms Oracle Argus Safety data structures into the star schemas required by Oracle Business Intelligence Enterprise Edition.

Oracle Business Intelligence Enterprise Edition reads from the star schemas and provides the user interface, where end-users can view and analyze data through dashboards and reports.

Oracle Argus Analytics security includes:

Authentication

Oracle Argus Analytics user accounts are maintained in WLS Embedded LDAP. A customer who is using OAM to authenticate the source system access can also configure it for Oracle Business Intelligence Enterprise Edition authentication.

Authorization

You assign user accounts to user groups in WLS Embedded LDAP. On login, Oracle Business Intelligence Enterprise Edition ascertains the authenticated user's user group, where user groups with the same name determine which parts of Oracle Argus Analytics the user can use.

Predefined Oracle Business Intelligence Enterprise Edition user groups determine the privileges allowed to users and allow access to the shipped Oracle Argus Analytics dashboards and reports. You can create additional user groups as needed in OBIEE.

Data Access

In Oracle Argus Analytics, access is also performed at row level. This is done by extracting the access records for studies, products and sites from the source system.

For more information, see:

Example

Example

This section describes how to set up security for the following basic types of users as an example.

- Oracle Argus Analytics End Users are people who can view Oracle Argus Safety data in Oracle Argus Analytics through dashboards and reports. The specific dashboards and reports they can view is determined by the user groups they belong to.
- Oracle Argus Analytics Programmers are people who are authorized to create their own reports in the Answers component of Oracle Business Intelligence Enterprise Edition/Oracle Argus Analytics, which does not require any programming skills. You can distinguish between people who can simply create ad hoc reports and those who can save the reports they create to a dashboard so that other people can use them.
- ETL Programmers are people who can modify the functionality of Oracle Argus
 Analytics by modifying the predefined ETL Programs that Oracle Argus Analytics
 uses to transform transactional source data in ODI repository for use in Oracle
 Argus Analytics. They may also create new ETL Programs to support custom
 dashboards and reports in Oracle Argus Analytics.
- Oracle Argus Analytics Schedulers are people who schedule Oracle Argus Analytics jobs, including the data loading job and the user data access jobs. They need privileges similar to ETL Programmers.
- ODI Administrators are people who set up ODI Setups, and grant privileges to other users.

Setting Up User Authentication

ODI handles creation and maintenance of users for ETL administration of Oracle Argus Analytics. Oracle Argus Safety handles reports related user authentication for Oracle Argus Analytics.

For more information, see:

- · Creating User Accounts in ODI
- Creating Users and Groups for Oracle Argus Analytics
- Implementing Security using OAM and Configuring SSL for Oracle Argus Analytics

Creating User Accounts in ODI

For more information, refer to the *Oracle® Fusion Middleware Developer's Guide for Oracle Data Integrator 12c*.

Creating Users and Groups for Oracle Argus Analytics

Refer to the *Oracle Argus Analytics Installation Guide* for instructions on creating users and groups.

Implementing Security using OAM and Configuring SSL for Oracle Argus Analytics

Refer to the *Oracle Argus Analytics Installation Guide* for instructions on SSO installation to implement security using Oracle Access Manager, and on configuring SSL for Oracle Argus Analytics.



A

Dashboards and Reports

This section describes predefined dashboards and reports delivered with Oracle Argus Analytics.

You may also refer to:

- Using Oracle Argus Analytics
- Working with Reports

For more information, see:

- Oracle Argus Analytics Dashboards
- Oracle Argus Analytics Reports

Oracle Argus Analytics Dashboards

Oracle Argus Analytics is delivered with six dashboards. These dashboards can be accessed by users with a specific job responsibility and security privileges. Each dashboard has tabbed pages that display reports.

Click to Accessing Oracle Argus Analytics.

Log in to Oracle Argus Analytics, and from the following dashboards, select a dashboard you want to view:

- Case Processing History
- · Case Processing Management
- Personal User Dashboard
- Expedited Report History
- Expedited Report Management
- Case Work History

Case Processing History

This section describes the Case Processing History dashboard in Oracle Argus Analytics.

This dashboard of retrospective metrics (or trailing KPIs) can be accessed by an Executive Manager or Team Leader. It provides reports on completed case versions, that is case versions that are already locked.

This dashboard includes the following prompt, which is common to all its pages:

Enterprise ID: Lists the unique identifier for the enterprise.

For more information, see:

Case Processing History Dashboard Pages



Case Processing History Dashboard Pages

This dashboard includes the following tabbed pages:

Case Processing Volume History

This page displays reports on the volume of completed cases and case versions.

This page includes the following prompts, which are common to all its reports:

- Deleted Case: Lists whether the case is a deleted case.
- Case Processing Site: Lists the name of the case processing site.
- Country of Incidence: Lists the country of incidence.
- Case Seriousness: Lists the seriousness level for the case.
- Gender: Lists the gender of the patient reported in the case.
- Age Group: Lists the age group of the patient reported in the case.
- Case Type: Lists the type of case.
- Study ID: Lists the unique identifier for the study.
- Product Group: Lists the product group in the case.
- Product Family: Lists product family in the case.
- Product Name: Lists the product name in the case.
- · Version Receipt Month Between: Lists the month range for the version receipt.
- Initial Receipt Month Between: Lists the month range for the initial receipt.

This page includes the following reports:

- Completed Case Versions Volume Overview
- Completed Case Versions Volume Trend
- Completed Case Versions Line Listing
- Completed Cases Statistical Overview
- Completed Cases Volume Overview
- Completed Cases Volume Trend
- Completed Cases Line Listing

Case Processing Compliance History

This page displays reports on the lock compliance of completed case versions, that is whether cases have been locked on time or not.

This page includes the following prompts, which are common to all its reports:

- **Deleted Case**: Lists whether the case is a deleted case.
- Case Processing Site: Lists the name of the case processing site.
- Country of Incidence: Lists the country of incidence.
- Case Seriousness: Lists the seriousness level for the case.
- Gender: Lists the gender of the patient reported in the case.



- **Age Group**: Lists the age group of the patient reported in the case.
- Case Type: Lists the type of case.
- Study ID: Lists the unique identifier for the study.
- Product Group: Lists the product group in the case.
- Product Family: Lists product family in the case.
- Product Name: Lists the product name in the case.
- Version Receipt Month Between: Lists the month range for the version receipt.

This page includes the following reports:

- Completed Case Versions Lock Compliance Overview
- Completed Case Versions Lock Compliance Proportion
- Completed Case Versions Lock Compliance Trend
- Completed Case Versions Line Listing

Workflow State Repetition History

This page displays reports on the workflow state repetition of completed case versions, that is, whether workflow states in the same case version have been repeated or not.

This page includes the following prompts, which are common to all its reports:

- Case Processing Site: Lists the name of the case processing site.
- Study ID: Lists the unique identifier for the study.
- Product Group: Lists the product group in the case.
- Product Family: Lists product family in the case.
- Product Name: Lists the product name in the case.
- State Name: Lists the name of the state in the case.
- State Finalization User ID: Lists the state finalization User ID in the case.
- State Finalization User Group: Lists the state finalization in the case.
- State Start Date Between: Lists the start date for the state.
- State End Date Between: Lists the end date for the state.

This page includes the following reports:

- Repeated Workflow States Volume Overview
- Repeated Workflow States Volume Proportion
- Completed Workflow States Line Listing

Case Processing Management

This section describes the Case Processing Management dashboard in Oracle Argus Analytics.

This dashboard of current metrics (or effective KPIs) can be accessed by a Workflow Manager or Team Leader. It provides reports on pending case versions, that is case versions currently being processed in the workflow and not yet locked.



This dashboard includes the following prompt, which is common to all its pages:

Enterprise ID: Lists the unique identifier for the enterprise.

For more information, see:

Case Processing Management Dashboard Pages

Case Processing Management Dashboard Pages

This dashboard includes the following tabbed pages:

Case Processing Volume Management

This page displays reports on the volume of pending case versions.

This page includes the following prompts, which are common to all its reports:

- Case Processing Site: Lists the name of the case processing site.
- Country of Incidence: Lists the country of incidence.
- Case Seriousness: Lists the seriousness level for the case.
- Gender: Lists the gender of the patient reported in the case.
- Age Group: Lists the age group of the patient reported in the case.
- Product Name: Lists the product name in the case.
- State Name: Lists the state name in the case.
- **Routing User Group**: Lists the name of the routing user group in the case.
- Lock Due Date Between: Lists the date range for the due date for case lock.

This page includes the following reports:

- Pending Cases Volume Overview
- Pending Cases Line Listing

Case Processing Compliance Management

This page displays reports on the lock compliance of pending case versions, that is whether cases can still be locked on time or not.

This page includes the following prompts, which are common to all its reports:

- Case Processing Site: Lists the name of the case processing site.
- Country of Incidence: Lists the country of incidence.
- Case Seriousness: Lists the seriousness level for the case.
- Gender: Lists the gender of the patient reported in the case.
- Age Group: Lists the age group of the patient reported in the case.
- Product Name: Lists the product name in the case.
- State Name: Lists the state name in the case.
- Routing User Group: Lists the name of the routing user group in the case.
- Lock Due Date Between: Lists the date range for the due date for case lock.



- Pending Cases Lock Compliance Overview
- Pending Cases Lock Compliance In Days
- Pending Cases Line Listing

Workflow State Compliance Management

This page displays reports on the workflow state compliance of pending case versions, that is whether workflow states can still be completed on time or not.

This page includes the following prompts, which are common to all its reports:

- Case Processing Site: Lists the name of the case processing site.
- Country of Incidence: Lists the country of incidence.
- Case Seriousness: Lists the seriousness level for the case.
- **Gender**: Lists the gender of the patient reported in the case.
- Age Group: Lists the age group of the patient reported in the case.
- Product Name: Lists the product name in the case.
- State Name: Lists the state name in the case.
- Routing User Group: Lists the name of the routing user group in the case.
- Lock Due Date Between: Lists the date range for the due date for case lock.

This page includes the following reports:

- Pending Workflow States Compliance Overview
- Pending Cases Line Listing

Personal User Dashboard

This section describes the dashboard called Personal User Dashboard in Oracle Argus Analytics.

This dashboard of both retrospective and current metrics (trailing and effective KPIs) can be accessed by an individual Case Processor. It provides reports on cases that the Case Processor has worked on in the past, as well as cases that are currently assigned to the Case Processor and his/her user group(s).

This dashboard includes the following prompt, which is common to all its pages:

• Enterprise ID: Lists the unique identifier for the enterprise.

For more information, see:

Personal User Dashboard Pages

Personal User Dashboard Pages

This dashboard includes the following tabbed pages:

Personal User Case History

This page displays reports on the locked case versions that have been worked on (in any workflow state prior to case lock) by the user who is viewing this page.

This page includes the following prompt, which is common to all its reports:



Product Name: Lists the product name in the case.

This page includes the following reports:

- My Completed Workflow States Volume Trend
- My Repeated Workflow States Volume Overview
- My Completed Case Versions Line Listing
- My Completed Workflow States Line Listing
- My Completed Case Version Routing Line Listing

Personal User Case Management

This page displays reports on the cases that are currently assigned to the user who is viewing this page, as well as cases assigned to the group(s) to which that user belongs.

This page includes the following prompts, which are common to all its reports:

- Product Name: Lists the product name in the case.
- Routing User Group: Lists the names of the routing user groups in the case.

This page includes the following reports:

- My Pending Cases Overview
- My Assigned Cases Line Listing
- My Unassigned Cases Line Listing
- Other Assigned Cases Line Listing

Personal User Case Work History

This page displays reports on the case work that has been performed by the user who is viewing this page. Case work is measured using the timestamps recorded when the user opened and closed cases.

This page includes the following prompts, which are common to all its reports:

- Case Processing Site: Lists the name of the case processing site.
- **Case Type**: Lists the type of the case.
- Study ID: Lists the Study ID used in the case.
- **Product Name**: Lists the product name in the case.
- Case Seriousness: Lists the seriousness of the case.

This page includes the following reports:

- My Case Modified Duration Per State Statistical Overview
- My Case Unmodified Duration Per State Statistical Overview
- My Case Read Duration Per State Statistical Overview
- My Case Idle Duration Per State Statistical Overview
- My Completed Workflow States Line Listing

Personal User Expedited Report History



This page displays reports on the expedited reports that have been submitted by the user who is viewing this page.

This page includes the following prompts, which are common to all its reports:

- Report Destination: Lists the reporting destination for the case.
- Report Assigned User Group: Lists the names of the user group to which the report has been assigned.
- Report Submission/MDN Month Between: Lists the period of report submission/MDN month for the case.

This page includes the following reports:

- My Submitted Expedited Reports Volume Trend
- My Submitted Expedited Reports Submission Compliance Trend
- Completed Expedited Reports Line Listing
- Completed Expedited Report Routing Line Listing

Personal User Expedited Report Management

This page displays reports on the expedited reports that are currently assigned to the user who is viewing this page, as well as expedited reports assigned to the group(s) to which that user belongs.

This page includes the following prompts, which are common to all its reports:

- Report Destination: Lists the reporting destination for the case.
- Report Assigned User Group: Lists the names of the user group to which the report has been assigned.

This page includes the following reports:

- My Pending Expedited Reports Overview
- My Assigned Expedited Reports Line Listing
- My Unassigned Expedited Reports Line Listing
- Other Assigned Expedited Reports Line Listing

Expedited Report History

This section describes the dashboard called Expedited Report History in Oracle Argus Analytics. Go to:

Expedted Report History Dashboard Pages

Expedted Report History Dashboard Pages

This dashboard includes the following prompt, which is common to all its pages:

• **Enterprise ID**: Lists the unique identifier for the enterprise.

Expedited Submission Volume History

This page displays reports on the volume of submitted expedited reports.

This page includes the following prompts, which are common to all its reports:



- Report Destination: Lists the reporting destination for the case.
- Report Assigned User Group: Lists the names of the user group to which the report has been assigned.
- Report Submission/MDN Month Between: Lists the period of report submission/MDN month for the case.

This page includes the following reports:

- Submitted Expedited Reports Volume Overview
- Submitted Expedited Reports Volume Trend
- Completed Expedited Reports Line Listing
- Completed Expedited Report Routing Line Listing

Expedited Non-Submission Volume History

This page displays reports on the volume of expedited reports that have been deleted or marked as 'No Submission Required'.

This page includes the following prompts, which are common to all its reports:

- Report Destination: Lists the reporting destination for the case.
- Report Assigned User Group: Lists the names of the user group to which the report has been assigned.
- Report Generation Month Between: Lists the time period (range of months) of report generation for the case.

This page includes the following reports:

- Expedited Reports Never Submitted Volume Trend
- Completed Expedited Reports Line Listing
- Completed Expedited Report Routing Line Listing

Expedited Submission Compliance History

This page displays reports on the submission compliance of expedited reports, that is, whether expedited reports have been submitted on time or not.

This page includes the following prompts, which are common to all its reports:

- Report Destination: Lists the reporting destination for the case.
- Report Assigned User Group: Lists the names of the user groups to which the report has been assigned.
- Report Submission/MDN Month Between: Lists the period of report submission/MDN month for the case.

- Submitted Expedited Reports Submission Compliance By User Group
- Submitted Expedited Reports Submission Compliance By Destination
- Submitted Expedited Reports Submission Compliance Trend
- Completed Expedited Reports Line Listing
- Completed Expedited Report Routing Line Listing



Expedited Report Management

This dashboard of current metrics (or effective KPIs) can be accessed by a Workflow Manager or Team Leader. It provides reports on pending expedited reports, that is expedited reports currently being processed and not yet submitted, deleted or marked as 'No Submission Required'.

This dashboard includes the following prompt, which is common to all its pages:

• **Enterprise ID**: Lists the unique identifier for the enterprise.

For more information, see:

Expedited Report Management Dashboard Pages

Expedited Report Management Dashboard Pages

This dashboard includes the following tabbed pages:

Expedited Submission Volume Management

This page displays reports on the volume of pending expedited reports.

This page includes the following prompts, which are common to all its reports:

- Report Destination: Lists the reporting destination for the case.
- Report Assigned User Group: Lists the names of the user group to which the report has been assigned.
- Report Assigned User ID: Lists the User ID for the report assigned to the case.
- Report Generation Date Between: Lists the time period of report generation for the case.

This page includes the following reports:

- Pending Expedited Reports Volume Overview
- Pending Expedited Reports Line Listing

Expedited Submission Compliance Management

This page displays reports on the submission compliance of pending expedited reports, i.e. whether expedited reports can still be submitted on time or not.

This page includes the following prompts, which are common to all its reports:

- Report Destination: Lists the reporting destination for the case.
- Report Assigned User Group: Lists the names of the user group to which the report has been assigned.
- Report Assigned User ID: Lists the User ID for the report assigned to the case.
- Report Generation Date Between: Lists the time period of report generation for the case.

- Pending Expedited Reports Submission Compliance Overview
- Pending Expedited Reports Submission Compliance In Days



Pending Expedited Reports – Line Listing

Expedited Failed/Pending ACK Volume Management

This page displays reports on the volume of E2B reports that have been submitted but have received an ACK with a 'Failed' status, or for which the ACK is still pending.

This page includes the following prompts, which are common to all its reports:

- Report Destination: Lists the reporting destination for the case.
- Report Assigned User Group: Lists the names of the user group to which the report has been assigned.
- Report Generation Date Between: Lists the time period of report generation for the case.

This page includes the following reports:

- Failed/Pending ACK Expedited Reports Volume Overview
- Failed/Pending ACK Expedited Reports Volume Trend
- Completed Expedited Reports Line Listing
- Completed Expedited Report Routing Line Listing

Case Work History

This dashboard includes the following tabbed pages:

This dashboard includes the following prompt, which is common to all its pages:

• Enterprise ID: Lists the unique identifier for the enterprise.

For more information, see:

Case Work History Dashboard Pages

Case Work History Dashboard Pages

This dashboard includes the following tabbed pages:

Case Modified History

This page displays reports on the durations cases were modified, meaning opened in edit mode and then saved.

This page includes the following prompts, which are common to all its reports:

- Case Processing Site: Lists the name of the case processing site.
- Case Type: Lists the type of the case.
- Study ID: Lists the Study ID used in the case.
- Product Name: Lists the product name in the case.
- Case Seriousness: Lists the seriousness of the case.
- Initial Receipt Month Between: Lists the initial time period of the initial receipt month.



- Duration Case Modified Per Version and Case Statistical Overview
- Duration Case Modified Per State Statistical Overview
- Duration Case Modified Per User/State Statistical Overview
- Completed Cases Line Listing
- Completed Case Versions Line Listing
- Completed Workflow States Line Listing
- Completed Case Version Routing Line Listing

Case Unmodified History

This page displays reports on the durations cases were unmodified, meaning opened in edit mode but not saved.

This page includes the following prompts, which are common to all its reports:

- Case Processing Site: Lists the name of the case processing site.
- Case Type: Lists the type of the case.
- Study ID: Lists the Study ID used in the case.
- Product Name: Lists the product name in the case.
- Case Seriousness: Lists the seriousness of the case.
- Initial Receipt Month Between: Lists the initial time period of the initial receipt month.

This page includes the following reports:

- Duration Case Unmodified Per Version and Case Statistical Overview
- Duration Case Unmodified Per State Statistical Overview
- Duration Case Unmodified Per User/State Statistical Overview
- Completed Cases Line Listing
- Completed Case Versions Line Listing
- Completed Workflow States Line Listing
- Completed Case Version Routing Line Listing

Case Read History

This page displays reports on the durations cases were read, meaning opened in read-only mode.

This page includes the following prompts, which are common to all its reports:

- Case Processing Site: Lists the name of the case processing site.
- Case Type: Lists the type of the case.
- Study ID: Lists the Study ID used in the case.
- Product Name: Lists the product name in the case.
- Case Seriousness: Lists the seriousness of the case.
- Initial Receipt Month Between: Lists the initial time period of the initial receipt month.



This page includes the following reports:

- Duration Case Read Per Version and Case Statistical Overview
- Duration Case Read Per State Statistical Overview
- Duration Case Read Per User/State Statistical Overview
- Completed Cases Line Listing
- Completed Case Versions Line Listing
- Completed Workflow States Line Listing
- Completed Case Version Routing Line Listing

Case Idle History

This page displays reports on the durations cases were idle, meaning the time between a workflow state routing and the first time the case is opened after the routing.

This page includes the following prompts, which are common to all its reports:

- Case Processing Site: Lists the name of the case processing site.
- Case Type: Lists the type of the case.
- Study ID: Lists the Study ID used in the case.
- Product Name: Lists the product name in the case.
- Case Seriousness: Lists the seriousness of the case.
- Initial Receipt Month Between: Lists the initial time period of the initial receipt month.

This page includes the following reports:

- Duration Case Idle Statistical Overview
- Duration Case Idle Per State Statistical Overview
- Completed Cases Line Listing
- Completed Case Versions Line Listing
- Completed Workflow States Line Listing
- Completed Case Version Routing Line Listing

Oracle Argus Analytics Reports

To locate a report, you need to select a dashboard and access a page that contains the report.

Oracle Argus Analytics includes the following reports:

- Completed Case Versions Volume Overview
- Enterprise Incremental ETL Status
- Completed Case Versions Volume Trend
- Completed Case Versions Line Listing
- Completed Cases Statistical Overview



- Completed Cases Volume Overview
- Completed Cases Volume Trend
- Completed Cases Line Listing
- Completed Case Versions Lock Compliance Overview
- Completed Case Versions Lock Compliance Proportion
- Completed Case Versions Lock Compliance Trend
- Completed Workflow States Line Listing
- Completed Case Version Routing Line Listing
- Repeated Workflow States Volume Overview
- Repeated Workflow States Volume Proportion
- Pending Cases Volume Overview
- Pending Cases Line Listing
- Pending Cases Lock Compliance Overview
- Pending Cases Lock Compliance In Days
- Pending Workflow States Compliance Overview
- My Completed Workflow States Volume Trend
- My Repeated Workflow States Volume Overview
- My Completed Case Versions Line Listing
- My Completed Workflow States Line Listing
- My Pending Cases Overview
- My Assigned Cases Line Listing
- My Unassigned Cases Line Listing
- Other Assigned Cases Line Listing
- My Completed Case Version Routing Line Listing
- My Case Modified Duration Per State Statistical Overview
- My Case Unmodified Duration Per State Statistical Overview
- My Case Read Duration Per State Statistical Overview
- My Case Idle Duration Per State Statistical Overview
- My Submitted Expedited Reports Volume Trend
- My Submitted Expedited Reports Submission Compliance Trend
- Completed Expedited Reports Line Listing
- Completed Expedited Report Routing Line Listing
- My Pending Expedited Reports Overview
- My Assigned Expedited Reports Line Listing
- My Unassigned Expedited Reports Line Listing
- Other Assigned Expedited Reports Line Listing
- Submitted Expedited Reports Volume Overview



- Submitted Expedited Reports Volume Trend
- Expedited Reports Never Submitted Volume Trend
- Submitted Expedited Reports Submission Compliance By User Group
- Submitted Expedited Reports Submission Compliance By Destination
- Submitted Expedited Reports Submission Compliance Trend
- Pending Expedited Reports Volume Overview
- Pending Expedited Reports Line Listing
- Pending Expedited Reports Submission Compliance Overview
- Pending Expedited Reports Submission Compliance In Days
- Failed/Pending ACK Expedited Reports Volume Overview
- Failed/Pending ACK Expedited Reports Volume Trend
- Duration Case Modified Per Version and Case Statistical Overview
- Duration Case Modified Per State Statistical Overview
- Duration Case Modified Per User/State Statistical Overview
- Completed Case Version Routing Line Listing
- Duration Case Unmodified Per Version and Case Statistical Overview
- Duration Case Unmodified Per State Statistical Overview
- Duration Case Unmodified Per User/State Statistical Overview
- Duration Case Read Per Version and Case Statistical Overview
- Duration Case Read Per State Statistical Overview
- Duration Case Read Per User/State Statistical Overview
- Duration Case Idle Statistical Overview
- Duration Case Idle Per State Statistical Overview

Completed Case Versions - Volume Overview

This report displays an overview of the volume of completed case versions by product group.

This report can be used to compare the number of cases by product group, and to drill down into product families and products. This indicates which products are creating the greatest case processing workload.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report



Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- 2-D Vertical Bar Graph
- Group by Table

Location

Case Processing History dashboard > Case Processing Volume History page

Dimensions

Product.Product Group

Supplementary Prompts

None

Reports Referenced

Completed Case Versions - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Completed Case Versions – Volume Overview report:

Table A-1 Completed Case Versions – Volume Overview

| Table Heading | Column Heading | Measure |
|---------------|-----------------------|----------------------------|
| Product | Product Group | Product.ProductGroup |
| Case Version | #Versions Locked Once | Case Version.# Locked Once |

Enterprise Incremental ETL Status

This section describes the ETL Incremental Status per enterprise on every dashboard page and returns results which convey the last refresh date per Enterprise and if the ETL is currently executing or completed.

For more information, see:



- Audience
- Report Type
- Location
- Dimensions
- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

(All Users)

Report Type

Table

Location

All Dashboard pages



This report is common to all the dashboards listed below.

Dimensions

Enterprise

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Enterprise Incremental ETL Status report:

Table A-2 Enterprise Incremental ETL Status

| Table Heading | Column Heading | Measure |
|---------------|----------------|--------------------------|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |



Table A-2 (Cont.) Enterprise Incremental ETL Status

| Table Heading | Column Heading | Measure |
|---------------|------------------------|-----------------------------------|
| Enterprise | Enterprise Name | Enterprise.Enterprise Name |
| Enterprise | ETL Incremental Status | Enterprise.ETL Incremental Status |

Completed Case Versions – Volume Trend

This report displays the trend over time of the volume of completed cases by product group.

This report can be used to compare the case volume trend over the last three months by product group, and to drill down into months, weeks and days as well as product families and products. This indicates if the case processing workload for certain products is increasing, decreasing, or remaining constant over time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- 2-D Line Graph
- Pivot Table

Location

Case Processing History dashboard > Case Processing Volume History page

Dimensions

Product.Product Group

Period.Case Version - Version Receipt Date

Supplementary Prompts

None

Reports Referenced

Completed Case Versions - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Completed Case Versions – Volume Trend report:

Table A-3 Completed Case Versions - Volume Trend

| Table Heading | Column Heading | Measure |
|--|------------------------|--|
| Product | Product Group | Product.ProductGroup |
| Case Version | # Versions Locked Once | Case Version.# Versions Locked Once |
| Case Version - Version Receipt Date | Year | Product.Case Version - Version Receipt Date |

Completed Case Versions - Line Listing

This section describes the Completed Case Versions - Line Listing report.

This report lists the completed case versions by Case ID including data from key case fields.

This report can be used to drill down to the case details of the completed case versions. This indicates which cases can be targeted for a root cause analysis, such as an investigation of cases that were locked late.

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions



Audience

Executive Manager

Team Leader

Report Type

Narrative Table

Location

- Case Work History dashboard > Case Modified History page
- Case Work History dashboard > Case Unmodified History page
- Case Work History dashboard > Case Read History page
- Case Work History dashboard > Case Idle History page

Dimensions

Enterprise.EnterpriseID

Supplementary Prompts

None

Reports Referenced

Completed Workflow States - Line Listing

Reports Referencing This Report

Completed Cases - Line Listing

Column Descriptions

The following table describes the columns in the Completed Case Versions – Line Listing report:

Table A-4 Completed Case Versions - Line Listing

| Table Heading | Column Heading | Measure |
|---------------|----------------------|--------------------------------------|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Case Version | Version ID | Case Version.Version ID |
| Case Version | Version Type | Case Version. Version Type |
| Case Version | Case Processing Site | Case Version.Case Processing Site |
| Case Version | Case Type | Case Version.Case Type |



Table A-4 (Cont.) Completed Case Versions – Line Listing

| Table Heading | Column Heading | Measure |
|---------------|----------------------|--------------------------------------|
| Case Version | Case Seriousness | Case Version.Case Seriousness |
| Case Version | Case Listedness | Case Version.Case Listedness |
| Case Version | Case Causality | Case Version.Case Causality |
| Case Version | SUSAR | Case Version.SUSAR |
| Case Version | Initial Receipt Date | Case Version.Initial Receipt Date |
| Case Version | Clock Start Date | Case Version.Clock Start Date |
| Case Version | Lock Timestamp | Case Version.Lock Timestamp |
| Case Version | Lock Due Date | Case Version.Lock Due Date |

Completed Cases - Statistical Overview

This report displays an overview of statistics at the case level.

This report can be used to view the average, minimum, and maximum number of products, events, and follow-ups per case.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

Table

Location

Case Processing History dashboard > Case Processing Volume History page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Completed Cases - Statistical Overview report:

Table A-5 Completed Cases – Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|------------------------------------|---|
| Case | Avg # Suspect Products Per Case | Case.Avg # Suspect Products Per Case |
| Case | Min # Suspect Products Per Case | Case.Min # Suspect Products Per Case |
| Case | Max # Suspect Products Per Case | Case.Max # Suspect Products Per Case |
| Case | Avg # Events Per Case | Case.Avg # Events Per Case |
| Case | Min # Events Per Case | Case.Min # Events Per Case |
| Case | Max # Events Per Case | Case.Max # Events Per Case |
| Case | Avg # F/U Versions Per Case | Case.Avg # F/U Versions Per Case |
| Case | Min # F/U Versions Per Case | Case.Min # F/U Versions Per Case |
| Case | Max # F/U Versions Per Case | Case.Max # F/U Versions Per Case |
| Case | Avg # Sig F/U Versions Per Case | Case.Avg # Sig F/U Versions Per Case |
| Case | Min # Sig F/U Versions Per Case | Case.Min # Sig F/U Versions Per Case |



Table A-5 (Cont.) Completed Cases – Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|------------------------------------|---|
| Case | Max # Sig F/U Versions Per Case | Case.Max # Sig F/U Versions Per Case |
| Case | Avg # F/U Received Per Case | Case.Avg # F/U Received Per Case |
| Case | Min # F/U Received Per Case | Case.Min # F/U Received Per Case |
| Case | Max # F/U Received Per Case | Case.Max # F/U Received Per Case |
| Case | Avg # Sig F/U Received Per Case | Case.Avg # Sig F/U Received Per Case |
| Case | Min # Sig F/U Received Per Case | Case.Min # Sig F/U Received Per Case |
| Case | Max # Sig F/U Received Per Case | Case.Max # Sig F/U Received Per Case |

Completed Cases – Volume Overview

This report displays an overview of the volume of completed cases by product group.

This report can be used to compare the number of cases by product group, and to drill down into product families and products. This indicates which products are creating the greatest case processing workload.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- Group By Table
- 2-D Bar Graph



Location

Case Processing History dashboard > Case Processing Volume History page

Dimensions

Product.Product Group

Supplementary Prompts

None

Reports Referenced

Completed Cases - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Completed Cases – Volume Overview report:

Table A-6 Completed Cases - Volume Overview

| Table Heading | Column Heading | Measure |
|---------------|---------------------|--------------------------|
| Product | Product Group | Product.Product Group |
| Case | # Cases Locked Once | Case.# Cases Locked Once |

Completed Cases – Volume Trend

This report displays the trend over time of the volume of completed cases by product group.

This report can be used to compare the case volume trend over the last three months by product group, and to drill down into months, weeks and days as well as product families and products. This indicates if the case processing workload for certain products is increasing, decreasing, or remaining constant over time.

For more information, see:

- Audience
- · Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced



- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- Pivot Table
- 2-D Line Graph

Location

Case Processing History dashboard > Case Processing Volume History page

Dimensions

Period.Initial Receipt Date

Product.Product Group

Supplementary Prompts

None

Reports Referenced

Completed Cases - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Completed Cases – Volume Trend report:

Table A-7 Completed Cases - Volume Trend

| Table Heading | Column Heading | Measure |
|----------------------|---------------------|-------------------------------------|
| Product | Product Group | Product.Product Group |
| Initial Receipt Date | Year | Period.Initial Receipt Date.Year |
| Case | # Cases Locked Once | Case.# Cases Locked Once |



Completed Cases – Line Listing

This report lists the completed cases by Case ID including data from key case fields.

This report can be used to drill down to the case details of the completed cases. This indicates which cases can be targeted for a root cause analysis, e.g. an investigation of cases that were locked late.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

Narrative Table

Location

- Case Work History dashboard > Case Modified History page
- Case Work History dashboard > Case Unmodified History page
- Case Work History dashboard > Case Read History page
- Case Work History dashboard > Case Idle History page

Dimensions

Enterprise.EnterpriseID

Supplementary Prompts

None

Reports Referenced

Completed Case Versions - Line Listing



Reports Referencing This Report

Completed Cases - Statistical Overview

Completed Cases – Volume Overview

Completed Cases - Volume Trend

Column Descriptions

The following table describes the columns in the Completed Cases – Line Listing report:

Table A-8 Completed Cases - Line Listing

| Table Heading | Column Heading | Measure |
|---------------|-------------------------|---------------------------------|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Case | Case Processing Site | Case.Case Processing Site |
| Case | Country Of Incidence | Case.Country Of Incidence |
| Case | Case Type | Case.Case Type |
| Case | Study ID | Case.Study ID |
| Case | Case Seriousness | Case.Case Seriousness |
| Case | Case Listedness | Case.Case Listedness |
| Case | Case Causality | Case.Case Causality |
| Case | Case Outcome | Case.Case Outcome |
| Case | Primary Reporter Type | Case.Primary Reporter Type |
| Case | НСР | Case.HCP |
| Case | SUSAR | Case.SUSAR |
| Case | Initial Receipt Date | Case.Initial Receipt Date |
| Case | Primary Indication | Case.Primary Indication |
| Case | Primary Event | Case.Primary Event |
| Case | Primary Suspect Product | Case.Primary Suspect Product |

Completed Case Versions – Lock Compliance Overview

This report displays an overview of the lock compliance of completed cases by case processing site.

This report can be used to compare the retrospective lock compliance of case processing sites. This indicates which case processing sites might be having difficulties locking cases on time.

For more information, see:

Audience



- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- 2-D Stacked Bar Graph
- Group by Table

Location

Case Processing History dashboard > Case Processing Compliance History page

Dimensions

Case Processing Site. Case Processing Site

Supplementary Prompts

None

Reports Referenced

Completed Case Versions - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Completed Case Versions - Lock Compliance Overview report:

Table A-9 Completed Case Versions - Lock Compliance Overview

| Table Heading | Column Heading | Measure |
|----------------------|----------------------|---|
| Case Processing Site | Case Processing Site | Case Processing Site.Case Processing Site |



Table A-9 (Cont.) Completed Case Versions - Lock Compliance Overview

| Table Heading | Column Heading | Measure |
|---------------|---------------------------|---|
| Case Version | # Versions Locked On-Time | Case Version.# Versions Locked On-Time |
| Case Version | # Versions Locked Late | Case Version.# Versions Locked Late |

Completed Case Versions – Lock Compliance Proportion

This report displays the lock compliance of completed cases by percentage. This report can be used to compare the ratio of cases locked late to those locked on time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- 2-D Pie Graph
- Group by Table

Location

Case Processing History dashboard > Case Processing Compliance History page

Dimensions

Case Processing Site. Case Processing Site

Supplementary Prompts

None



Reports Referenced

Completed Case Versions - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Completed Case Versions - Lock Compliance Proportion report:

Table A-10 Completed Case Versions - Lock Compliance Proportion

| Table Heading | Column Heading | Measure |
|----------------------|---------------------------|--|
| Case Processing Site | Case Processing Site | Case Processing Site.Case Processing Site |
| Case Version | % Versions Locked On-Time | Case Version.% Versions Locked On-Time |
| Case Version | % Versions Locked Late | Case Version.% Versions Locked Late |

Completed Case Versions - Lock Compliance Trend

This report displays the trend over time of the lock compliance of completed cases.

This report can be used to view the lock compliance trend over the last three months and to drill down into months, weeks and days. This indicates if lock compliance is increasing, decreasing, or remaining constant over time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader



Report Type

- · 2-D Line Graph
- Group by Table

Location

Case Processing History dashboard > Case Processing Compliance History page

Dimensions

Period.Case Version - Version Receipt Date

Supplementary Prompts

None

Reports Referenced

Completed Case Versions - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Completed Case Versions - Lock Compliance Trend report:

Table A-11 Completed Case Versions - Lock Compliance Trend

| Table Heading | Column Heading | Measure |
|--|---------------------------|--|
| Case Version - Version Receipt Date | Year | Period.Case Version - Version Receipt Date.Year |
| Case Version | # Versions Locked On-Time | Case Version.# Versions Locked On-Time |
| Case Version | # Versions Locked Late | Case Version.# Versions Locked Late |

Completed Workflow States - Line Listing

This report lists the completed cases by Case ID including workflow states that were completed in each version of each case.

This report can be used to drill down to the workflow states of the completed cases. This indicates which workflow states can be targeted for a root cause analysis, such as an investigation of cases that were locked late.

For more information, see:



- Audience
- · Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

Narrative Table

Location

- Case Work History dashboard > Case Modified History page
- Case Work History dashboard > Case Unmodified History page
- Case Work History dashboard > Case Read History page
- Case Work History dashboard > Case Idle History page

Dimensions

Enterprise.Enterprise ID

Case Workflow State.State Name

Supplementary Prompts

None

Reports Referenced

Completed Case Version Routing – Line Listing

Reports Referencing This Report

You can also navigate to this report from the following report:

- Completed Case Versions Line Listing
- Duration Case Modified Per State Statistical Overview
- Duration Case Modified Per User/State Statistical Overview
- Duration Case Unmodified Per State Statistical Overview



- Duration Case Unmodified Per User/State Statistical Overview
- Duration Case Read Per State Statistical Overview
- Duration Case Read Per User/State Statistical Overview

Column Descriptions

The following table describes the columns in the Completed Workflow States - Line Listing report:

Table A-12 Completed Workflow States - Line Listing

| Table Heading | Column Heading | Measure |
|---------------------|-----------------------------|---|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Case Workflow State | Version ID | Case Workflow State. Version ID |
| Case Workflow State | State Name | Case Workflow State.State Name |
| Case Workflow State | Duration State-Start-To-End | Case Workflow State.Duration State-Start-To-End |
| Case Workflow State | Duration Within State | Case Workflow State.Duration Within State |
| Case Workflow State | # Times State Repeated | # Repeated States |

Completed Case Version Routing – Line Listing

This report lists the completed cases by Case ID including routing between workflow states that were completed in each version of each case.

This report can be used to drill down to the workflow state routing information of the completed cases. This indicates which routings can be targeted for a root cause analysis, such as an investigation of cases that were locked late.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager



Team Leader

Report Type

Narrative Table

Location

- Case Work History dashboard > Case Modified History page
- Case Work History dashboard > Case Unmodified History page
- Case Work History dashboard > Case Read History page
- Case Work History dashboard > Case Idle History page

Dimensions

Enterprise.Enterprise ID

Case Routing.State Routed From

Case Routing. State Routed To

Case Routing.Routing User Group

Case Routing.Routing User

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

You can also navigate to this report from the following report:

Duration Case Idle Per State – Statistical Overview

Column Descriptions

The following table describes the columns in the Completed Case Version Routing - Line Listing report:

Table A-13 Completed Case Version Routing - Line Listing

| Table Heading | Column Heading | Measure |
|---------------|----------------|--------------------------|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Case Routing | Version ID | Case Routing. Version ID |



Table A-13 (Cont.) Completed Case Version Routing - Line Listing

| Table Heading | Column Heading | Measure |
|---------------|------------------------------|--|
| Case Routing | State Routed From | Case Routing.State Routed From |
| Case Routing | State Routed To | Case Routing.State Routed To |
| Case Routing | Routing Timestamp From State | Case Routing.Routing Timestamp From State |
| Case Routing | Routing Timestamp To State | Case Routing.Routing Timestamp To State |
| Case Routing | Routing Justification | Case Routing.Routing Justification |
| Case Routing | Routing User Group | Case Routing.Routing User Group |
| Case Routing | Routing User ID | Case Routing.Routing User ID |

Repeated Workflow States – Volume Overview

This report displays an overview of the workflow state repetition of completed case versions.

This report can be used to highlight which workflow states have been repeated within a single case version. Repetition can be an indicator of case quality (returned for rework) as well as new follow-up information being added to a case version (returned for additional data entry).

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

2-D Bar Graph

Group by Table

Location

Case Processing History dashboard > Workflow State Repetition History page

Dimensions

Case Workflow State.State Name

Supplementary Prompts

None

Reports Referenced

Completed Workflow States - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Repeated Workflow States - Volume Overview report:

Table A-14 Repeated Workflow States - Volume Overview

| Table Heading | Column Heading | Measure |
|---------------------|------------------------|---|
| Case Workflow State | State Name | Case Workflow State.State Name |
| Case Workflow State | # Times State Repeated | Case Workflow State.# Times State Repeated |

Repeated Workflow States – Volume Proportion

This report displays the workflow state repetition of completed case versions by percentage.

This report can be used to compare the ratio of workflow states have been repeated within a single case version. Repetition can be an indicator of case quality (returned for rework) as well as new follow-up information being added to a case version (returned for additional data entry).

For more information, see:

- Audience
- Report Type
- Location
- Dimensions



- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- 2-D Pie Graph
- · Group by Table

Location

Case Processing History dashboard > Workflow State Repetition History page

Dimensions

Case Workflow State.State Name

Supplementary Prompts

None

Reports Referenced

Completed Workflow States - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Repeated Workflow States - Volume Proportion report:

Table A-15 Repeated Workflow States - Volume Proportion

| Table Heading | Column Heading | Measure |
|---------------------|------------------------|---|
| Case Workflow State | State Name | Case Workflow State.State Name |
| Case Workflow State | % Times State Repeated | Case Workflow State.% Times State Repeated |



Pending Cases – Volume Overview

This report displays an overview of the volume of pending cases by user group. This report can be used to compare the current, real-time workloads of the user groups that are processing cases. This indicates where immediate action could be taken to balance the workload among the groups, if necessary.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Wotkflow Manager

Team Leader

Report Type

- 2-D Bar Graph
- · Group by Table

Location

 Case Processing Management dashboard > Case Processing Volume Management page

Dimensions

User Group.Pending Cases - Routing User Group

Supplementary Prompts

None

Reports Referenced

Pending Cases - Line Listing

Reports Referencing This Report

None



Column Descriptions

The following table describes the columns in the Pending Cases - Volume Overview report:

Table A-16 Pending Cases - Volume Overview

| Table Heading | Column Heading | Measure |
|---------------------------------------|--------------------|--|
| Pending Cases - Routing User Group | Routing User Group | User Group.Pending Cases - Routing User Group.Routing User Group |
| Pending Cases | # Unlocked Cases | Pending Cases.# Unlocked Cases |

Pending Cases – Line Listing

This report lists the pending cases by Case ID, including data from key case fields.

This report can be used to drill down to the case details of the pending cases. This indicates which cases can be reassigned, if workflow balancing is necessary.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

Narrative Table

Location

- Case Processing Management dashboard > Case Processing Volume Management page
- Case Processing Management dashboard > Case Processing Compliance
 Management page



 Case Processing Management dashboard > Workflow State Compliance Management page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

Pending Cases – Volume Overview

Pending Cases - Lock Compliance Overview

Pending Workflow States - Compliance Overview

Column Descriptions

The following table describes the columns in the Pending Cases - Line Listing report:

Table A-17 Pending Cases - Line Listing

| | ı | 1 |
|---------------|----------------------|---------------------------------------|
| Table Heading | Column Heading | Measure |
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Cases | Follow-Up ID | Pending Cases.Follow-up ID |
| Pending Cases | Follow-Up Type | Pending Cases.Follow-up Type |
| Pending Cases | Case Processing Site | Pending Cases.Case Processing Site |
| Pending Cases | Case Type | Pending Cases.Case Type |
| Pending Cases | Study ID | Pending Cases.Study ID |
| Pending Cases | Case Seriousness | Pending Cases.Case Seriousness |
| Pending Cases | Case Listedness | Pending Cases.Case Listedness |
| Pending Cases | Case Causality | Pending Cases.Case Causality |
| Pending Cases | Case Outcome | Pending Cases.Case Outcome |



Table A-17 (Cont.) Pending Cases - Line Listing

| Table Heading | Column Heading | Measure |
|---|------------------------|---|
| Pending Cases | SUSAR | Pending Cases.SUSAR |
| Pending Cases | Lock Due Soon Date | Pending Cases.Lock Due Soon Date |
| Pending Cases | Lock Due Date | Pending Cases.Lock Due Date |
| User.Pending Cases - Assigned User | Assigned User ID | User.Pending Cases - Assigned Cases.Assigned User ID |
| Pending Cases | User with Case Open ID | Pending Cases.User with Case Open ID |
| Pending Cases | State Name | Pending Cases.State Name |
| Pending Cases | Routing ID | Pending Cases.Routing ID |
| UserGroup.Pending Cases - Routing User Group | Routing User Group | UserGroup.Pending Cases - Routing User Group.Routing User Group |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Pending Cases – Lock Compliance Overview

This report displays an overview of the lock compliance of pending cases by user group. This report can be used to compare the current, real-time lock compliance of the user groups that are processing cases. This indicates where immediate action could be taken to balance the workload among the groups, if necessary.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader



Report Type

- 2-D Stacked Bar Graph
- Group by Table

Location

 Case Processing Management dashboard > Case Processing Compliance Management page

Dimensions

User Group.Pending Cases - Routing User Group

Supplementary Prompts

None

Reports Referenced

Pending Cases - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Pending Cases - Lock Compliance Overview report:

Table A-18 Pending Cases - Lock Compliance Overview

| Table Heading | Column Heading | Measure |
|---------------------------------------|---------------------------|--|
| Pending Cases - Routing User Group | Routing User Group | User Group.Pending Cases - Routing User Group.Routing User Group |
| Pending Cases | # Unlocked Cases On-Time | Pending Cases.# Unlocked Cases On-Time |
| Pending Cases | # Unlocked Cases Due Soon | Pending Cases.# Unlocked Cases Due Soon |
| Pending Cases | # Unlocked Cases Overdue | Pending Cases.# Unlocked Cases Overdue |

Pending Cases – Lock Compliance In Days

This report displays an overview of the lock compliance of pending cases by number of days until case lock is due and number of days that case lock is overdue.



This report can be used to compare the volumes of cases due on each day. This indicates where to focus resources in order to lock cases on time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

- 2-D Bar Graph
- Group by Table

Location

 Case Processing Management dashboard > Case Processing Compliance Management page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Pending Cases - Lock Compliance In Days report:



Table A-19 Pending Cases - Lock Compliance In Days

| Table Heading | Column Heading | Measure |
|---------------|----------------|--------------------------------|
| Pending Cases | > +5 Days | Pending Cases.Lock Due Date |
| Pending Cases | +5 Days | Pending Cases.Lock Due Date |
| Pending Cases | +4 Days | Pending Cases.Lock Due Date |
| Pending Cases | +3 Days | Pending Cases.Lock Due Date |
| Pending Cases | +2 Days | Pending Cases.Lock Due Date |
| Pending Cases | +1 Day | Pending Cases.Lock Due Date |
| Pending Cases | 0 Day | Pending Cases.Lock Due Date |
| Pending Cases | -1 Day | Pending Cases.Lock Due Date |
| Pending Cases | -2 Days | Pending Cases.Lock Due Date |
| Pending Cases | -3 Days | Pending Cases.Lock Due Date |
| Pending Cases | -4 Days | Pending Cases.Lock Due Date |
| Pending Cases | -5 Days | Pending Cases.Lock Due Date |
| Pending Cases | > -5 Days | Pending Cases.Lock Due Date |

Pending Workflow States - Compliance Overview

This report displays an overview of the compliance of pending cases by workflow state.

This report can be used to highlight the current, real-time workflow state compliance of pending cases. This indicates where to focus resources in order to complete workflow states on time, which in turn can help to ensure that cases are later locked on time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced



- · Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

- 2-D Stacked Bar Graph
- Group by Table

Location

 Case Processing Management dashboard > Workflow State Compliance Management page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

Pending Cases - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Pending Workflow States - Compliance Overview report:

Table A-20 Pending Workflow States - Compliance Overview

| Table Heading | Column Heading | Measure |
|---------------|---------------------------|--|
| Pending Cases | State Name | Pending Cases.State Name |
| Pending Cases | # Unlocked Cases On-Time | Pending Cases.# Unlocked Cases On-Time |
| Pending Cases | # Unlocked Cases Due Soon | Pending Cases.# Unlocked Cases Due Soon |
| Pending Cases | # Unlocked Cases Overdue | Pending Cases.# Unlocked Cases Overdue |



My Completed Workflow States - Volume Trend

This report displays the trend over time of the volume of workflow states that have been completed by the user who is viewing this report.

This report can be used to highlight the user's personal workflow state volume trend over the last three months. This indicates if the user's personal workload is increasing, decreasing, or remaining constant over time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

- 2-D Line Graph
- Group by Table

Location

Personal User dashboard > Personal User Case History page

Dimensions

Case Workflow State. State Name

Supplementary Prompts

Routing Date

Reports Referenced

My Completed Case Versions - Line Listing

Reports Referencing This Report

None



Column Descriptions

The following table describes the columns in the My Completed Workflow States – Volume Trend report:

Table A-21 My Completed Workflow States - Volume Trend

| Table Heading | Column Heading | Measure |
|---------------------|-----------------|--|
| Case Workflow State | Workflow State | Case Workflow State.State Name |
| Case Routing | Routing Date | Case Routing.Routing Timestamp To State |
| Case | # Case Versions | Case.Case Internal ID |

My Repeated Workflow States - Volume Overview

This report displays an overview of the workflow states that have been repeated by the user who is viewing this report.

This report can be used to highlight which workflow states have been repeated by the viewing user within a single case version. Repetition can be an indicator of case quality (returned for rework) as well as new follow-up information being added to a case version (returned for additional data entry).

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- · Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

- 2-D Bar Graph
- Group by Table

Location

Personal User dashboard > Personal User Case History page



Dimensions

Case Workflow State. State Name

Supplementary Prompts

State End Date

Reports Referenced

My Completed Case Versions - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the My Repeated Workflow States – Volume Overview report:

Table A-22 My Repeated Workflow States - Volume Overview

| Table Heading | Column Heading | Measure |
|---------------------|------------------------|---|
| Case Workflow State | State Name | Case Workflow State.State Name |
| Case Workflow State | # Times State Repeated | Case Workflow State.# Times State Repeated |

My Completed Case Versions – Line Listing

This report lists the locked case versions that have been worked on (in any workflow state prior to case lock) by the user who is viewing this report.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- · Reports Referenced
- Reports Referencing This Report
- · Column Descriptions

Audience

Case Processor



Report Type

Narrative Table

Location

Personal User dashboard > Personal User Case History page

Dimensions

Enterprise ID

Supplementary Prompts

Routing Date

Start End Date

Reports Referenced

My Completed Workflow States - Line Listing

Reports Referencing This Report

My Completed Workflow States - Volume Trend

My Repeated Workflow States - Volume Overview

Column Descriptions

The following table describes the columns in the My Completed Case Versions – Line Listing report:

Table A-23 My Completed Case Versions – Line Listing

| | | I |
|---------------|----------------------|--------------------------------------|
| Table Heading | Column Heading | Measure |
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Case Version | Version ID | Case Version.Version ID |
| Case Version | Version Type | Case Version.Version Type |
| Case Version | Case Processing Site | Case Version.Case Processing Site |
| Case Version | Case Type | Case Version.Case Type |
| Case Version | Case Seriousness | Case Version.Case Seriousness |
| Case Version | Case Listedness | Case Version.Case Listedness |
| Case Version | Case Causality | Case Version.Case Causality |



Table A-23 (Cont.) My Completed Case Versions – Line Listing

| Table Heading | Column Heading | Measure |
|---------------|----------------------|-----------------------------------|
| Case Version | SUSAR | Case Version.SUSAR |
| Case Version | Initial Receipt Date | Case Version.Initial Receipt Date |
| Case Version | Clock Start Date | Case Version.Clock Start Date |
| Case Version | Lock Timestamp | Case Version.Lock Timestamp |
| Case Version | Lock Due Date | Case Version.Lock Due Date |

My Completed Workflow States - Line Listing

This report lists the completed workflow states of the locked case versions that have been worked on (in any workflow state prior to case lock) by the user who is viewing this report.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Case Work History page

Dimensions

Enterprise.Enterprise ID

Case Workflow State. State Name



Supplementary Prompts

None

Reports Referenced

My Completed Case Version Routing - Line Listing

Reports Referencing This Report

My Completed Case Versions – Line Listing

Column Descriptions

The following table describes the columns in the My Completed Workflow States – Line Listing report:

Table A-24 My Completed Workflow States - Line Listing

| Table Heading | Column Heading | Measure |
|---------------------|-----------------------------|---|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Case Workflow State | Version ID | Case Workflow State. Version ID |
| Case Workflow State | State Name | Case Workflow State.State Name |
| Case Workflow State | Duration State-Start-To-End | Case Workflow State.Duration State-Start-To-End |
| Case Workflow State | Duration Within State | Case Workflow State.Duration Within State |
| Case Workflow State | # Times State Repeated | # Repeated States |

My Pending Cases - Overview

The report displays an overview of the volume of cases that are currently assigned to the user who is viewing this report (My Assigned Cases), the cases that are assigned to the group(s) to which that user belongs but not to any individual users (My Unassigned Cases), and the cases that are assigned to other users in the group(s) to which the viewing user belongs (Other Assigned Cases).

This report can be used to highlight the current, real-time workload of the user viewing this report, the pool of cases that need to be worked on next (upcoming workload), and the workload of the viewing user's colleagues (potential workload if cases are reassigned). Therefore the user has a complete overview of his/her current, upcoming and potential workloads.

For more information, see:

- Audience
- Report Type



- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

- 2-D Bar Graph
- Count Table

Location

Personal User dashboard > Personal User Case Management page

Dimensions

User.Pending Cases - Assigned User

Supplementary Prompts

None

Reports Referenced

My Assigned Cases - Line Listing

My Unassigned Cases – Line Listing

Other Assigned Cases - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the My Pending Cases - Overview report:

Table A-25 My Pending Cases - Overview

| Table Heading | Column Heading | Measure |
|---------------|---------------------|---|
| Pending Cases | # My Assigned Cases | User.Pending Cases - Assigned User.Assigned User ID |



Table A-25 (Cont.) My Pending Cases - Overview

| Table Heading | Column Heading | Measure |
|---------------|------------------------|---|
| Pending Cases | # My Unassigned Cases | User.Pending Cases - Assigned User.Assigned User ID |
| Pending Cases | # Other Assigned Cases | User.Pending Cases - Assigned User.Assigned User ID |
| Pending Cases | Total Cases | Cases.Case ID |

My Assigned Cases – Line Listing

This report lists the cases that are currently assigned to the user who is viewing this report.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- · Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Case Management page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User



Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Pending Cases - Overview

Column Descriptions

The following table describes the columns in the My Assigned Cases - Line Listing report:

Table A-26 My Assigned Cases - Line Listing

| Table Heading | Column Heading | Measure |
|---------------------------------------|------------------------|--|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Cases | Follow-Up ID | Pending Cases.Follow-up ID |
| Pending Cases | Follow-Up Type | Pending Cases.Follow-up Type |
| Pending Cases | Case Processing Site | Pending Cases.Case Processing Site |
| Pending Cases | Case Type | Pending Cases.Case Type |
| Pending Cases | Study ID | Pending Cases.Study ID |
| Pending Cases | Case Seriousness | Pending Cases.Case Seriousness |
| Pending Cases | Case Listedness | Pending Cases.Case Listedness |
| Pending Cases | Case Causality | Pending Cases.Case Causality |
| Pending Cases | Case Outcome | Pending Cases.Case Outcome |
| Pending Cases | SUSAR | Pending Cases.SUSAR |
| Pending Cases | Lock Due Soon Date | Pending Cases.Lock Due Soon Date |
| Pending Cases | Lock Due Date | Pending Cases.Lock Due Date |
| User.Pending Cases - Assigned User | Assigned User ID | User.Pending Cases - Assigned Cases.Assigned User ID |
| Pending Cases | User with Case Open ID | Pending Cases.User with Case Open ID |



Table A-26 (Cont.) My Assigned Cases - Line Listing

| Table Heading | Column Heading | Measure |
|---|-----------------------|---|
| Pending Cases | State Name | Pending Cases.State Name |
| UserGroup.Pending Cases - Routing User Group | Routing User Group | UserGroup.Pending Cases - Routing User Group.Routing User Group |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

My Unassigned Cases – Line Listing

This report lists the cases that are assigned to the group(s) to which the viewing user belongs but not to any individual users.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- · Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Case Management page

Dimensions

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User



Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Pending Cases - Overview

Column Descriptions

The following table describes the columns in the My Unassigned Cases - Line Listing report:

Table A-27 My Unassigned Cases - Line Listing

| Table Heading | Column Heading | Measure |
|---------------------------------------|------------------------|--|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Cases | Follow-Up ID | Pending Cases.Follow-up ID |
| Pending Cases | Follow-Up Type | Pending Cases.Follow-up Type |
| Pending Cases | Case Processing Site | Pending Cases.Case Processing Site |
| Pending Cases | Case Type | Pending Cases.Case Type |
| Pending Cases | Study ID | Pending Cases.Study ID |
| Pending Cases | Case Seriousness | Pending Cases.Case Seriousness |
| Pending Cases | Case Listedness | Pending Cases.Case Listedness |
| Pending Cases | Case Causality | Pending Cases.Case Causality |
| Pending Cases | Case Outcome | Pending Cases.Case Outcome |
| Pending Cases | SUSAR | Pending Cases.SUSAR |
| Pending Cases | Lock Due Soon Date | Pending Cases.Lock Due Soon Date |
| Pending Cases | Lock Due Date | Pending Cases.Lock Due Date |
| User.Pending Cases - Assigned User | Assigned User ID | User.Pending Cases - Assigned Cases.Assigned User ID |
| Pending Cases | User with Case Open ID | Pending Cases.User with Case Open ID |



Table A-27 (Cont.) My Unassigned Cases - Line Listing

| Table Heading | Column Heading | Measure |
|---|-----------------------|---|
| Pending Cases | State Name | Pending Cases.State Name |
| UserGroup.Pending Cases - Routing User Group | Routing User Group | UserGroup.Pending Cases - Routing User Group.Routing User Group |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Other Assigned Cases – Line Listing

This report lists the cases that are assigned to other users in the group(s) to which the viewing user belongs.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Case Management page

Dimensions

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User



Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Pending Cases - Overview

Column Descriptions

The following table describes the columns in the Other Assigned Cases - Line Listing report:

Table A-28 Other Assigned Cases - Line Listing

| Table Heading | Column Heading | Measure |
|---------------------------------------|------------------------|--|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Cases | Follow-Up ID | Pending Cases.Follow-up ID |
| Pending Cases | Follow-Up Type | Pending Cases.Follow-up Type |
| Pending Cases | Case Processing Site | Pending Cases.Case Processing Site |
| Pending Cases | Case Type | Pending Cases.Case Type |
| Pending Cases | Study ID | Pending Cases.Study ID |
| Pending Cases | Case Seriousness | Pending Cases.Case Seriousness |
| Pending Cases | Case Listedness | Pending Cases.Case Listedness |
| Pending Cases | Case Causality | Pending Cases.Case Causality |
| Pending Cases | Case Outcome | Pending Cases.Case Outcome |
| Pending Cases | SUSAR | Pending Cases.SUSAR |
| Pending Cases | Lock Due Soon Date | Pending Cases.Lock Due Soon Date |
| Pending Cases | Lock Due Date | Pending Cases.Lock Due Date |
| User.Pending Cases - Assigned User | Assigned User ID | User.Pending Cases - Assigned Cases.Assigned User ID |
| Pending Cases | User with Case Open ID | Pending Cases.User with Case Open ID |



Table A-28 (Cont.) Other Assigned Cases - Line Listing

| Table Heading | Column Heading | Measure |
|---|-----------------------|---|
| Pending Cases | State Name | Pending Cases.State Name |
| UserGroup.Pending Cases - Routing User Group | Routing User Group | UserGroup.Pending Cases - Routing User Group.Routing User Group |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

My Completed Case Version Routing - Line Listing

This report lists the workflow state routing information of the locked case versions that have been worked on (in any workflow state prior to case lock) by the user who is viewing this report.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Case History page

Dimensions

Enterprise.Enterprise ID

State.Case Routing - State

User Group.Case Routing - Routing User Group



User.Case Routing - Routing User

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Completed Workflow States - Line Listing

Column Descriptions

The following table describes the columns in the My Completed Case Version Routing – Line Listing report:

Table A-29 My Completed Case Version Routing - Line Listing

| Table Heading | Column Heading | Measure |
|---|------------------------------|---|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Case Routing | Version ID | Case Routing. Version ID |
| State.Case Routing - State | State Routed From | State.Case Routing - State.State Routed From |
| State.Case Routing - State | State Routed To | State.Case Routing - State.State Routed To |
| Case Routing | Routing Timestamp From State | Case Routing.Routing Timestamp From State |
| Case Routing | Routing Timestamp To State | Case Routing.Routing Timestamp To State |
| Case Routing | Routing Justification | Case Routing.Routing Justification |
| User Group.Case Routing - Routing User Group | Routing User Group | User Group.Case Routing - Routing User Group.Routing User Group |
| User.Case Routing - Routing User | Routing User ID | User.Case Routing - Routing User.Routing User ID |

My Case Modified Duration Per State - Statistical Overview

This report displays an overview of statistics on the duration for which the cases were modified by the user who is viewing the report.

This report can be used to highlight the personal duration case modified statistics of the user. Modified refers to cases that are opened in Edit mode and the saved.

For more information, see:



- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

- Table
- 2-D Bar Graph

Location

Personal User dashboard > Personal User Case Work History page

Dimensions

Case Workflow State.State Name

Supplementary Prompts

None

Reports Referenced

My Completed Workflow States - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the My Case Modified Duration Per State – Statistical Overview report:

Table A-30 My Case Modified Duration Per State - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------------|----------------|-----------------------------------|
| Case Workflow State | State Name | Case Workflow State.State Name |



Table A-30 (Cont.) My Case Modified Duration Per State – Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------------|---|--|
| Case Workflow State | Avg Duration Case Modified Per State | Case Workflow State.Avg Duration Case Modified Per State |
| Case Workflow State | Min Duration Case Modified Per State | Case Workflow State.Min Duration Case Modified Per State |
| Case Workflow State | Max Duration Case Modified Per State | Case Workflow State.Max Duration Case Modified Per State |

My Case Unmodified Duration Per State – Statistical Overview

This report displays an overview of statistics on the durations cases were unmodified by the user who is viewing this report.

This report can be used to highlight the personal duration case unmodified statistics of the user. Unmodified refers to cases that are opened in Edit mode but not saved.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

- Table
- · 2-D Bar Graph

Location

Personal User dashboard > Personal User Case Work History page

Dimensions

Case Workflow State.State Name

Supplementary Prompts

None

Reports Referenced

My Completed Workflow States - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the My Case Unmodified Duration Per State – Statistical Overview report:

Table A-31 My Case Unmodified Duration Per State – Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------------|--|--|
| Case Workflow State | State Name | Case Workflow State.State Name |
| Case Workflow State | Avg Duration Case Unmodified Per State | Case Workflow State.Avg Duration Case Unmodified Per State |
| Case Workflow State | Min Duration Case Unmodified Per State | Case Workflow State.Min Duration Case Unmodified Per State |
| Case Workflow State | Max Duration Case Unmodified Per State | Case Workflow State.Max Duration Case Unmodified Per State |

My Case Read Duration Per State - Statistical Overview

This report displays an overview of statistics on the durations cases were read by the user who is viewing this report.

This report can be used to highlight the user's personal duration case read statistics. Read means cases opened in read-only mode.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report



Column Descriptions

Audience

Case Processor

Report Type

- Table
- · 2-D Bar Graph

Location

Personal User dashboard > Personal User Case Work History page

Dimensions

Case Workflow State.State Name

Supplementary Prompts

None

Reports Referenced

My Completed Workflow States - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the My Case Read Duration Per State – Statistical Overview report:

Table A-32 My Case Read Duration Per State - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------------|-------------------------------------|--|
| Case Workflow State | State Name | Case Workflow State.State Name |
| Case Workflow State | Avg Duration Case Read Per State | Case Workflow State.Avg Duration Case Read Per State |
| Case Workflow State | Min Duration Case Read Per State | Case Workflow State.Min Duration Case Read Per State |
| Case Workflow State | Max Duration Case Read Per State | Case Workflow State.Max Duration Case Read Per State |



My Case Idle Duration Per State – Statistical Overview

This report displays an overview of statistics on the durations cases were idle before being opened by the user who is viewing this report.

This report can be used to highlight the user's personal duration case idle statistics. Idle means the time between a workflow state routing and the first time the case is opened after the routing.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

- Table
- 2-D Bar Graph

Location

Personal User dashboard > Personal User Case Work History page

Dimensions

Case Routing. State Routed From

Supplementary Prompts

None

Reports Referenced

My Completed Workflow States - Line Listing

Reports Referencing This Report

None



Column Descriptions

The following table describes the columns in the My Case Idle Duration Per State – Statistical Overview report:

Table A-33 My Case Idle Duration Per State - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|------------------------------------|---|
| Case Routing | State Routed From | Case Routing.State Routed From |
| Case Routing | Avg Duration Case Idle Per Routing | Case Routing.Avg Duration Case Idle Per Routing |
| Case Routing | Min Duration Case Idle | Case Routing.Min Duration Case Idle |
| Case Routing | Max Duration Case Idle | Case Routing.Max Duration Case Idle |

My Submitted Expedited Reports - Volume Trend

This report displays the trend over time of the volume of expedited reports that have been submitted by the user who is viewing this report.

This report can be used to highlight the user's personal submitted expedited report volume trend over the last three months. This indicates if the user's personal workload is increasing, decreasing, or remaining constant over time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

- Group By Pivot
- 2-D Line Graph



Location

Personal User dashboard > Personal User Expedited Report History page

Dimensions

Expedited Submission Dimensions.Report Destination.Report Destination

Expedited Submission Dimensions.Report Submission Or MDN Date.Month

Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the My Submitted Expedited Reports – Volume Trend report:

Table A-34 My Submitted Expedited Reports - Volume Trend

| Table Heading | Column Heading | Measure |
|-------------------------------|---------------------|---|
| Report Destination | Report Destination | Expedited Submission Dimensions.Report Destination.Report Destination |
| Expedited Submission | # Reports Submitted | Expedited Submission.# Reports Submitted |
| Report Submission Or MDN Date | Month | Report Submission Or MDN Date.Month |

My Submitted Expedited Reports – Submission Compliance Trend

This report displays the trend over time of the submission compliance of expedited reports that have been submitted by the user who is viewing this report.

This report can be used to highlight the user's personal submission compliance trend over the last three months. This indicates if the user's personal submission compliance is increasing, decreasing, or remaining constant over time.

For more information, see:

Audience



- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

- Group By Pivot
- 2-D Line Graph

Location

Personal User dashboard > Personal User Expedited Report History page

Dimensions

Expedited Submission Dimensions.Report Submission Or MDN Date.Month User Group.Expedited Submission.Report Assigned User Group

Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the My Submitted Expedited Reports – Submission Compliance report:



Table A-35 My Submitted Expedited Reports – Submission Compliance Trend

| Table Heading | Column Heading | Measure |
|----------------------------------|-----------------------------|---|
| Expedited Submission | Report Assigned User Group | Expedited Submission.Report Assigned User Group |
| Report Submission Or MDN Date | Month | Expedited Submission Dimensions.Report Submission Or MDN Date.Month |
| Expedited Submission | # Reports Submitted On-Time | Expedited Submission.# Reports Submitted On-Time |
| Expedited Submission | # Reports Submitted Late | Expedited Submission.# Reports Submitted Late |

Completed Expedited Reports – Line Listing

This report lists the completed expedited reports by Case ID, including data from key report fields.

This report can be used to drill down to the details of the completed expedited reports. This indicates which expedited reports can be targeted for a root cause analysis, such as, for an investigation of expedited reports that were submitted late.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- · Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

Narrative Table

Location

 Expedited Report History dashboard > Expedited Submission Volume History page

- Expedited Report History dashboard > Expedited Submission Compliance History page
- Expedited Report History dashboard > Expedited Non-Submission on Volume History page

Dimensions

Enterprise.Enterprise ID

Expedited Submission Dimensions.Report Destination.Report Destination

Expedited Submission Dimensions.Report Destination.Report Destination Country

Expedited Submission Dimensions.License.Product Name

Supplementary Prompts

None

Reports Referenced

Completed Expedited Report Routing – Line Listing

Reports Referencing This Report

Submitted Expedited Reports – Volume Overview

Submitted Expedited Reports – Volume Trend

Submitted Expedited Reports – Submission Compliance By User Group

Submitted Expedited Reports – Submission Compliance By Destination

Submitted Expedited Reports – Submission Compliance Trend

Expedited Reports Never Submitted – Volume Trend

Failed/Pending ACK Expedited Reports - Volume Overview

Failed/Pending ACK Expedited Reports - Volume Trend

My Submitted Expedited Reports – Volume Trend

My Submitted Expedited Reports – Submission Compliance Trend

Column Descriptions

The following table describes the columns in the Completed Expedited Reports – Line Listing report:

Table A-36 Completed Expedited Reports – Line Listing

| Table Heading | Column Heading | Measure |
|---------------|----------------|--------------------------|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |



Table A-36 (Cont.) Completed Expedited Reports – Line Listing

| Table Heading | Column Heading | Measure |
|----------------------|--------------------------------------|---|
| Expedited Submission | Version ID | Expedited Submission.Version ID |
| Expedited Submission | Report ID | Expedited Submission.Report ID |
| Expedited Submission | Report Initial / Follow-Up ID | Expedited Submission.Report Initial / Follow-Up ID |
| Expedited Submission | Report Completion Type | Expedited Submission.Report Completion Type |
| Expedited Submission | Regulatory Report Type | Expedited Submission.Regulatory Report Type |
| Report Destination | Report Destination | Expedited Submission Dimensions.Report Destination.Report Destination |
| Expedited Submission | Report Timeframe | Expedited Submission.Report Timeframe |
| Report Destination | Report Destination Country | Expedited Submission Dimensions.Report Destination.Report Destination Country |
| License | Product Name | Expedited Submission Dimensions.License.Product Name |
| Expedited Submission | Report Due Date | Expedited Submission.Report Due Date |
| Expedited Submission | Report Submission/MDN Timestamp | Expedited Submission.Report Submission/MDN Timestamp |
| Expedited Submission | ACK Timestamp | Expedited Submission.ACK Timestamp |
| Expedited Submission | Report Submission User ID | Expedited Submission.Report Submission User ID |
| Expedited Submission | Report Submission Comments | Expedited Submission.Report Submission Comments |
| Expedited Submission | Report No Submission Required Reason | Expedited Submission.Report No Submission Required Reason |



Completed Expedited Report Routing – Line Listing

This report lists the completed expedited reports by Case ID, including routing between report states.

This report can be used to drill down to the report routing information of the completed expedited reports. This indicates which routings can be targeted for a root cause analysis, such as, for an investigation of expedited reports that were submitted late.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

Narrative Table

Location

- Expedited Report History dashboard > Expedited Submission Volume History page
- Expedited Report History dashboard > Expedited Submission Compliance History page
- Expedited Report History dashboard > Expedited Non-Submission on Volume History page

Dimensions

Enterprise.Enterprise ID

Supplementary Prompts

None



Reports Referenced

None

Reports Referencing This Report

Completed Expedited Reports - Line Listing

Column Descriptions

The following table describes the columns in the Completed Expedited Report Routing – Line Listing report:

Table A-37 Completed Expedited Report Routing – Line Listing

| Table Heading | Column Heading | Measure |
|----------------|--------------------------------------|--|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Report Routing | Report ID | Report Routing.Report ID |
| Report Routing | Report Routing Justification | Report Routing.Report Routing Justification |
| Report Routing | Report Routing ID | Report Routing.Report Routing ID |
| Report Routing | Report State Routed From | Report Routing.Report State Routed From |
| Report Routing | Report State Routed To | Report Routing.Report State Routed To |
| Report Routing | Report Routing Timestamp From State | Report Routing.Report Routing Timestamp From State |
| Report Routing | Report Routing Timestamp To State | Report Routing.Report Routing Timestamp To State |
| Report Routing | Report Routing User ID | Report Routing.Report Routing User ID |

My Pending Expedited Reports – Overview

This report displays an overview of the volume of expedited reports that are currently assigned to the user who is viewing this report (My Assigned Expedited Reports), the expedited reports that are assigned to the group(s) to which that user belongs but not to any individual users (My Unassigned Expedited Reports), and the expedited reports that are assigned to other users in the group(s) to which the viewing user belongs (Other Assigned Expedited Reports).

This report can be used to highlight the current, real-time workload of the user viewing this report, the pool of expedited reports that need to be worked on next (upcoming workload), and the workload of the viewing user's colleagues (potential workload if expedited reports are reassigned). Therefore the user has a complete overview of his/her current, upcoming and potential workloads.

For more information, see:



- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

- Table
- · 2-D Bar Graph

Location

Personal User dashboard > Personal User Expedited Report Management page

Dimensions

Pending Reports.Report Assigned User Group

Supplementary Prompts

None

Reports Referenced

My Assigned Expedited Reports – Line Listing

My Unassigned Expedited Reports - Line Listing

Other Assigned Expedited Reports – Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the My Pending Expedited Reports - Overview report:



Table A-38 My Pending Expedited Reports - Overview

| Table Heading | Column Heading | Measure |
|-----------------|--------------------------|---|
| Pending Reports | # My Assigned Reports | Pending Reports.Report Assigned User ID |
| Pending Reports | # My Unassigned Reports | Pending Reports.Report Assigned User GroupPending Reports.Report Assigned User ID |
| Pending Reports | # Other Assigned Reports | Pending Reports.Report Assigned User ID |
| Pending Reports | # Total Reports | Enterprise.Enterprise IDPending Reports.Report ID |

My Assigned Expedited Reports – Line Listing

This report lists the expedited reports that are currently assigned to the user who is viewing this report.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- · Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Expedited Report Management page

Dimensions

Enterprise.Enterprise ID

Expedited Submission Dimensions.Report Destination.Report Destination

Expedited Submission Dimensions.License.Product Name

Expedited Submission Dimensions.Report Destination.Report Destination Country

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Pending Expedited Reports – Overview

Column Descriptions

The following table describes the columns in the My Assigned Expedited Reports - Line Listing report:

Table A-39 My Assigned Expedited Reports - Line Listing

| Table Heading | Column Heading | Measure |
|--------------------|-------------------------------|---|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Reports | Report ID | Pending Reports.Report ID |
| Pending Reports | Regulatory Report Type | Pending Reports.Regulatory Report Type |
| Pending Reports | Report Assigned User Group | Pending Reports.Report Assigned User Group |
| Pending Reports | Report Due Date | Pending Reports.Report Due Date |
| Report Destination | Report Destination | Expedited Submission Dimensions.Report Destination.Report Destination |
| Pending Reports | Foreign / Domestic | Pending Reports.Foreign / Domestic |
| Pending Reports | Report 7/15 Timeframe | Pending Reports.Report 7/15 Timeframe |
| Pending Reports | Report Initial / Follow-Up ID | Pending Reports.Report Initial / Follow-Up ID |
| Report Destination | Report Destination Country | Expedited Submission Dimensions.Report Destination.Report Destination Country |
| License | Product Name | Expedited Submission Dimensions.License.Product Name |



Table A-39 (Cont.) My Assigned Expedited Reports - Line Listing

| Table Heading | Column Heading | Measure |
|-----------------|-----------------------------|--|
| License | License ID | Expedited Submission Dimensions.License.License ID |
| Case | Clock Start Date | Case.Clock Start Date |
| Pending Reports | Report Generation Timestamp | Pending Reports.Report Generation Timestamp |
| Pending Reports | Report Assigned User | Pending Reports.Report Assigned User |
| Pending Reports | Report Downgrade Indicator | Pending Reports.Report Downgrade Indicator |
| Pending Reports | # Days Report Late | Pending Reports.# Days Report Late |
| Pending Reports | # Days Report Open | Pending Reports.# Days Report Open |
| Case | Case Workflow State | Case.State Name |

My Unassigned Expedited Reports – Line Listing

This report lists the expedited reports that are assigned to the group(s) to which the viewing user belongs but not to any individual users.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Expedited Report Management page

Dimensions

Enterprise.Enterprise ID

Expedited Submission Dimensions.Report Destination.Report Destination Country

Expedited Submission Dimensions.Report Destination.Report Destination

Expedited Submission Dimensions.License.Product Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Pending Expedited Reports – Overview

Column Descriptions

The following table describes the columns in the My Unassigned Expedited Reports - Line Listing report:

Table A-40 My Unassigned Expedited Reports - Line Listing

| Table Heading | Column Heading | Measure |
|--------------------|-------------------------------|---|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Reports | Report ID | Pending Reports.Report ID |
| Pending Reports | Regulatory Report Type | Pending Reports.Regulatory Report Type |
| Pending Reports | Report Assigned User Group | Pending Reports.Report Assigned User Group |
| Pending Reports | Report Due Date | Pending Reports.Report Due Date |
| Report Destination | Report Destination | Expedited Submission Dimensions.Report Destination.Report Destination |
| Pending Reports | Foreign / Domestic | Pending Reports.Foreign / Domestic |
| Pending Reports | Report 7/15 Timeframe | Pending Reports.Report 7/15 Timeframe |
| Pending Reports | Report Initial / Follow-Up ID | Pending Reports.Report Initial / Follow-Up ID |



Table A-40 (Cont.) My Unassigned Expedited Reports - Line Listing

| Table Heading | Column Heading | Measure |
|--------------------|-----------------------------|---|
| Report Destination | Report Destination Country | Expedited Submission Dimensions.Report Destination.Report Destination Country |
| License | Product Name | Expedited Submission Dimensions.License.Product Name |
| License | License ID | Expedited Submission Dimensions.License.License ID |
| Case | Clock Start Date | Case.Clock Start Date |
| Pending Reports | Report Generation Timestamp | Pending Reports.Report Generation Timestamp |
| Pending Reports | Report Assigned User | Pending Reports.Report Assigned User |
| Pending Reports | Report Downgrade Indicator | Pending Reports.Report Downgrade Indicator |
| Pending Reports | # Days Report Late | Pending Reports.# Days Report Late |
| Pending Reports | # Days Report Open | Pending Reports.# Days Report Open |
| Case | Case Workflow State | Case.State Name |

Other Assigned Expedited Reports – Line Listing

This report lists the expedited reports that are assigned to other users in the group(s) to which the viewing user belongs.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Case Processor



Report Type

Narrative Table

Location

Personal User dashboard > Personal User Expedited Report Management1 page

Dimensions

Enterprise.Enterprise ID

Expedited Submission Dimensions.Report Destination.Report Destination

Expedited Submission Dimensions.Report Destination.Report Destination Country

Expedited Submission Dimensions.License.Product Name

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Pending Expedited Reports – Overview

Column Descriptions

The following table describes the columns in the Other Assigned Expedited Reports - Line Listing report:

Table A-41 Other Assigned Expedited Reports - Line Listing

| Table Heading | Column Heading | Measure |
|-----------------|----------------------------|---|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Reports | Report ID | Pending Reports.Report ID |
| Pending Reports | Regulatory Report Type | Pending Reports.Regulatory Report Type |
| Pending Reports | Report Assigned User Group | Pending Reports.Report Assigned User Group |
| Pending Reports | Report Due Date | Pending Reports.Report Due Date |



Table A-41 (Cont.) Other Assigned Expedited Reports - Line Listing

| Table Heading | Column Heading | Measure |
|--------------------|-------------------------------|---|
| Report Destination | Report Destination | Expedited Submission Dimensions.Report Destination.Report Destination |
| Pending Reports | Foreign / Domestic | Pending Reports.Foreign / Domestic |
| Pending Reports | Report 7/15 Timeframe | Pending Reports.Report 7/15 Timeframe |
| Pending Reports | Report Initial / Follow-Up ID | Pending Reports.Report Initial / Follow-Up ID |
| Report Destination | Report Destination Country | Expedited Submission Dimensions.Report Destination.Report Destination Country |
| License | Product Name | Expedited Submission Dimensions.License.Product Name |
| License | License ID | Expedited Submission Dimensions.License.License ID |
| Case | Clock Start Date | Case.Clock Start Date |
| Pending Reports | Report Generation Timestamp | Pending Reports.Report Generation Timestamp |
| Pending Reports | Report Assigned User | Pending Reports.Report Assigned User |
| Pending Reports | Report Downgrade Indicator | Pending Reports.Report Downgrade Indicator |
| Pending Reports | # Days Report Late | Pending Reports.# Days Report Late |
| Pending Reports | # Days Report Open | Pending Reports.# Days Report Open |
| Case | Case Workflow State | Case.State Name |
| | | - |

Submitted Expedited Reports – Volume Overview

This report displays an overview of the volume of submitted expedited reports by destination.

This report can be used to compare the number of expedited reports by destination. This indicates which destinations are creating the greatest reporting workload.

For more information, see:

- Audience
- Report Type
- Location



- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- · Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- Group By Table
- 2-D Bar Graph

Location

 Expedited Report History dashboard > Expedited Submission Volume History page

Dimensions

Report Destination. Report Destination

Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports – Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Submitted Expedited Reports – Volume Overview report:

Table A-42 Submitted Expedited Reports – Volume Overview

| Table Heading | Column Heading | Measure |
|--------------------|--------------------|---------------------------------------|
| Report Destination | Report Destination | Report Destination.Report Destination |



Table A-42 (Cont.) Submitted Expedited Reports – Volume Overview

| Table Heading | Column Heading | Measure |
|----------------------|----------------|---|
| Expedited Submission | | Expedited Submission.# Reports Submitted |

Submitted Expedited Reports – Volume Trend

This report displays the trend over time of the volume of submitted expedited reports by destination.

This report can be used to compare the expedited report volume trend over the last three months by destination, and to drill down into months, weeks and days. This indicates if the reporting workload for certain destinations is increasing, decreasing, or remaining constant over time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- Group By Table
- 2-D Line Graph

Location

Expedited Report History dashboard > Expedited Submission Volume History page

Dimensions

Report Destination. Report Destination

Expedited Submission Dimensions.Report Submission Or MDN Date



Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Submitted Expedited Reports – Volume Trend report:

Table A-43 Submitted Expedited Reports – Volume Trend

| Table Heading | Column Heading | Measure |
|----------------------------------|---------------------|---|
| Report Destination | Report Destination | Report Destination.Report Destination |
| Report Submission Or MDN Date | Year | Report Submission Or MDN Date.Year |
| Expedited Submission | # Reports Submitted | Expedited Submission.# Reports Submitted |

Expedited Reports Never Submitted – Volume Trend

This report displays an overview of the volume of expedited reports that have been deleted or marked as 'No Submission Required'.

This report can be used to view how many expedited reports are not submitted at the end of the reporting process. This indicates how accurately the configured reporting rules reflect real business rules.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions



Audience

Executive Manager

Team Leader

Report Type

- Group By Pivot
- 2-D Line Graph

Location

 Expedited Report History dashboard > Expedited Non-Submission Volume History page

Dimensions

Expedited Submission Dimensions.Report Generation Date

Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Expedited Reports Never Submitted – Volume Trend report:

Table A-44 Expedited Reports Never Submitted – Volume Trend

| Table Heading | Column Heading | Measure |
|------------------------|-------------------------------------|---|
| Report Generation Date | Year | Report Generation Date. Year |
| Expedited Submission | # Reports Deleted | Expedited Submission.# Reports Deleted |
| Expedited Submission | # Reports No Submission Required | Expedited Submission.# Reports No Submission Required |



Submitted Expedited Reports – Submission Compliance By User Group

This report displays an overview of the submission compliance of expedited reports by user group.

This report can be used to compare retrospective submission compliance by user group. This indicates which user groups might be having difficulties submitting expedited reports on time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- Group By Table
- · 2-D Bar Graph

Location

Expedited Report History dashboard > Expedited Submission Compliance History page

Dimensions

User Group. Expedited Submission. Report Assigned User Group

Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports – Line Listing



Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Submitted Expedited Reports – Submission Compliance By User Group report:

Table A-45 Submitted Expedited Reports – Submission Compliance By User Group

| Table Heading | Column Heading | Measure |
|----------------------|-----------------------------|---|
| Expedited Submission | Report Assigned User Group | Expedited Submission.Report Assigned User Group |
| Expedited Submission | # Reports Submitted On-Time | Expedited Submission.# Reports Submitted On-Time |
| Expedited Submission | # Reports Submitted Late | Expedited Submission.# Reports Submitted Late |

Submitted Expedited Reports – Submission Compliance By Destination

This report displays an overview of the submission compliance of expedited reports by destination.

This report can be used to compare retrospective submission compliance by destination. This indicates which destinations are receiving reports on time and late.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader



Report Type

- · Group By Table
- · 2-D Bar Graph

Location

Expedited Report History dashboard > Expedited Submission Compliance History page

Dimensions

Report Destination. Report Destination

Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Submitted Expedited Reports – Submission Compliance By Destination report:

Table A-46 Submitted Expedited Reports – Submission Compliance By Destination

| Table Heading | Column Heading | Measure |
|----------------------|-----------------------------|---|
| Report Destination | Report Destination | Report Destination.Report Destination |
| Expedited Submission | # Reports Submitted On-Time | Expedited Submission.# Reports Submitted On-Time |
| Expedited Submission | # Reports Submitted Late | Expedited Submission.# Reports Submitted Late |

Submitted Expedited Reports – Submission Compliance Trend

This report displays the trend over time of the submission compliance of expedited reports.

This report can be used to view the submission compliance trend over the last three months and to drill down into months, weeks and days. This indicates if submission compliance is increasing, decreasing, or remaining constant over time.



For more information, see:

- Audience
- · Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- · Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- Group By Pivot
- 2-D Line Graph

Location

Expedited Report History dashboard > Expedited Submission Compliance History page

Dimensions

Expedited Submission Dimensions.Report Submission Or MDN Date

Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Submitted Expedited Reports – Submission Compliance Trend report:



Table A-47 Submitted Expedited Reports – Submission Compliance Trend

| Table Heading | Column Heading | Measure |
|-------------------------------|-----------------------------|---|
| Report Submission Or MDN Date | Year | Report Submission Or MDN Date.Year |
| Expedited Submission | # Reports Submitted On-Time | Expedited Submission.# Reports Submitted On-Time |
| Expedited Submission | # Reports Submitted Late | Expedited Submission.# Reports Submitted Late |

Pending Expedited Reports – Volume Overview

This report displays an overview of the volume of pending expedited reports by user group. This report can be used to compare the current, real-time workloads of the user groups that are submitting expedited reports. This indicates where immediate action could be taken to balance the workload among the groups, if necessary.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

- Group By Table
- 2-D Bar Graph

Location

 Expedited Report Management dashboard > Expedited Submission Volume Management page

Dimensions

User Group.Pending Reports - Report Assigned User Group



Supplementary Prompts

None

Reports Referenced

Pending Expedited Reports – Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Pending Expedited Reports – Volume Overview report:

Table A-48 Pending Expedited Reports – Volume Overview

| Table Heading | Column Heading | Measure |
|-----------------|----------------------------|---|
| Pending Reports | Report Assigned User Group | Pending Reports.Report Assigned User Group |
| Pending Reports | # Pending Reports | Pending Reports.# Pending Reports |

Pending Expedited Reports – Line Listing

This report lists the pending expedited reports by Case ID, including data from key report fields.

This report can be used to drill down to the details of the pending expedited reports. This indicates which expedited reports can be reassigned, if workload balancing is necessary.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Column Descriptions
- Reports Referenced
- · Reports Referencing This Report

Audience

Workflow Manager



Team Leader

Report Type

Narrative Table

Location

- Expedited Report Management dashboard > Expedited Submission Volume Management page
- Expedited Report Management dashboard > Expedited Submission Compliance Management page

Dimensions

Enterprise.Enterprise ID

Expedited Submission Dimensions.Report Destination.Report Destination

Expedited Submission Dimensions.License.Product Name

Expedited Submission Dimensions.Report Destination.Report Destination Country

Supplementary Prompts

None

Column Descriptions

The following table describes the columns in the Pending Expedited Reports – Line Listing report:

Table A-49 Pending Expedited Reports – Line Listing

| Table Heading | Column Heading | Measure |
|--------------------|----------------------------|---|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Reports | Report ID | Pending Reports.Report ID |
| Pending Reports | Regulatory Report Type | Pending Reports.Regulatory Report Type |
| Pending Reports | Report Assigned User Group | Pending Reports.Report Assigned User Group |
| Pending Reports | Report Due Date | Pending Reports.Report Due Date |
| Report Destination | Report Destination | Expedited Submission Dimensions.Report Destination.Report Destination |
| Pending Reports | Foreign / Domestic | Pending Reports.Foreign / Domestic |



Table A-49 (Cont.) Pending Expedited Reports – Line Listing

| Table Heading | Column Heading | Measure | |
|--------------------|-------------------------------|---|--|
| Pending Reports | Report 7/15 Timeframe | Pending Reports.Report 7/15 Timeframe | |
| Pending Reports | Report Initial / Follow-Up ID | Pending Reports.Report Initial / Follow-Up ID | |
| Report Destination | Report Destination Country | Expedited Submission Dimensions.Report Destination.Report Destination Country | |
| License | Product Name | Expedited Submission Dimensions.License.Product Name | |
| License | License ID | Expedited Submission Dimensions.License.License ID | |
| Case | Clock Start Date | Case.Clock Start Date | |
| Pending Reports | Report Generation Timestamp | Pending Reports.Report Generation Timestamp | |
| Pending Reports | Report Assigned User | Pending Reports.Report Assigned User | |
| Pending Reports | Report Downgrade Indicator | Pending Reports.Report Downgrade Indicator | |
| Pending Reports | # Days Report Late | Pending Reports.# Days Report Late | |
| Pending Reports | # Days Report Open | Pending Reports.# Days Report Open | |
| Case | Case Workflow State | Case.State Name | |

Reports Referenced

None

Reports Referencing This Report

Pending Expedited Reports – Volume Overview

Pending Expedited Reports – Submission Compliance Overview

Pending Expedited Reports – Submission Compliance In Days

Pending Expedited Reports – Submission Compliance Overview

This report displays an overview of the submission compliance of pending expedited reports by user group.

This report can be used to compare the current, real-time submission compliance of the user groups that are processing expedited reports. This indicates where immediate action could be taken to balance the workload among the groups, if necessary.



For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

- Group By Table
- 2-D Bar Graph

Location

 Expedited Report Management dashboard > Expedited Submission Compliance Management page

Dimensions

User Group.Pending Reports - Report Assigned User Group

Supplementary Prompts

None

Reports Referenced

Pending Expedited Reports - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Pending Expedited Reports – Submission Compliance Overview report:



Table A-50 Pending Expedited Reports – Submission Compliance Overview

| Table Heading | Column Heading | Measure |
|-----------------|----------------------------|---|
| Pending Reports | Report Assigned User Group | Pending Reports.Report Assigned User Group |
| Pending Reports | # Pending Reports On-Time | Pending Reports.# Pending Reports On-Time |
| Pending Reports | # Pending Reports Due Soon | Pending Reports.# Pending Reports Due Soon |
| Pending Reports | # Pending Reports Overdue | Pending Reports.# Pending Reports Overdue |

Pending Expedited Reports – Submission Compliance In Days

This report displays an overview of the submission compliance of pending expedited reports by number of days until submission is due and number of days that submission is overdue.

This report can be used to compare the volumes of expedited reports due on each day. This indicates where to focus resources, in order to submit expedited reports on time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

- Group By Table
- · 2-D Bar Graph

Location

 Expedited Report Management dashboard > Expedited Submission Compliance Management page



Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Pending Expedited Reports – Submission Compliance In Days report:

Table A-51 Pending Expedited Reports – Submission Compliance In Days

| T . 1. 1 | | M |
|-----------------|----------------|---------------------------------|
| Table Heading | Column Heading | Measure |
| Pending Reports | > +5 Days | Pending Reports.Report Due Date |
| Pending Reports | +5 Days | Pending Reports.Report Due Date |
| Pending Reports | +4 Days | Pending Reports.Report Due Date |
| Pending Reports | +3 Days | Pending Reports.Report Due Date |
| Pending Reports | +2 Days | Pending Reports.Report Due Date |
| Pending Reports | +1 Days | Pending Reports.Report Due Date |
| Pending Reports | 0 Days | Pending Reports.Report Due Date |
| Pending Reports | -1 Days | Pending Reports.Report Due Date |
| Pending Reports | -2 Days | Pending Reports.Report Due Date |
| Pending Reports | -3 Days | Pending Reports.Report Due Date |
| Pending Reports | -4 Days | Pending Reports.Report Due Date |
| Pending Reports | -5 Days | Pending Reports.Report Due Date |
| Pending Reports | > -5 Days | Pending Reports.Report Due Date |

Failed/Pending ACK Expedited Reports - Volume Overview

This report displays an overview of the volume of E2B reports that may have been submitted but have received an ACK with a 'Failed' status, or for which the ACK is still pending. Even though E2B reports these have been submitted, they are not considered completed till they receive a successful ACK.



This report can be used to keep track of E2B reports that are submitted but not yet completed, perhaps due to technical or content issues. This indicates where immediate action could be taken to fix such issues, if necessary.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- · Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

- Group By Table
- 2-D Bar Graph

Location

 Expedited Report Management dashboard > Expedited Failed/Pending ACK Volume Management page

Dimensions

Expedited Submission Dimensions.Report Destination.Report Destination

Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports - Line Listing

Reports Referencing This Report

None



Column Descriptions

The following table describes the columns in the Failed/Pending ACK Expedited Reports – Volume Overview report:

Table A-52 Failed/Pending ACK Expedited Reports - Volume Overview

| Table Heading | Column Heading | Measure |
|----------------------|--------------------------------|---|
| Report Destination | Report Destination | Report Destination.Report Destination |
| Expedited Submission | # Failed / Pending ACK Reports | Expedited Submission.# Failed / Pending ACK Reports |

Failed/Pending ACK Expedited Reports – Volume Trend

This report displays the trend over time of the volume of E2B reports that may have been submitted but have received an ACK with a 'Failed' status, or for which the ACK is still pending.

This report can be used to indicate if the number of reports with failed ACKs is increasing, decreasing, or remaining constant over time.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Workflow Manager

Team Leader

Report Type

- Group By Pivot
- 2-D Line Graph

Location

 Expedited Report Management dashboard > Expedited Failed/Pending ACK Volume Management page



Dimensions

Report Destination. Report Destination

Period.Report Submission Or MDN Date.Month

Supplementary Prompts

None

Reports Referenced

Completed Expedited Reports - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Failed/Pending ACK Expedited Reports – Volume Trend report:

Table A-53 Failed/Pending ACK Expedited Reports – Volume Trend

| Table Heading | Column Heading | Measure |
|-------------------------------|--------------------------------|---|
| Report Destination | Report Destination | Report Destination.Report Destination |
| Report Submission Or MDN Date | Month | Report Submission Or MDN Date.Month |
| Expedited Submission | # Failed / Pending ACK Reports | Expedited Submission.# Failed / Pending ACK Reports |

Duration Case Modified Per Version and Case – Statistical Overview

This report displays an overview of statistics on the durations cases were modified, meaning opened in edit mode and then saved. These statistics are shown at the case and case version level.

This report can be used to view the average, minimum, and maximum durations cases were modified per case, and case version.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts



- · Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

Table

Location

Case Work History dashboard > Case Modified History page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Modified Per Version and Case - Statistical Overview report:

Table A-54 Duration Case Modified Per Version and Case - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|------------------------------|---|
| Case | Avg Modified Duration (Days) | Case.Avg Duration Case Modified Per Case |
| Case | Min Modified Duration (Days) | Case.Min Duration Case Modified Per Case |
| Case | Max Modified Duration (Days) | Case.Max Duration Case Modified Per Case |
| Case Version | Avg Modified Duration (Days) | Case Version.Avg Duration Case Modified Per Version |



Table A-54 (Cont.) Duration Case Modified Per Version and Case - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|------------------------------|--|
| Case Version | Min Modified Duration (Days) | Case Version.Min Duration Case Modified Per Version |
| Case Version | Max Modified Duration (Days) | Case Version.Max Duration Case Modified Per Version |

Duration Case Modified Per State – Statistical Overview

This report displays an overview of statistics on the durations cases were modified, meaning opened in edit mode and then saved. These statistics are shown at the workflow state level.

This report can be used to view the average, minimum, and maximum durations cases were modified per workflow state.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- Table
- · 2-D Bar Graph

Location

Case Work History dashboard > Case Modified History page

Dimensions

Case Workflow State.State Name

Supplementary Prompts

None

Reports Referenced

Completed Workflow States - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Modified Per State - Statistical Overview report:

Table A-55 Duration Case Modified Per State - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------------|--|--|
| Case Workflow State | State Name | Case Workflow State.State Name |
| Case Workflow State | Avg Duration Case Modified Per State (Days) | Case Workflow State.Avg Duration Case Modified Per State |
| Case Workflow State | Min Duration Case Modified Per State (Days) | Case Workflow State.Min Duration Case Modified Per State |
| Case Workflow State | Max Duration Case Modified Per State (Days) | Case Workflow State.Max Duration Case Modified Per State |

Duration Case Modified Per User/State – Statistical Overview

This report displays an overview of statistics on the durations cases were modified, meaning opened in edit mode and then saved. These statistics are shown at the user per workflow state level.

This report can be used to view the average, minimum, and maximum durations cases were modified per workflow state.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Reports Referenced
- · Reports Referencing This Report



Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- · Group By Pivot
- 2-D Line Graph

Location

Case Work History dashboard > Case Modified History page

Dimensions

User.Case Work User.User With Case Open ID

Case Work User. Workflow State At Case Open

Reports Referenced

None

Reports Referencing This Report

None

Supplementary Prompts

Supplementary Prompts

None

Column Descriptions

The following table describes the columns in the Duration Case Modified Per User/ State - Statistical Overview report:

Table A-56 Duration Case Modified Per User/State - Statistical Overview

| Table Heading | Column Heading | Measure |
|----------------|---|--|
| Case Work User | User With Case Open ID | Case Work User.User With Case Open ID |
| Case Work User | Workflow State At Case Open | Case Work User.Workflow State At Case Open |
| Case Work User | Avg Duration Case Modified Per User / State (Days) | Case Work User.Avg Duration Case Modified Per User / State |



Completed Case Version Routing – Line Listing

This report lists the cases that are assigned to other users in the group(s) to which the viewing user belongs.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

Report Type

Narrative Table

Location

- Case Work History dashboard > Case Modified History page
- Case Work History dashboard > Case Unmodified History page
- Case Work History dashboard > Case Read History page
- Case Work History dashboard > Case Idle History page

Dimensions

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

Supplementary Prompts

None



Reports Referenced

None

Reports Referencing This Report

My Pending Cases – Overview

Column Descriptions

The following table describes the columns in the Completed Case Version Routing – Line Listing report:

Table A-57 Completed Case Version Routing – Line Listing

| | I | |
|---|------------------------|---|
| Table Heading | Column Heading | Measure |
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Cases | Follow-Up ID | Pending Cases.Follow-up ID |
| Pending Cases | Follow-Up Type | Pending Cases.Follow-up Type |
| Pending Cases | Case Processing Site | Pending Cases.Case Processing Site |
| Pending Cases | Case Type | Pending Cases.Case Type |
| Pending Cases | Study ID | Pending Cases.Study ID |
| Pending Cases | Case Seriousness | Pending Cases.Case Seriousness |
| Pending Cases | Case Listedness | Pending Cases.Case Listedness |
| Pending Cases | Case Causality | Pending Cases.Case Causality |
| Pending Cases | Case Outcome | Pending Cases.Case Outcome |
| Pending Cases | SUSAR | Pending Cases.SUSAR |
| Pending Cases | Lock Due Soon Date | Pending Cases.Lock Due Soon Date |
| Pending Cases | Lock Due Date | Pending Cases.Lock Due Date |
| User.Pending Cases - Assigned User | Assigned User ID | User.Pending Cases - Assigned Cases.Assigned User ID |
| Pending Cases | User with Case Open ID | Pending Cases.User with Case Open ID |
| Pending Cases | State Name | Pending Cases.State Name |
| UserGroup.Pending Cases - Routing User Group | Routing User Group | UserGroup.Pending Cases - Routing User Group.Routing User Group |



Table A-57 (Cont.) Completed Case Version Routing – Line Listing

| Table Heading | Column Heading | Measure |
|---------------|-----------------------|-------------------------------------|
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Duration Case Unmodified Per Version and Case – Statistical Overview

This report displays an overview of statistics on the durations cases were unmodified, meaning opened in edit mode but not saved. These statistics are shown at the case and case version level.

This report can be used to view the average, minimum and maximum durations cases were unmodified per case and case version.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

Group By Table

Location

Case Work History dashboard > Case Unmodified History page

Dimensions

None



Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Unmodified Per Version and Case - Statistical Overview report:

Table A-58 Duration Case Unmodified Per Version and Case - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|--------------------------------|---|
| Case | Avg Unmodified Duration (Days) | Case.Avg Duration Case Unmodified Per Case |
| Case | Min Unmodified Duration (Days) | Case.Min Duration Case Unmodified Per Case |
| Case | Max Unmodified Duration (Days) | Case.Max Duration Case Unmodified Per Case |
| Case Version | Avg Unmodified Duration (Days) | Case Version.Avg Duration Case Unmodified Per Version |
| Case Version | Min Unmodified Duration (Days) | Case Version.Min Duration Case Unmodified Per Version |
| Case Version | Max Unmodified Duration (Days) | Case Version.Max Duration Case Unmodified Per Version |

Duration Case Unmodified Per State – Statistical Overview

This report displays an overview of statistics on the durations cases were unmodified, meaning opened in edit mode but not saved. These statistics are shown at the workflow state level.

This report can be used to view the average, minimum, and maximum durations cases were unmodified per workflow state.

- Audience
- Report Type



- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Executive Manager

Team Leader

Report Type

- Table
- 2-D Bar Graph

Location

Case Work History dashboard > Case Unmodified History page

Dimensions

Case Workflow State.State Name

Supplementary Prompts

State Name

Reports Referenced

Completed Workflow States - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Unmodified Per State - Statistical Overview report:

Table A-59 Duration Case Unmodified Per State - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------------|----------------|-----------------------------------|
| Case Workflow State | State Name | Case Workflow State.State Name |



| Table Heading | Column Heading | Measure |
|---------------------|--|--|
| Case Workflow State | Avg Duration Case Unmodified Per State (Days) | Case Workflow State.Avg Duration Case Unmodified Per State |
| Case Workflow State | Min Duration Case Unmodified Per State (Days) | Case Workflow State.Min Duration Case Unmodified Per State |
| Case Workflow State | Max Duration Case Unmodified Per State (Days) | Case Workflow State.Max Duration Case Unmodified Per State |

Duration Case Unmodified Per User/State - Statistical Overview

This report displays an overview of statistics on the durations cases were unmodified, meaning opened in edit mode but not saved. These statistics are shown at the user per workflow state level.

This report can be used to view the average duration cases were unmodified per user per workflow state.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- · Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- Group By Pivot
- 2-D Line Graph

Location

Case Work History dashboard > Case Unmodified History page



Dimensions

User.Case Work User.User With Case Open ID

Case Work User. Workflow State At Case Open

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Unmodified Per User/ State - Statistical Overview report:

Table A-60 Duration Case Unmodified Per User/State - Statistical Overview

| Table Heading | Column Heading | Measure |
|----------------|---|--|
| Case Work User | User With Case Open ID | Case Work User.User With Case Open ID |
| Case Work User | Workflow State At Case Open | Case Work User.Workflow State At Case Open |
| Case Work User | Avg Duration Case Unmodified Per User / State (Days) | Case Work User.Avg Duration Case Unmodified Per User / State |

Duration Case Read Per Version and Case - Statistical Overview

This report displays an overview of statistics on the durations cases were read, meaning opened in read-only mode. These statistics are shown at the case and case version level.

This report can be used to view the average, minimum and maximum durations cases were read per case and case version.

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts



- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Executive Manager

Team Leader

Report Type

Table

Location

Case Work History dashboard > Case Read History page

Dimensions

None

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Read Per Version and Case - Statistical Overview report:

Table A-61 Duration Case Read Per Version and Case - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|--------------------------|--|
| Case | Avg Read Duration (Days) | Case.Avg Duration Case Read Per Case |
| Case | Min Read Duration (Days) | Case.Min Duration Case Read Per Case |
| Case | Max Read Duration (Days) | Case.Max Duration Case Read Per Case |
| Case Version | Avg Read Duration (Days) | Case Version.Avg Duration Case Read Per Version |



Table A-61 (Cont.) Duration Case Read Per Version and Case - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|--------------------------|--|
| Case Version | Min Read Duration (Days) | Case Version.Min Duration Case Read Per Version |
| Case Version | Max Read Duration (Days) | Case Version.Max Duration Case Read Per Version |

Duration Case Read Per State - Statistical Overview

This report displays an overview of statistics on the durations cases were read, meaning opened in read-only mode. These statistics are shown at the workflow state level.

This report can be used to view the average, minimum and maximum durations cases were read per workflow state.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

- Table
- · 2-D Bar Graph

Location

Case Work History dashboard > Case Read History page

Dimensions

Case Workflow State.State Name



Supplementary Prompts

State Name

Reports Referenced

Completed Workflow States - Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Read Per State - Statistical Overview report:

Table A-62 Duration Case Read Per State - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------------|--|--|
| Case Workflow State | State Name | Case Workflow State.State Name |
| Case Workflow State | Avg Duration Case Read Per State (Days) | Case Workflow State.Avg Duration Case Read Per State |
| Case Workflow State | Min Duration Case Read Per State (Days) | Case Workflow State.Min Duration Case Read Per State |
| Case Workflow State | Max Duration Case Read Per State (Days) | Case Workflow State.Max Duration Case Read Per State |

Duration Case Read Per User/State - Statistical Overview

This report displays an overview of statistics on the durations cases were read, meaning opened in read-only mode. These statistics are shown at the user per workflow state level.

This report can be used to view the average duration cases were read per user per workflow state.

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced



- Reports Referencing This Report
- Column Descriptions

Executive Manager

Team Leader

Report Type

- Group By Pivot
- 2-D Line Graph

Location

Case Work History dashboard > Case Read History page

Dimensions

User.Case Work User.User With Case Open ID

Case Work User. Workflow State At Case Open

Supplementary Prompts

User With Case Open ID

Workflow State At Case Open

Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Read Per User/State - Statistical Overview report:

Table A-63 Duration Case Read Per User/State - Statistical Overview

| Table Heading | Column Heading | Measure |
|----------------|-----------------------------|---|
| Case Work User | User With Case Open ID | Case Work User.User With Case Open ID |
| Case Work User | Workflow State At Case Open | Case Work User.Workflow State At Case Open |



Table A-63 (Cont.) Duration Case Read Per User/State - Statistical Overview

| Table Heading | Column Heading | Measure |
|----------------|---|--|
| Case Work User | Avg Duration Case Read Per User / State (Days) | Case Work User.Avg Duration Case Read Per User / State |

Duration Case Idle – Statistical Overview

This report displays an overview of statistics on the durations cases were idle, meaning the time between a workflow state routing and the first time the case is opened after the routing. These statistics are shown at the case, case version and case routing level.

This report can be used to view the minimum and maximum durations cases were idle, and the average idle duration per case, case version and case routing.

For more information, see:

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions

Audience

Executive Manager

Team Leader

Report Type

Table

Location

Case Work History dashboard > Case Idle History page

Dimensions

None

Supplementary Prompts

None



Reports Referenced

None

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Idle - Statistical Overview report:

Table A-64 Duration Case Idle - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|--|---|
| Case Routing | Min Duration Case Idle (Days) | Case Routing.Min Duration Case Idle |
| Case Routing | Max Duration Case Idle (Days) | Case Routing.Max Duration Case Idle |
| Case Routing | Avg Duration Case Idle Per Routing (Days) | Case Routing.Avg Duration Case Idle Per Routing |
| Case Routing | Avg Duration Case Idle Per Version (Days) | Case Routing.Avg Duration Case Idle Per Version |
| Case Routing | Avg Duration Case Idle Per Case (Days) | Case Routing.Avg Duration Case Idle Per Case |

Duration Case Idle Per State – Statistical Overview

This report displays an overview of statistics on the durations cases were idle, meaning the time between a workflow state routing and the first time the case is opened after the routing. These statistics are shown at the workflow state level.

This report can be used to view the average, minimum and maximum durations cases were idle per workflow state.

- Audience
- Report Type
- Location
- Dimensions
- Supplementary Prompts
- Reports Referenced
- Reports Referencing This Report
- Column Descriptions



Executive Manager

Team Leader

Report Type

- Table
- 2-D Bar Graph

Location

Case Work History dashboard > Case Idle History page

Dimensions

Case Routing.State Routed From

Supplementary Prompts

State Routed From

Reports Referenced

Completed Case Version Routing – Line Listing

Reports Referencing This Report

None

Column Descriptions

The following table describes the columns in the Duration Case Idle Per State - Statistical Overview report:

Table A-65 Duration Case Idle Per State - Statistical Overview

| Table Heading | Column Heading | Measure |
|---------------|--|---|
| Case Routing | State Routed From | Case Routing.State Routed From |
| Case Routing | Min Duration Case Idle (Days) | Case Routing.Min Duration Case Idle |
| Case Routing | Max Duration Case Idle (Days) | Case Routing.Max Duration Case Idle |
| Case Routing | Avg Duration Case Idle Per Routing (Days) | Case Routing.Avg Duration Case Idle Per Routing |



B

Oracle Argus Analytics Presentation Catalog

The Oracle Argus Analytics Presentation Catalog displays columns that you can use to create requests.

You may also refer to Working with Reports.

This appendix contains the following topics:

- Dimensions in Oracle Argus Analytics Presentation Catalog
- Facts and Sources in Oracle Argus Analytics Presentation Catalog

Dimensions in Oracle Argus Analytics Presentation Catalog

Table B-1 describes the Dimensions displayed in the Oracle Argus Analytics Presentation Catalog. For each column, it shows the name of the Column, its description, and the Dimension containing the column. The table is sorted by Dimension, and by Column within Dimension. This corresponds to how the Dimension columns are organized in the Presentation Catalog.

Please note that some columns have been de-normalized, so that they appear in more than one Dimension. This de-normalization speeds query execution by eliminating the need for a join to that column in another Dimension. It also supports the ability to constrain columns in a Prompt, so that when you select a value in one column, the other columns are constrained to those related to your selection. When you select a de-normalized column from a Dimension, your results will be limited to the grain of the Dimension.

Table B-1 Presentation Catalog - Dimensions

| Dimension | Column | Description |
|----------------------|------------------------|--|
| Case Processing Site | Case Processing Site | Case Processing Site that the user belongs to. |
| Enterprise | Enterprise ID | CRO Enterprise (Client) Short Name |
| Enterprise | Last Refresh Date | Program_run_dt from w_control_s/pva_control_s Table |
| Enterprise | ETL Incremental Status | Value 'Running' if source_extraction_end_dt < source_extraction_start_dt from w_control_s/pva_control_s else has a value 'Completed' Table |
| Enterprise | Enterprise Name | Enterprise Name |
| Period | Year | Per_name_year From W_day_d Table |
| Period | Quarter | Per_name_qtr From W_day_d Table |
| Period | Month | Per_name_month From W_day_d Table |
| Period | Week | Per_name_week From W_day_d Table |
| Period | Day | Calendar_date From W_day_d Table |



Table B-1 (Cont.) Presentation Catalog - Dimensions

| Dimension | Column | Description |
|--------------------|----------------------------|--|
| Product | Product Group | Therapeutic Alignment Of User Groups By Product Indication (For Example, Oncology Group, Gynecology Group Etc) |
| Product | Product Family | Product Family - It is used to group Like products that share Datasheets and Primary Ingredients. |
| Product | PSUR Group | PSUR Group Name |
| Product | Product Name | Product Name |
| Product | Product Formulation | Formulation of the Product |
| Product | Product Concentration | Concentration/Strength of the Product |
| Study | Study ID | Study ID |
| Study | Project ID | Project ID for Study |
| Product | Generic Name | Generic Name of the Product |
| License | Product Name | Product Name |
| License | Product Formulation | Formulation of the Product |
| License | Product Concentration | Concentration/Strength of the Product |
| License | License ID | Product License Number |
| License | License Type | Product License Type (like Marketed Drug, Investigational Vaccine etc.) |
| License | License Name | Concatenated value of license trade name, license authorization country and license number displayed as - trade name ' (' country ') ' license number |
| License | License MAH | Manufacturer of the licensed product |
| License | License Country | Country of license award |
| License | CTPR Group | CTPR Group Name |
| License | Trade Name | Trade Name |
| Report Destination | Report Destination Country | Country of destination to which the report is submitted |
| Report Destination | Report Destination | Destination to which the report is submitted |

Facts and Sources in Oracle Argus Analytics Presentation Catalog

This section lists the Facts and Sources displayed in the Oracle Argus Analytics Presentation Catalog.

For each Fact, it shows the name of the Column, its Description, and the Source Table/Column that contains the Column.

This corresponds to how the Fact columns are organized in the Presentation Catalog, within the Fact folder.



Table B-2 Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|-------------------------------|--|---|---|
| Case | Case ID | Case Identification (same as Manufacturer Code Number [MCN]) | case_master.case_num | |
| Case | Case Internal ID | Internal Case ID Generated | case_master.case_id | |
| Case | Enterprise ID | CRO Enterprise (Client) Short Name | cfg_enterprise.enterprise_ab brv | |
| Case | Initial / Follow-Up | Initial or Follow-up entry of the Case | N/A | If Version = 1 then Initial Else Follow-up |
| Case | Case Deletion Indicator | A Flag to Identify that case has been "Deleted" or not | nvl(case_master.state_id, 0) = 1 or case_master.deleted is not null | |
| Case | Case Creator ID | ID of Case Author (who created the case) | case_master.user_id | |
| Case | Case Creator Name | Case Author (who created the case) | cfg_users.user_fullname where cfg_users.user_id = case_master.user_id | |
| Case | Case Processing Site | Site (for ex., drug safety case processing location) | case_master.site_id | |
| Case | Country Of Incidence | Country where the adverse event occurred | case_master.country_id | |
| Case | Case Type | Case Report Type (for ex., Spontaneous/Clinical/Literature etc.) | case_master.Report_type | |
| Case | Compliance Classification | 7-day Case, 15-day Case, Non-Expedited Case | lm_case_classification.description | where Im_case_classificatio n.description has values in (7-day Case, 15-day Case, Non-Expedited Case) |
| Case | S/R/U Classification | SAE Case, SAR Case, SUSAR Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (SAE Case, SAR Case, SUSAR Case) |
| Case | F/LT Classification | Fatal / Life-Threatening Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (Fatal / Life- Threatening Case) |
| Case | Pregnancy Classification | Pregnancy Case | lm_case_classification.description | where Im_case_classificatio n.description has values in (Pregnancy Case) |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|------------------------------------|--|---|--|
| Case | Source Classification | Authority Case, Consumer Case, Literature Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (Authority Case, Consumer Case, Literature Case) |
| Case | Confirmation Classification | Medically Confirmed Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (Medically Confirmed Case) |
| Case | Case Classification Group 7 | Case Classification Group 7 | Im_case_classification.description | where Im_case_classificatio n.description has values in (Case Classification 7) |
| Case | Case Classification Group 8 | Case Classification Group 8 | Im_case_classification.description | where Im_case_classificatio n.description has values in (Case Classification 8) |
| Case | Case Classification Group 9 | Case Classification Group 9 | Im_case_classification.description | where Im_case_classificatio n.description has values in (Case Classification 9) |
| Case | Case Classification Group 10 | Case Classification Group 10 | Im_case_classification.description | where Im_case_classificatio n.description has values in (Case Classification 10) |
| Case | Product Type | Drug, Device and Vaccine | case_product.views_available | |
| Case | Study ID | Study ID | case_study.study_num | |
| Case | Center ID | Center ID for the Study in the case | <pre>Im_centers.center_no where case_study.center_id = Im_centers.center_id</pre> | |
| Case | Case Seriousness | Case Serious or Non-Serious (Y/N) | case_assess.seriousness | |
| Case | Case Listedness | Unlisted/Unexpected/listed/ expected | case_assess.listedness | |
| Case | Case Causality | Adverse event caused by the product (related/not related) | case_assess.agent_suspect | |
| Case | Case Outcome | Case Level Outcome using the ICH guidelines eg "Recovered" | case_assess.outcome | |
| Case | Gender | Gender of the Patient | case_pat_info.gender_id | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|-------------------------------|---|--|------------------|
| Case | Pregnant | Patient pregnant (Yes/No) | case_pat_info.pat_stat_preg | |
| Case | Age Group | Patient Age Group | case_pat_info.age_group_id | |
| Case | Ethnicity | Ethnicity of the Patient | case_pat_info.ethnicity_id | |
| Case | Lactation | Patient breastfeeding | case_pregnancy.breastfeedin g | |
| Case | Primary Reporter Type | Type of the first/primary reporter (for ex., Physician, Consumer etc) | case_reporters.reporter_type where primary_contact = 1 | |
| Case | Primary Suspect Product | Primary Suspect Product for a case | case_product.product_name where case_product.first_sus_prod = 1 | |
| Case | НСР | Health Care Professional (ex., physician, nurse, pharmacist) flag. Primary Reporter of the case is HCP or not | case_reporters.hcp_flag where primary_contact = 1 | |
| Case | SUSAR | Suspected Unexpected Serious Adverse Reaction Flag(0 / 1) | case_master.susar | |
| Case | Case Owner ID | ID of user who is responsible for the case throughout its lifetime | case_master.worklist_owner _id | |
| Case | Case Owner Name | User who is responsible for the case throughout its lifetime | cfg_users.user_fullname where cfg_users.user_id = case_master.worklist_owner _id | |
| Case | Initial Receipt Date | Date on which initial case information was received | case_master.init_rept_date | |
| Case | Safety Receipt Date | Case receipt date at Central Safety | case_master.safety_date | |
| Case | Clock Start Date | Case Aware Date | Max(case_master.init_rept_d ate/ (case_followup.receipt_date where significant = 1)) | |
| Case | Case Deletion Timestamp | Date of the case deletion | nvl(case_master.deleted, case_master.last_update_tim e) where nvl(case_master.state_id, 0) = 1 or case_master.deleted is not null | - |
| Case | Lock Timestamp | Case is ready for submission. Lock date of the case. | case_master.date_locked | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|-------------------------------|---|---|---|
| Case | Lock Target Days | Number of target days for processing a case which is Number of days from Clock Start Date to Lock Timestamp | | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - If Case Serious then 10 Days else 30 Days |
| Case | Lock Due Date | Due Date For Locking A Case (Case Processing Completion) | N/A | Clock Start Date + Lock Target Days |
| Case | Lock Due Soon Date | Internal Due Date For Locking A Case (Case Processing Completion) | N/A | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days Lock Due Date - (2) |
| Case | Local Lock Timestamp | Latest Local Lock Timestamp for the Case post it being Globally Locked. Will be null if either global lock or local lock is null. | CASE_ROUTING.ROUTE_D ATE | |
| Case | CRO Project Code | If clinical case then Study Configuration -> Other ID else Product Configuration -> Company Drug Code for the Primary Suspect Product | LM_REPORT_TYPE.INCL_T RIAL LM_STUDIES.OTHER_ID LM_PRODUCTS.DRUG_CO DE | If LM_REPORT_TYPE .INCL_TRIAL = 1 then LM_STUDIES.OTHE R_ID else LM_PRODUCTS.DR UG_CODE for Primary Suspect Product |
| Case | Case Deletion User ID | ID of user who deleted the case | case_master.last_update_us er_id | |
| Case | Case Deletion User Name | User who deleted the case | cfg_users.user_fullname where cfg_users.user_id = case_master.last_update_us er_id | |
| Case | Case Deletion Reason | Reason for deleting the case | case_justifications.j_text where field_id = 2110018 | |
| Case | Primary Event PT | Primary event (Preferred Term) for the case | case_event.pref_term for min sort_id for min seq_num | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|---|--|---|---|
| Case | Duration Global to Local Lock Per Case | Calculates the time between the latest local case lock and the last global case lock that occurred before that local case lock. Will be null if either global lock or local lock are null. | N/A | |
| Case | Primary Indication | Primary indication (Preferred Term) for the primary suspect product | case_prod_indications.ind_pr ef_term for min seq_num | |
| Case | Duration Case Modified Per Case | Sum of Edit Duration Per Case | N/A | sum(Duration Case Modified Per User/ State) Group by Case ID |
| Case | Duration Case Unmodified Per Case | Sum of Edit Duration Per Case | N/A | sum(Duration Case Unmodified Per User/State) Group by Case ID |
| Case | Duration Case Read Per Case | Sum of Read Duration Per Case | N/A | sum(Duration Case Read Per User/ State) Group by Case ID |
| Case | Avg Duration Case Modified Per Case | Average time spent in actual work done on one case across all users and all workflow states | N/A | sum(Duration Case Modified Per Case) / (total number of records in Case History) |
| Case | Avg Duration Case Unmodified Per Case | Average time spent in work done without any modification on one case across all users and all workflow states | N/A | sum(Duration Case Unmodified Per Case) / (total number of records in Case History) |
| Case | Avg Duration Case Read Per Case | Average time spent in work done in read-only mode on one case across all users and all workflow states | N/A | sum(Duration Case Read Per Case) / (total number of distinct records in Case History) |
| Case | Avg # Suspect Products Per Case | Average number of suspect products in a case | N/A | sum(# Products Per Case) / # Cases Locked Once |
| Case | Avg # Events Per Case | Average number of events in a case | N/A | sum(# Events Per Case) / # Cases Locked Once |
| Case | Avg # F/U Versions Per Case | Average number of follow-up versions processed per case (number of significant f/u locks. It is not the case f/u [case_followup]) | N/A | sum(# F/U Versions Per Case) / # Cases Locked Once |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|--|--|---------------------|---|
| Case | Avg # Sig F/U Versions Per Case | Average Significant Follow- up versions processed per case (number of significant f/u locks. It is not the case f/u [case_followup]) | N/A | sum(# Sig F/U Versions Per Case) / # Cases Locked Once |
| Case | Avg # F/U Received Per Case | Average number of follow-up received per case (It is the case f/u [case_followup]) | N/A | sum(# F/U Received Per Case) / # Cases Locked Once |
| Case | Avg # Sig F/U Received Per Case | Average Significant Follow- up received per case (It is the case f/u [case_followup]) | N/A | sum(# Sig F/U Received Per Case) / # Cases Locked Once |
| Case | Min Duration Case Modified Per Case | Minimum time spent in actual work done on one case across all users and all workflow states | N/A | min(Duration Case Modified Per Case) |
| Case | Min Duration Case Unmodified Per Case | Minimum time spent in work done without any modification on one case across all users and all workflow states | N/A | min(Duration Case Unmodified Per Case) |
| Case | Min Duration Case Read Per Case | Minimum time spent in work done in read-only mode on one case across all users and all workflow states | N/A | min(Duration Case Read Per Case) |
| Case | Min # Suspect Products Per Case | Minimum number of suspect products in a case | N/A | min(# Products Per Case) |
| Case | Min # Events Per Case | Minimum number of events in a case | N/A | min(# Events Per Case) |
| Case | Min # F/U Versions Per Case | Minimum number of follow- up versions processed per case (number of significant f/u locks. It is not the case f/u [case_followup]) | N/A | min(# F/U Versions Per Case) |
| Case | Min # Sig F/U Versions Per Case | Minimum Significant Follow- up versions processed per case (number of significant f/u locks. It is not the case f/u [case_followup]) | N/A | min(# Sig F/U Versions Per Case) |
| Case | Min # F/U Received Per Case | Minimum number of follow-up received per case (It is the case f/u [case_followup]) | N/A | min(# F/U Received Per Case) |
| Case | Min # Sig F/U Received Per Case | Minimum Significant Follow- up received per case (It is the case f/u [case_followup]) | N/A | min(# Sig F/U Received Per Case) |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|--|--|---|--|
| Case | Max Duration Case Modified Per Case | Maximum time spent in actual work done on one case across all users and all workflow states | N/A | max(Duration Case Modified Per Case) |
| Case | Max Duration Case Unmodified Per Case | Maximum time spent in work done without any modification on one case across all users and all workflow states | N/A | max(Duration Case Unmodified Per Case) |
| Case | Max Duration Case Read Per Case | Maximum time spent in work done in read-only mode on one case across all users and all workflow states | N/A | max(Duration Case Read Per Case) |
| Case | Max # Suspect Products Per Case | Maximum number of suspect products in a case | N/A | max(# Products Per Case) |
| Case | Max # Events Per Case | Maximum number of events in a case | N/A | max(# Events Per Case) |
| Case | Max # F/U Versions Per Case | Maximum number of follow- up versions processed per case (number of significant f/u locks. It is not the case f/u [case_followup]) | N/A | max(# F/U Versions Per Case) |
| Case | Max # Sig F/U Versions Per Case | Maximum Significant Follow- up versions processed per case (number of significant f/u locks. It is not the case f/u [case_followup]) | N/A | max(# Sig F/U Versions Per Case) |
| Case | Max # F/U Received Per Case | Maximum number of follow- up received per case (It is the case f/u [case_followup]) | N/A | max(# F/U Received Per Case) |
| Case | Max # Sig F/U Received Per Case | Maximum Significant Follow- up received per case (It is the case f/u [case_followup]) | N/A | max(# Sig F/U Received Per Case) |
| Case | # Cases Locked Once | Count of Cases that have been locked atleast once | count(distinct case_routing.case_id) where case_routing.comment_text like 'case locked%' | |
| Case | # Suspect Products Per Case | Total number of suspect products in a case | count(1) where drug_type = 1 group by case_product.case_id | |
| Case | # Events Per Case | Total number of events in a case | count(1) group by case_event.case_id | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|--------------|-----------------------------------|---|--|--|
| Case | # F/U Versions Per Case | Total number of follow-up versions processed per case (number of significant f/u locks. It is not the case f/u [case_followup]) | N/A | count(number of records from Case Version History where Version Type in (Significant, Non- Significant)) group by Case ID |
| Case | # Sig F/U Versions Per Case | Total Significant Follow-up versions processed per case (number of significant f/u locks. It is not the case f/u [case_followup]) | N/A | count(number of records from Case Version History where Version Type = Significant) group by Case ID |
| Case | # F/U Received Per Case | Total number of follow-up received per case (It is the case f/u [case_followup]) | N/A | (total follow-up records in case_followup table for locked cases) group by Case ID |
| Case | # Sig F/U Received Per Case | Total Significant Follow-up received per case (It is the case f/u [case_followup]) | N/A | (total significant follow-up records in case_followup table for locked cases) |
| Case Version | Version ID | Case Version (1,2,3) | | A new case version is created whenever a case is unlocked or reopened. Version number starting with 1 and incremented by 1 for every new version. |
| Case Version | Version Type | Significant, Non-Significant, No Followup - Significant/ Non-Significant (Is this follow-up information considered significant, based on company specific policies? If this follow-up information is marked as significant, the regulatory report algorithm will re-run and will calculate the due date based on the most recent significant follow-up date. 1 = Yes, 0 = No) | N/A | No Followup: If there is no followup between two Version Lock DateTime Significant: If there is atleast 1 significant followup between two Version Lock DateTime Non-Significant: If there is followup but no significant followup between two Version Lock DateTime |
| Case Version | Version Receipt Date | Date on which initial/follow- up information was received | case_followup.receipt_date (Case_Master.init_rept_date for Initial case version) | |
| Case Version | Safety Receipt Date | Case Version receipt date at Central Safety | case_followup.safety_date (Case_Master.safety_date for Initial case version) | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|--------------|---|--|---|---|
| Case Version | Clock Start Date | Case Version Aware Date | Max(case_master.init_rept_d ate/ (case_followup.receipt_date where significant = 1)) | |
| Case Version | Version Creation Timestamp | The timestamp when the case version was created (Case Book-in timestamp for initial case version or routing timestamp when the case was unlocked/unarchived for other case versions) | N/A | For initial case version, case_master.create_time and for other case versions it is case_routing.route_d ate where lower(case_routing.c omment_text) like 'case unlocked%' or case_routing.to_stat e_id = 2 |
| Case Version | Lock Timestamp | Case is ready for submission. First lock date of the case version. | case_routing.route_date where case_routing.comment_text like 'case locked%' or case_routing.to_state_id = 2 | |
| Case Version | Lock Target Days | Number of target days for processing a case version which is Number of days from Clock Start Date to Lock Timestamp | N/A | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - If Case Serious then 10 Days else 30 Days |
| Case Version | Lock Due Date | Due Date For Locking A Case (Case Processing Completion) | N/A | Clock Start Date + Lock Target Days |
| Case Version | Lock Due Soon Date | Internal Due Date For Locking A Case (Case Processing Completion) | N/A | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days Lock Due Date - (2) |
| Case Version | Local Lock Timestamp | Latest Local Lock Timestamp for the Case Version post it being Globally Locked. Will be null if either global lock or local lock are null within the specific case version. | CASE_ROUTING.ROUTE_D ATE | |
| Case Version | Duration Case Modified Per Version | Sum of Edit Duration Per Case Version | N/A | sum(Duration Case Modified Per User/ State) Group by Case ID, Version ID |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|--------------|--|--|---------------------|--|
| Case Version | Duration Case Unmodified Per Version | Sum of Edit Duration Per Case Version | N/A | sum(Duration Case Unmodified Per User/State) Group by Case ID, Version ID |
| Case Version | Duration Case Read Per Version | Sum of Read Duration Per Case Version | N/A | sum(Duration Case Read Per User/ State) Group by Case ID, Version ID |
| Case Version | Duration Version- Receipt-To- Safety- Receipt | (How Long Does It Take Before A Case Version Reaches The Safety Group?) The Difference Between The Case Version Receipt Date And The Case Version Safety Receipt Date. | | days between (Safety Receipt Date, Version Receipt Date) |
| Case Version | Duration Clock-Start- To-Lock | Interval Between Case Version Clock Start Date And Case Version Lock Datetime | | days between (Clock Start Date, Lock Timestamp) |
| Case Version | Duration Version- Creation-To- Lock | Interval Between Case Version Create DateTime And Case Version Lock Datetime | | days between (Version Creation Timestamp, Lock Timestamp) |
| Case Version | Duration Global to Local Lock Per Case Version Sum | Calculates the time between the latest local case lock in the specific version and the last global case lock that occurred before that local case lock in the same version. Will be null if either global lock or local lock are null within the specific case version | | |
| Case Version | Avg Duration Clock-Start- To-Lock | Average Interval between Case Version Clock Start Date and Case Version Lock DateTime | | sum(Duration Clock- Start-To-Lock)/# Versions Locked Once |
| Case Version | Avg Duration Version- Creation-To- Lock | Average Interval Between Case Version Create DateTime And Case Version Lock DateTime | | sum(Duration Version-Creation-To- Lock)/# Versions Locked Once |
| Case Version | Avg Duration Case Modified Per Version | Average time spent in actual work done on one case version across all users and all workflow states | N/A | sum(Duration Case Modified Per Version) / (total number of records in Case Version History) |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|--------------|---|---|---------------------|---|
| Case Version | Avg Duration Case Unmodified Per Version | Average time spent in work done without any modification on one case version across all users and all workflow states | N/A | sum(Duration Case Unmodified Per Version) / (total number of records in Case Version History) |
| Case Version | Avg Duration Case Read Per Version | Average time spent in work done in read-only mode on one case version across all users and all workflow states | N/A | sum(Duration Case Read Per Version) / (total number of distinct records in Case Version History) |
| Case Version | Min Duration Clock-Start- To-Lock | Minimum Interval Between Case Version Clock Start Date And Case Version Lock DateTime | | min(Duration Clock- Start-To-Lock) |
| Case Version | Min Duration Version- Creation-To- Lock | Minimum Interval Between Case Version Create DateTime And Case Version Lock DateTime | | min(Duration Version-Creation-To- Lock) |
| Case Version | Min Duration Case Modified Per Version | Minimum time spent in actual work done on one case version across all users and all workflow states | N/A | min(Duration Case Modified Per Version) |
| Case Version | Min Duration Case Unmodified Per Version | Minimum time spent in work done without any modification on one case version across all users and all workflow states | N/A | min(Duration Case Unmodified Per Version) |
| Case Version | Min Duration Case Read Per Version | Minimum time spent in work done in read-only mode on one case version across all users and all workflow states | N/A | min(Duration Case Read Per Version) |
| Case Version | Max Duration Clock-Start- To-Lock | Maximum Interval Between Case Version Clock Start Date And Case Version Lock DateTime | | max(Duration Clock- Start-To-Lock) |
| Case Version | Max Duration Version- Creation-To- Lock | Maximum Interval Between Case Version Create DateTime And Case Version Lock DateTime | | max(Duration Version-Creation-To- Lock) |
| Case Version | Max Duration Case Modified Per Version | Maximum time spent in actual work done on one case version across all users and all workflow states | N/A | max(Duration Case Modified Per Version) |
| Case Version | Max Duration Case Unmodified Per Version | Maximum time spent in work done without any modification on one case version across all users and all workflow states | N/A | max(Duration Case Unmodified Per Version) |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|--------------|--|---|--|---|
| Case Version | Max Duration Case Read Per Version | Maximum time spent in work done in read-only mode on one case version across all users and all workflow states | N/A | max(Duration Case Read Per Version) |
| Case Version | #Versions Locked Once | Number Of Case Versions Received (Including All Versions) | | Count (Number of records from Case Version History) |
| Case Version | #Sig Versions Locked Once | Number Of Case Versions Received (Including Significant Versions Only) | | Count (Number of records from Case Version History) where Version Type = Significant |
| Case Version | #Versions Locked On- Time | Number Of Case Versions Processed Within Target Days | | Lock Timestamp - Clock Start Date <= Lock Target Days |
| Case Version | %Versions Locked On- Time | Percentage Of Case Versions Processed On Time | | (# Versions Locked On-Time/# Versions Locked Once) * 100 |
| Case Version | #Versions Locked Late | Number Of Case Versions Processed Over Target Days | | Lock Timestamp - Clock Start Date > Lock Target Days |
| Case Version | %Versions Locked Late | Percentage Of Case Versions Not Processed Within Target Days | | (# Versions Locked Late/# Versions Locked Once) * 100 |
| Case Routing | Version ID | Case Version (1,2,3) | | A new case version is created whenever a case is unlocked or reopened. Version number starting with 1 and incremented by 1 for every new version. |
| Case Routing | Version Type | Significant, Non-Significant, No Followup - Significant/ Non-Significant (Is this follow-up information considered significant, based on company specific policies? If this follow-up information is marked as significant, the regulatory report algorithm will re-run and will calculate the due date based on the most recent significant follow-up date. 1 = Yes, 0 = No) | N/A | No Followup: If there is no followup between two Version Lock DateTime Significant: If there is atleast 1 significant followup between two Version Lock DateTime Non- Significant: If there is followup but no significant followup between two Version Lock DateTime |
| Case Routing | Version Receipt Date | Date on which initial/follow- up information was received | case_followup.receipt_date (Case_Master.init_rept_date for Initial case version) | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|--------------|----------------------------------|--|---|---|
| Case Routing | Safety Receipt Date | Case Version receipt date at Central Safety | case_followup.safety_date (Case_Master.safety_date for Initial case version) | |
| Case Routing | Clock Start Date | Case Version Aware Date | Max(case_master.init_rept_d ate/ (case_followup.receipt_date where significant = 1)) | |
| Case Routing | Version Creation Timestamp | The timestamp when the case version was created (Case Book-in timestamp for initial case version or routing timestamp when the case was unlocked/unarchived for other case versions) | case_master.create_time case_routing.route_date | For initial case version, case_master.create_time and for other case versions it is case_routing.route_d ate where lower(case_routing.c omment_text) like 'case unlocked%' or case_routing.to_stat e_id = 2 |
| Case Routing | Lock Timestamp | Case is ready for submission. First lock date of the case version. | case_routing.route_date where case_routing.comment_text like 'case locked%' or case_routing.to_state_id = 2 | |
| Case Routing | Lock Target Days | Number of target days for processing a case version which is Number of days from Clock Start Date to Lock Timestamp | | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - If Case Serious then 10 Days else 30 Days |
| Case Routing | Lock Due Date | Due Date For Locking A Case (Case Processing Completion) | N/A | Clock Start Date + Lock Target Days |
| Case Routing | Lock Due Soon Date | Internal Due Date For Locking A Case (Case Processing Completion) | N/A | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days Lock Due Date - (2) |
| Case Routing | Local Lock Timestamp | Latest Local Lock Timestamp for the Case Version post it being Globally Locked. Will be null if either global lock or local lock are null within the specific case version. | CASE_ROUTING.ROUTE_D ATE | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|--------------|------------------------------------|--|--|---|
| Case Routing | Routing User Group | User Group which worked on the workflow step | cfg_workflow_rules.group_id where cfg_workflow_rules.seq_num = case_routing.workflow_seq_ num | |
| Case Routing | Routing Justification | Case Routing Justification | case_routing.justification_id | |
| Case Routing | Routing ID | Workflow Sequence Number | case_routing.seq_num | |
| Case Routing | State Routed From | Workflow state from which case was promoted to next workflow state | cfg_workflow_states.state_n ame where case_routing.fr_state_id = cfg_workflow_states.state_id | |
| Case Routing | State Routed To | Workflow state to which case was promoted from previous workflow state | cfg_workflow_states.state_n ame where case_routing.to_state_id = cfg_workflow_states.state_id | |
| Case Routing | Routing Timestamp From State | The timestamp on which case was routed From Workflow State | case_routing.route_date | |
| Case Routing | Routing Timestamp To State | The timestamp on which case was routed To Workflow State | case_routing.route_date | |
| Case Routing | Routing User ID | ID of the user who last worked on the Workflow step | case_routing.user_id | |
| Case Routing | Routing User Name | The User who last worked on the Workflow step | cfg_users.user_fullname where cfg_users.user_id = case_routing.user_id | |
| Case Routing | Follow-Up ID | Follow-up number of the case to which this routing record belongs | | Followup # as appear on Argus Case Form against each followup starting with 1 and incremented by 1 for every new folllowup. (case_routing.followup_num joins with case_followup.seq_n um) |
| Case Routing | Comments | Routing comments | case_routing.comment_text | |
| Case Routing | Pseudo State | | | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|--|--|---------------------|---|
| Case Routing | Duration Case Idle | Duration from case version routing timestamp to minimum open timestamp greater than the current routing timestamp and less than next routing timestamp. If case version is not open after routing then duration shall be the complete duration the case was in that particular workflow state (from workflow state date - to workflow state date). Duration from case workflow state route date to minimum/ first open timestamp for same workflow state | N/A | min(Case Open Timestamp) - Routing Timestamp To State |
| Case Routing | Avg Duration Case Idle Per Case | Average idle duration per case | N/A | sum(Idle Duration Per Version Routing) / (total number of distinct Case ID) |
| Case Routing | Avg Duration Case Idle Per Version | Average idle duration per case version | N/A | sum(Idle Duration Per Version Routing) / (total number of distinct Case ID, Version ID) |
| Case Routing | Avg Duration Case Idle Per Routing | Average idle duration per case version routing timestamp | N/A | total(Idle Duration Per Version Routing) for all case versions / (total number of routing records) |
| Case Routing | Min Duration Case Idle | Minimum idle duration per case version routing timestamp | N/A | min(Idle Duration Per Version Routing) |
| Case Routing | Max Duration Case Idle | Maximum idle duration per case version routing timestamp | N/A | max(Idle Duration Per Version Routing) |
| Case Workflow State | Version ID | Case Version (1,2,3) | | A new case version is created whenever a case is unlocked or reopened. Version number starting with 1 and incremented by 1 for every new version. |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|----------------------------------|---|--|--|
| Case Workflow State | Version Type | Significant, Non-Significant, No Followup - Significant/ Non-Significant (Is this follow-up information considered significant, based on company specific policies? If this follow-up information is marked as significant, the regulatory report algorithm will re-run and will calculate the due date based on the most recent significant follow-up date. 1 = Yes, 0 = No) | | No Followup: If there is no followup between two Version Lock DateTime Significant: If there is atleast 1 significant followup between two Version Lock DateTime Non-Significant: If there is followup but no significant followup between two Version Lock DateTime |
| Case Workflow State | Version Receipt Date | Date on which initial/follow- up information was received | case_followup.receipt_date Case_Master.init_rept_date | case_followup.receip t_date (Case_Master.init_re pt_date for Initial case version) |
| Case Workflow State | Safety Receipt Date | Case Version receipt date at Central Safety | case_followup.safety_date Case_Master.safety_date | case_followup.safety _date (Case_Master.safety _date for Initial case version) |
| Case Workflow State | Clock Start Date | Case Version Aware Date | Max(case_master.init_rept_d ate/ (case_followup.receipt_date where significant = 1)) | |
| Case Workflow State | Version Creation Timestamp | The timestamp when the case version was created (Case Book-in timestamp for initial case version or routing timestamp when the case was unlocked/unarchived for other case versions) | case_master.create_time case_routing.route_date | For initial case version, case_master.create_ time and for other case versions it is case_routing.route_d ate where lower(case_routing.c omment_text) like 'case unlocked%' or case_routing.to_stat e_id = 2 |
| Case Workflow State | Lock Timestamp | Case is ready for submission. First lock date of the case version. | case_routing.route_date | case_routing.route_d ate where case_routing.comme nt_text like 'case locked%' or case_routing.to_stat e_id = 2 |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|-------------------------------------|--|-----------------------------|---|
| Case Workflow State | Lock Target Days | Number of target days for processing a case version which is Number of days from Clock Start Date to Lock Timestamp | | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - If Case Serious then 10 Days else 30 Days |
| Case Workflow State | Lock Due Date | Due Date For Locking A Case (Case Processing Completion) | N/A | Clock Start Date + Lock Target Days |
| Case Workflow State | Lock Due Soon Date | Internal Due Date For Locking A Case (Case Processing Completion) | N/A | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days Lock Due Date - (2) |
| Case Workflow State | Local Lock Timestamp | Latest Local Lock Timestamp for the Case Version post it being Globally Locked. Will be null if either global lock or local lock are null within the specific case version. | CASE_ROUTING.ROUTE_D ATE | |
| Case Workflow State | State Name | Workflow State (From Workflow State) | | |
| Case Workflow State | State Finalization User Group | The Last User Group To Which The Case Version Was Routed To For The Workflow State | | |
| Case Workflow State | State Finalization User ID | ID of the User Who Finished The Last Execution Of The Workflow State For The Case Version | | |
| Case Workflow State | State Finalization User Name | The User Who Finished The Last Execution Of The Workflow State For The Case Version | | |
| Case Workflow State | State Start Timestamp | The First Timestamp When The Workflow State Was Started | | |
| Case Workflow State | State End Timestamp | The Last Timestamp When The Workflow State Was Completed | | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|--|---|---------------------|--|
| Case Workflow State | Duration Case Modified Per State | Total time spent in each workflow state (across all users) for actual work done on one case version | N/A | sum(Duration Case Modified Per User/ State) group by State Name, Case ID, Case Version |
| Case Workflow State | Duration Case Unmodified Per State | Total time spent in each workflow state (across all users) for work done without any modification on one case version | N/A | sum(Duration Case Unmodified Per User/State) group by State Name, Case ID, Case Version |
| Case Workflow State | Duration Case Read Per State | Sum of Read Duration Per Workflow State | N/A | sum(Duration Case Read Per User/ State) Group by Workflow State At Case Open, Case ID, Version ID |
| Case Workflow State | Duration State-Start- To-End | Number Of Days Taken From The First Time The Workflow State Was Started To The Last Time The Workflow State Was Completed (Within A Case Version) | N/A | If case goes through workflow states A -> B -> A -> B -> A -> B -> C, then result for B is duration from beginning of first B through end of last B, including time spent in second and third A |
| Case Workflow State | Duration Within State | Total Time The Case Spent In The Workflow State (Within A Case Version) | N/A | Sum ("Case Routing History".Routing Timestamp To State - "Case Routing History".Routing Timestamp From State) Group by ("Case Routing History"."Case ID", "Version", "State Routed From") If case goes through workflow states A -> B -> A -> B -> A -> B -> C, then result for B is duration of first B plus duration of second B plus duration of third B (does NOT include any time spent in A) |
| Case Workflow State | Duration Version- Creation-To- State- End | Time Taken To Accomplish A Workflow State After A Case Version Was Created (Including Any Repetition) | N/A | State End Timestamp - Version Creation Timestamp |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|---|---|---------------------|---|
| Case Workflow State | Average Duration State-Start- To-End | Average Number Of Days Taken From The First Time The Workflow State Was Started To The Last Time The Workflow State Was Completed (Within A Case Version) | N/A | total(Duration State- Start-To-End) for all case versions / # Versions Locked Once |
| Case Workflow State | Average Duration Within State | Average Time The Case Spent In The Workflow State (Within A Case Version) | N/A | total(Duration Within State) for all case versions / # Versions Locked Once |
| Case Workflow State | Average Duration Version- Creation-To- State- End | Average Time Taken To Accomplish A Workflow State After A Case Version Was Created (Including Any Repetition) | N/A | total(Duration Version-Creation-To- State-End) for all case versions / # Versions Locked Once |
| Case Workflow State | Avg Duration Case Modified Per State | Average time spent in each workflow state (across all users) for actual work done on one case version | N/A | (sum(Duration Case Modified Per State) group by State Name) / (total number of distinct Case ID, Version ID group by State Name) |
| Case Workflow State | Avg Duration Case Unmodified Per State | Average time spent in each workflow state (across all users) for work done without any modification on one case version | N/A | (sum(Duration Case Unmodified Per State) group by State Name) / (total number of distinct Case ID, Version ID group by State Name) |
| Case Workflow State | Avg Duration Case Read Per State | Average time spent in each workflow state (across all users) for work done in readonly mode on one case version | N/A | sum(Duration Case Read Per State) / (total number of records in Workflow State History) |
| Case Workflow State | Min Duration Case Modified Per State | Minimum time spent in each workflow state (across all users) for actual work done on one case version | N/A | min((Duration Case Modified Per State) group by State Name) |
| Case Workflow State | Min Duration Case Unmodified Per State | Minimum time spent in each workflow state (across all users) for work done without any modification on one case version | N/A | min((Duration Case Unmodified Per State) group by State Name) |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|---|---|---------------------|---|
| Case Workflow State | Min Duration Case Read Per State | Minimum time spent in each workflow state (across all users) for work done in readonly mode on one case version | N/A | min(Duration Case Read Per State) |
| Case Workflow State | Max Duration Case Modified Per State | Maximum time spent in each workflow state (across all users) for actual work done on one case version | N/A | max((Duration Case Modified Per State) group by State Name) |
| Case Workflow State | Max Duration Case Unmodified Per State | Maximum time spent in each workflow state (across all users) for work done without any modification on one case version | N/A | max((Duration Case Unmodified Per State) group by State Name) |
| Case Workflow State | Max Duration Case Read Per State | Maximum time spent in each workflow state (across all users) for work done in readonly mode on one case version | N/A | max(Duration Case Read Per State) |
| Case Workflow State | #Time State Repeated | The Number Of Times A Workflow State Is Repeated (Within A Case Version) | | Count(*) -1 Group by ("Case Routing History"."Case ID", "Version", "State Routed From") If case goes through workflow states A -> B -> A -> B -> A -> B -> C, then result for B is 2 |
| Case Workflow State | #Users Who Worked On State | Number Of Distinct Users Who Worked On A Workflow State For A Case Version | | count(Distinct "Case Routing History".Routing User) Group by ("Case Routing History"."Case ID", "Version", "State Routed From") |
| Case Workflow State | # Completed State | Total Number Of Workflow States Completed | | count (State Name) If case goes through workflow states A -> B -> A -> B -> A -> B -> C, then result is 3 |
| Case Workflow State | # Repeated State | Total Count Of All The Workflow States That Were Repeated | | count (State Name) where "# Times State Repeated" > 0 If case goes through workflow states A -> B -> A -> B -> A -> B -> C, then result is 2 |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|-------------------------------|---|--|--|
| Case Workflow State | % Repeated State | Total Percentage Of All The Workflow States That Were Repeated | | (# Repeated States / # Completed States) * 100 If case goes through workflow states A -> B -> A - > B -> A -> B -> C, then result is 66.6% |
| Case Work | Version ID | Case Version (1,2,3) | | A new case version is created whenever a case is unlocked or reopened. Version number starting with 1 and incremented by 1 for every new version. |
| Case Work | Version Type | Significant, Non-Significant, No Followup - Significant/ Non-Significant (Is this follow-up information considered significant, based on company specific policies? If this follow-up information is marked as significant, the regulatory report algorithm will re-run and will calculate the due date based on the most recent significant follow-up date. 1 = Yes, 0 = No) | | No Followup: If there is no followup between two Version Lock DateTime Significant: If there is atleast 1 significant followup between two Version Lock DateTime Non-Significant: If there is followup but no significant followup between two Version Lock DateTime |
| Case Work | Version Receipt Date | Date on which initial/follow- up information was received | case_followup.receipt_date Case_Master.init_rept_date | case_followup.receip t_date (Case_Master.init_re pt_date for Initial case version) |
| Case Work | Safety Receipt Date | Case Version receipt date at Central Safety | case_followup.safety_date Case_Master.safety_date | case_followup.safety _date (Case_Master.safety _date for Initial case version) |
| Case Work | Clock Start Date | Case Version Aware Date | Max(case_master.init_rept_d ate/ (case_followup.receipt_date where significant = 1)) | |
| Case Work | Case Deletion Timestamp | Date of the case deletion | nvl(case_master.deleted, case_master.last_update_tim e) where nvl(case_master.state_id, 0) = 1 or case_master.deleted is not null | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-----------|----------------------------------|--|--|---|
| Case Work | Version Creation Timestamp | The timestamp when the case version was created (Case Book-in timestamp for initial case version or routing timestamp when the case was unlocked/unarchived for other case versions) | case_master.create_time case_routing.route_date | For initial case version, case_master.create_time and for other case versions it is case_routing.route_d ate where lower(case_routing.c omment_text) like 'case unlocked%' or case_routing.to_stat e_id = 2 |
| Case Work | Lock Timestamp | Case is ready for submission. First lock date of the case version. | case_routing.route_date | case_routing.route_d ate where case_routing.comme nt_text like 'case locked%' or case_routing.to_stat e_id = 2 |
| Case Work | Lock Target Days | Number of target days for processing a case version which is Number of days from Clock Start Date to Lock Timestamp | | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - If Case Serious then 10 Days else 30 Days |
| Case Work | Lock Due Date | Due Date For Locking A Case (Case Processing Completion) | N/A | Clock Start Date + Lock Target Days |
| Case Work | Lock Due Soon Date | Internal Due Date For Locking A Case (Case Processing Completion) | N/A | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days Lock Due Date - (2) |
| Case Work | Local Lock Timestamp | Latest Local Lock Timestamp for the Case Version post it being Globally Locked. Will be null if either global lock or local lock are null within the specific case version. | CASE_ROUTING.ROUTE_D ATE | |
| Case Work | Case Open Timestamp | Date with timestamp when a case version was opened | USER_CASE_PROCESSIN G_TIME.OPEN_DATE | |
| Case Work | Case Close Timestamp | Date with timestamp when a case version was closed | USER_CASE_PROCESSIN G_TIME.CLOSE_DATE | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------|-----------------------------------|---|---|--|
| Case Work | Duration Case Open | Duration between case version open timestamp to case version close timestamp. | N/A | Case Close Timestamp - Case Open Timestamp |
| Case Work | User With Case Open ID | ID of user who opens a case version | USER_CASE_PROCESSIN G_TIME.USER_ID | |
| Case Work | User With Case Open Name | User who opens a case version | cfg_users.user_fullname where cfg_users.user_id = USER_CASE_PROCESSIN G_TIME.USER_ID | |
| Case Work | Case Open Type | Whether the case version was opened up in (read-only mode) or (editable mode and modified) or (editable mode and not modified). Values - Read, Modified, Unmodified | USER_CASE_PROCESSIN G_TIME.READ_ONLY USER_CASE_PROCESSIN G_TIME.ISMODIFIED | If USER_CASE_PROC ESSING_TIME.REA D_ONLY = 1 then Read If USER_CASE_PROC ESSING_TIME.ISM ODIFIED = 1 then Modified If USER_CASE_PROC ESSING_TIME.REA D_ONLY = 0 and USER_CASE_PROC ESSING_TIME.ISM ODIFIED = 0 then Unmodified |
| Case Work | Workflow State At Case Open | Workflow state of a case version when it is opened by a user | USER_CASE_PROCESSIN G_TIME.WORKFLOW_STAT E_ID | |
| Case Work | Routing ID | | | |
| Case Work User | Version ID | Case Version (1,2,3) | | A new case version is created whenever a case is unlocked or reopened. Version number starting with 1 and incremented by 1 for every new version. |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------|----------------------------------|---|--|---|
| Case Work User | Version Type | Significant, Non-Significant, No Followup - Significant/ Non-Significant (Is this follow-up information considered significant, based on company specific policies? If this follow-up information is marked as significant, the regulatory report algorithm will re-run and will calculate the due date based on the most recent significant follow-up date. 1 = Yes, 0 = No) | | No Followup: If there is no followup between two Version Lock DateTime Significant: If there is atleast 1 significant followup between two Version Lock DateTime Non- Significant: If there is followup but no significant followup between two Version Lock DateTime |
| Case Work User | Version Receipt Date | Date on which initial/follow- up information was received | case_followup.receipt_date Case_Master.init_rept_date | case_followup.receip t_date (Case_Master.init_re pt_date for Initial case version) |
| Case Work User | Safety Receipt Date | Case Version receipt date at Central Safety | case_followup.safety_date Case_Master.safety_date | case_followup.safety _date (Case_Master.safety _date for Initial case version) |
| Case Work User | Clock Start Date | Case Version Aware Date | Max(case_master.init_rept_d ate/ (case_followup.receipt_date where significant = 1)) | |
| Case Work User | Version Creation Timestamp | The timestamp when the case version was created (Case Book-in timestamp for initial case version or routing timestamp when the case was unlocked/unarchived for other case versions) | case_master.create_time case_routing.route_date | For initial case version, case_master.create_ time and for other case versions it is case_routing.route_d ate where lower(case_routing.c omment_text) like 'case unlocked%' or case_routing.to_stat e_id = 2 |
| Case Work User | Lock Timestamp | Case is ready for submission. First lock date of the case version. | case_routing.route_date | case_routing.route_d ate where case_routing.comme nt_text like 'case locked%' or case_routing.to_stat e_id = 2 |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------|--|--|---|---|
| Case Work User | Lock Target Days | Number of target days for processing a case version which is Number of days from Clock Start Date to Lock Timestamp | | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - If Case Serious then 10 Days else 30 Days |
| Case Work User | Lock Due Date | Clock Start Date + Lock Target Days | N/A | Clock Start Date + Lock Target Days |
| Case Work User | Lock Due Soon Date | Due Date For Locking A Case (Case Processing Completion) | N/A | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days Lock Due Date - (2) |
| Case Work User | Local Lock Timestamp | Latest Local Lock Timestamp for the Case Version post it being Globally Locked. Will be null if either global lock or local lock are null within the specific case version. | CASE_ROUTING.ROUTE_D ATE | |
| Case Work User | Workflow State At Case Open | Internal Due Date For Locking A Case (Case Processing Completion) | USER_CASE_PROCESSIN G_TIME.WORKFLOW_STAT E_ID | |
| Case Work User | User With Case Open ID | ID of user who opens a case version | USER_CASE_PROCESSIN G_TIME.USER_ID | |
| Case Work User | User With Case Open Name | User who opens a case version | cfg_users.user_fullname where cfg_users.user_id = USER_CASE_PROCESSIN G_TIME.USER_ID | |
| Case Work User | Duration Case Modified Per User/State | Total edit work duration of open timestamp to close timestamp per user per workflow state per case version. If the workflow state is repeated within same case version then the time spent in every iteration of that state shall be aggregated. | N/A | sum(Duration Case Open) group by User At Case Open, Workflow State At Case Open, Case ID, Version ID where Case Open Type = Modified |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------|--|---|---------------------|--|
| Case Work User | Duration Case Unmodified Per User/ State | Total unmodified duration of open timestamp to close timestamp per user per workflow state per case version. If the workflow state is repeated within same case version then the time spent in every iteration of that state shall be aggregated. | N/A | sum(Duration Case Open) group by User At Case Open, Workflow State At Case Open, Case ID, Version ID where Case Open Type = Unmodified |
| Case Work User | Duration Case Read Per User/ State | Total read work duration of open timestamp to close timestamp per user per workflow state per case version. If the workflow state is repeated within same case version then the time spent in every iteration of that state shall be aggregated. | N/A | sum(Duration Case Open) group by User At Case Open, Workflow State At Case Open, Case ID, Version ID where Case Open Type = Read |
| Case Work User | Avg Duration Case Modified Per User/State | Average time spent for actual work done on one case version by each user within each workflow state. Comparison metrics for work efficiency of users within one workflow state. | N/A | (sum(Duration Case Modified Per User/ State) group by User At Case Open, Workflow State At Case Open) / (total number of distinct Case ID, Version ID group by User At Case Open, Workflow State At Case Open, Workflow State At Case Open Type = Modified |
| Case Work User | Avg Duration Case Unmodified Per User/ State | Average time spent for work done without any modification on one case version by each user within each workflow state. | N/A | (sum(Duration Case Unmodified Per User/State) group by User At Case Open, Workflow State At Case Open) / (total number of distinct Case ID, Version ID group by User At Case Open, Workflow State At Case Open) where Case Open Type = Unmodified |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------|--|---|---------------------|---|
| Case Work User | Avg Duration Case Read Per User/ State | Average time spent for work done in read-only mode on one case version by each user within each workflow state. | N/A | (sum(Duration Case Read Per User/ State) group by User At Case Open, Workflow State At Case Open) / (total number of distinct Case ID, Version ID group by User At Case Open, Workflow State At Case Open) where Case Open Type = Read |
| Case Work User | Min Duration Case Modified Per User/State | Minimum time spent for actual work done on a case version by each user within each workflow state. Comparison metrics for work efficiency of users within one workflow state. | N/A | min(Duration Case Modified Per User/ State) group by User At Case Open, Workflow State At Case Open |
| Case Work User | Min Duration Case Unmodified Per User/ State | Minimum time spent for work done without any modification on a case version by each user within each workflow state. | N/A | min(Duration Case Unmodified Per User/State) group by User At Case Open, Workflow State At Case Open |
| Case Work User | Min Duration Case Read Per User/ State | Minimum time spent for work done in read-only on a case version by each user within each workflow state. | N/A | min(Duration Case Read Per User/ State) group by User At Case Open, Workflow State At Case Open |
| Case Work User | Max Duration Case Modified Per User/State | Maximum time spent for actual work done on a case version by each user within each workflow state. Comparison metrics for work efficiency of users within one workflow state. | N/A | max(Duration Case Modified Per User/ State) group by User At Case Open, Workflow State At Case Open |
| Case Work User | Max Duration Case Unmodified Per User/ State | Maximum time spent for work done without any modification on a case version by each user within each workflow state. | N/A | max(Duration Case Unmodified Per User/State) group by User At Case Open, Workflow State At Case Open |
| Case Work User | Max Duration Case Read Per User/ State | Maximum time spent for work done in read-only mode on a case version by each user within each workflow state. | N/A | max(Duration Case Read Per User/ State) group by User At Case Open, Workflow State At Case Open |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|----------------------------------|---|--|--|
| Expedited Submission | Version ID | Case Version (1,2,3) | | A new case version is created whenever a case is unlocked or reopened. Version number starting with 1 and incremented by 1 for every new version |
| Expedited Submission | Version Type | Significant, Non-Significant, No Followup - Significant/ Non-Significant (Is this follow-up information considered significant, based on company specific policies? If this follow-up information is marked as significant, the regulatory report algorithm will re-run and will calculate the due date based on the most recent significant follow-up date. 1 = Yes, 0 = No) | | No Followup: If there is no followup between two Version Lock DateTime Significant: If there is atleast 1 significant followup between two Version Lock DateTime Non-Significant: If there is followup but no significant followup between two Version Lock DateTime |
| Expedited Submission | Version Receipt Date | Date on which initial/follow- up information was received | case_followup.receipt_date Case_Master.init_rept_date | case_followup.receip t_date (Case_Master.init_re pt_date for Initial case version) |
| Expedited Submission | Safety Receipt Date | Case Version receipt date at Central Safety | case_followup.safety_date Case_Master.safety_date | case_followup.safety _date (Case_Master.safety _date for Initial case version) |
| Expedited Submission | Version Creation Timestamp | The timestamp when the case version was created (Case Book-in timestamp for initial case version or routing timestamp when the case was unlocked/unarchived for other case versions) | case_master.create_time case_routing.route_date | For initial case version, case_master.create_ time and for other case versions it is case_routing.route_d ate where lower(case_routing.c omment_text) like 'case unlocked%' or case_routing.to_stat e_id = 2 |
| Expedited Submission | Lock Timestamp | Case is ready for submission. First lock date of the case version. | case_routing.route_date | case_routing.route_d ate where case_routing.comme nt_text like 'case locked%' or case_routing.to_stat e_id = 2 |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|----------------------------------|--|---|---|
| Expedited Submission | Lock Target Days | Number of target days for processing a case version which is Number of days from Clock Start Date to Lock Timestamp | | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - If Case Serious then 10 Days else 30 Days |
| Expedited Submission | Lock Due Date | Due Date For Locking A Case (Case Processing Completion) | N/A | Clock Start Date + Lock Target Days |
| Expedited Submission | Lock Due Soon Date | Internal Due Date For Locking A Case (Case Processing Completion) | N/A | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days Lock Due Date - (2) |
| Expedited Submission | Local Lock Timestamp | Latest Local Lock Timestamp for the Case Version post it being Globally Locked. Will be null if either global lock or local lock are null within the specific case version. | CASE_ROUTING.ROUTE_D ATE | |
| Expedited Submission | Report ID | Unique Identifier for the report | cmn_reg_reports.reg_report _id | |
| Expedited Submission | Regulatory Report Type | Report Form ID | cmn_reg_reports.report_for m_id | |
| Expedited Submission | Report Destination | CRO Client/Sponsor/License Partner/Regulatory Authority | cmn_reg_reports.agency_id | |
| Expedited Submission | Foreign / Domestic | Domestic if the Agency Country = Country of Incidence for the Case else Foreign | CASE_MASTER.COUNTRY _ID LM_REGULATORY_CONTA CT.COUNTRY | Domestic if CASE_MASTER.CO UNTRY_ID = (SELECT COUNTRY FROM LM_REGULATORY_ CONTACT WHERE AGENCY_ID = CMN_REG_REPOR TS.AGENCY_ID) else Foreign |
| Expedited Submission | Report Assigned User Group | User Group responsible for the report | cmn_reg_reports.group_id | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|--|---|---|--|
| Expedited Submission | Report Timeframe | Timeframe when the report is due. This field specifies the report's scheduled duedate based on the number of days, after the initial receipt or significant follow-up date. | cmn_reg_reports.timeframe | |
| Expedited Submission | Report Submission Country | Country of destination to which report is submitted | cmn_reg_reports.country_id | |
| Expedited Submission | Report Nullification Indicator | A flag to identify nullified reports | cmn_reg_reports.nullification _reason | If cmn_reg_reports.null ification = 1 then 'Yes' else 'No' |
| Expedited Submission | Report Nullification Reason | Reason for report nullification | cmn_reg_reports.nullification _reason | |
| Expedited Submission | Report Submission User ID | ID of user submitting the case to the agency | cmn_reg_reports.user_id | |
| Expedited Submission | Report Submission User Name | User submitting the case to the agency | cfg_users.user_fullname where cfg_users.user_id = cmn_reg_reports.user_id | |
| Expedited Submission | Report Due Date | Date the report is due | cmn_reg_reports.due_date | |
| Expedited Submission | Report Submission / MDN Timestamp | For non-E2B reports - Date on which submission was sent to the destination For E2B reports - Date when report was successfully received by the destination. Only those reports which are accepted by the destination. | N/A | If Report Completion Type = Submitted then: For non- E2B reports - Report Submission Timestamp For E2B reports - MDN Timestamp Else Null |
| Expedited Submission | Report Submission Timestamp | Date on which submission was sent to the agency | cmn_reg_reports.date_submitted | |
| Expedited Submission | Report Schedule Timestamp | Date on which report got scheduled | cmn_reg_reports.date_sched uled | |
| Expedited Submission | Report Generation Timestamp | Report Generation Date | cmn_reg_reports.date_gener ated | |
| Expedited Submission | Report Approval Timestamp | Report Approved Date | case_reg_reports.date_appr oved | |
| Expedited Submission | Report Submission Comments | Submission Notes | cmn_reg_reports.submit_not es | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|-------------------------------------|--|----------------------------------|--|
| Expedited Submission | Report Initial / Follow-Up ID | Report Followup Number (1,2,3 . 0 - for Initial) 'Initial' if followup number = 0 else 'F/U #' followup number | cmn_reg_reports.followup_n um | DECODE (cmn_reg_reports.foll owup_num, 0, 'Initial', 'F/U #' cmn_reg_reports.foll owup_num) |
| Expedited Submission | Report Completion Type | 1 - Submitted, 2 - Deleted, 3 - No Submission Required, 4 - Failed / Pending ACK: 1 - Submitted: If non-E2B report is submitted (submission date is present) or successful ACK is present for E2B reports then 'Submitted' 2 - Deleted: If report is deleted (deleted date is present) then 'Deleted'. It includes the reports which are marked as Submission Not Required but deleted. 3 - No Submission Required: If report is marked as Submission Not Required and report is not deleted then 'No Submission Required' 4 - Failed / Pending ACK: For E2B reports, if ACK failed or ACK is not received then 'Failed / Pending ACK' | | Submitted: cmn_reg_reports.dat e_submitted is not null and ((cmn_reg_reports.re port_form_id <> 27) or (SAFETYREPORT.R EPORTACKNOWLE DGMENT.REPORTA CKNOWLEDGMENT CODE in ("1","01") and (cmn_reg_reports.re port_form_id = 27)) Deleted: cmn_reg_reports.del eted is not null No Submission Required: cmn_reg_reports.sub mit_required = 0 and cmn_reg_reports.del eted is null Failed / Pending ACK: cmn_reg_reports.dat e_submitted is not null and SAFETYREPORT.R EPORTACKNOWLE DGMENT.REPORTA CKNOWLEDGMENT CODE not in ("1","01") and cmn_reg_reports.rep ort_form_id = 27 |
| Expedited Submission | Report Downgrade Indicator | A flag to identify downgrade reports | cmn_reg_reports.submit_not es | If cmn_reg_reports.sub mit_notes like '*Downgrade*%' then 'Yes' else 'No' |
| Expedited Submission | Report Deletion Timestamp | Date when report is deleted | cmn_reg_reports.deleted | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|--|--|---|------------------|
| Expedited Submission | Report No Submission Required Timestamp | Date that non-submission of report was determined | cmn_reg_reports.date_submi ssion_determined | |
| Expedited Submission | Report No Submission Required Reason | Reason if submission is not required | cmn_reg_reports.non_submit _reason | |
| Expedited Submission | Report Submission User Site | Site of the person submitting the case to the destination | Im_sites.site_desc where Im_sites.site_id = cfg_users.site_id where cmn_reg_reports.owner_id = cfg_users.user_id | 1 |
| Expedited Submission | ACK Timestamp | Report acknowledgement timestamp - timestamp when outgoing E2B report is accepted / rejected by recipient's database | messages.acknowledgmenth eader.messagedate | |
| Expedited Submission | MDN Timestamp | Message delivery notification timestamp - timestamp when outgoing E2B report is received by recipient's gateway from sender's gateway | EDI_INFO.EDI_COMPLETE _DATE where MESSAGES.EDI_TRACKIN G_ID = EDI_INFO.EDI_TRACKING_I D and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_report _id = safetyreport.report_id | |
| Expedited Submission | EDI In Timestamp | Timestamp when outgoing E2B report is received by sender's gateway from Argus Safety | MESSAGES .DATE_TRANS MITTED where safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_report _id = safetyreport.report_id | |
| Expedited Submission | EDI Out Timestamp | Timestamp when outgoing E2B report is transmitted by sender's gateway to recipient's gateway | EDI_INFO.EDI_TRANSMIT_ DATE where MESSAGES.EDI_TRACKIN G_ID = EDI_INFO.EDI_TRACKING_I D and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_report _id = safetyreport.report_id | 1 |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|----------------------|------------|---|---|------------------|
| Expedited Submission | ACK Status | Values - Success, Pending, Warning, Failure, Not Applicable | If (esm_ae_status_lkup.esm_st atus_type_cd in (4,10) and cfg_sender.transmission_met hod = 2) then 'Failure' If (esm_ae_status_lkup.esm_st atus_type_cd = 5 and messages.acknowledgmenth eader.transmissionacknowle dgmentcode in ('01', '02', '1', '2')) then If safetyreport.reportacknowled gment.reportacknowledgmen tcode in ('02', '2') then 'Failure' If safetyreport.reportacknowled gment.reportacknowledgmen tcode in ('01', '1') and safetyreport.reportacknowled gment.errormessagecomme nt is not null then 'Warnings' If safetyreport.reportacknowled gment.reportacknowledgmen tcode in ('01', '1') then 'Success' IF esm_ae_status_lkup.esm_st atus_type_cd in (12,13,14,17,18,19) then 'Pending' Else 'Not Applicable' where ESM_AE_STATUS_LKUP.ES M_STATUS_TYPE_CD = MESSAGES.STATUS and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_report _id = safetyreport.report_id | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|---------------|---|---|------------------|
| Expedited Submission | MDN Status | Values - Success, Pending, Failure, Not Applicable | If cfg_sender.transmission_met hod = 2 then 'Not Applicable' If esm_ae_status_lkup.esm_st atus_type_cd = 11 then 'Pending' If esm_ae_status_lkup.esm_st atus_type_cd in (5,12,13,14,17,18,19) then 'Success' If esm_ae_status_lkup.esm_st atus_type_cd = 15 then 'Failure' Else 'Not Applicable' where ESM_AE_STATUS_LKUP.ES M_STATUS_TYPE_CD = MESSAGES.STATUS and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_report _id = safetyreport.report_id | |
| Expedited Submission | EDI In Status | Values - Success, Pending, Failure, Not Applicable | If esm_ae_status_lkup.esm_st atus_type_cd = 1 then 'Pending' If esm_ae_status_lkup.esm_st atus_type_cd in (2,3,4,5,10,11,12,13,14,15,1 7,18,19) then 'Success' If esm_ae_status_lkup.esm_st atus_type_cd in (6, 7) then 'Failure' Else 'Not Applicable' where ESM_AE_STATUS_LKUP.ES M_STATUS_TYPE_CD = MESSAGES.STATUS and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_report _id = safetyreport.report_id | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|---|--|--|--|
| Expedited Submission | EDI Out Status | Values - Success, Pending, Failure, Not Applicable | If cfg_sender.transmission_met hod = 2 then 'Not Applicable' If esm_ae_status_lkup.esm_st atus_type_cd in (2, 3) then 'Pending' If esm_ae_status_lkup.esm_st atus_type_cd in (5,11,12,13,14,15,17,18,19) then 'Success' If esm_ae_status_lkup.esm_st atus_type_cd in (4, 10) then 'Failure' Else 'Not Applicable' where ESM_AE_STATUS_LKUP.ES M_STATUS_TYPE_CD = MESSAGES.STATUS and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_report _id = safetyreport.report_id | |
| Expedited Submission | ACK Comments | Acknowledgement comments received from the receiver | SAFETYREPORT.REPORTA CKNOWLEDGMENT.ERRO RMESSAGECOMMENT | |
| Expedited Submission | Duration Clock-Start- Date-To- Submission | Time taken (in days) to submit a report from the Aware Date | N/A | days between (Report Submission / MDN Timestamp, Clock Start Date) |
| Expedited Submission | Duration Version-Lock- To- Submission | Time taken (in days) to submit a case from the completion date | N/A | days between (Report Submission / MDN Timestamp, Lock Timestamp) |
| Expedited Submission | Duration Report- Generation- To- Submission | Interval between Report Generation Date and Report Submission / MDN Timestamp | N/A | days between (Report Submission / MDN Timestamp, Report Generation Date) |
| Expedited Submission | Duration Report- Schedule-To- Submission | Interval between Report Schedule Date and Report Submission / MDN Timestamp | N/A | days between (Report Submission / MDN Timestamp, Report Schedule Date) |
| Expedited Submission | Avg Duration Report- Generation- To- Submission | Average duration between Report Generation Date and Report Submission Date | N/A | Sum(Duration Report-Generation- To-Submission)/# Reports Submitted |
| Expedited Submission | Avg Duration Report- Schedule-To- Submission | Average duration between Report Schedule Date and Report Submission Date | N/A | Sum(Duration Report-Schedule-To- Submission)/# Reports Submitted |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|---|--|---------------------|---|
| Expedited Submission | Min Duration Report- Generation- To- Submission | Minimum duration between Report Generation Date and Report Submission Date | N/A | Minimum(Duration Report-Generation- To-Submission) |
| Expedited Submission | Min Duration Report- Schedule-To- Submission | Minimum duration between Report Schedule Date and Report Submission Date | N/A | Minimum(Duration Report-Schedule-To- Submission) |
| Expedited Submission | Max Duration Report- Generation- To- Submission | Maximum duration between Report Generation Date and Report Submission Date | N/A | Maximum(Duration Report-Generation- To-Submission) |
| Expedited Submission | Max Duration Report- Schedule-To- Submission | Maximum duration between Report Schedule Date and Report Submission Date | N/A | Maximum(Duration Report-Schedule-To- Submission) |
| Expedited Submission | # Reports Nullified | Total number of Nullified Submitted reports | N/A | count(Nullification Report Flag) where Nullification Report Flag = 'Yes' |
| Expedited Submission | # Days Report Late | Number of days taken from Due Date to Report Submission / MDN Timestamp | N/A | Report Completion Type = Submitted If Days between (Report Submission / MDN Timestamp, Report Due Date) > 0 then Days between (Report Submission / MDN Timestamp, Report Due Date) else 0 |
| Expedited Submission | # Reports Submitted | Total number of submissions | N/A | count(Number of records from Expedited Submission History) where Report Submission / MDN Timestamp is not null |
| Expedited Submission | # Reports Submitted On-Time | Number of reports submitted by the regulatory due date | N/A | count(Number of records from Expedited Submission History) where Report Submission / MDN Timestamp <= Report Due Date and Report Submission / MDN Timestamp is not null |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|--|--|---|--|
| Expedited Submission | % Reports Submitted On-Time | Percentage of reports submitted on time by the regulatory due date | N/A | (# Reports Submitted On-Time/# Reports Submitted) * 100 |
| Expedited Submission | # Reports Submitted Late | Number of reports submitted late by the regulatory due date | N/A | count(Number of records from Expedited Submission History) where Report Submission / MDN Timestamp > Report Due Date and Report Submission / MDN Timestamp is not null |
| Expedited Submission | % Reports Submitted Late | Percentage of reports submitted late by the regulatory due date | N/A | (# Reports Submitted Late/# Reports Submitted) * 100 |
| Expedited Submission | # Reports Deleted | Total number of deleted reports | N/A | count(Report Deleted Indicator) where Report Deleted Indicator = 'Yes' |
| Expedited Submission | # Reports No Submission Required | Total number of reports marked as Submission Not Required | N/A | count(Number of records from Expedited Submission History) where Report Submission Type = 'No Submission Required' |
| Expedited Submission | # Reports Downgraded | Total number of downgraded reports | N/A | count(Report Downgrade Indicator) where Report Downgrade Indicator = 'Yes' |
| Report Routing | Report ID | Unique Identifier for the report | rpt_routing.reg_report_id | |
| Report Routing | Report Routing ID | Workflow Sequence Number | rpt_routing.seq_num | |
| Report Routing | Report Routing Justification | Report Routing Justification | LM_JUSTIFICATIONS.JUSTI FICATION WHERE JUSTIFICATION_ID = RPT_ROUTING.JUSTIFICAT ION_ID AND LM_JUSTIFICATIONS.FIELD _ID=6150002 | |
| Report Routing | Report State Routed From | Workflow state from which case was promoted to next workflow state | CFG_RPT_WF_STATES.stat e_name where rpt_routing.from_report_state _id = CFG_RPT_WF_STATES.RE PORT_STATE_ID | |



Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------|--|--|--|------------------------------|
| Report Routing | Report State Routed To | Workflow state to which case was promoted from previous workflow state | CFG_RPT_WF_STATES.stat e_name where rpt_routing.from_report_state _id = CFG_RPT_WF_STATES.RE PORT_STATE_ID | |
| Report Routing | Report Routing Timestamp From State | The timestamp on which case was routed From Workflow State | rpt_routing.route_date | - |
| Report Routing | Report Routing Timestamp To State | The timestamp on which case was routed To Workflow State | rpt_routing.route_date | |
| Report Routing | Report Routing User ID | ID of the User who last worked on the Workflow step | rpt_routing.user_id | |
| Report Routing | Report Routing User Name | The User who last worked on the Workflow step | cfg_users.user_fullname where cfg_users.user_id = rpt_routing.user_id | |
| Report Routing | Report Comments | Routing comments | rpt_routing.comment_text | rpt_routing.comment _text |

The following table displays how Argus Analytics populates each column from an Argus Safety database.

Table B-3 Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|----------------------------|--|---|------------------|
| Case | Case ID | Case Identification (same as Manufacturer Code Number [MCN]) | case_master.case_num | |
| Case | Case Internal ID | Internal Case ID Generated | case_master.case_id | |
| Case | Enterprise ID | CRO Enterprise (Client) Short Name | cfg_enterprise.enterprise_ab brv | |
| Case | Case Creator ID | ID of Case Author (who created the case) | case_master.user_id | |
| Case | Case Creator Name | Case Author (who created the case) | cfg_users.user_fullname where cfg_users.user_id = case_master.user_id | |
| Case | Case Processing Site | Site (for ex., drug safety case processing location) | case_master.site_id | |
| Case | Country Of Incidence | Country where the adverse event occurred | case_master.country_id | |



Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|-----------------------------------|--|------------------------------------|--|
| Case | Case Type | Case Report Type (for ex., Spontaneous/Clinical/Literature etc.) | case_master.Report_type | |
| Case | Compliance Classification | 7-day Case, 15-day Case, Non-Expedited Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (7-day Case, 15-day Case, Non-Expedited Case) |
| Case | S/R/U Classification | SAE Case, SAR Case, SUSAR Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (SAE Case, SAR Case, SUSAR Case) |
| Case | F/LT Classification | Fatal / Life-Threatening Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (Fatal / Life- Threatening Case) |
| Case | Pregnancy Classification | Pregnancy Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (Pregnancy Case) |
| Case | Source Classification | Authority Case, Consumer Case, Literature Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (Authority Case, Consumer Case, Literature Case) |
| Case | Confirmation Classification | Medically Confirmed Case | Im_case_classification.description | where Im_case_classificatio n.description has values in (Medically Confirmed Case) |
| Case | Case Classification Group 7 | Case Classification Group 7 | Im_case_classification.description | where Im_case_classificatio n.description has values in (Case Classification 7) |
| Case | Case Classification Group 8 | Case Classification Group 8 | Im_case_classification.description | where Im_case_classificatio n.description has values in (Case Classification 8) |



Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|------------------------------------|---|--|--|
| Case | Case Classification Group 9 | Case Classification Group 9 | Im_case_classification.description | where Im_case_classificatio n.description has values in (Case Classification 9) |
| Case | Case Classification Group 10 | Case Classification Group 10 | Im_case_classification.description | where Im_case_classificatio n.description has values in (Case Classification 10) |
| Case | Product Type | Drug, Device and Vaccine | case_product.views_available | |
| Case | Study ID | Study ID | case_study.study_num | |
| Case | Center ID | Center ID for the Study in the case | Im_centers.center_no where case_study.center_id = Im_centers.center_id | |
| Case | Case Seriousness | Case Serious or Non-Serious (Y/N) | case_assess.seriousness | |
| Case | Case Listedness | Unlisted/Unexpected/listed/ expected | case_assess.listedness | |
| Case | Case Causality | Adverse event caused by the product (related/not related) | case_assess.agent_suspect | |
| Case | Case Outcome | Case Level Outcome using the ICH guidelines eg "Recovered" | case_assess.outcome | |
| Case | Gender | Gender of the Patient | case_pat_info.gender_id | |
| Case | Pregnant | Patient pregnant (Yes/No) | case_pat_info.pat_stat_preg | |
| Case | Age Group | Patient Age Group | case_pat_info.age_group_id | |
| Case | Ethnicity | Ethnicity of the Patient | case_pat_info.ethnicity_id | |
| Case | Lactation | Patient breastfeeding | case_pregnancy.breastfeedin g | |
| Case | Primary Reporter Type | Type of the first/primary reporter (for ex., Physician, Consumer etc) | case_reporters.reporter_type where primary_contact = 1 | |
| Case | Primary Suspect Product | Primary Suspect Product for a case | case_product.product_name where case_product.first_sus_prod = 1 | |
| Case | НСР | Health Care Professional (ex., physician, nurse, pharmacist) flag. Primary Reporter of the case is HCP or not | case_reporters.hcp_flag where primary_contact = 1 | |
| Case | SUSAR | Suspected Unexpected Serious Adverse Reaction Flag(0 / 1) | case_master.susar | |



Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------------------|-------------------------|--|---|---|
| Case | Initial Receipt Date | Date on which initial case information was received | case_master.init_rept_date | |
| Case | Clock Start Date | Case Aware Date | Max(case_master.init_rept_d ate/ (case_followup.receipt_date where significant = 1)) | |
| Case | Lock Timestamp | Case is ready for submission. Lock date of the case version. | case_master.date_locked | |
| Case | Locked Indicator | Flag to indicate whether the case version is locked or unlocked | case_master.date_locked | If case_master.date_lo cked is not null then 'Yes' else 'No' |
| Case | Case Owner ID | ID of user who is responsible for the case throughout its lifetime | case_master.worklist_owner _id | |
| Case | Case Owner Name | User who is responsible for the case throughout its lifetime | cfg_users.user_fullname where cfg_users.user_id = case_master.worklist_owner _id | |
| Case | State Name | Workflow State (From Workflow State) | | |
| Case | CRO Project Code | If clinical case then Study Configuration -> Other ID, else Product Configuration -> Company Drug Code for the Primary Suspect Product | LM_REPORT_TYPE.INCL_T RIAL LM_STUDIES.OTHER_ID LM_PRODUCTS.DRUG_CO DE | If LM_REPORT_TYPE .INCL_TRIAL = 1 then LM_STUDIES.OTHE R_ID, else LM_PRODUCTS.DR UG_CODE for Primary Suspect Product |
| Pending Cases | Follow-up ID | Latest Case Follow-up # (0,1,2,3) | case_routing.followup_num | Followup # as appear on Argus Case Form for the latest followup. It shall be 0 if the latest case version is Initial |
| Pending Cases | Initial / Follow-Up | Initial or Follow-up entry of the Case | N/A | If Version = 1 then Initial Else Follow-up |



Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------------------|------------------------------------|---|--|--|
| Pending Cases | Follow-up Type | Significant, Non-Significant - Significant/Non-Significant (Is This Follow-up Information Considered Significant, Based On Company Specific Policies? If This Follow-up Information Is Marked As Significant, The Regulatory Report Algorithm Will Re- Run And Will Calculate The Due Date Based On The Most Recent Significant Follow-up Date) | case_followup.significant | If Case_followup.Signifi cant = 1 then 'Significant' else 'Non-Significant'. If the latest case version is Initial then 'Significant'. |
| Pending Cases | Latest Followup Receipt Date | Date On Which Latest Follow-up Information Was Received. If There Is No Followup Then Followup Receipt Date Will Be Null | case_followup.receipt_date | |
| Pending Cases | Case Deletion Date | Date On Which Latest Follow-up Information WasReceived. If There Is No Followup Then FollowupReceipt Date Will Be Null | case_followup.receipt_date | |
| Pending Cases | Assigned User ID | ID of the User Assigned To The Current Work | case_master.owner_id | |
| Pending Cases | Assigned User Name | User Assigned To The Current Work | cfg_users.user_fullname where cfg_users.user_id = case_master.owner_id | |
| Pending Cases | User With Case ID | Case Worklist User. User Who Has The Case Open. (It May Be Null If Case Is Not Open) | web_cases_open.user_id | |
| Pending Cases | User With Case Open Name | Case Worklist User. User Who Has The Case Open (It May Be Null If Case Is Not Open) | cfg_users.user_fullname where cfg_users.user_id = web_cases_open.user_id | |
| Pending Cases | Routing Justification | Case Routing Justification For The Latest Routing | case_routing.justification_id | |
| Pending Cases | Routing ID | Workflow Sequence Number | case_routing.seq_num | |
| Pending Cases | Routing Timestamp | The Timestamp On Which Case Was Routed To Current Workflow State | case_routing.route_date | |
| Pending Cases | Routing User Group | User Group To Which A Case Is Routed. | cfg_workflow_rules.group_id where cfg_workflow_rules.seq_num =case_routing.workflow_seq _num | |



Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------------|-------------------------------------|---|--|------------------|
| Pending Cases | Routing User ID | Id of the User Group To Which A Case Is Routed. | case_routing.user_id | |
| Pending Cases | Routing User Name | User Group To Which A Case Is Routed. | cfg_users.user_fullname where cfg_users.user_id = case_routing.user_id | |
| Pending Cases | Local Lock Timestamp | Latest Local Lock Timestamp when the current version of the case is Locally Locked or Globally and Locally Locked. Will be null if either global lock or local lock is null. | CASE_ROUTING.ROUTE_D ATE | |
| Pending Cases | Local Locked Indicator | Will be 1 when the current version of the case is Locally Locked or Globally and Locally Locked. Otherwise, it will be 0 or null. | CASE_ROUTING.ROUTE_D ATE | |
| Pending Cases | Duration Global to Local Lock | Is the time between the Current Versions latest local case lock timestamp and the Current Versions last global case lock that occurred before that local case lock. Will be null if either global lock or local lock is null. | CASE_ROUTING.ROUTE_D ATE | |
| Pending Cases | # Days Case Open | Number of days elapsed since aware date (Clock Start Date) of the case | NVL(TRUNC(SYSDATE) - TRUNC(Max(case_master.ini t_rept_date/ (case_followup.receipt_date where significant = 1))), 0) | |
| Pending Cases | # Days Remaining | Number of days remaining for case processing as per the due soon date configured in Argus Safety | NVL(TRUNC(case_master.d ue_soon) - TRUNC (SYSDATE), 0) | |
| Pending Expedited Reports | Report ID | Unique Identifier for the report | cmn_reg_reports.reg_report _id | |
| Pending Expedited Reports | Report Initial / Follow-Up ID | Report Followup Number (1,2,3 0 - for Initial)'Initial' if followup number = 0 else 'F/U #' followup number | DECODE (cmn_reg_reports.followup_n um, 0, 'Initial', 'F/U #' cmn_reg_reports.followup_n um) | |
| Pending Expedited Reports | Regulatory Report Type | Report Form ID | cmn_reg_reports.report_for m_id | |



Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------------|----------------------------------|--|--|---|
| Pending Expedited Reports | Report 7/15 Timeframe | Timeframe when the report is due. This field specifies the report's scheduled duedate based on the number of days, after the initial receipt or significant follow-up date. If timeframe <= 7 then '7' else '15' | case when cmn_reg_reports.timeframe <= 7 then 7 else 15 end | |
| Pending Expedited Reports | Foreign / Domestic | Domestic if the Agency Country = Country of Incidence for the Case else Foreign | | Domestic if CASE_MASTER.CO UNTRY_ID = (SELECT COUNTRY FROM LM_REGULATORY_ CONTACT WHERE AGENCY_ID = CMN_REG_REPOR TS.AGENCY_ID) else Foreign |
| Pending Expedited Reports | Report Assigned User Group | User Group responsible for the report | cmn_reg_reports.group_id | |
| Pending Expedited Reports | Report Assigned User ID | ID of the user assigned to the report | cmn_reg_reports.owner_id | |
| Pending Expedited Reports | Report Assigned User Name | User assigned to the report | cfg_users.user_fullname where cfg_users.user_id = cmn_reg_reports.owner_id | |
| Pending Expedited Reports | Report Due Date | Date the report is due | cmn_reg_reports.due_date | |
| Pending Expedited Reports | Pending Expedited Reports | Internal due date for report submission | | It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days"Pending Expedited Reports".Report Due Date - (2) |



Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------------|------------------------------------|---|---|---|
| Pending Expedited Reports | Report On- Time Indicator | Report submission on-time indicator. The values here are Red, Yellow and Green.Green: when Report Due Soon Date has not elapsedYellow: when no. of days remaining for report submission are less than or equal to the no. of due soon days configured in the PVARed: when Report Due Date has elapsed | | Green: count(Number of records from Pending Expedited Reports) where sysdate <= Report Due Soon DateYellow: count(Number of records from Pending Expedited Reports) where sysdate > Report Due Soon Date and sysdate <= Report Due DateRed: count(Number of records from Pending Expedited Reports) where sysdate > Report Due DateRed: count(Number of records from Pending Expedited Reports) where sysdate > Report Due Date |
| Pending Expedited Reports | Report Schedule Timestamp | Date on which report got scheduled | cmn_reg_reports.date_sched uled | |
| Pending Expedited Reports | Report Generation Timestamp | Report Generation Date | cmn_reg_reports.date_gener ated | |
| Pending Expedited Reports | Report Approval Timestamp | Report Approved Date | case_reg_reports.date_appr oved | |
| Pending Expedited Reports | Report Downgrade Indicator | A flag to identify downgrade reports | If cmn_reg_reports.submit_not es like '*Downgrade*%' then 'Yes' else 'No' | |
| Pending Expedited Reports | # Days Report Late | Number of days by which report is past due date | N/A | sysdate - Report Due Date |
| Pending Expedited Reports | # Days Report Open | Number of days that the report is open | N/A | sysdate - NVL(Clock Start Date, Report Schedule Timestamp) |
| Pending Expedited Reports | # Pending Reports | Total number of reports not submitted | N/A | count(Number of records from Pending Expedited Reports) |
| Pending Expedited Reports | # Pending Reports Downgraded | Total number of downgraded reports | N/A | count(Report Downgrade Indicator) where Report Downgrade Indicator = 'Yes' |



Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------------|----------------------------------|--|---------------------|---|
| Pending Expedited Reports | # Pending Reports On- Time | Count of pending reports where submission is On-Time (Report On-Time Indicator is Green)[Number of cases submitted by the inernal due soon date] | N/A | where Report On- Time Indicator is Green |
| Pending Expedited Reports | % Pending Reports On- Time | Percentage of cases submitted on time by the internal due soon date | N/A | (# Pending Reports On-Time/# Pending Reports) * 100 |
| Pending Expedited Reports | # Pending Reports Due Soon | Count of pending reports where submission is Due Soon (Report On-Time Indicator is Yellow)[Number of reports due soon for submission] | N/A | where Report On- Time Indicator is Yellow |
| Pending Expedited Reports | % Pending Reports Due Soon | Percentage of reports due soon for submission | N/A | (# Pending Reports Due Soon/# Reports Not Submitted) * 100 |
| Pending Expedited Reports | # Pending Reports Overdue | Count of pending reports that have not been submitted by due date (Report On- Time Indicator is Red) [Number of reports overdue for submission] | N/A | where Report On- Time Indicator is Red |
| Pending Expedited Reports | % Pending Reports Overdue | Percentage of reports overdue for submission | N/A | (# Reports Overdue For Submission/# Reports Not Submitted) * 100 |



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Troubleshooting

This appendix contains troubleshooting tips in handling the following scenarios:

Unable to Sign In to Oracle Argus Analytics

Unable to Sign In to Oracle Argus Analytics

You might be unable to sign in to Oracle Argus Analytics in either of the following scenarios:

- The Login page displays an Internal Server Error message.
- You are logged in but while working on something, you might encounter an error and could get logged out.

In such scenarios, try executing the following steps:

- You can log in to the Console to check the BI Server status.
- You can also log in to the Enterprise Manager and check the status of all the Oracle Business Intelligence Enterprise Edition components. Enter the \oracle\fmw\instances\instancel\bin> opmnctl status command to view the status of each component in Oracle Business Intelligence Enterprise Edition.

