Oracle® Health Sciences Pharmacovigilance Operational Analytics

User and Administrator Guide

Release 1.0

E23554-01

September 2011

ORACLE®

Oracle Health Sciences Pharmacovigilance Operational Analytics User and Administrator Guide, Release 1.0

E23554-01

Contents

Preface

This guide provides information about how to use and administer Oracle Pharmacovigilance Operational Analytics (OPVA).

This preface contains the following topics:

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 Warehouse Administration Console.
- Knowledge of Informatica PowerCenter.
- 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 Pharmacovigilance Operational 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 documentation set*
- *Oracle Business Intelligence Enterprise Edition Release 11.1.1.5 documentation set*
- *Oracle Business Intelligence Data Warehouse Administration Console 10.1.3.4.1 documentation set*

Oracle Clinical Documentation

The Oracle Clinical documentation set includes:

- *Oracle Argus Safety 7.0 Administrator's Guide* (E20621-01)
- *Oracle Argus Safety 7.0 User's Guide* (E20623-01)
- *Oracle Argus Safety 7.0 Installation Guide* (E20622-01)

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 Health Sciences Pharmacovigilance Operational Analytics

This part of the Oracle Health Sciences Pharmacovigilance Operational Analytics (OPVA) User and Administrator Guide describes how to use this product.

Part I contains the following chapters:

1

Getting Started with OPVA

This chapter contains the following topics:

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 Pharmacovigilance Operational Analytics (OPVA) 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 Health Sciences Pharmacovigilance Operational Analytics (OPVA) 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. OPVA 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.

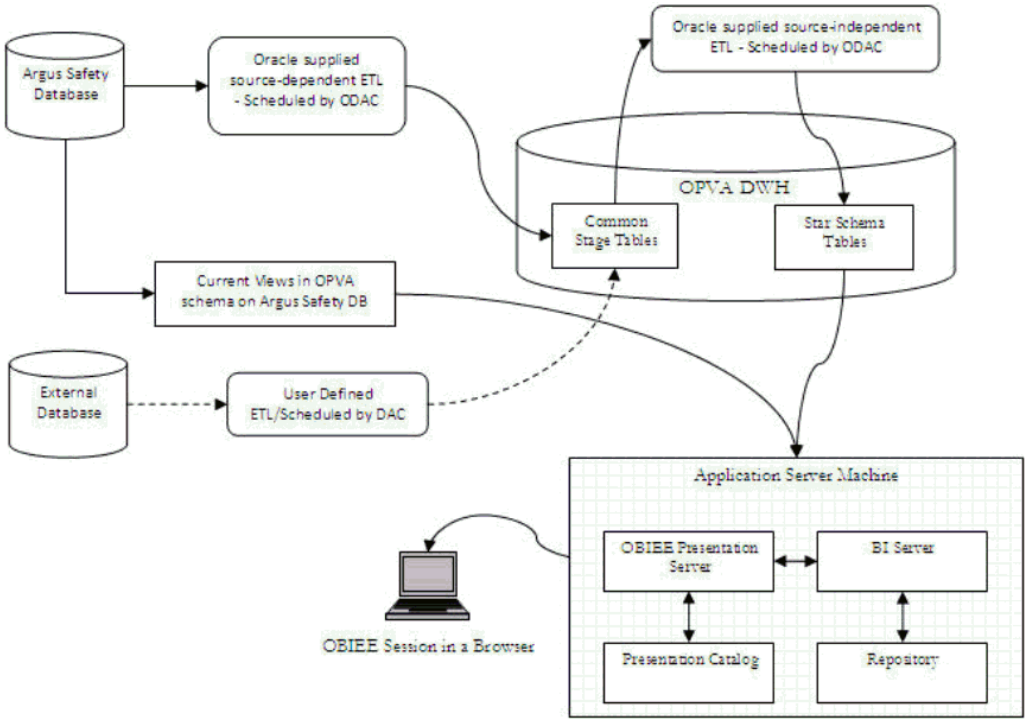
What Can I Do Using Oracle Health Sciences Pharmacovigilance Operational Analytics?

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

- Extract all necessary drug safety data from Oracle Argus Safety into a predefined data warehouse, 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 Health Sciences Pharmacovigilance Operational Analytics Architecture



The OPVA 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

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

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

- Case Version Metrics Reports answer questions related to the volume of cases, and the time taken to complete a case, at case version level.
- Case Routing History Reports answer 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 Reports answer 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.

Current Metrics Reports include the following type of reports:

- Pending Cases Report will answer questions related to pending on-time, due soon and overdue cases.

See Also:

- Chapter 2, Using OPVA
- Chapter 3, Working with Reports
- Appendix A, Dashboards and Reports

Regulatory Compliance

OPVA 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 to manage ETL versions.

Executing the ETLs

Execution of the ETLs is controlled by Oracle Data warehouse Administration Console (DAC). You can create users and set the roles for various accessibility in DAC. Please refer to the DAC Administration and User Guides for more information.

Security

Data within the data warehouse 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

2

Using OPVA

This chapter contains the following topics:

> **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

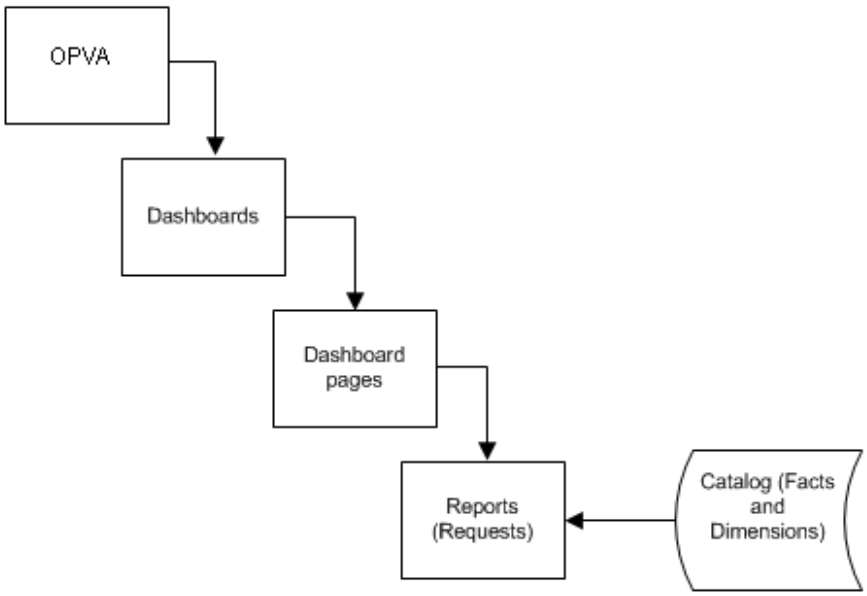
OPVA includes dashboards, reports, and metrics that let you view relevant, interactive information—current as at the last date the data warehouse was refreshed. It also includes dashboards and reports to access the run-time data.

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

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

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

Figure 2–1 The Report Hierarchy



In addition to the dashboards and reports that are packaged with OPVA, 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 OPVA. These include Oracle BI Agents and Oracle BI Publisher. These applications extend the usefulness of the information provided by OPVA.

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, OPVA Presentation Catalog for more information about the columns in OPVA that you can use to create and modify reports.
- *Oracle Business Intelligence Administrator Guide and User Guide*.

Accessing Oracle Health Sciences Pharmacovigilance Operational Analytics

Your security privileges determine what reports you can see and what you can do in OPVA.

Viewing a Dashboard

Perform the following steps to view a dashboard:

1. Log in to OPVA.
2. Click the Dashboard drop-down menu and select the relevant dashboard.

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 OPVA, 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 OPVA Installation Guide.

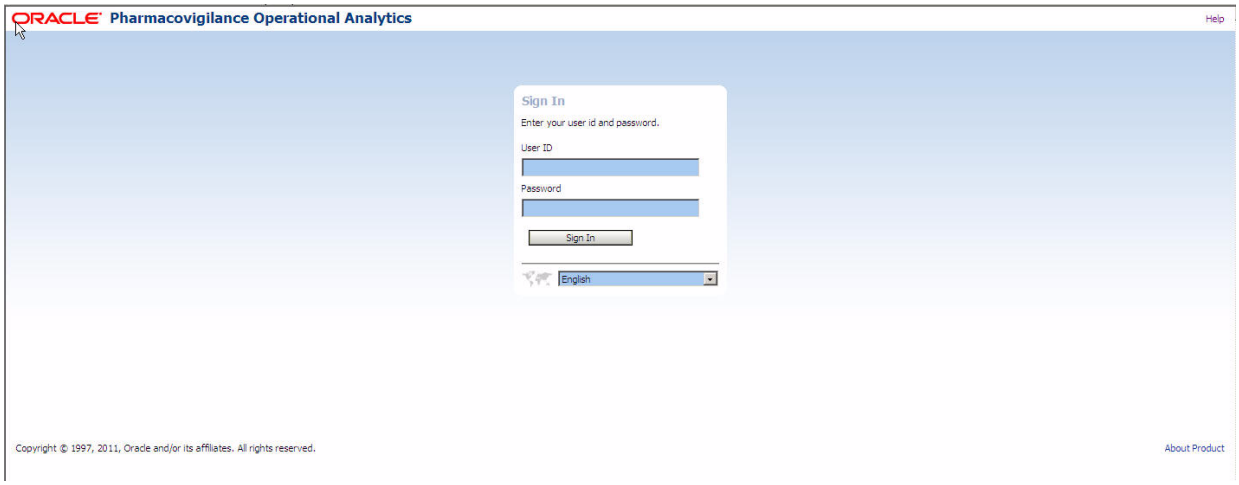
1. Open your browser and enter the URL provided by your company.

   Typically, the URL to access the dashboards will be

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

   Figure 2-2 displays the OPVA login page.

Figure 2–2 Oracle Health Sciences Pharmacovigilance Operational Analytics Login Page



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

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

Working with Oracle Business Intelligence

In the Oracle 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 OPVA-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

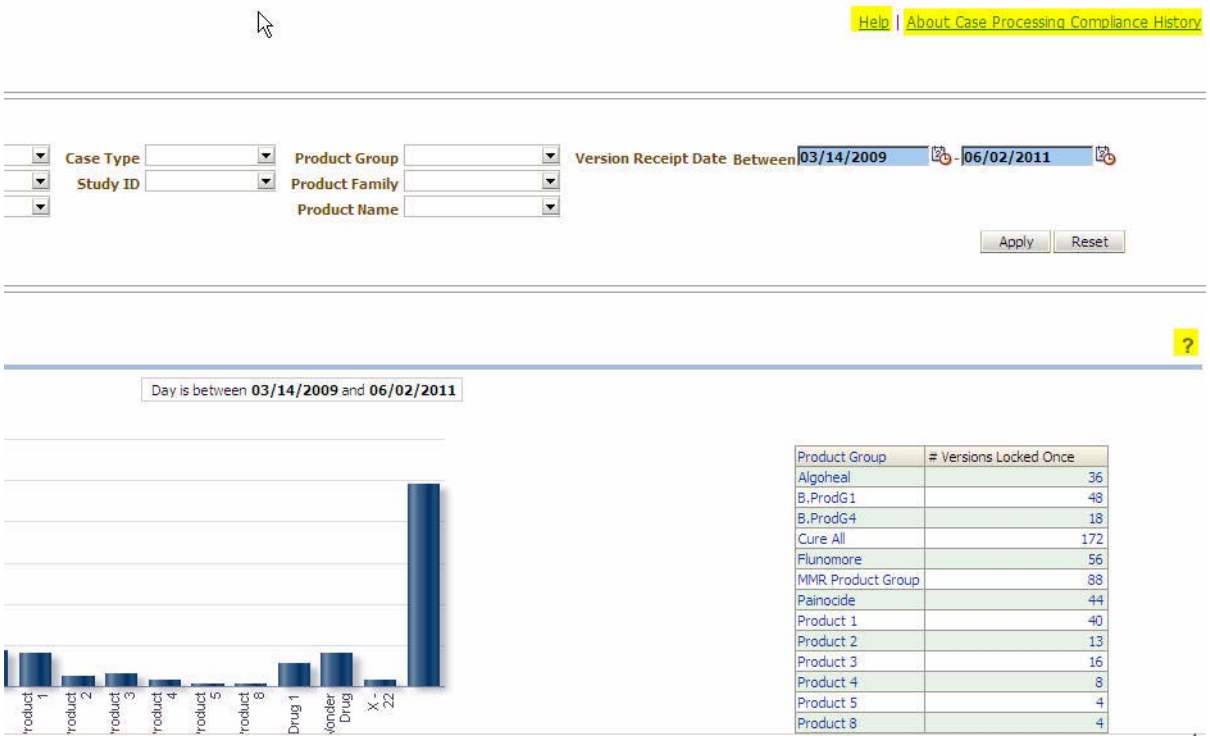


Table 2–1 Accessing Online Help

Name of Help Link	Clicking on this link...
Help	Opens the entire Help system, in an online book format.
<Name of Dashboard/Page-specific Help>	Re-directs to the description about the specific <Dashboard/Page>.
?	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

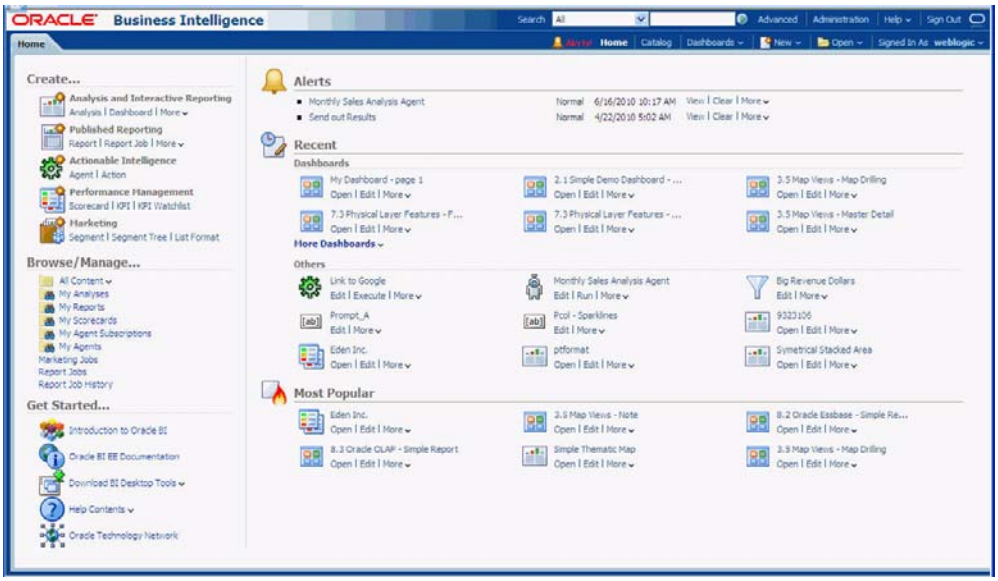
From the Home page, you can learn how to get started with OBIEE, create and modify objects, and browse and manage objects in the catalog. After you have accessed the starting point of a task, the interface then presents you with the page, dialog, or editor that you use to perform the task.

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.

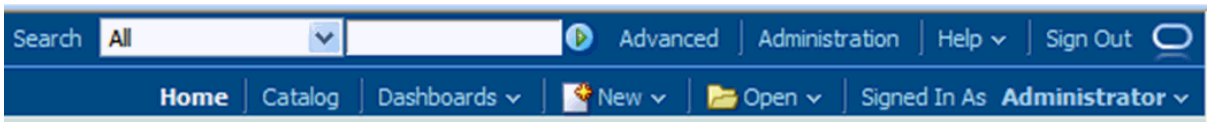


What is the OBIEE Global Header?

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 user.

Setting Preferences

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

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

Steps to Set Preferences

Execute the following steps to set preferences:

1. In the global header, click **Signed In As <username>** and select **My Account**. The My Account dialog is displayed.
2. Complete the appropriate settings.
3. 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.
  3. The **File Download** dialog opens. Click **Open** or **Save** in the File Download dialog.
  4. Based on the user action, the result would either open 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.
  3. The **File Download** dialog opens. Click **Open** or **Save** in the File Download dialog.
  4. Based on the user action, the result would either open as an Excel sheet (if Microsoft Excel is available in the machine) or will proceed with the Save.

- **Exporting to Microsoft Powerpoint**

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

  Execute the following steps:

  1. Click **Export**.
  2. Select the **Powerpoint** option.
  3. Select from one of the secondary options: **Powerpoint 2003** or Powerpoint 2007+.

4. The **File Download** dialog opens. Click **Open** or **Save** in the File Download dialog.
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.
  3. The **File Download** dialog opens. Click **Open** or **Save** in the File Download dialog.
  4. Based on the user action, the result would either open as an MHT file or will proceed with the Save.

- **Exporting the results in Data Format**

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

  Execute the following steps:

  1. Click **Export**.
  2. Select the **Data** option.
  3. Select the **CSV** sub-option.
  4. The **File Download** dialog opens. Click **Open** or **Save** in the File Download dialog.
  5. 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:

1. 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.
7. Click **OK**.
8. 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:

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

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

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

Emailing an Oracle 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:

1. Navigate to the dashboard page or request that you want to send.
2. 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.

3

Working with Reports

Using Oracle BI Analysis, you can run or display predefined reports (delivered with OPVA), and you can also create or modify custom reports.

This chapter contains the following topics:

Pre-defined Reports

OPVA 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 OPVA for more information about report-related tasks.
- Appendix A, Dashboards and Reports for more information about predefined reports.
- *Oracle Health Sciences Pharmacovigilance Operational Analytics Installation Guide* for instructions on installing OPVA.

Opening and Using Dashboards

Perform the following steps to open and use dashboards:

1. In the global header, click **Catalog** to view the Catalog page.
2. Navigate to the dashboard and click the **Open** link. The dashboard is opened to the first Dashboard Page. If no content has been added, an Empty Dashboard Page notification message is displayed.
3. This is an optional step - You may choose to perform any of the following tasks:
   a. Display the dashboard in the Dashboard Builder for editing.
   b. Navigate among dashboard page by clicking the page tabs.
   c. Print a page.
   d. 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 OPVA 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 OPVA Administrators group.
- Limit the right to place requests onto shared dashboards to members of the OPVA 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:

1. On your device, go to iTunes, and search the App Store for 'Oracle'.
2. 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 Health Sciences Pharmacovigilance Operational Analytics.

Part II contains the following chapters:

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

4

Extract Transform Load Programs

This chapter contains the following topics:

To load data from the source systems to the data warehouse, OPVA uses Extract Transform and Load (ETL) programs that

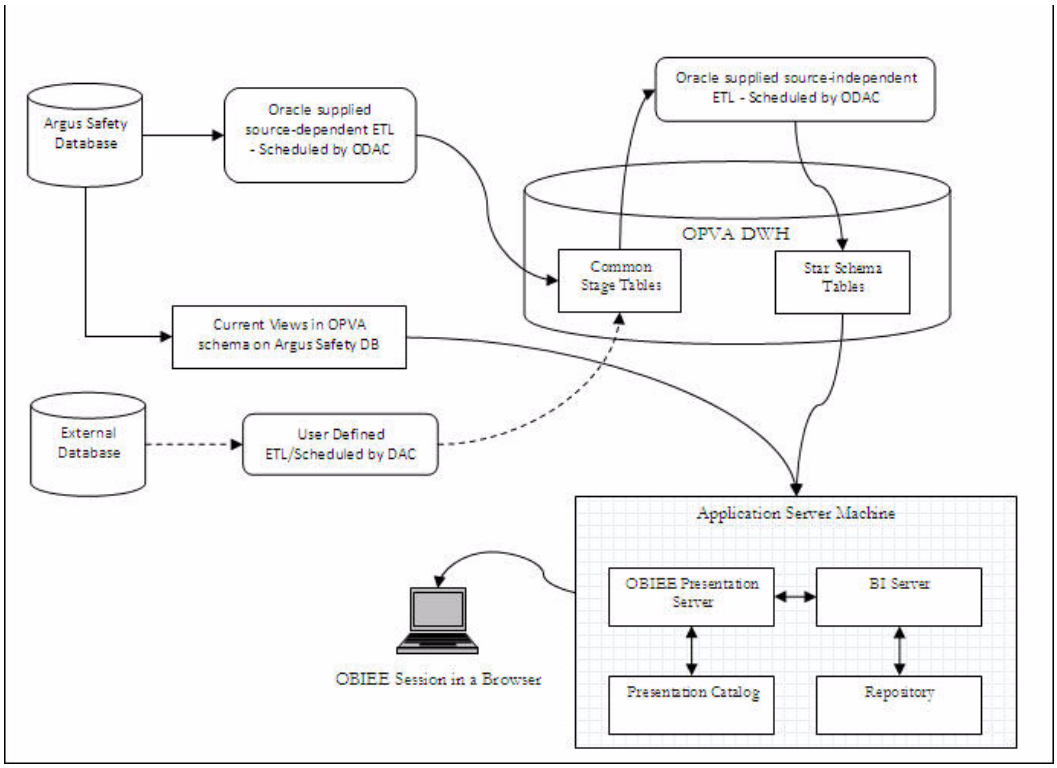
- Identify and read desired data from different data source systems,
- Clean and format data uniformly, and
- Write it to the target data warehouse.

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

ETL Architecture

Figure 5-1 displays the ETL process delivered with OPVA.

Figure 4–1 The OPVA ETL Architecture



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

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

The staged data is transformed using the source-independent loads (SILs) to star-schema tables, where such data are organized for efficient query by the Oracle BI Server.

There is one SDE mapping for each target table, which extracts data from the source system and loads it to the staging tables. SDEs have the following features:

- Incremental submission mode: OPVA-supplied ETL uses timestamps and journal tables in the source transactional system to optimize periodic loads.
- Bulk and normal load: *Bulk load* uses block transfers to expedite loading of large data volume. It is intended for use during initial data warehouse 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 warehouse, 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.
2. Navigate to the Mappings subtab and select '**Bulk/Normal**' under Target Load type.
3. Save the workflow.

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

- Concerning changes to dimension values over time, OPVA overwrites old values with new ones. This strategy is termed as *Slowly Changing Dimension approach 1*.
- OPVA'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.
- The results of each ETL execution is logged by Informatica. The logs hold information about errors encountered, during execution.

  Informatica provides the following four error tables:

  – PMERR_DATA

  – PMERR_MSG

  – PMERR_SESS

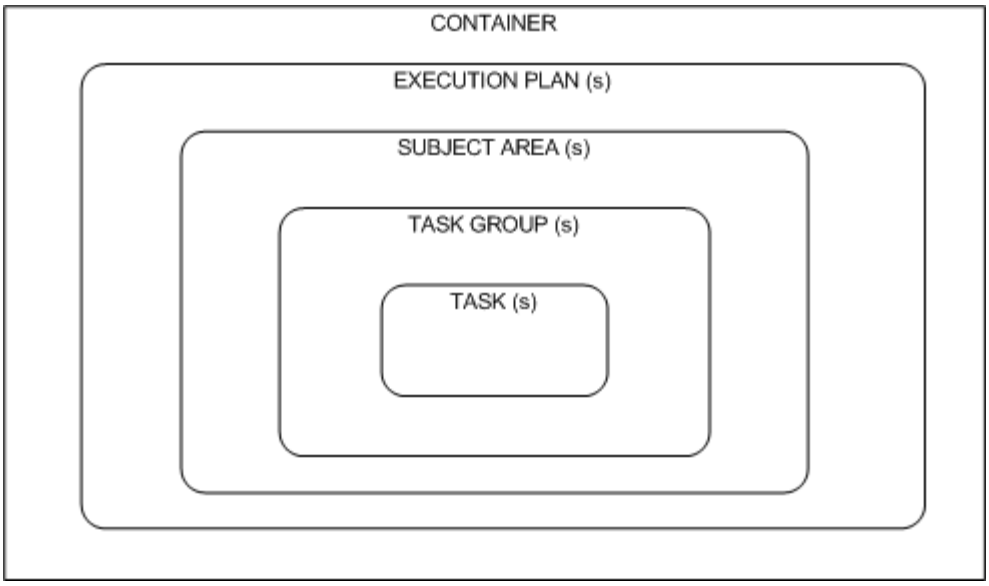
  – PMERR_TRANS

  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. You can review which records did not make it into the data warehouse, and decide on appropriate action with respect to them.

Oracle Health Sciences Pharmacovigilance Operational Analytics Hierarchy

Figure 5-2 displays the OPVA hierarchy:

Figure 4–2 OPVA Hierarchy



Following is the OPVA hierarchy:

- CONTAINER (OPVA_Datawarehouse) - A single container that holds all objects used for OPVA.
- EXECUTION PLAN (OPVA Data Warehouse 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 warehouse 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.

Executing the ETL Execution Plans

To load data from the source to their target tables in the data warehouse, run the Execution Plan packaged with OPVA. Perform the following tasks in DAC:

1. Navigate to the **Execute** view.
2. Select **OPVA Warehouse** execution plan.
3. Set the parameter values under the **Parameter** tab.
4. Build the execution plan.
5. Click **Run**.

Note: The p_last_extract_date parameter provides information about the last time the ETL was performed.

Customizing an ETL Execution Plan

When you customize an ETL Execution Plan, it is your responsibility to maintain version control over changes to ETL mappings.

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.

Creating an ETL Execution Plan

Though OPVA includes ETL Execution Plans for extracting data from Oracle Argus Safety to OPVA data warehouse, 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. If you want to add your own data sources, set this value to a number greater than 100.

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 table, perform the following tasks:

1. Create the new source and target table metadata inside Informatica.
2. Work in Informatica PowerCenter and create the ETL components (transformation or workflow) for this program.
3. Create the required workflow for this mapping.
4. Connect to DAC and create a new task for this new mapping.
5. Synchronize the task.
6. Add the task to subject area.
7. Build the Execution Plan (OPVA Data Warehouse Load).

Modifying an ETL Execution Plan

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:

1. Identify the Execution Plan that needs to be modified in Informatica repository.
2. Open and Modify the ETLs (transformation and/or workflow).
3. Test and save the changes in repository.

4. Connect to DAC and navigate to the corresponding task.
5. Right-click the task and synchronize it.
6. Navigate to the execution plan and execute ETL to verify the changes.

> **Note:** The ETL Execution Plans that extract data for the warehouse 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, OPVA ETL workflows ensure this interlock by executing the ETL for related dimensions immediately before running the ETL for a fact. This is standard warehouse 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.

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

1. Change the table properties as needed.
2. Save the mapping and refresh the workflow.
3. 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 warehouse 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.

Scheduling an ETL Execution Plan

When you submit a Execution Plan for execution in DAC, you can schedule it execute at regular intervals. To schedule a Execution Plan, perform the following tasks:

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

Customizable User Exits in OPVA ETLs

The opvaUtilCustomisableValues package can be used to customize some of the attribute values used in OPVA per the organizations requirement. It is called during the ETL executions for the Case Version Fact table present in the Retrospective Metrics and also in the source code for the view Pending Cases Fact present in the Current Metrics of OPVA.

It is available in the OPVA_SRC schema created on the Argus Safety DB Instance specified during OPVA Installation.

The package contains two functions:

1. fgetDefaultSeriousTgtDayValues

   This function, by default installation of OPVA, will return a value of 10 days for a SERIOUS case and 30 days if the case is not, per enterprise present. It can be modified as per the needs of the organization accordingly.

Table 4–1 OPVA 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 in OPVA Presentation Catalog for the other attributes that are dependent on the attributes mentioned in the above table.

2. fgetDefaultDueSoonValue

   This function, by default installation of OPVA, will return a value of 2 days for the attributes mentioned below, per enterprise present. It can be modified as per the needs of the organization accordingly.

Table 4–2 OPVA 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 in OPVA Presentation Catalog for the other attributes that are dependent on the attributes mentioned in the above table.

5

Maintaining the Repository and Warehouse

This chapter contains the following topics:

Maintaining the Oracle Health Sciences Pharmacovigilance Operational Analytics Repository

Each release of Oracle Health Sciences Pharmacovigilance Operational Analytics (OPVA) 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 warehouse to the Presentation Layer, which holds the columns and tables available for use in OBIEE Requests. As shipped, the RPD corresponds to the OPVA data warehouse, and can be used without any modification.

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

- You want to add a column or table to the data warehouse, 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 OPVA. 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 OPVA 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 OPVA 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 OPVA Repository directly.

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

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

Maintaining the Oracle Health Sciences Pharmacovigilance Operational Analytics Data Warehouse

You may need to modify the OPVA data warehouse, 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 OPVA.
- *Substitution*: Swapping data from a different source for a column that was delivered with OPVA.

Caution: Exercise caution when you modify the data warehouse. 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. OPVA 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 warehouse.

  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 warehouse.

Example: 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 warehouse 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:

1. 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 Warehouse Administration Console (DAC):

   a. Duplicate the container in DAC (to ensure that the changes are not overwritten in the next OPVA 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.

2. 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 OPVA 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:

   a. Navigate to **Design** > **Tasks** subtab.

   b. Navigate to SDE of Study Dimension. Right-click and select **Synchronize Tasks**.

3. 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.

4. Add column AGENCY_ID to W_RXI_STUDY_D to hold the AGENCY_ID. To add a column, perform the following tasks in DAC:
   a. Duplicate the container in DAC (to ensure that the changes are not overwritten in the next OPVA upgrade) or use an existing customized table definition.
   b. Navigate to Tables subtab Under Design Tab and add the new column under W_RXI_STUDY_DS and save it.
5. 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 record.

   To modify the SIL, perform the following tasks in DAC:
   a. Copy the SIL into another folder (to ensure that the changes are not overwritten in the next OPVA upgrade) or use an existing customized SIL.
   b. Add the new column and save.
6. 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 OPVA. Alternatively, you can use an existing customized repository.

   a. 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 OPVA populates from Oracle Argus Safety. For example, you may want to load the W_RXI_STUDY_D.STUDY_SPONSOR other than what OPVA is loading. You will have to perform the following tasks:

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

   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 OPVA 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.
Modified table has modified layout	1. Modify the SDE to read the modified layout. 2. Modify the staging table populated by the SDE to include the modified layout. 3. Modify the SIL to read the modified layout. 4. Modify the target table to include the modified layout. 5. Modify the RPD to accept the changed data warehouse 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 warehouse table to make the new data available to the BI Server. 4. Add an SIL to populate the new data warehouse table from the new staging table. 5. Modify the RPD to accept the new warehouse table.

Modifying Data Warehouse Tables

Depending on what changes are required to the data warehouse, it is necessary to modify either the source table in Informatica and DAC, or the source, staging, and target tables.

Managing Indexes

OPVA is delivered with a set of indexes. If you wish, you can create additional indexes to meet your query requirements. Use DAC for this purpose.

> **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 warehouse tables before loading large volumes of data, and to recreate them afterward. DAC can automate this process for you. To drop indexes before a load, and recreate them afterward, perform the following tasks in DAC:

1. Navigate to the **Execute** > **OPVA Warehouse** execution tab.
2. Select **Drop and Re-create Index** and save.

If set to Yes, Oracle DAC drops all indexes on all target tables before the Informatica Program is executed, and recreates them after execution.

6

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 OPVA

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 OPVA.

Table 6–1 Conformed Dimensions

Retrospective	
Facts	**Conformed Dimensions**
Case Version Fact	Enterprise
	Case Processing Site
	Product

Table 6–1 (Cont.) Conformed Dimensions

Retrospective	
	Study
	Period - Clock Start Date
	Period - Version Receipt Date
Case Routing Fact	Enterprise
	Case Processing Site
	Product
	Study
	State - Routing State
	User - Routing User
	User Group - Routing User Group
Case Workflow State Fact	Enterprise
	Case Processing Site
	Product
	Study
	State - Workflow State
	User - Workflow Finalization User
	User Group - Workflow Finalization User Group
Current	
Facts	Conformed Dimensions
Pending Cases	Enterprise
	Case Processing Site
	Product
	Study
	Period - Latest Follow-up Receipt Date
	Period - Initial Receipt Date
	User - Assigned User
	User Group - Routing User Group

Aggregate Facts in OPVA

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 OPVA, we have introduced the following two 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 and Case Processing Site dimensions (as they are used in implementing Row Level Security). 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.

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
	Study
	Period - Version Receipt Date (at the hierarchical level of Month in the Period dimension)

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 OPVA 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.

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

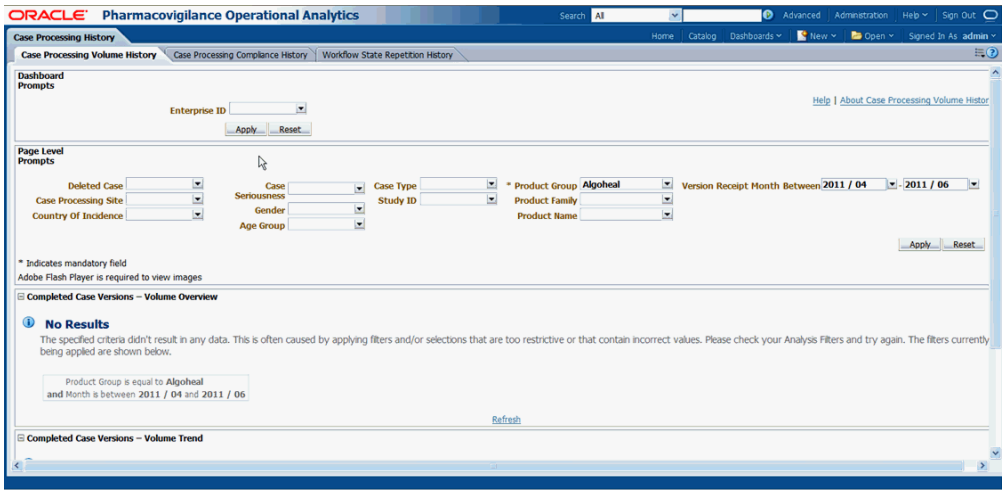
The prompts that are present in the dashboard can be made mandatory. By making a prompt mandatory, the particular report can be forced to use the aggregate facts, thereby improving performance significantly.

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.

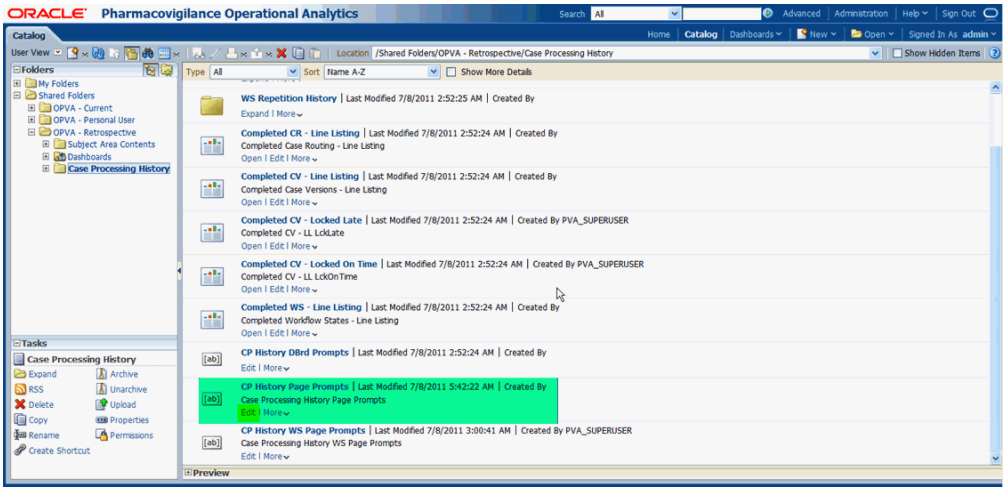
Figure 6–1 Dashboard Reports



2. Navigate to the folder in the catalog where prompts are saved. Example: Catalog > Shared folders > OPVA - Retrospective > Case Processing History.

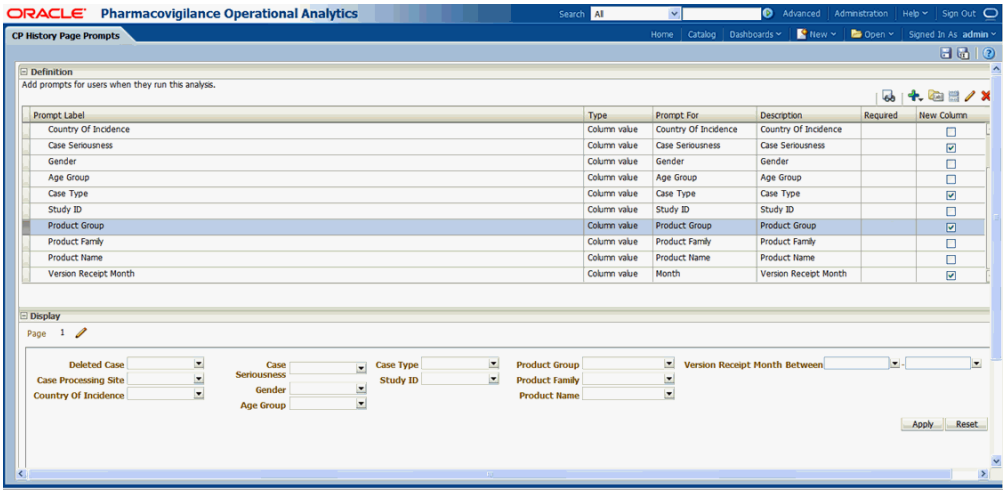
3. Click the **Edit** link to make the change. Example: CP History Page Prompts.

Figure 6–2 OBIEE Objects in Catalog Folders



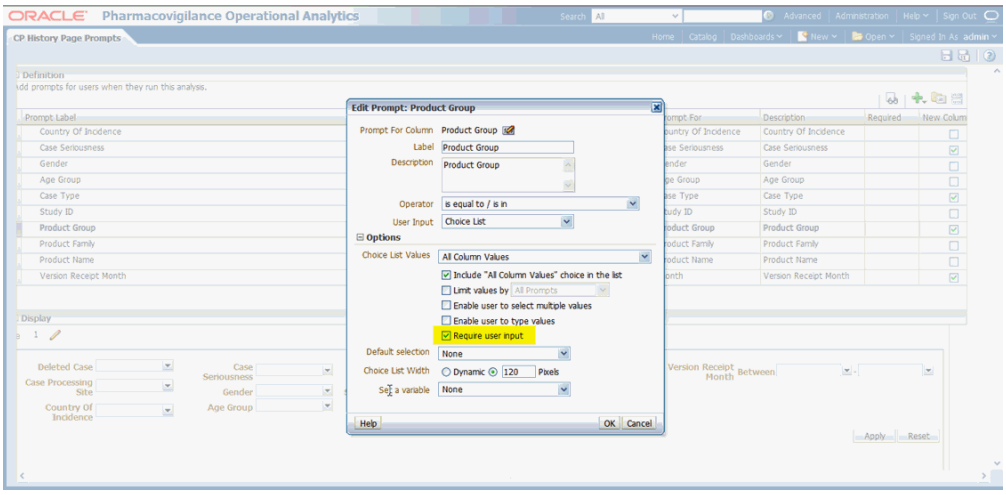
4. Select the field which is to be made mandatory and click the **Edit** icon (present on the top right of the opened screen), such as the **Product Group** field selected below.

Figure 6–3 Catalog Prompt Edit Page



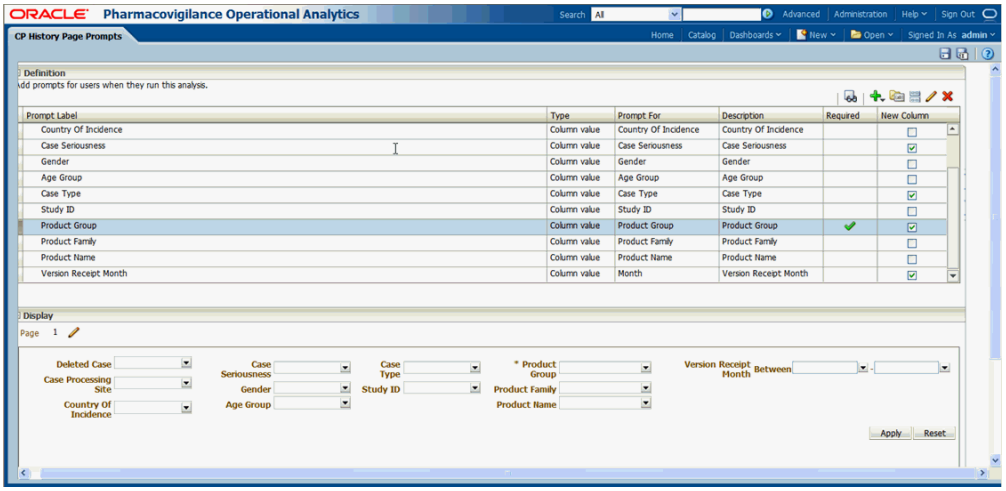
5. An **Edit Prompt** dialog appears, with options to customize the prompt. To make the field mandatory, check the **Require user input** checkbox and click **OK**.

Figure 6–4 Edit Prompt Dialog



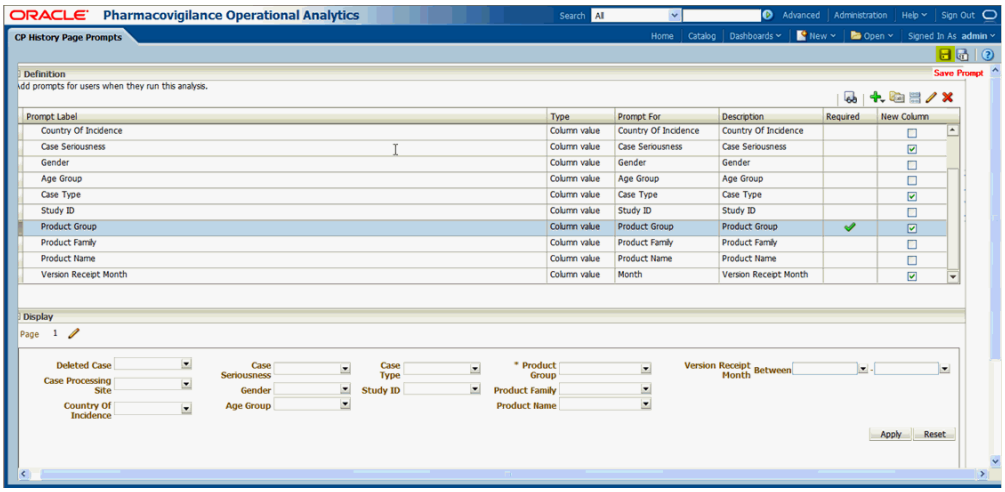
6. You can verify the change by checking the **Required** column of the field (**Product Group** below). Mandatory fields have a tick mark displayed against them. In the **Preview** window, an asterisk (*) appears before the name of the mandatory field.

Figure 6–5 Preview Changes in Dashboard Prompts



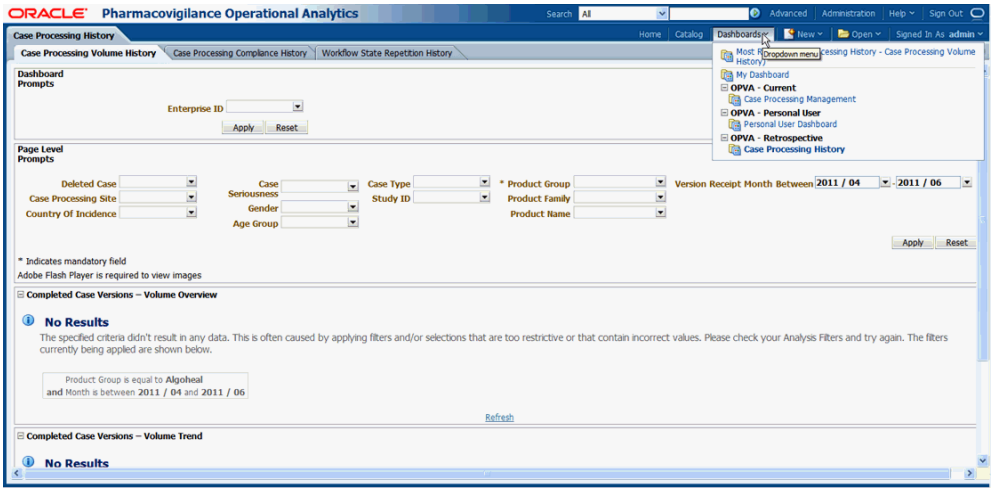
7. Save the prompt by selecting the **Save** icon (highlighted below), present on the top right side of the screen.

Figure 6–6 Saving Dashboard Prompts



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

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



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

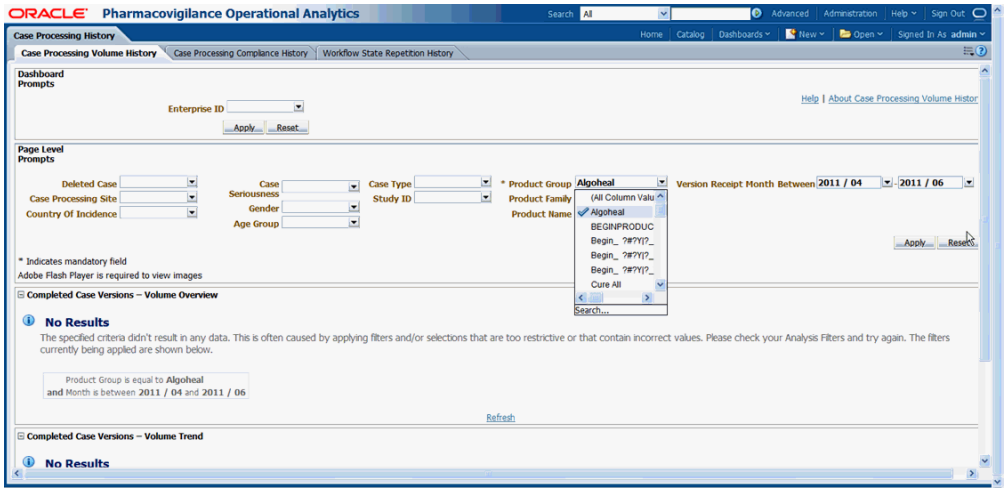
Setting up default values

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

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

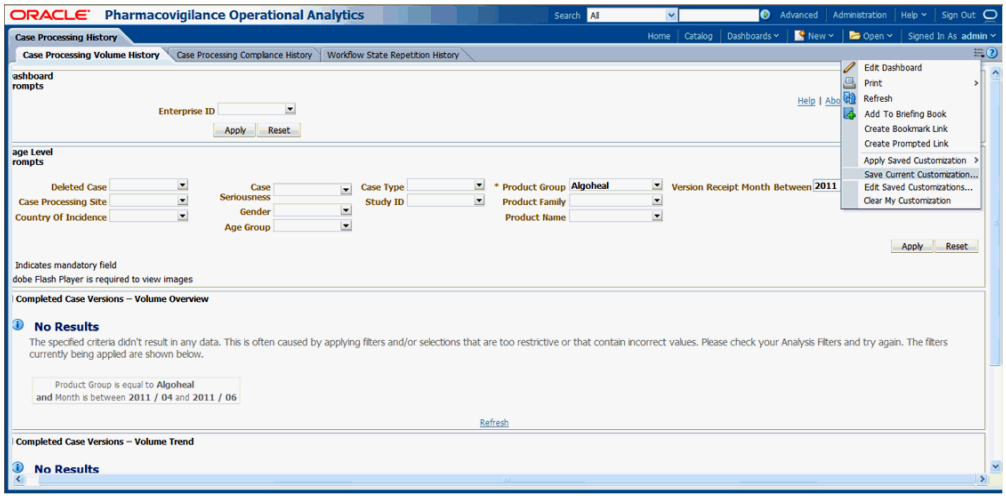
1. Navigate to the report where the default prompt value is to be saved. Go to the prompt, select the value, and click **Apply**.

Figure 6–8 Default Value Selection for Mandatory Prompts



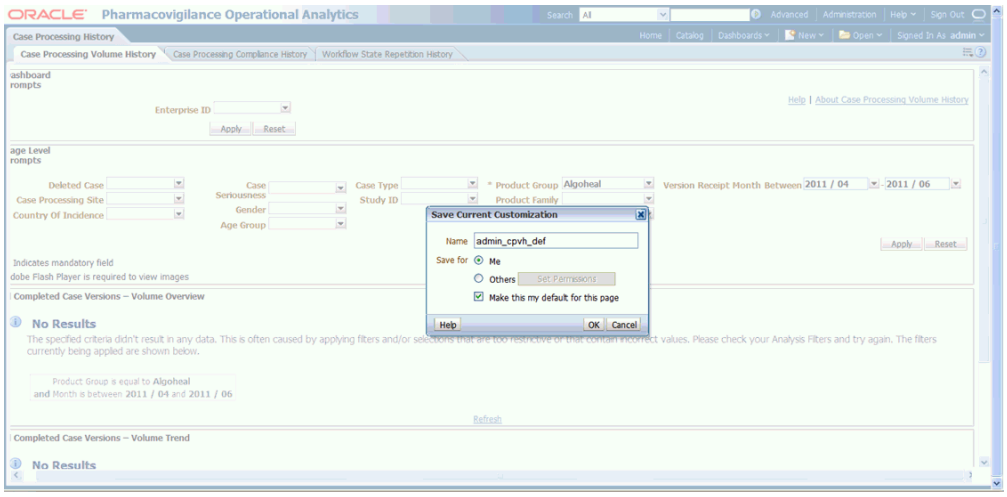
2. To save the current selection, click the **Page Option** icon present on the top right corner of the opened report. Select **Save Current Customization** from the drop-down menu.

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.

7

Implementing Security

This chapter contains the following topics:

About Security in Oracle Health Sciences Pharmacovigilance Operational Analytics

Oracle Health Sciences Pharmacovigilance Operational Analytics (OPVA) 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.

OPVA security includes:

- **Authentication** OPVA 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 OPVA the user can use.

  Predefined OBIEE user groups determine the privileges allowed to users and allow access to the shipped OPVA dashboards and reports. You can create additional user groups as needed in OBIEE.
- **Data Access** In OPVA, 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.

- **OPVA End Users** are people who can view Oracle Argus Safety data in OPVA through dashboards and reports. The specific dashboards and reports they can view is determined by the user groups they belong to.
- **OPVA Programmers** are people who are authorized to create their own reports in the Answers component of OBIEE/OPVA, 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.
- **INFA Programmers** are people who can modify the functionality of OPVA by modifying the predefined ETL Programs that OPVA uses to transform transactional source data in Infa repository for use in OPVA. They may also create new ETL Programs to support custom dashboards and reports in OPVA.
- **OPVA Schedulers** are people who schedule OPVA jobs, including the data loading job and the user data access jobs. They need privileges similar to INFA Programmers.
- **DAC/INFA Administrators** are people who set up DAC, including Informatica Setups, and grant privileges to other users.

Setting Up User Authentication

DAC handles creation and maintenance of users for ETL administration of OPVA. OBIEE handles reports related user authentication for OPVA .

Creating User Accounts in DAC

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*.

Creating Users and Groups for OPVA

Refer to the *Oracle Health Sciences Pharmacovigilance Operational Analytics Installation Guide* for instructions on creating users and groups.

Implementing Security using OAM and Configuring SSL for OPVA

Refer to the *Oracle Health Sciences Pharmacovigilance Operational Analytics Installation Guide* for instructions on SSO installation to implement security using OAM, and on configuring SSL for OPVA.

Part III

Appendices

Part III contains the following appendices:

- Appendix A, Dashboards and Reports,
- Appendix B, OPVA Presentation Catalog,
- Appendix C, Troubleshooting,

A

Dashboards and Reports

This section describes predefined dashboards and reports delivered with Oracle Health Sciences Pharmacovigilance Operational Analytics (OPVA):

- Oracle Health Sciences Pharmacovigilance Operational Analytics Dashboards
- Oracle Health Sciences Pharmacovigilance Operational Analytics Reports

See Also:

- Chapter 2, Using OPVA
- Chapter 3, Working with Reports

Oracle Health Sciences Pharmacovigilance Operational Analytics Dashboards

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

OPVA includes the following dashboards:

- Case Processing History
- Case Processing Management
- Personal User Dashboard

Log in to OPVA, and select the dashboard you want to view. For more information, refer to Accessing Oracle Health Sciences Pharmacovigilance Operational Analytics.

Case Processing History

This section describes the Case Processing History dashboard in OPVA.

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 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

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 OPVA.

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 OPVA.

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 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

Oracle Health Sciences Pharmacovigilance Operational Analytics Reports

OPVA includes the following reports:

- Completed Case Versions - Volume Overview
- Completed Case Versions – Volume Trend
- Completed Case Versions – 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

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

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 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-1 describes the columns in the Completed Case Versions – Volume Overview report:

Table A–1 Completed Case Versions – Volume Overview

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

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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-2 describes the columns in the Completed Case Versions – Volume Trend report:

Table A–2 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 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

Report Type

- Narrative Table

Location

- **Case Processing History** dashboard > **Case Processing Volume History** page
- **Case Processing History** dashboard > **Case Processing Compliance History** page
- **Case Processing History** dashboard > **Case Processing Repetition History** page

Dimensions

Enterprise.EnterpriseID

Supplementary Prompts

None

Reports Referenced

Completed Workflow States – Line Listing

Reports Referencing This Report

Completed Case Versions - Volume Overview

Completed Case Versions – Volume Trend

Completed Case Versions – Lock Compliance Overview

Completed Case Versions – Lock Compliance Proportion

Completed Case Versions – Lock Compliance Trend

Column Descriptions

Table A-3 describes the columns in the Completed Case Versions – Line Listing report:

Table A–3 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
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

Table A–3 (Cont.) Completed Case Versions – Line Listing

Table Heading	Column Heading	Measure
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 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-4 describes the columns in the Completed Case Versions - Lock Compliance Overview report:

Table A–4 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-5 describes the columns in the Completed Case Versions - Lock Compliance Proportion report:

Table A–5 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-6 describes the columns in the Completed Case Versions - Lock Compliance Trend report:

Table A–6 Completed Case Versions - Lock Compliance Trend

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

Completed Workflow States – Line Listing

This 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, e.g. an investigation of cases that were locked late.

Audience

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

Report Type

- Narrative Table

Location

- **Case Processing History** dashboard > **Case Processing Volume History** page
- **Case Processing History** dashboard > **Case Processing Compliance History** page
- **Case Processing History** dashboard > **Workflow State Repetition 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:

- Repeated Workflow States – Volume Overview
- Repeated Workflow States – Volume Proportion

Column Descriptions

Table A-7 describes the columns in the Completed Workflow States - Line Listing report:

Table A–7 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

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, e.g. an investigation of cases that were locked late.

Audience

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

Report Type

- Narrative Table

Location

- **Case Processing History** dashboard > **Case Processing Compliance History** page
- **Case Processing History** dashboard > **Workflow State Repetition 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:

- Completed Workflow States – Line Listing

Column Descriptions

Table A-8 describes the columns in the Completed Case Version Routing - Line Listing report:

Table A–8 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-9 describes the columns in the Repeated Workflow States - Volume Overview report:

Table A–9 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-10 describes the columns in the Repeated Workflow States - Volume Proportion report:

Table A–10 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-11 describes the columns in the Pending Cases - Volume Overview report:

Table A–11 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 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-12 describes the columns in the Pending Cases - Line Listing report:

Table A–12 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

Table A–12 (Cont.) Pending 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
Pending Cases	Routing ID	Pending Cases.Routing ID
UserGroup.Pending Cases - Routing User Group	Routing User Group	UserGroup.Pending Cases - Routing User Group.Routing User Group
Pending Cases	Routing Timestamp	Pending Cases.Routing Timestamp
Pending Cases	Routing Justification	Pending Cases.Routing Justification

Pending Cases – Lock Compliance Overview

This 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-13 describes the columns in the Pending Cases - Lock Compliance Overview report:

Table A–13 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-14 describes the columns in the Pending Cases - Lock Compliance In Days report:

Table A–14 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

Drug Safety Manager

Drug Safety Team Leader

Pharmacovigilance Executive Management

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

Table A-15 describes the columns in the Pending Workflow States - Compliance Overview report:

Table A–15 Pending Workflow States - Compliance Overview

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

My Completed Workflow States – Volume Trend

This 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

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

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

Table A-20 describes the columns in the My Completed Workflow States – Volume Trend report:

Table A–16 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

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

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

Table A-21 describes the columns in the My Repeated Workflow States – Volume Overview report:

Table A–17 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

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

Report Type

- Narrative Table

Location

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

Dimensions

Enterprise.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

Table A-22 describes the columns in the My Completed Case Versions – Line Listing report:

Table A–18 My 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
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

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

Report Type

- Narrative Table

Location

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

Dimensions

Enterprise.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

Table A-23 describes the columns in the My Completed Workflow States – Line Listing report:

Table A–19 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

Table A–19 (Cont.) My Completed Workflow States - Line Listing

Table Heading	Column Heading	Measure
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

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

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

Table A-16 describes the columns in the My Pending Cases - Overview report:

Table A–20 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

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

Report Type

- Narrative Table

Location

- **Personal User** dashboard > **Personal User Case Management** page

Dimensions

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Pending Cases – Overview

Column Descriptions

Table A-17 describes the columns in the My Assigned Cases - Line Listing report:

Table A–21 My Assigned Cases - Line Listing

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

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

Report Type

- Narrative Table

Location

- **Personal User** dashboard > **Personal User Case Management** page

Dimensions

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Pending Cases – Overview

Column Descriptions

Table A-18 describes the columns in the My Unassigned Cases - Line Listing report:

Table A–22 My Unassigned Cases - Line Listing

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

Table A–22 (Cont.) My Unassigned Cases - Line Listing

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

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

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

Report Type

- Narrative Table

Location

- **Personal User** dashboard > **Personal User Case Management** page

Dimensions

Enterprise.Enterprise ID

User Group.Pending Cases - Routing User Group

User.Pending Cases - Assigned User

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Pending Cases – Overview

Column Descriptions

Table A-19 describes the columns in the Other Assigned Cases - Line Listing report:

Table A–23 Other Assigned Cases - Line Listing

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

Table A–23 (Cont.) Other Assigned Cases - Line Listing

Table Heading	Column Heading	Measure
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

Drug Safety Data Entry Personnel

Drug Safety Medical Assessment Physician

Drug Safety Quality Reviewer

Drug Safety and Surveillance Specialist

Report Type

- Narrative Table

Location

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

Dimensions

Enterprise.Enterprise ID

State.Case Routing - State

User Group.Case Routing - Routing User Group

User.Case Routing - Routing User

Supplementary Prompts

None

Reports Referenced

None

Reports Referencing This Report

My Completed Workflow States – Line Listing

Column Descriptions

Table A-24 describes the columns in the My Completed Case Version Routing – Line Listing report:

Table A–24 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

B

OPVA Presentation Catalog

The OPVA Presentation Catalog displays columns that you can use to create requests.

This appendix contains the following topics:

- Dimensions in OPVA Presentation Catalog
- Facts in OPVA Presentation Catalog
- Oracle Argus Safety Sources for OPVA Presentation Catalog

See Also:

Chapter 3, Working with Reports

Dimensions in OPVA Presentation Catalog

Table B-1 describes the Dimensions displayed in the OPVA 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. Each Dimension column has an ID number, which is provided for cross-reference to other tables in this appendix.

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

ID	Dimension	Column	Description
AD05-03	Case Processing Site	Case Processing Site	Case Processing Site That The User Belongs To.
TA-CVH04	Enterprise	Enterprise ID	CRO Enterprise (Client) Short Name
	Enterprise	Enterprise Name	Enterprise Name
AD01-01	Period	Year	Per_name_year From W_day_d Table
AD01-02	Period	Quarter	Per_name_qtr From W_day_d Table
AD01-03	Period	Month	Per_name_month From W_day_d Table
AD01-04	Period	Week	Per_name_week From W_day_d Table

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

ID	Dimension	Column	Description
AD01-05	Period	Day	Calendar_date From W_day_d Table
AD02-02	Product	Product Group	Therapeutic Alignment Of User Groups By Product Indication (For Example, Oncology Group, Gynecology Group Etc)
AD02-03	Product	Product Family	Product Family - It Is Used To Group Like Products That Share Datasheets And Primary Ingredients
AD02-04	Product	PSUR Group	PSUR Group Name
AD02-01	Product	Product Name	Product Name
AD02-05	Product	Product Formulation	Formulation Of The Product
AD02-06	Product	Product Concentration	Concentration/Strength Of The Product
TA-CRH06	State	State Routed From	Workflow State From Which The Case Was Promoted To The Next Workflow State
TA-CRH07	State	State Routed To	Workflow State From Which The Case Was Promoted From The Previous Workflow State
TA-CWSH04	State	State Name	Workflow State (From Workflow State)
AD03-01	Study	Study ID	Study ID
AD03-02	Study	Project ID	Project ID For Study
TA-CRH10	User	Routing User ID	The User Who Last Worked On The Workflow Step
AD05-02	User	Routing User Name	Routing User Name
AD05-03	User	Case Processing Site	Case Processing Site That The User Belongs To.
TA-CWSH07	User	State Finalization User ID	The User Who Finished The Last Execution Of The Workflow State For The Case Version
AD05-02	User	State Finalization User Name	State Finalization User Name
TA-CRH11	User Group	Routing User Group	User Group Which Worked On The Workflow Step
TA-CWSH08	User Group	State Finalization User Group	The Last User Group To Which The Case Version Was Routed To For The Workflow State
AD06-01	User Group	Routing User Group	User Group Name

Facts in OPVA Presentation Catalog

Table B-2 describes the Facts displayed in the OPVA Presentation Catalog, and their Columns. For each Column, it shows the name of the Column, its description, and the Fact and Group within the Fact that contain the Column. The table is sorted by Group and Column, within Fact. This corresponds to how the Fact columns are organized in the Presentation Catalog, within the Fact folder. Each Fact Column has an ID number, which is provided for cross-reference to other tables in this Appendix.

Table B–2 Presentation Catalog - Facts

ID	Fact	Column	Description
TA-CVH01	Case	Case ID	Case Identification (Same As Manufacturer Code Number [Mcn])
TA-CVH02	Case	Version ID	Case Version (1,2,3...)
	Case	Case Internal ID	Internal Case Id Generated

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

ID	Fact	Column	Description
TA-CVH03	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)
TA-CVH04	Case Version	Enterprise ID	CRO (Enterprise) Short Name
TA-CVH05	Case Version	Initial/Follow-up	Initial Or Follow-up Entry Of The Case
TA-CVH06	Case Version	Case Deleted Indicator	A Flag To Identify If The Case Has Been "Deleted" Or Not
TA-CVH07	Case Version	Case Creator ID	Case Author (Who Created The Case)
TA-CVH08	Case Version	Case Creator Name	
TA-CVH09	Case Version	Case Processing Site	Site (Example: Drug Safety Case Processing Location)
TA-CVH10	Case Version	Country Of Incidence	Country Where The Adverse Event Occurred
TA-CVH10	Case Version	Case Type	Case Report Type (For Ex., Spontaneous/Clinical/Literature, Etc.)
TA-CVH11	Case Version	Compliance Classification	7-day Case, 15-day Case, Non-Expedited Case
TA-CVH12	Case Version	S/R/U Classification	SAE Case, SAR Case, SUSAR Case
TA-CVH13	Case Version	F/LT Classification	Fatal/Life-Threatening Case
TA-CVH14	Case Version	Pregnancy Classification	Pregnancy Case
TA-CVH15	Case Version	Source Classification	Authority Case, Consumer Case, Literature Case
TA-CVH16	Case Version	Confirmation Classification	Medically Confirmed Case
TA-CVH17	Case Version	Case Classification Group7	Case Classification Group7
TA-CVH18	Case Version	Case Classification Group8	Case Classification Group8
TA-CVH19	Case Version	Case Classification Group9	Case Classification Group9
TA-CVH20	Case Version	Case Classification Group10	Case Classification Group10
TA-CVH21	Case Version	Product Type	Drug, Device, And Vaccine
TA-CVH22	Case Version	Study ID	Study ID
TA-CVH23	Case Version	Center ID	Center ID For The Study In The Case Version
TA-CVH24	Case Version	Case Seriousness	Case Serious or Non-Serious (Y/N)
TA-CVH25	Case Version	Case Listedness	Unlisted/Unexpected/Listed/Expected
TA-CVH26	Case Version	Case Causality	Adverse Event Caused By The Product (Related/Not Related)
TA-CVH27	Case Version	Case Outcome	Case Level Outcome Using The ICH Guidelines. Example: 'Recovered;
TA-CVH28	Case Version	Gender	Gender Of The Patient
TA-CVH29	Case Version	Pregnant	Patient Pregnant (Yes/No)

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

ID	Fact	Column	Description
TA-CVH30	Case Version	Age Group	Patient Age Group
TA-CVH31	Case Version	Ethnicity	Ethnicity Of The Patient
TA-CVH32	Case Version	Lactation	Patient Breastfeeding
TA-CVH33	Case Version	Primary Reporter Type	Type Of The First/Primary Reporter (Example: Physician, Consumer, Etc.)
TA-CVH34	Case Version	Primary Suspect Product	Primary Suspect Product For A Case
TA-CVH35	Case Version	HCP	Health Care Professional (Example: Physician, Nurse, Pharmacist) Flag. Primary Reporter Of The Case Is HCP Or Not.
TA-CVH36	Case Version	SUSAR	Suspected Unexpected Serious Adverse Reaction Flag (0 / 1)
TA-CVH37	Case Version	Case Owner ID	User Who Is Responsible For The Case Throughout Its Lifetime
	Case Version	Case Owner Name	
TA-CVH38	Case Version	Initial Receipt Date	Date On Which Initial Case Information Was Received
TA-CVH39	Case Version	Version Receipt Date	Date On Which Initial/follow-up Information Was Received
TA-CVH40	Case Version	Safety Receipt Date	Case Version Receipt Date At Central Safety
TA-CVH41	Case Version	Clock Start Date	Case Version Aware Date
TA-CVH42	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)
TA-CVH43	Case Version	Lock Timestamp	Case Is Ready For Submission. First Lock Date Of The Case Version.
TA-CVH44	Case Version	Case Deletion Date	Date Of Case Deletion
M-CVH01	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
M-CVH02	Case Version	Lock Due Date	Clock Start Date + Lock Target Days
M-CVH03	Case Version	Lock Due Due Date Soon	Customizable By The Customer, By Default - 2 Days Lock Due Date - (2)
M-CVH04	Case Version	Duration Version-Receipt-To-Safety-Receipt	(How Long Does It Take Before A Case Version Reaches The Safety Group?) The Difference Between The Case Version Receipt Date And The Case Version Safety Receipt Date.
M-CVH05	Case Version	Duration Clock-Start-To-Lock	Interval Between Case Version Clock Start Date And Case Version Lock Datetime
M-CVH06	Case Version	Duration Version-Creation-To-Lock	Interval Between Case Version Create DateTime And Case Version Lock Datetime
M-CVH07	Case Version	Avg Duration Clock-Start-To-Lock	Average Interval between Case Version Clock Start Date and Case Version Lock DateTime
M-CVH08	Case Version	Avg Duration Version-Creation-To-Lock	Average Interval Between Case Version Create DateTime And Case Version Lock DateTime

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

ID	Fact	Column	Description
M-CVH09	Case Version	Min Duration Clock-Start-To-Lock	Minimum Interval Between Case Version Clock Start Date And Case Version Lock DateTime
M-CVH10	Case Version	Min Duration Version-Creation-To-Lock	Minimum Interval Between Case Version Create DateTime And Case Version Lock DateTime
M-CVH11	Case Version	Max Duration Clock-Start-To-Lock	Maximum Interval Between Case Version Clock Start Date And Case Version Lock DateTime
M-CVH12	Case Version	Max Duration Version-Creation-To-Lock	Maximum Interval Between Case Version Create DateTime And Case Version Lock DateTime
M-CVH13	Case Version	#Versions Locked Once	Number Of Case Versions Received (Including All Versions)
M-CVH14	Case Version	#Sig Versions Locked Once	Number Of Case Versions Received (Including Significant Versions Only)
M-CVH15	Case Version	#Versions Locked On-Time	Number Of Case Versions Processed Within Target Days
M-CVH16	Case Version	%Versions Locked On-Time	Percentage Of Case Versions Processed On Time
M-CVH17	Case Version	#Versions Locked Late	Number Of Case Versions Processed Over Target Days
M-CVH18	Case Version	%Versions Locked Late	Percentage Of Case Versions Not Processed Within Target Days
TA-CRH03	Case Routing	Enterprise ID	CRO Enterprise (Client) ID
TA-CRH04	Case Routing	Routing Justification	Case Routing Justification
TA-CRH05	Case Routing	Routing ID	Workflow Sequence Number
TA-CRH08	Case Routing	Routing Timestamp From State	The Timestamp On Which Case Was Routed From Workflow State
TA-CRH09	Case Routing	Routing Timestamp To State	The Timestamp On Which Case Was Routed To Workflow State
TA-CRH12	Case Routing	Follow-up ID	Follow-up Number Of The Case To Which This Routing Record Belongs.
TA-CRH13	Case Routing	Comments	Routing Comments
	Case Routing	Pseudo State	
TA-CRH03	Case Workflow State	Enterprise ID	CRO Enterprise (Client) Short Name
TA-CRH05	Case Workflow State	State Start Timestamp	The First Timestamp When The Workflow State Was Started
TA-CRH06	Case Workflow State	State End Timestamp	The Last Timestamp When The Workflow State Was Completed
M-CWSH01	Case Workflow State	#Time State Repeated	The Number Of Times A Workflow State Is Repeated (Within A Case Version)
M-CWSH02	Case Workflow State	#Users Who Worked On State	Number Of Distinct Users Who Worked On A Workflow State For A Case Version

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

ID	Fact	Column	Description
M-CWSH03	Case Workflow State	Duration State-Start-To-End	Number Of Days Taken From The First Time The Workflow State Was Started To The Last Time The Workflow State Was Completed (Within A Case Version)
M-CWSH04	Case Workflow State	Duration Within State	Total Time The Case Spent In The Workflow State (Within A Case Version)
M-CWSH05	Case Workflow State	# Completed State	Total Number Of Workflow States Completed
M-CWSH06	Case Workflow State	# Repeated State	Total Count Of All The Workflow States That Were Repeated
M-CWSH07	Case Workflow State	% Repeated State	Total Percentage Of All The Workflow States That Were Repeated
M-CWSH08	Case Workflow State	Duration Version-Creation-To-State-End	Time Taken To Accomplish A Workflow State After A Case Version Was Created (Including Any Repetition)
M-CWSH09	Case Workflow State	Average Duration State-Start-To-End	Average Number Of Days Taken From The First Time The Workflow State Was Started To The Last Time The Workflow State Was Completed (Within A Case Version)
M-CWSH10	Case Workflow State	Average Duration Within State	Average Time The Case Spent In The Workflow State (Within A Case Version)
M-CWSH11	Case Workflow State	Average Duration Version-Creation-To-State-End	Average Time Taken To Accomplish A Workflow State After A Case Version Was Created (Including Any Repetition)
M-CWSH12	Case Workflow State	Minimum Duration State-Start-To-End	Minimum 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)
M-CWSH13	Case Workflow State	Minimum Duration Within State	Minimum Time The Case Spent In The Workflow State (Within A Case Version)
M-CWSH14	Case Workflow State	Minimum Duration Version-Creation-To-State-End	Minimum Time Taken To Accomplish A Workflow State After A Case Version Was Created (Including Any Repetition)
M-CWSH15	Case Workflow State	Maximum Duration State-Start-To-End	Maximum 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)
M-CWSH16	Case Workflow State	Maximum Duration Within State	Maximum Time The Case Spent In The Workflow State (Within A Case Version)
M-CWSH17	Case Workflow State	Maximum Duration Version-Creation-To-State-End	Maximum Time Taken To Accomplish A Workflow State After A Case Version Was Created (Including Any Repetition)
TA-PC01	Pending Cases	Case ID	Case Identification (Same As Manufacturer Code Number - MCN)

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

ID	Fact	Column	Description
	Pending Cases	Case Internal ID	
TA-PC02	Pending Cases	Follow-up ID	Latest Case Follow-up # (0,1,2,3...)
TA-PC03	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)
TA-PC04	Pending Cases	Enterprise ID	CRO Enterprise (Client) Short Name
TA-PC06	Pending Cases	Case Creator ID	Case Author (Who Created The Case)
TA-PC07	Pending Cases	Case Processing Site	Site (For Example, Drug Safety Case Processing Location)
TA-PC08	Pending Cases	Country of Incidence	Country Where The Adverse Event Occurred
TA-PC09	Pending Cases	Case Type	Case Report Type (For Example, Spontaneous/Clinical/Literature, Etc.)
TA-PC10	Pending Cases	Compliance Classification	7-day Case, 15-day Case, Non-Expedited Case
TA-PC11	Pending Cases	S/R/U Classification	SAE Case, SAR Case, SUSAR Case
TA-PC12	Pending Cases	F/LT Classification	Fatal / Life-Threatening Case
TA-PC13	Pending Cases	Pregnancy Classification	Pregnancy Case
TA-PC14	Pending Cases	Source Classification	Authority Case, Consumer Case, Literature Case
TA-PC15	Pending Cases	Confirmation Classification	Medically Confirmed Case
TA-PC16	Pending Cases	Case Classification Group 7	Case Classification Group 7
TA-PC17	Pending Cases	Case Classification Group 8	Case Classification Group 8
TA-PC18	Pending Cases	Case Classification Group 9	Case Classification Group 9
TA-PC19	Pending Cases	Case Classification Group 10	Case Classification Group 10
TA-PC20	Pending Cases	Product Type	Drug, Device and Vaccine
TA-PC21	Pending Cases	Study Type	Study ID
TA-PC22	Pending Cases	Center ID	Center ID for the Study in the case version

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

ID	Fact	Column	Description
TA-PC23	Pending Cases	Case Seriousness	Case Serious Or Non-serious (Y/N)
TA-PC24	Pending Cases	Case Listedness	Unlisted/Unexpected/Listed/Expected
TA-PC25	Pending Cases	Case Causality	Adverse Event Caused By The Product (Related/Not Related)
TA-PC26	Pending Cases	Case Outcome	Case Level Outcome Using The ICH Guidelines, Such As 'Recovered'
TA-PC27	Pending Cases	Gender	Gender Of The Patient
TA-PC28	Pending Cases	Pregnant	Patient Pregnant (Yes/No)
TA-PC29	Pending Cases	Age Group	Patient Age Group
TA-PC30	Pending Cases	Ethnicity	Ethnicity Of The Patient
TA-PC31	Pending Cases	Lactation	Patient Breastfeeding
TA-PC32	Pending Cases	Primary Reporter Type	Type Of Reporter (Example: Physician, Consumer, Etc.)
TA-PC33	Pending Cases	Primary Suspect Product	Primary Suspect Product For A Case
TA-PC34	Pending Cases	HCP	Health Care Professional (Such As Physician, Nurse, Pharmacist) Flag. Primary Reporter Of The Case Is Hcp Or Not
TA-PC35	Pending Cases	SUSAR	Suspected Unexpected Serious Adverse Reaction Flag (0 / 1)
TA-PC36	Pending Cases	Initial Receipt Date	Date On Which Initial Case Information Was Received
TA-PC37	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
TA-PC40	Pending Cases	Clock Start Date	Case Version Aware Date
TA-PC50	Pending Cases	Case Deletion Date	Deletion Date Of The Case
TA-PC41	Pending Cases	Case Owner	User Who Is Responsible For The Case Throughout Its Lifetime
TA-PC42	Pending Cases	Assigned User	User Assigned To The Current Work
TA-PC43	Pending Cases	User With Case Open	Case Worklist User. User Who Has The Case Open (It May Be Null If Case Is Not Open)
TA-PC44	Pending Cases	Routing Justification	Case Routing Justification For The Latest Routing
TA-PC45	Pending Cases	Routing ID	Workflow Sequence Number

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

ID	Fact	Column	Description
TA-PC46	Pending Cases	Routing Timestamp	The Timestamp On Which Case Was Routed To Current Workflow State
TA-PC47	Pending Cases	Start Name	Workflow State To Which Case Was Promoted From Previous Workflow State
TA-PC48	Pending Cases	Routing User	The User To Whom The Case Has Been Routed In The Current Workflow State
TA-PC49	Pending Cases	Routing User Group	User Group To Which A Case Is Routed.
M-PC01	Pending Cases	Earliest Exp Report Due Date	Earliest Due Date By External(Regulatory/sla) For Expedited Report For This Case Version. This Measure Will Have Null Value If There Are No Reports Due For This Case Version.
M-PC02	Pending Cases	Earliest Exp Report Due Soon Date	Earliest Due Date By Internal Process For Expedited Report For This Case Version. This Measure Will Have Null Value If There Are No Reports Due For This Case Version.
M-PC03	Pending Cases	Earliest Exp Report On-Time Indicator	Earliest Expedited Report Submission On-time Indicator. The Values Here Are Red, Yellow And Green.
M-PC04	Pending Cases	Lock Target Days	Target Days For Processing A Case Version Which Is Number Of Days From Clock Start Date To Lock Datetime.
M-PC05	Pending Cases	Lock Due Date	Due Date For Locking A Case (Case Processing Completion)
M-PC06	Pending Cases	Lock Due Soon Date	Internal Due Date For Locking A Case (Case Processing Completion)
M-PC07	Pending Cases	Lock On-Time Indicator	Case Version Lock On-time Indicator. The Values Here Are Red, Yellow And Green.
M-PC08	Pending Cases	Start Due Date - I	Due Date For Completion Of A Workflow State By Static Workflow Method
M-PC09	Pending Cases	Start Due Soon Date - I	Due Soon Date For Completion Of A Workflow State By Static Workflow Method
M-PC10	Pending Cases	Start On-Time Indicator - I	Workflow State On-Time Indicator by Static Workflow Method. The values here are Red, Yellow and Green
M-PC11	Pending Cases	Start Due Date - II	Due Date For Completion Of A Workflow State By Dynamic Workflow Method
M-PC12	Pending Cases	Start Due Soon Date - II	Due Soon Date For Completion Of A Workflow State By Dynamic Workflow Method
M-PC13	Pending Cases	Start On-Time Indicator - II	Workflow State On-time Indicator By Dynamic Workflow Method. The Values Here Are Red, Yellow And Green
M-PC14	Pending Cases	Case-Open-By-User Indicator	Case Currently Worked Upon By Any User
M-PC15	Pending Cases	# Unlocked Cases w Expedited Report On-Time	Count Of Open Cases With Expedited Report On-time (Where Earliest Exp Report On-time Indicator Is Green)

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

ID	Fact	Column	Description
M-PC16	Pending Cases	# Unlocked Cases w Expedited Report Due Soon	Count Of Open Cases With Expedited Report Due Soon (Where Earliest Exp Report On-time Indicator Is Yellow)
M-PC17	Pending Cases	# Unlocked Cases w Expedited Report Overdue	Count Of Open Cases With Expedited Report Overdue (Where Earliest Exp Report On-time Indicator Is Red)
M-PC18	Pending Cases	# Unlocked Cases On-Time	Count Of Open Cases Where Case Processing Is On-time (Lock On-time Indicator Is Green)
M-PC19	Pending Cases	# Unlocked Cases Due Soon	Count Of Open Cases Where Case Processing Is Due Soon (Lock On-time Indicator Is Yellow)
M-PC20	Pending Cases	# Unlocked Cases Overdue	Count Of Open Cases That Have Not Been Completed Past Due Date (Lock On-time Indicator Is Red)
M-PC21	Pending Cases	# Unlocked Cases w State On-Time - I	Count Of Cases With Workflow State Completion On-time By Static Workflow Method
M-PC22	Pending Cases	# Unlocked Cases w State Due Soon - I	Count Of Cases With Workflow State Completion Due Soon By Static Workflow Method
M-PC23	Pending Cases	# Unlocked Cases w State Overdue - I	Count Of Cases With Workflow State Not Been Completed Past Due Date By Static Workflow Method
M-PC24	Pending Cases	# Unlocked Cases w State On-Time - II	Count Of Cases With Workflow State Completion On-time By Dynamic Workflow Method
M-PC25	Pending Cases	# Unlocked Cases w State Due Soon - II	Count Of Cases With Workflow State Completion Due Soon By Dynamic Workflow Method
M-PC26	Pending Cases	# Unlocked Cases w State Overdue - II	Count of cases with Workflow State not been completed past due date by Dynamic Workflow method
M-PC27	Pending Cases	# Unlocked Cases	Total Number of Pending Cases

Oracle Argus Safety Sources for OPVA Presentation Catalog

Table B-3 describes how OPVA populates each column from an Oracle Argus Safety database. Each Measure has an ID number, which is provided for cross-reference to other tables in this Appendix. To display the information compactly, Table B-3 uses aliases for table names.

Table B–3 Presentation Catalog - Oracle Argus Safety Sources

ID	Source Table/Column	Comments/Details
TA-CVH01	case_master.case_num	
TA-CVH02		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_master.case_id	

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

ID	Source Table/Column	Comments/Details
TA-CVH03		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
TA-CVH04	cfg_enterprise.enterprise_abbrv	
TA-CVH05		If Version = 1 then Initial Else Follow-up
TA-CVH06	case_master.deleted	
TA-CVH07	case_master.user_id	
	cfg_users.user_fullname	
TA-CVH08	case_master.site_id	
TA-CVH09	case_master.country_id	
TA-CVH10	case_master.Report_type	
TA-CVH11		..where lm_case_classification.description has values in (7-day Case, 15-day Case, Non-Expedited Case)
TA-CVH12		..where lm_case_classification.description has values in (SAE Case, SAR Case, SUSAR Case)
TA-CVH13		..where lm_case_classification.description has values in (Fatal / Life-Threatening Case)
TA-CVH14		..where lm_case_classification.description has values in (Pregnancy Case)
TA-CVH15		..where lm_case_classification.description has values in (Authority Case, Consumer Case, Literature Case)
TA-CVH16		..where lm_case_classification.description has values in (Medically Confirmed Case)
TA-CVH17		..where lm_case_classification.description has values in (Case Classification 7)
TA-CVH18		..where lm_case_classification.description has values in (Case Classification 8)
TA-CVH19		..where lm_case_classification.description has values in (Case Classification 9)
TA-CVH20		..where lm_case_classification.description has values in (Case Classification 10)
TA-CVH21	case_product.views_available	
TA-CVH22	case_study.study_num	
TA-CVH23	lm_centers.center_no	
TA-CVH24	case_assess.seriousness	
TA-CVH25	case_assess.listedness	
TA-CVH26	case_assess.agent_suspect	
TA-CVH27	case_assess.outcome	

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

ID	Source Table/Column	Comments/Details
TA-CVH28	case_pat_info.gender_id	
TA-CVH29	case_pat_info.pat_stat_preg	
TA-CVH30	case_pat_info.age_group_id	
TA-CVH31	case_pat_info.ethnicity_id	
TA-CVH32	case_pregnancy.breastfeeding	
TA-CVH33	case_reporters.reporter_type	
TA-CVH34	case_product.product_name	
TA-CVH35	case_reporters.hcp_flag	
TA-CVH36	case_master.susar	
TA-CVH37	case_master.worklist_owner_id	
	cfg_users.user_fullname	
TA-CVH38	case_master.init_rept_date	
TA-CVH39	case_followup.receipt_date (Case_Master.init_rept_date for Initial case version)	
TA-CVH40	case_followup.safety_date	
TA-CVH41		Max(case_master.init_rept_date/(case_followup.receipt_date where significant = 1))
TA-CVH42		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_state_id = 2
TA-CVH43		case_routing.route_date where case_routing.comment_text like 'case locked%' or case_routing.to_state_id = 2
TA-CVH44	case_master.deleted	
M-CVH01		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
M-CVH02		Clock Start Date + Lock Target Days
M-CVH03		Customizable By The Customer, By Default - 2 Days Lock Due Date - (2)
M-CVH04		days between (Safety Receipt Date, Version Receipt Date)
M-CVH05		days between (Clock Start Date, Lock Timestamp)
M-CVH06		days between (Version Creation Timestamp, Lock Timestamp)
M-CVH07		Sum(Duration Clock-Start-To-Lock)/# Versions Locked Once

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

ID	Source Table/Column	Comments/Details
M-CVH08		Sum(Duration Version-Creation-To-Lock)/# Versions Locked Once
M-CVH09		Minimum(Duration Clock-Start-To-Lock)
M-CVH10		Minimum(Duration Version-Creation-To-Lock)
M-CVH11		Maximum(Duration Clock-Start-To-Lock)
M-CVH12		Maximum(Duration Version-Creation-To-Lock)
M-CVH13		Count (Number of records from Case Version History)
M-CVH14		Count (Number of records from Case Version History) where Version Type = Significant
M-CVH15		Lock Timestamp - Clock Start Date <= Lock Target Days
M-CVH16		(# Versions Locked On-Time/# Versions Locked Once) * 100
M-CVH17		Lock Timestamp - Clock Start Date > Lock Target Days
M-CVH18		(# Versions Locked Late/# Versions Locked Once) * 100
TA-CRH03	cfg_enterprise.enterprise_abbrv	
TA-CRH04	case_routing.justification_id	
TA-CRH05	case_routing.seq_num	
TA-CRH08	case_routing.route_date	
TA-CRH09	case_routing.route_date	
TA-CRH12		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)
TA-CRH13	case_routing.comment_text	Routing Comments
		Derived Column: 2. There are three Pseudo states – a. Locked – Whenever there is a lock, 'Routing From State' shall be TO_STATE_ID of case and 'Routing To State' shall be 'Locked'. b. F/U Data Entry - Whenever there is Unlock, 'Routing From State' shall be 'F/U Data Entry' and 'Routing To State' shall be TO_STATE_ID of the routing record immediately after the unlock. c. Unarchived – Whenever case is unarchived, 'Routing From State' shall be FROM_STATE_ID of case and 'Routing To State' shall be 'Unarchived'.
TA-CRH03	cfg_enterprise.enterprise_abbrv	
TA-CRH05		
TA-CRH06		The Last Timestamp When The Workflow State Was Completed

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

ID	Source Table/Column	Comments/Details
M-CWSH01		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
M-CWSH02		count(Distinct "Case Routing History".Routing User) Group by ("Case Routing History"."Case ID", "Version", "State Routed From")
M-CWSH03		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
M-CWSH04		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)
M-CWSH05		count (State Name) If case goes through workflow states A -> B -> A -> B -> A -> B -> C, then result is 3
M-CWSH06		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
M-CWSH07		(# Repeated States / # Completed States) * 100 If case goes through workflow states A -> B -> A -> B -> A -> B -> C, then result is 66.6%
M-CWSH08		State End Timestamp - Version Creation Timestamp
M-CWSH09		total(Duration State-Start-To-End) for all case versions / # Versions Locked Once
M-CWSH10		total(Duration Within State) for all case versions / # Versions Locked Once
M-CWSH11		total(Duration Version-Creation-To-State-End) for all case versions / # Versions Locked Once
M-CWSH12		minimum(Duration State-Start-To-End)
M-CWSH13		minimum(Duration Within State)
M-CWSH14		minimum(Duration Version-Creation-To-State-End)
M-CWSH15		maximum(Duration State-Start-To-End)
M-CWSH16		maximum(Duration Within State)
M-CWSH17		maximum(Duration Version-Creation-To-State-End)
AD06-01	cfg_groups.group_name	
TA-PC01	case_master.case_num	
	case_master.case_id	

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

ID	Source Table/Column	Comments/Details
TA-PC02	case_routing.followup_num	Followup # as appear on Argus Case Form for the latest followup. It shall be 0 if the latest case version is Initial
TA-PC03	case_followup.significant	If Case_followup.Significant = 1 then 'Significant' else 'Non-Significant'. If the latest case version is Initial then 'Significant'
TA-PC04	cfg_enterprise.enterprise_abbrv	
TA-PC06	case_master.user_id	
TA-PC07	case_master.site_id	
TA-PC08	case_master.country_id	
TA-PC09	case_master.report_type	
TA-PC10	lm_case_classification.description	..where lm_case_classification.description has values in (7-day Case, 15-day Case, Non-Expedited Case)
TA-PC11	lm_case_classification.description	..where lm_case_classification.description has values in (SAE Case, SAR Case, SUSAR Case)
TA-PC12	lm_case_classification.description	..where lm_case_classification.description has values in (Fatal / Life-Threatening Case)
TA-PC13	lm_case_classification.description	..where lm_case_classification.description has values in (Pregnancy Case)
TA-PC14	lm_case_classification.description	..where lm_case_classification.description has values in (Authority Case, Consumer Case, Literature Case)
TA-PC15	lm_case_classification.description	..where lm_case_classification.description has values in (Medically Confirmed Case)
TA-PC16	lm_case_classification.description	..where lm_case_classification.description has values in (Case Classification 7)
TA-PC17	lm_case_classification.description	..where lm_case_classification.description has values in (Case Classification 8)
TA-PC18	lm_case_classification.description	..where lm_case_classification.description has values in (Case Classification 9)
TA-PC19	lm_case_classification.description	..where lm_case_classification.description has values in (Case Classification 10)
TA-PC20	case_product.views_available	
TA-PC21	case_study.study_num	
TA-PC22	lm_centers.center_no	where case_study.center_id = lm_centers.center_id
TA-PC23	case_assess.seriousness	
TA-PC24	case_assess.listedness	
TA-PC25	case_assess.agent_suspect	
TA-PC26	case_assess.outcome	
TA-PC27	case_pat_info.gender_id	
TA-PC28	case_pat_info.pat_stat_preg	
TA-PC29	case_pat_info.age_group_id	

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

ID	Source Table/Column	Comments/Details
TA-PC30	case_pat_info.ethnicity_id	
TA-PC31	case_pregnancy.breastfeeding	
TA-PC32	case_reporters.reporter_type	where primary_contact = 1
TA-PC33	case_product.product_name	where case_product.first_sus_prod = 1
TA-PC34	case_reporters.hcp_flag where	primary_contact = 1
TA-PC35	case_master.susar	
TA-PC36	case_master.init_rept_date	
TA-PC37	case_followup.receipt_date	
TA-PC40	max(case_master.init_rept_date/(case_followup.receipt_date where significant = 1))	
TA-PC50	case_master.deleted	
TA-PC41	case_master.worklist_owner_id	
TA-PC42	case_master.owner_id	
TA-PC43	web_cases_open.user_id	
TA-PC44	case_routing.justification_id	
TA-PC45	case_routing.seq_num	
TA-PC46	case_routing.route_date	
TA-PC47	cfg_workflow_states.state_name	where case_routing.to_state_id = cfg_workflow_states.state_id
TA-PC48	case_routing.user_id	
TA-PC49	cfg_workflow_rules.group_id	where cfg_workflow_rules.seq_num = case_routing.workflow_seq_num
M-PC01	case_master.due_soon	
M-PC02	case_master.due_soon - (2)	It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days
M-PC03		when due_soon - due_soon_val > sysdate then 1; when sysdate between (due_soon - due_soon_val) and due_soon then 2; when sysdate > cvd.due_soon then 3
M-PC04		It is customizable by the customer. They can write the logic to populate this column. By default, if Case Serious then 10 Days, else 30 Days
M-PC05		clock_start_date + lock_target_days
M-PC06		It shall be customizable by the customer, they shall be able to write the logic to populate this column. By default - 2 Days Pending Cases Fact. Lock Due Date - (2)

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

ID	Source Table/Column	Comments/Details
M-PC07		when (clock_start_date + lock_target_days - due_soon_val) > sysdate then 1 when sysdate between (clock_start_date + lock_target_days - due_soon_val) and (clock_start_date + lock_target_days) then 2 when sysdate > (clock_start_date + lock_target_days) then 3
M-PC08		case_routing.route_date + cfg_workflow_rules.max_time
M-PC09		nvl(to_number(to_char(routing_timestamp + max_time, 'RRRRMMDD')), -1)
M-PC10		when routing_timestamp + normal_time > sysdate then 1 when sysdate between (routing_timestamp + normal_time) and (routing_timestamp + max_time) then 2 when sysdate > (routing_timestamp + max_time) then 3
M-PC11		routing_timestamp + ((case due_soon - trunc(due_soon) when 0 then (due_soon + (86399 / 86400)) else cvd.due_soon - case when followup_max_time_stamp > nvl(create_time, followup_max_time_stamp - 1) then followup_max_time_stamp else reate_time)*(state_unit/total_state_units)) case_dyn_due_date_2, nvl(to_number(to_char(cvd.routing_timestamp + ((case cvd.due_soon - trunc(cvd.due_soon) when 0 then (cvd.due_soon + (86399 / 86400)) else due_soon"
M-PC12		routing_timestamp - due_soon_val +((case due_soon - trunc(due_soon) when 0 then (due_soon + (86399 / 86400)) else due_soon - case when followup_max_time_stamp > nvl(create_time, followup_max_time_stamp - 1) then followup_max_time_stamp else create_time) * (state_unit/total_state_units)
M-PC13		when state due date - II > current_date then 1 when current_date between state due soon date - II and state due date - II then 2 when current_date > state due soon date - II then 3
M-PC14	web_cases_open.case_id	
M-PC15		sum(if due soon >= sysdate then 1 else 0)
M-PC16		sum(if due soon - due soon val >= sysdate then 1 else 0)
M-PC17		sum(if due soon < sysdate then 1 else 0)
M-PC18		sum(if clock start date + lock target days - due soon val) >= sysdate then 1 else 0)
M-PC19		sum(if sysdate between (clock start date + lock target days - due soon val) and (clock start date + lock target days) then 1 else 0)

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

ID	Source Table/Column	Comments/Details
M-PC20		sum(if (clock start date + lock target days) < sysdate then 1 else 0)
M-PC21		sum(if (routing timestamp + normal time) >= sysdate then 1 else 0)
M-PC22		sum(if sysdate between (routing timestamp + normal time) and (routing timestamp + max time) then 1 else 0)
M-PC23		sum(if (routing timestamp + max time) < sysdate then 1 else 0)
M-PC24		sum(dynamic case on time)
M-PC25		sum(dynamic case due soon)
M-PC26		sum(dynamic case overdue)
M-PC27		count(case when not case_internal_id is null then 1 end)

C

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 OPVA

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*.
3. 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:

1. 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).
2. Verify that the PATH variable includes the path to the Informatica binaries (such as D:\Informatica\9.0.1\clients\PowerCenterClient\CommandLineUtilities\PC\server\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.
3. 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:

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

Method 2

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

1. Open the Informatica PowerCenter Workflow Monitor.
2. In the Repositories tree, navigate to the particular folder that contains the Informatica job.
3. 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 OPVA

You might be unable to sign in to OPVA 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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