Oracle® Argus Analytics

User's Guide

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Preface

This guide provides information about how to use and administer Oracle Argus Analytics. Oracle Argus Analytics was previously named Oracle Health Sciences Pharmacovigilance Operational Analytics (OPVA).

This preface contains the following topics:

- Audience
- Documentation Accessibility
- Finding Information and Patches on My Oracle Support
- Finding Documentation on Oracle Technology Network
- Related Documents
- Conventions

Audience

The first and second chapters of this guide are intended for the following job classifications:

- Drug Safety Administrator
- Drug Safety Manager
- Drug Safety Team Leader
- Drug Safety and Surveillance Specialist
- Drug Safety Quality Reviewer
- Drug Safety Data Entry Personnel
- Pharmacovigilance Executive Management
- Drug Safety Medical Assessment Physician

This guide assumes that you have the following general skills:

- Knowledge of Oracle Business Intelligence Enterprise Edition
- Knowledge of Oracle Business Intelligence Data Mart Administration Console
- Knowledge of Informatica PowerCenter or Oracle Data Integrator
- Familiarity with Oracle Argus Safety

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.

Access to Oracle Support

Oracle customers 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.

Finding Information and Patches on My Oracle Support

Your source for the latest information about Oracle Argus Analytics is Oracle Support's self-service Web site, My Oracle Support (formerly MetaLink).

Before you install and use an Oracle software release, always visit the My Oracle Support Web site for the latest information, including alerts, release notes, documentation, and patches.

Creating a My Oracle Support Account

You must register at My Oracle Support to obtain a user name and password accountbefore you can enter the Web site.

To register for My Oracle Support:

- 1. Open a Web browser to http://support.oracle.com.
- **2.** Click the **Register here** link to create a My Oracle Support account. The registration page opens.
- **3.** Follow the instructions on the registration page.

Signing In to My Oracle Support

To sign in to My Oracle Support:

- 1. Open a Web browser to http://support.oracle.com.
- 2. Click Sign In.
- **3.** Enter your user name and password.
- **4.** Click **Go** to open the My Oracle Support home page.

Searching for Knowledge Articles by ID Number or Text String

The fastest way to search for product documentation, release notes, and white papers is by the article ID number.

To search by the article ID number:

- 1. Sign in to My Oracle Support at http://support.oracle.com.
- **2.** Locate the Search box in the upper right corner of the My Oracle Support page.
- **3.** Click the sources icon to the left of the search box, and then select Article ID from the list.
- **4.** Enter the article ID number in the text box.

5. Click the magnifying glass icon to the right of the search box (or press the Enter key) to execute your search.

The Knowledge page displays the results of your search. If the article is found, click the link to view the abstract, text, attachments, and related products.

In addition to searching by article ID, you can use the following My Oracle Support tools to browse and search the knowledge base:

- Product Focus On the Knowledge page, you can drill into a product area through the Browse Knowledge menu on the left side of the page. In the Browse any Product, By Name field, type in part of the product name, and then select the product from the list. Alternatively, you can click the arrow icon to view the complete list of Oracle products and then select your product. This option lets you focus your browsing and searching on a specific product or set of products.
- Refine Search Once you have results from a search, use the Refine Search
 options on the right side of the Knowledge page to narrow your search and make
 the results more relevant.
- Advanced Search You can specify one or more search criteria, such as source, exact phrase, and related product, to find knowledge articles and documentation.

Finding Patches on My Oracle Support

Be sure to check My Oracle Support for the latest patches, if any, for your product. You can search for patches by patch ID or number, or by product or family.

To locate and download a patch:

- 1. Sign in to My Oracle Support at http://support.oracle.com.
- **2.** Click the **Patches & Updates** tab.

The Patches & Updates page opens and displays the Patch Search region. You have the following options:

- In the Patch ID or Number is field, enter the primary bug number of the patch you want. This option is useful if you already know the patch number.
- To find a patch by product name, release, and platform, click the Product or Family link to enter one or more search criteria.
- **3.** Click **Search** to execute your query. The Patch Search Results page opens.
- **4.** Click the patch ID number. The system displays details about the patch. In addition, you can view the Read Me file before downloading the patch.
- **5.** Click **Download**. Follow the instructions on the screen to download, save, and install the patch files.

Finding Documentation on Oracle Technology Network

The Oracle Technology Network Web site contains links to all Oracle user and reference documentation. To find user documentation for Oracle products:

- 1. Go to the Oracle Technology Network at
 - http://www.oracle.com/technetwork/index.html and log in.
- **2.** Mouse over the Support tab, then click the **Documentation** hyperlink.
 - Alternatively, go to Oracle Documentation page at
 - http://www.oracle.com/technology/documentation/index.html

- **3.** Navigate to the product you need and click the link.
 - For example, scroll down to the Applications section and click Oracle Health Sciences Applications.
- **4.** Click the link for the documentation you need.

Related Documents

For more information, see the following documents:

- Oracle Oracle Argus Safety Release 7.0.2 documentation set
- Oracle Business Intelligence Enterprise Edition Release 11.1.1.6.5 documentation set
- Oracle Business Intelligence Data Warehouse Administration Console 10.1.3.4.1 documentation set

Oracle Argus Safety Documentation

The Oracle Argus Safety documentation set includes:

- Oracle Argus Safety 7.0.2 Administrator's Guide
- Oracle Argus Safety 7.0.2 User's Guide
- Oracle Argus Safety 7.0.2 Installation Guide

Oracle Fusion Middleware Documentation

The Oracle Fusion Middleware documentation set includes:

- Oracle Fusion Middleware Quick Installation Guide for Oracle Business Intelligence 11g Release 1 (11.1.1) (E16518-02)
- Oracle Fusion Middleware Installation Guide for Oracle Business Intelligence 11g Release 1 (11.1.1) (E10539-02)
- Oracle Fusion Middleware Upgrade Guide for Oracle Business Intelligence 11g Release 1 (11.1.1) (E16452-02)
- Oracle Fusion Middleware Enterprise Deployment Guide for Oracle Business Intelligence 11g Release 1 (11.1.1) (E15722-02)
- Oracle Fusion Middleware User's Guide for Oracle Business Intelligence 11g Release 1 (11.1.1) (E10544-02)
- Oracle Fusion Middleware System Administrator's Guide for Oracle Business Intelligence 11g Release 1 (11.1.1) (E10541-02)
- Oracle Fusion Middleware Developer's Guide for Oracle Business Intelligence 11g Release 1 (11.1.1) (E10545-02)
- *Oracle Fusion Middleware Security Guide for Oracle Business Intelligence 11g Release 1* (11.1.1) (E10543-03)
- Oracle Fusion Middleware Metadata Repository Builder's Guide for Oracle Business Intelligence 11g Release 1 (11.1.1) (E10540-02)

Oracle Business Intelligence Data Warehouse Administration Console (DAC) Documentation

The Oracle Business Intelligence Data Warehouse Administration Console (DAC) documentation set includes:

- Oracle Business Intelligence Data Warehouse Administration Console User's Guide (Part E12652)
- Oracle Business Intelligence Data Warehouse Administration Console Installation, Configuration, and Upgrade Guide (Part E12653)

Conventions

The following text conventions are used in this document:

| Convention | Meaning |
|------------|--|
| boldface | Boldface type indicates graphical user interface elements associated with an action, or terms defined in the text. |
| italic | Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values. |
| monospace | Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter. |

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:

- Chapter 1, Getting Started with Oracle Argus Analytics
- Chapter 2, Using Oracle Argus Analytics
- Chapter 3, Working with Reports

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 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.

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

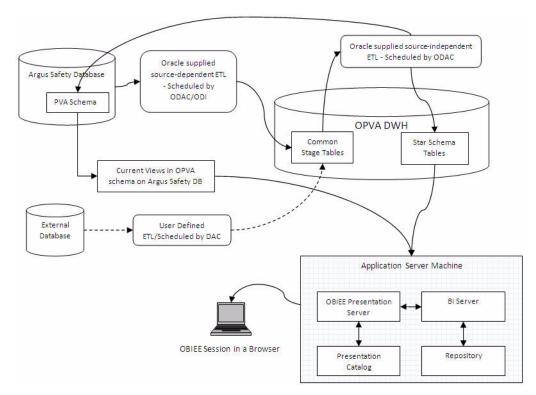


Figure 1–1 The Oracle Argus Analytics Architecture

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
- **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:

- Chapter 2, Using Oracle Argus Analytics
- Chapter 3, Working with Reports
- Appendix A, 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.

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 OBIEE Repository can be versioned and saved permanently in a third-party versioning tool.

Calculations can also be performed in reports managed through OBIEE Analytics. The OBIEE 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 Informatica/ODI to manage ETL versions.

Executing the ETLs

In case of Informatica, the execution of the ETLs is controlled by Oracle Data Warehouse Administration Console (DAC). You can create users and set the roles for various types of accessibility in DAC. Please refer to the DAC Administration and User Guides for more information.

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 11.1.1.6.3 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:

Chapter 7, Implementing Security

Using Oracle Argus Analytics

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

Note: 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

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.

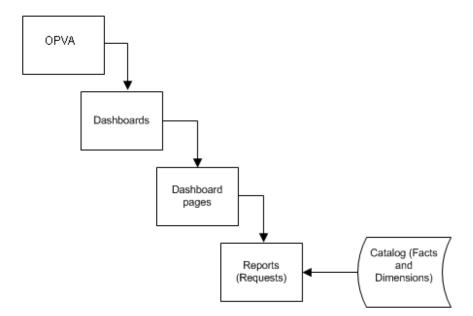


Figure 2–1 The Report Hierarchy

Figure 2-1 displays 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.

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

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

See Also:

- Chapter 3, Working with Reports for more information about creating and managing reports.
- Appendix B, 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.

Viewing a Dashboard

Perform the following steps to view a dashboard:

- Log in to Oracle Argus Analytics.
- 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 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 OBIEE (if using the built-in LDAP of WLS or external LDAP) should be the same as that in the Argus Safety system. For example, if 'admin' is the login for the OBIEE user that has been created, then the same login should have been present in the 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 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 Argus Saftey at the time you are trying to access these reports.

Using Oracle Business Intelligence

Oracle BI 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 Safety data. These capabilities enable the pharmaceutical organization to make better decisions, take informed action, and implement more efficient business processes.

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.

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/sa w.dll?Dashboard

Figure 2-2 displays the Oracle Argus Analytics login page.

Figure 2–2 Oracle Argus Analytics Login Page



- Enter your user ID and password.
- Click **Login**.

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

Working with Oracle Business Intelligence

In the Oracle BI Enterprise Edition (BI EE), you can work with:

Analysis

This area of OBIEE 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 OBIEE 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 analyses, links to Web sites, Oracle BI 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 analyses 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 analyses.

Agents

This area of OBIEE 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 analyses 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 OBIEE 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

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

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 BI Presentation Catalog

Links to websites

Links to documents

Embedded content (such as Web pages or documents)

Oracle BI 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 BI 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 analyses.

Analysis that you create can be saved in the Oracle BI Presentation Catalog and integrated into any OBIEE dashboard. Analyses 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 BI:

- Signing Out of Oracle Business Intelligence Enterprise Edition
- Using Online Help
- **Exporting the Oracle BI Results**

Signing Out of Oracle Business Intelligence Enterprise Edition

Note: Do not close the browser window to sign out of OBIEE.

To sign out of OBIEE:

1. 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

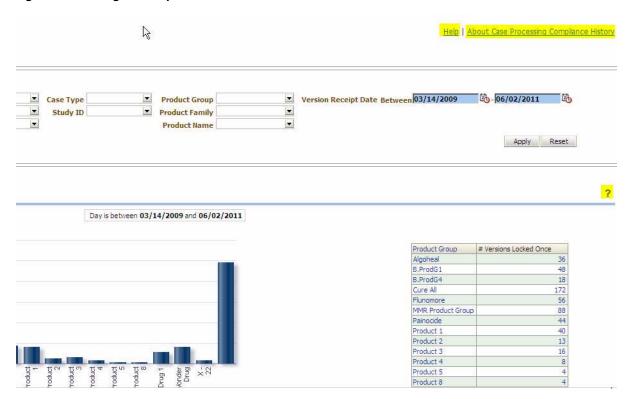


Table 2-1 Accessing Online Help

| Name of Help Link | Clicking on this link |
|---|---|
| Help | Opens the entire Help system, in an online book format. |
| <name dashboard="" help="" of="" page-specific=""></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 BI.

What is Available to You After Accessing Oracle BI?

After signing in to OBIEE, 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 OBIEE. As you work, you can use the global header and the Home page as the primary ways to navigate OBIEE.

The Global Header:

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

The Home Page

From the Home page, you can learn how to get started with OBIEE, 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 OBIEE Home Page?

The Home page provides a starting point for performing tasks in OBIEE. 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 OBIEE.

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



What is the OBIEE 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 BI 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 OBIEE, BI Publisher, and Marketing.

Documentation - Displays the documentation library for OBIEE.

OTN - Displays the Business Intelligence and Data Warehousing Technology Center page on the Oracle Technology Network (OTN).

About OBIEE - Displays a dialog identifying the OBIEE version and copyright information.

- Sign Out Signs you out of OBIEE.
- **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

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
- View and modify your delivery options for agents
- View the roles and groups to which you belong

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.
- Complete the appropriate settings.
- Click **OK** to save your changes.

Exporting the Oracle BI Results

Oracle BI 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.
- **4.** 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:

- 1. Click Export.
- 2. Select the Excel 2003+ 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 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.
- 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.
- **5.** 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:

- 1. Click Export.
- **2.** Select the **WebArchive** (**mht**) option.
- 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:

- 1. Click Export.
- **2.** Select the **Data** option.
- Select the **CSV** sub-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 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 about briefing books and steps to add contents to briefing books.

About Briefing Books A briefing book is a collection of static or updatable snapshots of dashboard pages, individual analyses, 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 analyses 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.
- **2.** 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 OK.

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

For more information about the briefing book, please refer to the OBIEE 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.

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.

Note: 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 BI 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.

Note: 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:

- Navigate to an existing dashboard or request.
- 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

Emailing an Oracle BI 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.

Note: 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:

- 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.

Note: 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 BI 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:

- Chapter 2, Using Oracle Argus Analytics for more information about report-related tasks.
- Appendix A, Dashboards and Reports for more information about predefined reports.
- Oracle Argus Analytics Installation Guide for instructions on installing Oracle Argus Analytics.

Opening and Using Dashboards

Perform the following steps to open and use dashboards:

- 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.
- This is an optional step You may choose to perform any of the following tasks:
 - 1. 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 BI 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:

- Chapter 4, Extract Transform Load Programs
- Chapter 5, Maintaining the Repository and Data Mart
- Chapter 6, Performance Considerations
- Chapter 7, Implementing Security

Extract Transform Load Programs

This chapter contains the following topics:

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

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.

ETL Architecture

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

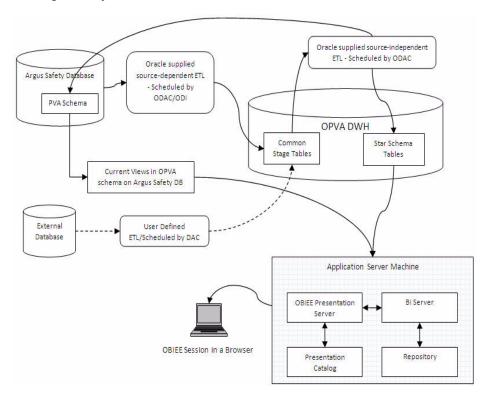


Figure 4–1 The Oracle Argus Analytics ETL Architecture

Oracle Argus Analytics has ETLs defined in the following two technology flavors:

- Informatica
- Oracle Data Integrator (ODI)

Set up as a recurring job in DAC/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 (in case of Informatica)/Interfaces (in case of ODI) for the Oracle Argus Safety database. However, you can also define SDE mappings/interfaces 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 star-schema tables, where such data are organized for efficient query by the Oracle BI Server.

There is one SDE mapping/interface 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.
- Bulk and Normal Load (for Informatica ETLs only): Bulk load uses block transfers to expedite loading of large data volume. It is intended for use during initial data mart population. Bulk load is faster, if data volume is sufficiently large. However, if load is interrupted (for example, disk space is exhausted, power failure), load cannot be restarted in the middle; you must restart the load.

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.

Setting Bulk or Normal load option should be done at Workflow session in Informatica. Perform the following steps to set the load option:

- 1. Navigate to Session in a workflow and edit the task properties.
- Navigate to the Mappings subtab and select 'Bulk/Normal' under Target Load type.
- **3.** Save the workflow.

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.
- By default, bulk load is disabled for all SILs for incremental load (in case of Informatica ETLs only).
- The results of each ETL execution is logged by Informatica/ODI. The logs hold information about errors encountered, during execution.

Informatica provides the following four error tables:

- PMERR DATA
- PMERR MSG
- PMERR SESS
- PMERR_TRANS

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 Informatica PowerCenter error tables/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.

Oracle Argus Analytics Hierarchy

Figure 4-2 displays the Oracle Argus Analytics hierarchy using DAC:

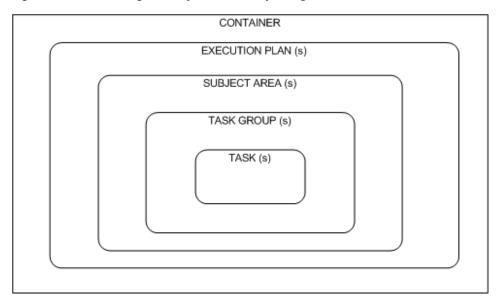


Figure 4–2 Oracle Argus Analytics Hierarchy using DAC

Oracle Argus Analytics follows the hierarchy using DAC, as listed below:

- CONTAINER (OPVA_Datawarehouse) A single container that holds all objects used for Oracle Argus Analytics.
- EXECUTION PLAN (Oracle Argus Analytics Data Mart Load) A data transformation plan defined on subject areas that needs to be transformed at certain frequencies of time. An execution plan is defined based on business requirements for when the data mart needs to be loaded. Single Execution Plan to Load Complete Warehouse.
- SUBJECT AREAS A logical grouping of tables related to a particular subject or application context. It also includes the tasks that are associated with the tables, as well as the tasks required to load the tables. Subject areas are assigned to execution plans, which can be scheduled for full or incremental loads.
- TASK GROUPS This is a group of tasks that should be run in a given order.
- TASKS A unit of work for loading one or more tables. A task comprises the following: source and target tables, phase, execution type, truncate properties, and commands for full or incremental loads. A single Informatica workflow.

Figure 4-3 displays the Oracle Argus Analytics hierarchy using:

ODI REPOSITORY PROJECT(S) LOAD PLAN(S) SCENARIO(S) INTERFACE(S) PROCEDURE(S) VARIABLE(S) KNOWLEDGE MODULE(S) PACKAGE(S) INTERFACE(S) PROCEDURE(S) VARIABLE(S)

Figure 4–3 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 Argus Analytics-related ODI ETL objects.
- KNOWLEDGE MODULE Templates of PLSQL code used in interfaces 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, 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, Procedures, variables and packages as well to be executed in a defined manner.
- INTERFACE 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 Execution Plans in Informatica

To load data from the source to their target tables in the data mart, run the Execution Plan packaged with Oracle Argus Analytics. Perform the following tasks in DAC:

- Navigate to the **Execute** view.
- 2. Select Oracle Argus Analytics Warehouse execution plan.
- Set the parameter values under the **Parameter** tab.
- Build the execution plan.

5. Click Run.

Parameters Used by Informatica ETLs

The following parameters are used by Informatica ETLs:

Table 4-1 Informatica ETL Parameters

| Parameters | Description | Allowed Values |
|--------------------------------------|--|--|
| \$\$p_config_days | Reduces the incremental extract window by the specified number of days. E.g.: Extract all changed rows between LAST_EXTRACT_DATE and (SYSDATE - \$\$p_config_days) | Integers Recommended value: 0 |
| \$\$p_enterprise_id | The specific Enterprise ID to run the ETL for | -1: Runs the Incremental ETL for the entire Warehouse |
| | | 0: Runs the Incremental ETL for all the enterprises the user (\$\$p_user_name) has access to. |
| | | Integer Value [1,2,3, etc]: Runs the Incremental ETL for the specified Enterprise only. |
| \$\$p_etl_proc_id | The unique Identifier for the ETL Process that is run and it takes its value by default from DAC or from ODI | Do not change or specify any other value. Please leave it unmodified. |
| \$\$p_include_pseud | | Default value is 1. |
| o_state_flag | workflow states present between the Locking record and the Unlocking record of a case in the Case Workflow State Fact table. | 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. |
| \$\$p_last_extract_d ate | System-defined value for defining the start date of the extract window for Incremental Data or the last time the ETL ran successfully for the enterprise specified | Do not change |
| \$\$p_override_last_ extract_date | Specify a Date value in the format MM/DD/RRRR in case you want to override the last extract date for the Incremental Data. | Date Values such as 01/01/1999 or 12/23/2007 |
| \$\$p_rekey_fact | To rekey fact tables in case data in the W_HS_MAPPING_S defined for match and | 0: Will not rekey the Fact tables |
| | merge has changed | 1: Will rekey the Fact tables |
| \$\$p_user_name | The user name which the Incremental ETL shall use to set the VPD Context for the specified enterprise in the parameter: \$\$p_enterprise_id. This value should be passed inside single quotes: such as 'username'. | Default Value: 'admin' |
| \$\$START_DATE | 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 | Default Value: 01/01/1980 |

Table 4–1 (Cont.) Informatica ETL Parameters

| Parameters | Description | Allowed Values |
|--------------|--|---------------------------|
| \$\$END_DATE | 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 | Default Value: 01/01/2020 |

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:

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

Table 4–2 ODI Parameters

| Parameters | Load Type | Description | Allowed Values |
|----------------------------|-----------|---|---|
| VAR_ALN_PERIOD_FR | 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: |
| OM_DATE | | | 01/01/1980 |
| | | | Recommended value: |
| | | | 01/01/1980 |
| VAR_ALN_PERIOD_TO _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: 01/01/2020 |
| | | | Recommended Value: 01/01/2020 |
| VAR_INT_TRUNCATE_ | 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: |
| STAGE | | | 0: Does not truncate Stage table |
| | | | 1: Truncate Stage table |
| | | | Should be specified as 1 always in case of Single Argus Safety Instance as source information |
| | | | Recommended Value: 1 |
| VAR_INT_SAMPLE_SIZ E | Both | This variable is used during Analyze tables for evaluating ESTIMATE_PERCENTA GE parameter value. | Integer Values |
| | | | Recommended Value: 5 |

Table 4–2 (Cont.) ODI Parameters

| Parameters | Load Type | Description | Allowed Values |
|--------------------------------|---------------------|--|--|
| VAR_ALN_ENTERPRIS E | Both | The specific Enterprise ID to run the ETL for. | -1: Runs the ETL for the entire Warehouse |
| | | | 0: Runs the ETL for all the enterprises the user (\$\$p_user_name) has access to |
| | | | Integer Value [1,2,3, etc]: Runs the Incremental ETL for the specified Enterprise only. |
| | | | Note: For Full Load, this value has to be -1. |
| VAR_ALN_ERROR_REJ ECT_LIMIT | Both | This variable is used to set the number of rows that will be tracked in the | Valid Values: |
| | | respective error tables prior to aborting the ETL in case of errors. | Positive Integer numbers: (E.g. 0, 100, 1000, etc.) |
| | | | UNLIMITED: All the error records are logged |
| | | | Recommended Value: UNLIMITED |
| VAR_ALN_USER_NAM E | Both | The user name for which the ETL shall use to set the VPD Context for the specified enterprise in the parameter: VAR_ALN_ENTERPRIS E. This value should be passed inside single quotes: such as 'username'. | Default value: 'admin' |
| VAR_INT_RAISE_ERRO R | Both | Setting this variable to 0 or 1 will appropriately either stop a Load Plan/Interface or | 0: Do not raise data error when encountered during ETLs |
| | | continue the same when data errors are encountered during the | 1: Raise data error when encountered during ETLs |
| | | load. | Recommended Value: 1 |
| 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_DATE and (SYSDATE - \$\$p_config_days) | Integers Recommended Value: 0 |

Table 4-2 (Cont.) ODI Parameters

| Parameters | Load Type | Description | Allowed Values |
|---|---|---|--|
| 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 |
| VAR_INT_OVERRIDE_L | Incremental | Specify a Date value in | Date values such as: |
| AST_EXTRACT_DATE | Load | the format MM/DD/RRRR if you want to override the last | 01/01/1900 or 12/23/2012 |
| extract date for the Incremental Data for the specific ETL run. This will cause reload of data | 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 | Recommended Value: NULL (Change this with discretion) | |
| VAR_INT_INCLUDE_PS | Both | The parameter defines | Date values is 1. |
| EUDO_ST_CODE_FLG | | 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. | 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. |

4. Click **OK** to run the Load Plan.

Customizing an ETL Execution Plan (Informatica)/Load Plan (ODI)

When you customize an ETL Execution Plan (Informatica)/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 Execution Plan (Informatica Only)

Though Oracle Argus Analytics includes ETL Execution Plans for extracting data from Oracle Argus Safety to Oracle Argus Analytics data mart, you may want to create your own ETL 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 Argus Analytics Source Schema. 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 Argus Analytics. By default, we advise not to change this value (view).

See Also:

Informatica PowerCenter Online Help

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

- Create the new source and target table metadata inside Informatica.
- Work in Informatica PowerCenter and create the ETL components (transformation or workflow) for this program.
- Create the required workflow for this mapping.
- Connect to DAC and create a new task for this new mapping.
- Synchronize the task.
- Add the task to subject area.
- Build the Execution Plan (Oracle Argus Analytics Data Mart Load).

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 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 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 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

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:

- 1. 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 and its Scenario) for this program to populate the table or column appropriately.
- Edit or create an existing Load Plan. 3.
- Add the scenario generated at the appropriate hierarchical level and position where it needs to be executed, in the Load Plan.
- Save the Load Plan.

Modifying an ETL Execution Plan (Informatica Only)

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

See Also:

Informatica PowerCenter Online Help

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

- Identify the Execution Plan that needs to be modified in Informatica repository.
- Open and Modify the ETLs (transformation and/or workflow).
- Test and save the changes in repository. 3.
- Connect to DAC and navigate to the corresponding task.
- 5. Right-click the task and synchronize it.
- Navigate to the execution plan and execute ETL to verify the changes.

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

- Change the table/view properties, as required.
- Save the mapping and refresh the workflow.
- Connect to DAC and navigate to corresponding task and refresh it.

Note: If the changes to the tables or columns are not compatible with the table that is installed in the data mart schema, you will get a warning while making the change. For example, if you are reducing the length of a number column from 15 to 10, the change is not compatible with the data existing in the table.

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

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 Informatica repository.
- Identify the Interface or Package in the Load Plan that you intend to modify.

- 3. Open and modify the ETLs (Interface/Procedure) in ODI Studio under the Project ArgusAnalytics111.
- Test and save the changes in ODI Studio.
- Verify that the changes made have been applied successfully.
- Regenerate the associated scenario with the Interface/Procedure.
- Connect to DAC and navigate to the corresponding task.

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

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

Scheduling an ETL Execution Plan (Informatica Only)

When you submit an Execution Plan for execution in DAC, you can schedule it execute at regular intervals.

To schedule an Execution Plan, perform the following tasks:

- Navigate to the **Scheduler** tab within the **Execute** view.
- Create a new schedule plan.
- Enter the required details and click **Save**.

Scheduling an ETL Load Plan (ODI Only)

When you submit a Load Plan for execution in DAC, you can schedule it execute at regular intervals.

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.
- Right-click on the **Scheduling** tree node and select **New Scheduling**.
- Enter the required details and click **Save**.
- 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.

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 4–3 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 |

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.

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.

Oracle Argus Analytics 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.

Maintaining the Repository and Data Mart

This chapter contains the following topics:

- Maintaining the Oracle Argus Analytics Repository
- Maintaining the 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.

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:

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

Maintaining the 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.

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.

Extensions

An extension is a new column added to the data mart.

Example for Informatica ETL: Adding the Agency ID as an attribute of the study dimension for each study. The following is assumed:

The information about agency is available in a table called LM_STUDY_SUSAR.

To minimize the level of effort required when implementing a release with a new repository, Oracle recommends that you add extensions to the data mart through user-defined extension tables, rather than by adding new columns directly into the relevant staging and target tables.

Perform the following tasks to add the study manager to the study dimension for each study:

- Modify staging table W_RXI_STUDY_DS, adding the AGENCY_ID column. To modify the staging table, perform the following tasks in Oracle Business Intelligence Data Mart Administration Console (DAC):
 - Duplicate the container in DAC (to ensure that the changes are not overwritten in the next Oracle Argus Analytics upgrade) or use an existing customized table definition.
 - **b.** Navigate to the **Design** > **Tables** subtab and add the new column under W_RXI_STUDY_DS and save it.
- Modify the SDE that populates W_RXI_STUDY_DS, in two steps:
 - Copy the SDE into another folder (to ensure that the changes are not overwritten in the next Oracle Argus Analytics upgrade) or use an existing customized SDE.
 - Add the LM_STUDY_SUSAR table as a source in the Informatica program.
 - Add a mapping of column AGENCY_ID from LM_STUDY_SUSAR to W_RXI_STUDY_DS.

To modify the SDE, perform the following tasks in DAC:

- Navigate to **Design** > **Tasks** subtab.
- Navigate to SDE of Study Dimension. Right-click and select **Synchronize** Tasks.
- If it does not already exist to support some other extension, create extension table W_RXI_STUDY_DX, containing one column [STUDY_WID] to function as a foreign key that joins to the primary key in W_RXI_STUDY_D. This table is populated with one row for each row in W_RXI_STUDY_D when the Study SIL executes.
- Add column AGENCY_ID to W_RXI_STUDY_D to hold the AGENCY_ID. To add a column, perform the following tasks in DAC:
 - Duplicate the container in DAC (to ensure that the changes are not overwritten in the next Oracle Argus Analytics upgrade) or use an existing customized table definition.
 - Navigate to Tables subtab Under Design Tab and add the new column under W_RXI_STUDY_DS and save it.
- Modify the SIL that populates W_RXI_STUDY_D. Add instructions to create a record in W_RXI_STUDY_DX for each record in W_RXI_STUDY_D, and to copy

W_RXI_STUDY_DS. AGENCY_ID into W_RXI_STUDY_DX.AGENCY_ID for each

To modify the SIL, perform the following tasks in DAC:

- Copy the SIL into another folder (to ensure that the changes are not overwritten in the next Oracle Argus Analytics upgrade) or use an existing customized SIL.
- Add the new column and save.
- Modify the repository:

Important: Before you modify the repository, ensure that you have copied the repository to a different location. This ensures that the changes are not overwritten automatically in the next upgrade of Oracle Argus Analytics. Alternatively, you can use an existing customized repository.

Import the definition of the extension table, W_RXI_STUDY_DX, into the Repository.

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:

- 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.
- 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.

To modify the SDE, perform the following tasks in Informatica:

- **a.** Copy the SDE into another folder (to ensure that the changes are not overwritten in the next Oracle Argus Analytics upgrade) or use an existing customized SDE.
- **b.** Modify the definitions and save.

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. |

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

| Scenario | Ad | justments Required |
|-----------------------------|----|---|
| Modified table has modified | 1. | Modify the SDE to read the modified layout. |
| 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. |
| New table | 1. | Add a staging table to accept the new input. |
| | 2. | Add an SDE to read from the new table and write to the staging table. |
| | 3. | Add a data mart table to make the new data available to the BI Server. |
| | 4. | 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 either the source table in Informatica and DAC, or the source, staging, and target tables.

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.

Note: 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. DAC/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).

Note: 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.

Performance Considerations

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

This chapter comprises the following topics:

- Conformed Dimensions in Oracle Argus Analytics
- Aggregate Facts in Oracle Argus Analytics
- Creation of Prompts and Filters
- **OBIEE 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 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 Conformed Dimensions

| Retrospective | |
|---------------|----------------------|
| Facts | Conformed Dimensions |
| Case Fact | Enterprise |
| | Case Processing Site |
| | Product |

Table 6–1 (Cont.) Conformed Dimensions

| Retrospective | |
|--------------------------|-------------------------------|
| | Study |
| | Period - Clock Start Date |
| | Period - Initial Receipt Date |
| | - |
| Case Version Fact | Enterprise |
| | Case Processing Site |
| | Product |
| | Study |
| | Period - Clock Start Date |
| | Period - Initial Receipt Date |
| | Period - Version Receipt Date |
| | |
| Case Routing Fact | Enterprise |
| | Case Processing Site |
| | Product |
| | Study |
| | Period - Clock Start Date |
| | Period - Initial Receipt Date |
| | Period - Version Receipt Date |
| | |
| Case Workflow State Fact | Enterprise |
| | Case Processing Site |
| | Product |
| | Study |
| | Period - Clock Start Date |
| | Period - Initial Receipt Date |
| | Period - Version Receipt Date |
| | |
| Case Work User Fact | Enterprise |
| | Case Processing Site |
| | Product |
| | Study |
| | Period - Clock Start Date |
| | Period - Initial Receipt Date |
| | Period - Version Receipt Date |
| | , |
| Case Work Fact | Enterprise |

Table 6–1 (Cont.) Conformed Dimensions

| Retrospective | |
|----------------------|---|
| • | Case Processing Site |
| | Product |
| | Study |
| | Period - Clock Start Date |
| | Period - Initial Receipt Date |
| | Period - Version Receipt Date |
| | renou - version receipt Date |
| Expedited Submission | Enterprise |
| | Case Processing Site |
| | Product |
| | Study |
| | Period - Clock Start Date |
| | Period - Initial Receipt Date |
| | Period - Version Receipt Date |
| | Expedited Submission Dimensions - Report Generation Date |
| | Expedited Submission Dimensions - Report Submission Or MDN Date |
| | Expedited Submission Dimensions - License |
| | Expedited Submission Dimensions - Report Destination |
| | |
| Report Routing | Enterprise |
| | Case Processing Site |
| | Product |
| | Study |
| | |
| Current | |
| Facts | Conformed Dimensions |
| Pending Cases | Enterprise |
| | Case Processing Site |
| | Product |
| | Study |
| | Period - Initial Receipt Date |
| Pending Reports | Enterprise |
| 0 1 | Case Processing Site |
| | Product |
| | Study |
| | - Cidaly |

Table 6–1 (Cont.) Conformed Dimensions

| Retrospective | |
|---------------|--|
| | Period - Initial Receipt Date |
| | Pending Report Dimensions - License |
| | 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 6–2 Aggregate Case Version Fact - Conformed Dimensions

| Retrospective | |
|--|----------------------|
| Facts | Conformed Dimensions |
| Aggregate Case Version Fact - Version Receipt Month | Enterprise |
| | Case Processing Site |
| | Product |

Table 6–2 (Cont.) Aggregate Case Version Fact - Conformed Dimensions

| Retrospective | |
|---------------|--|
| | Study |
| | Period - Version Receipt Date (at the hierarchical level of Month in the Period dimension) |
| | Case Type |
| | Case Seriousness |
| | 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 6–3 Aggregate Case Version Fact - Conformed Dimensions

| Retrospective | |
|--|--|
| Facts | Conformed Dimensions |
| Aggregate Case Fact - Initial Receipt Month | Enterprise |
| | Case Processing Site |
| | Product |
| | Study |
| | Period - Initial Receipt Date (at the hierarchical level of Month in the Period dimension) |
| | Case Type |
| | Case Seriousness |
| | 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 6-4 Aggregate Case Version Fact - Conformed Dimensions

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

This chapter contains a sub-chapter called Mandatory Prompts. It comprises the following sub-sections:

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

Mandatory Prompts

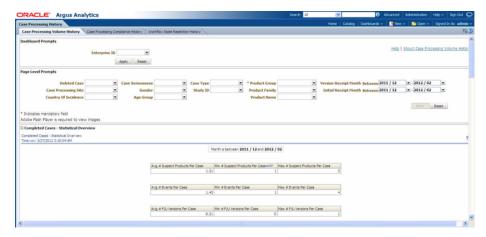
The prompts that are present in the dashboard can be made mandatory. By making a prompt mandatory, the particular report can be forced to use the aggregate facts, thereby improving performance significantly.

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:

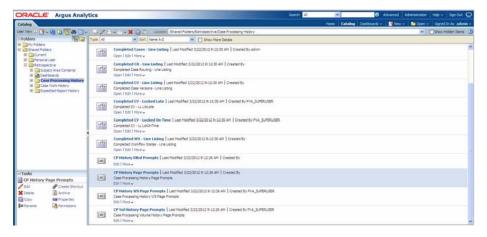
1. Login to the OBIEE application as a user with administrative rights and access to edit the dashboards. Typically, this would be the administrator.

Figure 6-1 Dashboard Reports



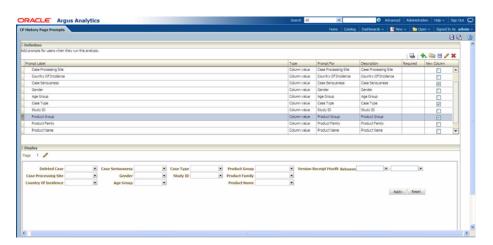
- Navigate to the folder in the catalog where prompts are saved. Example: Catalog > Shared folders > Retrospective > Case Processing History.
- Click the **Edit** link to make the change. Example: CP History Page Prompts.

Figure 6–2 OBIEE Objects in Catalog Folders



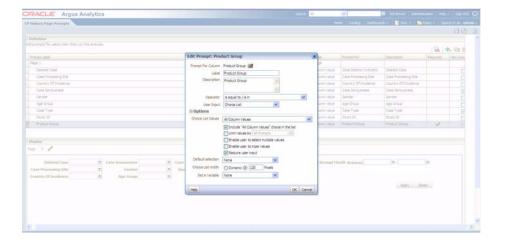
Select the field which is to be made mandatory and click the Edit icon (present on the top right of the opened screen), such as the **Product Group** field selected below.

Figure 6-3 Catalog Prompt Edit Page



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



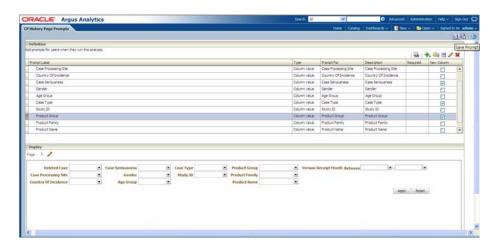
You can verify the change by checking the **Required** column of the field (**Product Group** below). Mandatory fields have a tick mark displayed against them. In the **Preview** window, an asterisk (*) appears before the name of the mandatory field.

ORACLE Argus Analytics

Figure 6–5 Preview Changes in Dashboard Prompts

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



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**:

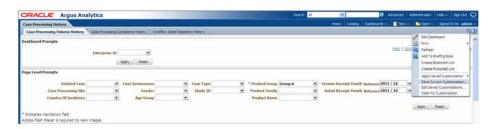
Navigate to the report where the default prompt value is to be saved. Go to the prompt, select the value, and click **Apply**.

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



OBIEE 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 OBIEE. In OBIEE cache will be stored as files on the Hard Disk of the OBIEE Server in the form of files. By Default caching is enabled in the OBIEE server configuration.

For time-consuming Dashboard Pages, we can use the concept of cache seeding in OBIEE, 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.

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.

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

OBIEE 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 OBIEE authentication.

Authorization

You assign user accounts to user groups in WLS Embedded LDAP. On login, OBIEE 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 OBIEE 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.

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 Informatica/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.
- DAC/INFA/ODI Administrators are people who set up DAC, Informatica, or ODI Setups, and grant privileges to other users.

Setting Up User Authentication

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

Creating User Accounts in DAC/ODI

You can create user accounts in the following way:

- Create users in DAC. For more information, refer to the *Oracle® Business* Intelligence Data Warehouse Administration Console Guide.
- Create users in ODI. For more information, refer to the Oracle® Fusion Middleware *Developer's Guide for Oracle Data Integrator 11g.*

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 OAM, and on configuring SSL for Oracle Argus Analytics.

Part III

Appendices

Part III contains the following appendices:

- Appendix A, Dashboards and Reports,
- Appendix B, Oracle Argus Analytics Presentation Catalog,
- Appendix C, Troubleshooting,

Dashboards and Reports

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

- Oracle Argus Analytics Dashboards
- **Oracle Argus Analytics Reports**

See Also:

- Chapter 2, Using Oracle Argus Analytics
- Chapter 3, Working with 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.

Oracle Argus Analytics includes the following dashboards:

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

Log in to Oracle Argus Analytics, and select the dashboard you want to view. For more information, refer to Accessing Oracle Argus Analytics.

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.

Case Processing History Dashboard Pages

This dashboard includes the following tabbed pages:

- Case Processing Volume History
- Case Processing Compliance History
- Workflow State Repetition History

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.

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 fina 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.

Case Processing Management Dashboard Pages

This dashboard includes the following tabbed pages:

- Case Processing Volume Management
- Case Processing Compliance Management
- Workflow State Compliance Management

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.

This page includes the following reports:

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.

Personal User Dashboard Pages

This dashboard includes the following tabbed pages:

- Personal User Case History
- Personal User Case Management
- Personal User Case Work History
- Personal User Expedited Report History
- Personal User Expedited Report Management

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 Timestamp Between: Lists the period of report submission/MDN timestamp 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.

Expedted Report History Dashboard Pages

This dashboard includes the following tabbed pages:

- **Expedited Submission Volume History**
- **Expedited Non-Submission Volume History**
- **Expedited Submission Compliance History**

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:

- **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:

- 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:

- **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:

- 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 includes the following tabbed pages:

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'.

Expedited Report Management Dashboard Pages

This dashboard includes the following tabbed pages:

- **Expedited Submission Volume Management**
- **Expedited Submission Compliance Management**
- Expedited Failed/Pending ACK Volume Management

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**: 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**: Lists the time period of report generation for the case.

This page includes the following reports:

- 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**: 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:

- Case Modified History
- Case Unmodified History
- Case Read History
- Case Idle History

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.

This page includes the following reports:

- 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

Oracle Argus Analytics includes the following reports:

- Enterprise Incremental ETL Status
- 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
- 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

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

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.

Audience

Case Processor

(All Users)

Report Type

Table

Location

All Dashboard pages

Note: 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-1 Enterprise Incremental ETL Status

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

Table A-1 (Cont.) Enterprise Incremental ETL Status

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

Completed Case Versions - Volume Overview

This section describes the Completed Case Versions - Volume Overview report.

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.

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-2 Completed Case Versions - Volume Overview

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

Completed Case Versions – Volume Trend

This section describes the Completed Case Versions - Volume Trend report.

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.

Audience

Executive Manager

Team Leader

Report Type

- 2-D Line Graph
- Group by 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

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 | ID | Case.ID |
| Case | Version ID | Case.Version ID |
| Case Version | Version Type | Case Version.Version Type |
| Case Version | Case Processing Site | Case Version.Case Processing Site |

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

| Table Heading | Column Heading | Measure |
|---------------|----------------------|--------------------------------------|
| 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 |
| 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 section describes the Completed Cases - Statistical Overview report.

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.

Audience

Executive Manager

Team Leader

Report Type

Table

Location

Case Processing History dashboard > Case Processing Volume History page

Dimensions

Enterprise.EnterpriseID

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 – 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 | Min # 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 |
| 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 section describes the Completed Cases - Volume Overview report.

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.

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

Enterprise.EnterpriseID

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 section describes the Completed Cases - Volume Trend report.

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.

Audience

Executive Manager

Team Leader

Report Type

- Group By Table
- 2-D Line Graph

Location

Case Processing History dashboard > Case Processing Volume History page

Dimensions

Period.Initial Receipt Date.Year

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 section describes the Completed Cases - Line Listing report.

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.

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 section describes the Completed Case Versions - Lock Compliance Overview report.

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.

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 |
| 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 section describes the Completed Case Versions - Lock Compliance Proportion report.

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.

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:

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 section describes the Completed Case Versions - Lock Compliance Trend report.

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.

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:

Completed Case Versions - Lock Compliance Trend Table A-11

| 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 section describes the Completed Workflow States - Line Listing report.

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.

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

State.Case Workflow - State

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:

Completed Workflow States - Line Listing Table A-12

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

Table A-12 (Cont.) Completed Workflow States - Line Listing

| Table Heading | Column Heading | Measure |
|--------------------------------|-----------------------------|---|
| State.Case Workflow - State | State Name | State.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 section describes the Completed Case Version Routing - Line Listing report.

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.

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

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

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 | ID | Case.ID |
| Case | Version ID | Case. 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 |

Repeated Workflow States – Volume Overview

This section describes the Repeated Workflow States - Volume Overview report.

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).

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

State.Case Workflow - State

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 | State.Case Workflow - State.State Name |
| Case Workflow State | # Times State Repeated | Case Workflow State.# Times State Repeated |

Repeated Workflow States – Volume Proportion

This section describes the Repeated Workflow States - Volume Proportion report.

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).

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

State.Case Workflow - State

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 | State.Case Workflow - State.State Name |
| Case Workflow State | % Times State Repeated | Case Workflow State.% Times State Repeated |

Pending Cases – Volume Overview

This section describes the Pending Cases - Volume Overview report.

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.

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 section describes the Pending Cases - Line Listing report.

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.

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.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

| 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 |
| Pending Cases | Routing ID | Pending Cases.Routing ID |

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

| Table Heading | Column Heading | Measure |
|---|-----------------------|---|
| 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 section describes the Pending Cases - Lock Compliance Overview report.

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.

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 section describes the Pending Cases - Lock Compliance In Days report.

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.

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 section describes the Pending Workflow States - Compliance Overview report.

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.

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:

Pending Workflow States - Compliance Overview Table A-20

| 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 section describes the My Completed Workflow States – Volume Trend report.

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.

Audience

Case Processor

Report Type

- 2-D Line Graph
- Group by Table

Location

Personal User dashboard > **Personal User Case History** page

Dimensions

State.Case Workflow - State

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 | 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 section describes the My Repeated Workflow States - Volume Overview report.

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).

Audience

Case Processor

Report Type

- 2-D Bar Graph
- Group by Table

Location

Personal User dashboard > **Personal User Case History** page

Dimensions

State.Case Workflow - State

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 | State.Case Workflow - State.State Name |
| Case Workflow State | # Times State Repeated | Case Workflow State.# Times State Repeated |

My Completed Case Versions – Line Listing

This section describes the My Completed Case Versions – Line Listing report.

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.

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:

My Completed Case Versions - Line Listing Table A-23

| Table Heading | Column Heading | Measure |
|---------------|----------------------|--------------------------------------|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | ID | Case.ID |
| Case | Version ID | Case. 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 |
| 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 section describes the My Completed Workflow States – Line Listing report.

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.

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Case Work History page

Dimensions

Enterprise ID

State.Case Workflow - State

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 | ID | Case.ID |
| Case | Version ID | Case. Version ID |
| State.Case Workflow - State | State Name | State.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

This section describes the My Pending Cases - Overview report.

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.

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 |
| 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 section describes the My Assigned Cases - Line Listing report.

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

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 |

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

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

My Unassigned Cases - Line Listing

This section describes the My Unassigned Cases - Line Listing report.

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

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 Unassigned Cases - Line Listing report:

My Unassigned Cases - Line Listing Table A-27

| 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 |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Other Assigned Cases – Line Listing

This section describes the Other Assigned Cases - Line Listing report.

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

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 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 |

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

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

My Completed Case Version Routing – Line Listing

This section describes the My Completed Case Version Routing – Line Listing report.

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.

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > **Personal User Case History** page

Dimensions

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 | ID | Case.ID |
| Case | Version ID | Case.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 section describes the My Case Modified Duration Per State - Statistical Overview report.

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.

Audience

Case Processor

Report Type

- **Table**
- 2-D Bar Graph

Location

Personal User dashboard > **Personal User Case Work History** page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
| 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 section describes the My Case Unmodified Duration Per State – Statistical Overview report.

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.

Audience

Case Processor

Report Type

- **Table**
- 2-D Bar Graph

Location

Personal User dashboard > Personal User Case Work History page

Dimensions

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 section describes the My Case Read Duration Per State – Statistical Overview report.

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.

Audience

Case Processor

Report Type

- Table
- 2-D Bar Graph

Location

Personal User dashboard > **Personal User Case Work History** page

Dimensions

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 section describes the My Case Idle Duration Per State – Statistical Overview report.

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.

Case Processor

Report Type

- **Table**
- 2-D Bar Graph

Location

Personal User dashboard > **Personal User Case Work History** page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 section describes the My Submitted Expedited Reports – Volume Trend report.

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.

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 section describes the My Submitted Expedited Reports - Submission Compliance Trend report.

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.

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

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 section describes the Completed Expedited Reports – Line Listing report.

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.

Workflow Manager

Team Leader

Report Type

Narrative Table

Location

- **Expedited Report History** dashboard > **Expedited Submission Volume History**
- **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:

Completed Expedited Reports – Line Listing Table A-36

| Table Heading | Column Heading | Measure |
|----------------------|---|--|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| 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 | Expedited Submission.Report Submission User |
| 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 section describes the Completed Expedited Report Routing – Line Listing report.

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.

Audience

Workflow Manager

Team Leader

Report Type

Narrative Table

Location

- Expedited Report History dashboard > Expedited Submission Volume History
- **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 Report Routing – 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 |

Table A-37 (Cont.) Completed Expedited Report Routing - Line Listing

| Table Heading | Column Heading | Measure |
|----------------|--|--|
| 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 | Report Routing.Report Routing User |
| Report Routing | Report Comments | Report Routing.Report Comments |

My Pending Expedited Reports – Overview

This section describes the My Pending Expedited Reports - Overview report.

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.

Audience

Case Processor

Report Type

- **Table**
- 2-D Bar Graph

Location

Personal User dashboard > Personal User Expedited Report Management page

Dimensions

Enterprise.Enterprise ID

Supplementary Prompts

None

Reports Referenced

None

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 Group |
| | | Pending Reports.Report Assigned User ID |
| Pending Reports | #Other Assigned Reports | Pending Reports.Report Assigned User ID |
| Pending Reports | # Total Reports | Enterprise.Enterprise ID |
| | | Pending Reports.Report ID |

My Assigned Expedited Reports – Line Listing

This section describes the My Assigned Expedited Reports - Line Listing report.

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

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

None

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 |
| 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 |

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

| Table Heading | Column Heading | Measure |
|-----------------|---------------------|---------------------------------------|
| 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 section describes the My Unassigned Expedited Reports - Line Listing report.

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.

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Expedited Report Management page

Dimensions

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

None

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 |

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

| Table Heading | Column Heading | Measure |
|--------------------|-------------------------------|--|
| 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 |
| 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 section describes the Other Assigned Expedited Reports - Line Listing report.

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

Audience

Case Processor

Report Type

Narrative Table

Location

Personal User dashboard > Personal User Expedited Report Management page

Dimensions

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

None

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 |
| 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-41 (Cont.) Other Assigned 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 |

Submitted Expedited Reports – Volume Overview

This section describes the Submitted Expedited Reports - Volume Overview report.

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.

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

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---------------------------------------|------------------------|--|
| 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 |

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

| Table Heading | Column Heading | Measure |
|---|-----------------------|---|
| 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 |

Submitted Expedited Reports – Volume Trend

This section describes the Submitted Expedited Reports – Volume Trend report.

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.

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

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---|------------------------|---|
| 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 |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Expedited Reports Never Submitted – Volume Trend

This section describes the Expedited Reports Never Submitted – Volume Trend report.

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.

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

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---------------|----------------------|---------------------------------------|
| 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 |

Table A-44 (Cont.) Expedited Reports Never Submitted - Volume Trend

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

Submitted Expedited Reports – Submission Compliance By User Group

This section describes the Submitted Expedited Reports - Submission Compliance By User Group report.

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.

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

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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:

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

| 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 |

Table A-45 (Cont.) Submitted Expedited Reports - Submission Compliance By User

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

Submitted Expedited Reports – Submission Compliance By Destination

This section describes the Submitted Expedited Reports - Submission Compliance By Destination report.

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.

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

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---|------------------------|---|
| 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 |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Submitted Expedited Reports – Submission Compliance Trend

This section describes the Submitted Expedited Reports – Submission Compliance Trend report.

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.

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

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---------------|----------------|----------------------------|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Cases | Follow-Up ID | Pending Cases.Follow-up ID |

Table A-47 (Cont.) Submitted Expedited Reports - Submission Compliance Trend

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

Pending Expedited Reports – Volume Overview

This section describes the Pending Expedited Reports – Volume Overview report.

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.

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

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---------------|----------------------|---------------------------------------|
| 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-48 (Cont.) Pending Expedited Reports - Volume Overview

| 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 |
| 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 Expedited Reports – Line Listing

This section describes the Pending Expedited Reports – Line Listing report.

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.

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

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

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 |
| 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 |

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

| Table Heading | Column Heading | Measure |
|-----------------|-----------------------------|--|
| 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 |

Pending Expedited Reports – Submission Compliance Overview

This section describes the Pending Expedited Reports – Submission Compliance Overview report.

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.

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

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---|------------------------|---|
| Enterprise | Enterprise ID | Enterprise.Enterprise ID |
| Case | Case ID | Case.Case ID |
| Pending Cases | Follow-Up ID | Pending Cases.Follow-up |
| 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 |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Pending Expedited Reports – Submission Compliance In Days

This section describes the Pending Expedited Reports – Submission Compliance In Days report.

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.

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

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 In Days report:

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

| 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 |

Table A-51 (Cont.) Pending Expedited Reports - Submission Compliance In Days

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

Failed/Pending ACK Expedited Reports – Volume Overview

This section describes the Failed/Pending ACK Expedited Reports - Volume Overview report.

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.

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

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---------------|----------------------|---------------------------------------|
| 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 |

Table A-52 (Cont.) Failed/Pending ACK Expedited Reports - Volume Overview

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

Failed/Pending ACK Expedited Reports - Volume Trend

This section describes the Failed/Pending ACK Expedited Reports – Volume Trend report.

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.

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

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---------------------------------------|------------------------|--|
| 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 |

Table A-53 (Cont.) Failed/Pending ACK Expedited Reports - Volume Trend

| Table Heading | Column Heading | Measure |
|---|-----------------------|---|
| 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 |

Duration Case Modified Per Version and Case – Statistical Overview

This section describes the Duration Case Modified Per Version and Case - Statistical Overview report.

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.

Audience

Executive Manager

Team Leader

Report Type

Table

Location

Case Work History dashboard > Case Modified History 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

None

Column Descriptions

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

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

| 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 |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Duration Case Modified Per State – Statistical Overview

This section describes the Duration Case Modified Per State - Statistical Overview report.

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.

Audience

Executive Manager

Team Leader

Report Type

- **Table**
- 2-D Bar Graph

Location

Case Work History dashboard > Case Modified History page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 |
|---------------|----------------------|---------------------------------------|
| 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 |

Table A-55 (Cont.) Duration Case Modified Per State - Statistical Overview

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

Duration Case Modified Per User/State – Statistical Overview

This section describes the Duration Case Modified Per User/State - Statistical Overview report.

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.

Audience

Executive Manager

Team Leader

Report Type

- Group By Pivot
- 2-D Line Graph

Location

Case Work History dashboard > Case Modified History page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group User.Pending Cases - Assigned User

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 User/State - Statistical Overview report:

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

| 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 |

Table A-56 (Cont.) Duration Case Modified Per User/State - Statistical Overview

| Table Heading | Column Heading | Measure |
|---|-----------------------|---|
| 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 |

Completed Case Version Routing – Line Listing

This section describes the Completed Case Version Routing – Line Listing report.

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

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 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

| 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 |
| 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 section describes the Duration Case Unmodified Per Version and Case - Statistical Overview report.

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.

Audience

Executive Manager

Team Leader

Report Type

Group By Table

Location

Case Work History dashboard > Case Unmodified History 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

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 |
|---------------|----------------------|---------------------------------------|
| 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 |

Table A-58 (Cont.) Duration Case Unmodified Per Version and Case - Statistical

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

Duration Case Unmodified Per State – Statistical Overview

This section describes the Duration Case Unmodified Per State - Statistical Overview report.

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

Executive Manager

Team Leader

Report Type

- **Table**
- 2-D Bar Graph

Location

Case Work History dashboard > Case Unmodified History page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 Unmodified Per State -Statistical Overview report:

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

| 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 |

Table A-59 (Cont.) Duration Case Unmodified Per State - Statistical Overview

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

Duration Case Unmodified Per User/State – Statistical Overview

This section describes the Duration Case Unmodified Per User/State - Statistical Overview report.

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.

Audience

Executive Manager

Team Leader

Report Type

- Group By Pivot
- 2-D Line Graph

Location

Case Work History dashboard > Case Unmodified History page

Dimensions

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 Unmodified Per User/State - Statistical Overview report:

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

| 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 |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Duration Case Read Per Version and Case – Statistical Overview

This section describes the Duration Case Read Per Version and Case - Statistical Overview report.

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

Executive Manager

Team Leader

Report Type

Table

Location

Case Work History dashboard > Case Read 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

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 |
|---------------|----------------|---------------------------------|
| 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 |

Table A-61 (Cont.) Duration Case Read Per Version and Case - Statistical Overview

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

Duration Case Read Per State – Statistical Overview

This section describes the Duration Case Read Per State - Statistical Overview report.

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.

Audience

Executive Manager

Team Leader

Report Type

Table

2-D Bar Graph

Location

Case Work History dashboard > Case Read History page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 Read Per State -Statistical Overview report:

Table A-62 Duration Case Read Per State - Statistical Overview

| 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 |

Table A-62 (Cont.) Duration Case Read Per State - Statistical Overview

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

Duration Case Read Per User/State – Statistical Overview

This section describes the Duration Case Read Per User/State - Statistical Overview report.

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

Executive Manager

Team Leader

Report Type

- Group By Pivot
- 2-D Line Graph

Location

Case Work History dashboard > Case Read History page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

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 Read Per User/State -Statistical Overview report:

Table A-63 Duration Case Read Per User/State - Statistical Overview

| 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 |
| Pending Cases | Routing Timestamp | Pending Cases.Routing Timestamp |
| Pending Cases | Routing Justification | Pending Cases.Routing Justification |

Duration Case Idle – Statistical Overview

This section describes the Duration Case Idle - Statistical Overview report.

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.

Audience

Executive Manager

Team Leader

Report Type

Table

Location

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

None

Column Descriptions

The following table describes the columns in the Duration Case Idle - Statistical Overview report:

Duration Case Idle - Statistical Overview Table A-64

| 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 |

Table A-64 (Cont.) Duration Case Idle - Statistical Overview

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

Duration Case Idle Per State – Statistical Overview

This section describes the Duration Case Idle Per State - Statistical Overview report.

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

Executive Manager

Team Leader

Report Type

Table

2-D Bar Graph

Location

Case Work History dashboard > Case Idle History page

Dimensions

Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

Supplementary Prompts

None

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 |
|---------------|----------------------|---------------------------------------|
| 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 |

Table A-65 (Cont.) Duration Case Idle Per State - Statistical Overview

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

Oracle Argus Analytics Presentation Catalog

The Oracle Argus Analytics Presentation Catalog displays columns that you can use to create requests.

This appendix contains the following topics:

- Dimensions in Oracle Argus Analytics Presentation Catalog
- Facts and Sources in Oracle Argus Analytics Presentation Catalog

See Also:

Chapter 3, Working with Reports

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 |

Table B-1 (Cont.) Presentation Catalog - Dimensions

| Dimension | Column | Description |
|--------------------|-------------------------------|--|
| 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 |
| 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_a bbrv | |
| 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/Liter ature etc.) | case_master.Report_type | |
| Case | Compliance Classificatio n | 7-day Case, 15-day Case, Non-Expedited Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (7-day Case, 15-day Case, Non-Expedited Case) |
| Case | S/R/U Classificatio n | SAE Case, SAR Case, SUSAR Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (SAE Case, SAR Case, SUSAR Case) |
| Case | F/LT Classificatio n | Fatal / Life-Threatening Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Fatal / Life-Threatening Case) |
| Case | Pregnancy Classificatio n | Pregnancy Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Pregnancy Case) |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|--|--|--|--|
| Case | Source Classificatio n | Authority Case, Consumer Case, Literature Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Authority Case, Consumer Case, Literature Case) |
| Case | Confirmatio n Classificatio n | Medically Confirmed Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Medically Confirmed Case) |
| Case | Case Classificatio n Group 7 | Case Classification Group 7 | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Case Classification 7) |
| Case | Case Classificatio n Group 8 | Case Classification Group 8 | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Case Classification 8) |
| Case | Case Classificatio n Group 9 | Case Classification Group 9 | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Case Classification 9) |
| Case | Case Classificatio n Group 10 | Case Classification Group 10 | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Case Classification 10) |
| Case | Product Type | Drug, Device and Vaccine | case_product.views_availab | |
| Case | Study ID | Study ID | case_study.study_num | |
| Case | Center ID | Center ID for the Study in the case | lm_centers.center_no where case_study.center_id = lm_centers.center_id | |
| Case | Case Seriousness | Case Serious or Non-Serious (Y/N) | case_assess.seriousness | |
| Case | Case Listedness | Unlisted/Unexpected/liste d/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 | |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|-------------------------------|---|--|---|
| Case | Ethnicity | Ethnicity of the Patient | case_pat_info.ethnicity_id | |
| Case | Lactation | Patient breastfeeding | case_pregnancy.breastfeedi ng | |
| Case | Primary Reporter Type | Type of the first/primary reporter (for ex., Physician, Consumer etc) | case_reporters.reporter_typ e where primary_contact = 1 | |
| Case | Primary Suspect Product | Primary Suspect Product for a case | case_product.product_nam e where case_product.first_sus_pro d = 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_owne r_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_owne r_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_date/(case_followup.receip t_date where significant = 1)) | |
| Case | Case Deletion Timestamp | Date of the case deletion | nvl(case_master.deleted, case_master.last_update_ti me) 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 | |
| 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 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|---|--|---|--|
| 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 | 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_ TRIAL LM_STUDIES.OTHER_ID LM_PRODUCTS.DRUG_C ODE | If LM_REPORT_TYP E.INCL_TRIAL = 1 then LM_STUDIES.OTH ER_ID else LM_PRODUCTS.D RUG_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 | |
| Case | Primary Indication | Primary indication (Preferred Term) for the primary suspect product | case_prod_indications.ind_ pref_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) |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|---|---|---------------------|---|
| 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 |
| 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) |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|---|---|---------------------|--|
| 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) |
| 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) |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-----------------|--|---|--|---|
| 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 | |
| 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. |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-----------------|----------------------------------|--|---|--|
| 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_dat e 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) | |
| Case Version | Clock Start Date | Case Version Aware Date | Max(case_master.init_rept_date/(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_date where lower(case_routing.comment_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 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-----------------|--|--|---------------------|--|
| 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 | 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 |
| 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-Rec eipt-To-Safet y- 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-Cre ation-To-Loc k | Interval Between Case Version Create DateTime And Case Version Lock Datetime | | days between (Version Creation Timestamp, Lock Timestamp) |
| 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-Cre ation-To-Loc k | Average Interval Between Case Version Create DateTime And Case Version Lock DateTime | | sum(Duration Version-Creation-T o-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-Cre ation-To-Loc k | Minimum Interval Between Case Version Create DateTime And Case Version Lock DateTime | | min(Duration Version-Creation-T o-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-Cre ation-To-Loc k | Maximum Interval Between Case Version Create DateTime And Case Version Lock DateTime | | max(Duration Version-Creation-T o-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 Non-Significant 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_dat e 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_date/(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_date where lower(case_routing.comment_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 | Routing User Group | User Group which worked on the workflow step | cfg_workflow_rules.group_ id where cfg_workflow_rules.seq_nu m = case_routing.workflow_seq _num | |
| Case Routing | Routing Justification | Case Routing Justification | case_routing.justification_i | |
| Case Routing | Routing ID | Workflow Sequence Number | case_routing.seq_num | |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-----------------|------------------------------------|--|--|--|
| Case Routing | State Routed From | Workflow state from which case was promoted to next workflow state | cfg_workflow_states.state_ name where case_routing.fr_state_id = cfg_workflow_states.state_i d | |
| Case Routing | State Routed To | Workflow state to which case was promoted from previous workflow state | cfg_workflow_states.state_ name where case_routing.to_state_id = cfg_workflow_states.state_i d | |
| 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_num) |
| 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.recei pt_date (Case_Master.init_r ept_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.safet y_date (Case_Master.safety _date for Initial case version) |
| Case Workflow State | Clock Start Date | Case Version Aware Date | Max(case_master.init_rept_date/(case_followup.receip t_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_ date where lower(case_routing.comment_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_ date where case_routing.comm ent_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 | 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 | | |
| 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 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|--|---|---------------------|--|
| 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-T o-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-Cre ation-To-Stat e- 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 |
| Case Workflow State | Average Duration State-Start-T o-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 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|---|---|---------------------|---|
| Case Workflow State | Average Duration Version-Cre ation-To-Stat e- End | Average Time Taken To Accomplish A Workflow State After A Case Version Was Created (Including Any Repetition) | N/A | total(Duration Version-Creation-T o-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 read-only 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) |
| Case Workflow State | Min Duration Case Read Per State | Minimum time spent in each workflow state (across all users) for work done in read-only 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) |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------|---|--|---------------------|---|
| Case Workflow State | Max Duration Case Read Per State | Maximum time spent in each workflow state (across all users) for work done in read-only 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 |
| 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 -> 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. |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-----------|----------------------------------|--|--|---|
| 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 Date Time Significant: If there is atleast 1 significant followup between two Version Lock Date Time Non-Significant: If there is followup but no significant followup between two Version Lock Date Time Non-Significant followup but no significant followup between two Version Lock Date Time |
| 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.recei pt_date (Case_Master.init_r ept_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.safet y_date (Case_Master.safety _date for Initial case version) |
| Case Work | Clock Start Date | Case Version Aware Date | Max(case_master.init_rept_date/(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_ti me) where nvl(case_master.state_id, 0) = 1 or case_master.deleted is not null | |
| 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_ date where lower(case_routing. comment_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_ date where case_routing.comm ent_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 | 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 | 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 | |
| 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_ST ATE_ID | |
| Case Work | Routing ID | | | |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------|----------------------------------|--|---|---|
| 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. |
| 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 Date Time Significant: If there is atleast 1 significant followup between two Version Lock Date Time Non-Significant: If there is followup but no significant followup between two Version Lock Date Time |
| 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.recei pt_date (Case_Master.init_r ept_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.safet y_date (Case_Master.safety _date for Initial case version) |
| Case Work User | Clock Start Date | Case Version Aware Date | Max(case_master.init_rept_date/(case_followup.receip t_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_ date where lower(case_routing.comment_text) like 'case unlocked%' 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 Timestamp | Case is ready for submission. First lock date of the case version. | case_routing.route_date | case_routing.route_ date where case_routing.comm ent_text like 'case locked%' or case_routing.to_stat e_id = 2 |
| 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 | Workflow State At Case Open | Internal Due Date For Locking A Case (Case Processing Completion) | USER_CASE_PROCESSIN G_TIME.WORKFLOW_ST ATE_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 |
| 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 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------|--|--|---------------------|--|
| 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) where 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 |
| 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 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|--|--|---------------------|--|
| 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 |
| 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 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|----------------------------------|--|--|---|
| 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.recei pt_date (Case_Master.init_r ept_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.safet y_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_date where lower(case_routing.comment_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_ date where case_routing.comm ent_text like 'case locked%' or case_routing.to_stat e_id = 2 |
| 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 | 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 | |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|--|---|---|---|
| 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.COUNTR Y_ID LM_REGULATORY_CONT ACT.COUNTRY | Domestic if CASE_MASTER.C OUNTRY_ID = (SELECT COUNTRY FROM LM_REGULATOR Y_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 | |
| Expedited Submission | Report Timeframe | Timeframe when the report is due. This field specifies the report's scheduled due-date 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_i | |
| Expedited Submission | Report Nullification Indicator | A flag to identify nullified reports | cmn_reg_reports.nullificati on_reason | If cmn_reg_reports.nu llification = 1 then 'Yes' else 'No' |
| Expedited Submission | Report Nullification Reason | Reason for report nullification | cmn_reg_reports.nullificati on_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 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|--|--|------------------------------------|--|
| Expedited Submission | Report Submission Timestamp | Date on which submission was sent to the agency | cmn_reg_reports.date_sub mitted | |
| Expedited Submission | Report Schedule Timestamp | Date on which report got scheduled | cmn_reg_reports.date_sche duled | |
| Expedited Submission | Report Generation Timestamp | Report Generation Date | cmn_reg_reports.date_gene rated | |
| 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_n otes | |
| 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_ num | DECODE (cmn_reg_reports.fo llowup_num, 0, 'Initial', 'F/U #' cmn_reg_reports.fol lowup_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.da te_submitted is not null and ((cmn_reg_reports.r eport_form_id <> 27) or (SAFETYREPORT.R EPORTACKNOWL EDGMENT.REPOR TACKNOWLEDG MENTCODE in ("1","01") and (cmn_reg_reports.re port_form_id = 27)) Deleted: cmn_reg_reports.de leted is not null No Submission Required: cmn_reg_reports.su bmit_required = 0 and cmn_reg_reports.de leted is null Failed / Pending ACK: cmn_reg_reports.da te_submitted is not null and SAFETYREPORT.R EPORTACKNOWL EDGMENT.REPOR TACKNOWLEDG MENTCODE not in ("1","01") and cmn_reg_reports.re port_form_id = 27 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|--|--|---|---|
| Expedited Submission | Report Downgrade Indicator | A flag to identify downgrade reports | cmn_reg_reports.submit_n otes | If cmn_reg_reports.su bmit_notes like '*Downgrade*%' then 'Yes' else 'No' |
| Expedited Submission | Report Deletion Timestamp | Date when report is deleted | cmn_reg_reports.deleted | |
| Expedited Submission | Report No Submission Required Timestamp | Date that non-submission of report was determined | cmn_reg_reports.date_sub mission_determined | |
| Expedited Submission | Report No Submission Required Reason | Reason if submission is not required | cmn_reg_reports.non_subm it_reason | |
| Expedited Submission | Report Submission User Site | Site of the person submitting the case to the destination | lm_sites.site_desc where lm_sites.site_id = cfg_users.site_id where cmn_reg_reports.owner_id = cfg_users.user_id | |
| Expedited Submission | ACK Timestamp | Report acknowledgement timestamp - timestamp when outgoing E2B report is accepted / rejected by recipient's database | messages.acknowledgment header.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_COMPLET E_DATE where MESSAGES.EDI_TRACKIN G_ID = EDI_INFO.EDI_TRACKIN G_ID and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_repor t_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_TRANSMITTED where safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_repor t_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_TRANSMI T_DATE where MESSAGES.EDI_TRACKIN G_ID = EDI_INFO.EDI_TRACKIN G_ID and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_repor t_id = safetyreport.report_id | |

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_s tatus_type_cd in (4,10) and cfg_sender.transmission_m ethod = 2) then 'Failure' If (esm_ae_status_lkup.esm_s tatus_type_cd = 5 and messages.acknowledgment header.transmissionacknow ledgmentcode in ('01', '02', '1', '2')) then If safetyreport.reportacknowledgment.reportacknowledgmentcode in ('02', '2') then 'Failure' If safetyreport.reportacknowledgmentcode in ('01', '1') and safetyreport.reportacknowledgmentcode in ('01', '1') and safetyreport.reportacknowledgment.srormessagecom ment is not null then 'Warnings' If safetyreport.reportacknowledgmentcode 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.E SM_STATUS_TYPE_CD = MESSAGES.STATUS and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_repor t_id = safetyreport.report_id | |
| Expedited Submission | MDN Status | Values - Success, Pending, Failure, Not Applicable | If cfg_sender.transmission_m ethod = 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.E SM_STATUS_TYPE_CD = MESSAGES.STATUS and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_repor t_id = safetyreport.report_id | |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|---|--|--|--|
| 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 (2,3,4,5,10,11,12,13,14,15,17, 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.E SM_STATUS_TYPE_CD = MESSAGES.STATUS and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_repor t_id = safetyreport.report_id | |
| Expedited Submission | EDI Out Status | Values - Success, Pending, Failure, Not Applicable | If cfg_sender.transmission_m ethod = 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.E SM_STATUS_TYPE_CD = MESSAGES.STATUS and safetyreport.msg_id = messages.msg_id and cmn_reg_reports.esm_repor t_id = safetyreport.report_id | |
| Expedited Submission | ACK Comments | Acknowledgement comments received from the receiver | SAFETYREPORT.REPORT ACKNOWLEDGMENT.ER RORMESSAGECOMMENT | |
| Expedited Submission | Duration Clock-Start- Date-To-Sub mission | 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-Loc k-To-Submis sion | 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-Gene ration-To-Su bmission | Interval between Report Generation Date and Report Submission / MDN Timestamp | N/A | days between (Report Submission / MDN Timestamp, Report Generation Date) |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|--|--|---------------------|---|
| Expedited Submission | Duration Report-Sche dule-To-Sub mission | 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-Gene ration-To-Su bmission | 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-Sche dule-To-Sub mission | Average duration between Report Schedule Date and Report Submission Date | N/A | Sum(Duration Report-Schedule-To -Submission)/# Reports Submitted |
| Expedited Submission | Min Duration Report-Gene ration-To-Su bmission | Minimum duration between Report Generation Date and Report Submission Date | N/A | Minimum(Duration Report-Generation- To-Submission) |
| Expedited Submission | Min Duration Report-Sche dule-To-Sub mission | Minimum duration between Report Schedule Date and Report Submission Date | N/A | Minimum(Duration Report-Schedule-To -Submission) |
| Expedited Submission | Max Duration Report-Gene ration-To-Su bmission | Maximum duration between Report Generation Date and Report Submission Date | N/A | Maximum(Duration Report-Generation- To-Submission) |
| Expedited Submission | Max Duration Report-Sche dule-To-Sub mission | 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 |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|---|--|---------------------|---|
| 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 |
| 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' |

Table B-2 (Cont.) Presentation Catalog - Facts

| Fact | Column | Description | Source Table/Column | Comments/Details |
|-------------------------|--|--|---|--|
| Expedited Submission | # Reports Downgrade d | 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.JUS TIFICATION WHERE JUSTIFICATION_ID = RPT_ROUTING.JUSTIFICA TION_ID AND LM_JUSTIFICATIONS.FIE LD_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_st ate_id = CFG_RPT_WF_STATES.RE PORT_STATE_ID | |
| 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_st ate_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.comme nt_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_a bbrv | |
| 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/Liter ature etc.) | case_master.Report_type | |
| Case | Compliance Classificatio n | 7-day Case, 15-day Case, Non-Expedited Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (7-day Case, 15-day Case, Non-Expedited Case) |
| Case | S/R/U Classificatio n | SAE Case, SAR Case, SUSAR Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (SAE Case, SAR Case, SUSAR Case) |
| Case | F/LT Classificatio n | Fatal / Life-Threatening Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Fatal / Life-Threatening Case) |
| Case | Pregnancy Classificatio n | Pregnancy Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Pregnancy Case) |
| Case | Source Classificatio n | Authority Case, Consumer Case, Literature Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Authority Case, Consumer Case, Literature Case) |

Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------|--|---|--|--|
| Case | Confirmatio n Classificatio n | Medically Confirmed Case | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Medically Confirmed Case) |
| Case | Case Classificatio n Group 7 | Case Classification Group 7 | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Case Classification 7) |
| Case | Case Classificatio n Group 8 | Case Classification Group 8 | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Case Classification 8) |
| Case | Case Classificatio n Group 9 | Case Classification Group 9 | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Case Classification 9) |
| Case | Case Classificatio n Group 10 | Case Classification Group 10 | lm_case_classification.descr iption | where lm_case_classificati on.description has values in (Case Classification 10) |
| Case | Product Type | Drug, Device and Vaccine | case_product.views_availab le | |
| Case | Study ID | Study ID | case_study.study_num | |
| Case | Center ID | Center ID for the Study in the case | lm_centers.center_no where case_study.center_id = lm_centers.center_id | |
| Case | Case Seriousness | Case Serious or Non-Serious (Y/N) | case_assess.seriousness | |
| Case | Case Listedness | Unlisted/Unexpected/liste d/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.breastfeedi ng | |
| Case | Primary Reporter Type | Type of the first/primary reporter (for ex., Physician, Consumer etc) | case_reporters.reporter_typ e where primary_contact = 1 | |

Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|------------------|-------------------------------|---|---|--|
| Case | Primary Suspect Product | Primary Suspect Product for a case | case_product.product_nam e where case_product.first_sus_pro d = 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 | 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_date/(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_owne r_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_owne r_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_ TRIAL LM_STUDIES.OTHER_ID LM_PRODUCTS.DRUG_C ODE | If LM_REPORT_TYP E.INCL_TRIAL = 1 then LM_STUDIES.OTH ER_ID, else LM_PRODUCTS.D RUG_CODE for Primary Suspect Product |
| Pending Cases | Follow-up ID | Latest Case Follow-up # (0,1,2,3) | case_routing.followup_nu m | 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.Sign ificant = 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 Was Received. If There Is No Followup Then Followup Receipt 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_i | |
| 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_nu m = 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 | # Days Case Open | Number of days elapsed since aware date (Clock Start Date) of the case | NVL(TRUNC(SYSDATE) - TRUNC(Max(case_master.i nit_rept_date/(case_follow up.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. due_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 _num, 0, 'Initial', 'F/U #' cmn_reg_reports.followup_ num) | |
| Pending Expedited Reports | Regulatory Report Type | Report Form ID | cmn_reg_reports.report_for m_id | |
| Pending Expedited Reports | Report 7/15 Timeframe | Timeframe when the report is due. This field specifies the report's scheduled due-date 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.C OUNTRY_ID = (SELECT COUNTRY FROM LM_REGULATOR Y_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 | |

Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------------|-----------------------------------|---|--|--|
| 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) |
| Pending Expedited Reports | Report On-Time Indicator | Report submission on-time indicator. The values here are Red, Yellow and Green. Green: when Report Due | | Green: count(Number of records from Pending Expedited Reports) where |
| | | Soon Date has not elapsed Yellow: when no. of days remaining for report submission are less than or equal to the no. of due soon days configured in the PVA | | sysdate <= Report Due Soon Date Yellow: count(Number of records from |
| | | Red: when Report Due Date has elapsed | | Pending Expedited Reports) where sysdate > Report Due Soon Date and sysdate <= Report Due Date |
| | | | | Red: 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_sche duled | |
| Pending Expedited Reports | Report Generation Timestamp | Report Generation Date | cmn_reg_reports.date_gene rated | |
| 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_n otes 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 |

Table B-3 (Cont.) Presentation Catalog - Oracle Argus Safety Sources

| Fact | Column | Description | Source Table/Column | Comments/Details |
|---------------------------------|--|--|---------------------|--|
| 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 Downgrade d | Total number of downgraded reports | N/A | count(Report Downgrade Indicator) where Report Downgrade Indicator = 'Yes' |
| 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 gubmitted by the inernal countries of t | N/A | where Report On-Time Indicator is Green |
| | | submitted by the inernal due soon date] | | |
| 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) | N/A | where Report On-Time Indicator is Yellow |
| | | [Number of reports due soon for submission] | | |
| 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 |

Troubleshooting

This appendix contains troubleshooting tips in handling the following scenarios:

- Verify whether the DAC client is able to use Informatica commands
- Unable to run Informatica Workflow from DAC
- Aborting a Workflow
- Unable to Sign In to Oracle Argus Analytics

Verify whether the DAC client is able to use Informatica commands

Perform these steps to ensure whether the DAC client is able to use the Informatica commands properly:

- 1. From the machine where the DAC client is installed, open a windows command prompt.
- **2.** Execute *pmrep* and *pmcmd*.
- If the above steps work without any errors, it means that the DAC client can invoke Informatica commands properly.

What If Informatica commands are not recognized?

Perform the following steps if Informatica commands are not recognized:

- Verify that the INFA_DOMAINS_FILE variable points to the domains.infa file located in the Informatica directory (such as D:\Informatica\9.0.1\clients\PowerCenterClient\domains.infa).
- Verify that the PATH variable includes the path to the Informatica binaries (such
 - D:\Informatica\9.0.1\clients\PowerCenterClient\CommandLineUtilities\PC\ser ver\bin), and that pmrep.exe and pmcmd.exe exist in the \bin folder.
- **3.** Ensure that Hotfix2 has been applied to Informatica PowerCenter 9.0.1.

Unable to run Informatica Workflow from DAC

Make sure that the user provided to run Informatica mapping has 'Execute' permission on the mapping in the respective folder.

Steps to check whether the User has 'Execute' permission:

Perform the following steps to check if the user has 'Execute' permissions:

- 1. Log in to the Informatica Administrator's Console as the user whose permission credentials are to be checked.
- **2.** Go to the Security tab and select the Users box, on the left side of the window.
- Click the Domains, on the right side of to check the permission level assigned to the user.

Aborting a Workflow

A workflow can be aborted by the following two methods:

Method 1

Perform the following steps in DAC to abort a workflow:

- Navigate to Execute > Execution Plan sub tab.
- Click the Execution Plan you want to abort.
- Click Abort. 3.

Method 2

Perform the following steps in Informatica PowerCenter to abort a workflow:

- 1. Open the Informatica PowerCenter Workflow Monitor.
- In the Repositories tree, navigate to the particular folder that contains the Informatica job.
- In the Workflow Run pane, select and right-click the workflow, and click **Abort**.

Method 3

A task/workflow can also be aborted through the Informatica commandline options. Execute the following Informatica commands to abort a workflow:

Informatica command to stop a task:

pmcmd aborttask -s \$server name -u \$user name -p \$pass -f \$folder -w \$wkf \$sess

Informatica command to stop a workflow:

pmcmd abortworkflow -s \$server_name -u \$user_name -p \$pass -f \$folder \$wkf

See Also:

Informatica PowerCenter Online Help

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 OBIEE components.

Enter the \oracle\fmw\instances\instance1\bin> opmnctl status command to view the status of each component in OBIEE.

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