

Oracle® Argus Insight

Administrator's Guide

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Glossary

Preface

This Oracle Argus Insight Administrator's Guide describes how to create queries, execute queries to generate a case series, and generate reports on the case series. In addition, this guide describes how to use the Argus Insight administration tools to configure, maintain, and secure the application.

This preface includes the following topics:

- [Audience](#)
- [The Oracle Health Sciences Safety Suite](#)
- [Documentation Accessibility](#)
- [Finding Information and Patches on My Oracle Support](#)
- [Finding Oracle Documentation](#)
- [Related Documents](#)
- [Conventions](#)

Audience

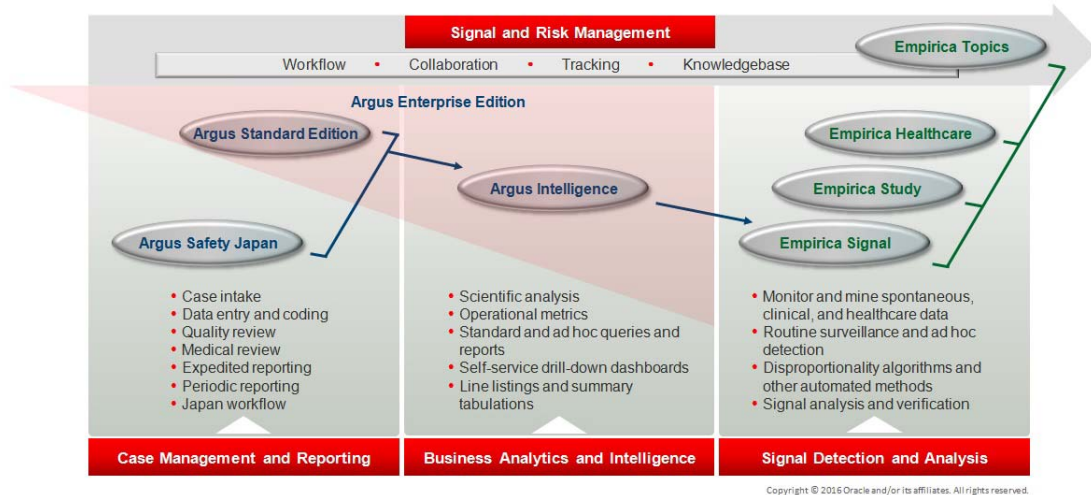
This document is intended for all Argus Insight administrators.

The Oracle Health Sciences Safety Suite

This product is part of the Oracle Health Sciences Safety Suite, an integrated solution for end-to-end vigilance from adverse event management to signal management, through the entire lifecycle of a medicinal product from clinical trials to post-marketing surveillance.

Oracle Health Sciences Safety Suite

Integrated Solution for End-to-End Vigilance Through the Entire Product Lifecycle



The Oracle Health Sciences Safety Suite consists of the following components:

- Oracle Argus Standard Edition: Manage and report adverse events through a workflow including case intake, data entry, coding, quality review, medical review, expedited reporting, and periodic reporting. Modules include Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, Oracle Argus Unblinding, and the Oracle Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus.
- Oracle Argus Enterprise Edition: In addition to managing the adverse event workflow and reporting, employ a powerful and flexible business analytics and intelligence platform for both scientific analysis and operational metrics. Modules include Oracle Argus Analytics, Oracle Argus Insight, Oracle Argus Mart, Oracle Argus Safety, Oracle Argus Interchange, Oracle Argus Affiliate, Oracle Argus Dossier, Oracle Argus Unblinding, and the Oracle Health Sciences Adverse Event Integration Pack for Oracle Health Sciences InForm and Oracle Argus.
- Oracle Argus Safety Japan: Manage and report adverse events in Japan, and connect the global and local workflows using a single database.
- Oracle Health Sciences Empirica Topics: Manage and document safety signals through a workflow including validation, prioritization, assessment, confirmation/refutation, and resulting actions.
- Oracle Health Sciences Empirica Study: Detect and analyze safety signals in clinical trial data including adverse events, clinically significant labs, electrocardiograms, vital signs, and shifts from baseline.
- Oracle Health Sciences Empirica Signal: Detect and analyze safety signals in post-marketing spontaneous adverse reaction data including public health authority databases and/or private inhouse databases such as Oracle Argus.
- Oracle Health Sciences Empirica Healthcare Analysis: Evaluate safety signals in healthcare data including electronic medical records and administrative claims, and support pharmacoepidemiology, comparative effectiveness analysis, and health economics and outcomes research.

For more information on Argus Safety, visit the Oracle Health Sciences Safety suite page at:

<http://www.oracle.com/goto/pharmacovigilance.html>

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 that have purchased support have access to electronic support through My Oracle Support. For information, visit

<http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info> or visit

<http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

Finding Information and Patches on My Oracle Support

Your source for the latest information about Argus Insight is Oracle Support's self-service website My Oracle Support.

Before you install and use Argus Insight, always visit the My Oracle Support website for the latest information, including alerts, White Papers, and bulletins.

Creating a My Oracle Support Account

You must register at My Oracle Support to obtain a user name and password account before you can enter the website.

To register for My Oracle Support:

1. Open a web browser to <https://support.oracle.com>.
2. Click the **Register** link to create a My Oracle Support account.

The Registration page appears.

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 <https://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.

Finding Information on My Oracle Support

There are many ways to find information on My Oracle Support.

Searching by Article ID

The fastest way to search for information, including alerts, White Papers, and bulletins is by the article ID number, if you know it.

To search by article ID:

1. Sign in to My Oracle Support at <https://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 appears with the search results.

If the article is found, click the link to view the abstract, text, attachments, and related products.

Searching by Product and Topic

You can use the following My Oracle Support tools to browse and search the knowledge base:

- **Product Focus** — On the Knowledge page under Select Product, type part of the product name and the product list is populated with the letters you have typed. (You do not need to type "Oracle.") Select the product you want from the filtered list, and then use other search or browse tools to find the information you need.
- **Advanced Search** — You can specify one or more search criteria, such as source, exact phrase, and related product, to find information. This option is available from the **Advanced** link on almost all pages.

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 <https://support.oracle.com>.
2. Click the **Patches & Updates** tab.

The Patches & Updates page appears and displays the Patch Search region. Do one of the following:

- In the **Patch ID or Number** field, enter the number of the patch you want. (This number is the same as the primary bug number fixed by the patch.) 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 appears.

4. Click the patch ID number.

The patch details appears.

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 Oracle Documentation

The Oracle website contains links to all Oracle user and reference documentation. You can view or download a single document or an entire product library.

Finding Oracle Health Sciences Documentation

To get user documentation for Oracle Health Sciences applications, go to the Oracle Health Sciences documentation page at:

<http://www.oracle.com/technetwork/documentation/hsgbu-154445.html>

Note: Always check the Oracle Health Sciences Documentation page to ensure you have the latest updates to the documentation.

Finding Other Oracle Documentation

To get user documentation for other Oracle products:

1. Go to the following web page:

<http://www.oracle.com/technology/documentation/index.html>

Alternatively, you can go to <http://www.oracle.com>, point to the Support tab, and then click **Documentation**.

2. Scroll to the product you need, and click the link.
3. Click the link for the documentation you need.

Related Documents

This section lists the documents in the Argus Insight documentation set, followed by their part number. The most recent version of each guide is posted on the Oracle website; see [Finding Oracle Health Sciences Documentation](#).

- *Oracle Argus Insight Installation Guide*
- *Oracle Argus Insight User's Guide*
- *Oracle Argus Insight Minimum Security Configuration Guide*
- *Oracle Argus Insight Extensibility Guide*

The release notes are also posted in the Oracle Health Sciences documentation library.

In addition, Argus Insight customers can request copies of the following Argus Insight technical reference manuals from Customer Support:

- *Oracle Argus Insight CMN Profile Enterprise Table Guide*
- *Oracle Argus Insight CMN Profile Global Table Guide*
- *Oracle Argus Insight Database Administrator's Guide*
- *Oracle Argus Insight Entity Relationship Diagram Reference*

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 text or the glossary.
<i>italic</i>	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values. Besides, it also indicate terms that are defined in the glossary.
monospace	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

Introduction

Argus Insight, formerly called Power Reports, is a highly optimized reporting module that compliments Argus Safety.

The Argus Insight Extract Transform and Load (ETL) engine extracts data from the Argus Safety database and populates a *data warehouse* in a format that allows efficient querying. The *query*, drill-down, and output components of Argus Insight let you analyze your safety, workflow, or product data from all angles and produce reports that provide immediate business impact and maximum efficiency in decision-making.

This chapter includes the following topics:

- [Overview of Generating Reports in Argus Insight](#)
- [Argus Insight Components](#)
- [Argus Insight Process Flow](#)
- [Product Compatibility and Upgrade Options](#)

Overview of Generating Reports in Argus Insight

With Argus Insight, you can generate a *report* in any of the following ways:

- Use a *query* to retrieve a specific set of cases (*a case series*) from Insight Mart, and then run a predefined report for those cases. Use the following Argus Insight components to retrieve the case series:
 - Query By Example (QBE)
 - Filters
 - Advanced Conditions
- Run the Built-in BIP standard reports on the case series to create and store these in the Reports library.
- Run the Custom reports on the case series/power queries to create and store these in the Reporting Tools.

Argus Insight Components

Argus Insight includes the following components:

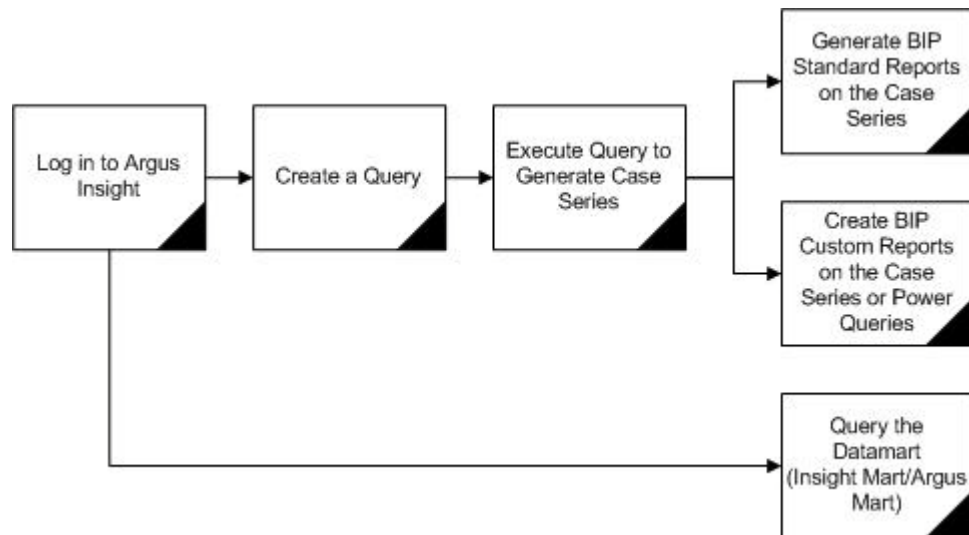
- **Query by Example (QBE)** — Lets you create simple queries by entering specific values in fields on a *form* that looks substantially like the Argus Safety case form.
- **Filters** — Lets you create queries by selecting a set of predefined fields and specifying multiple values in a *field*.

- **Advanced Conditions** — Lets you create complex queries by selecting any of the fields in the data mart (Insight Mart/Argus Mart), and then applying Boolean and Set operations on them.
- **Case Series** — Provides a listing of all the cases that match the specified query criteria.
- **BIP Standard Reports** — Lets you run one or more reports on the case series. The BIP Standard Reports are predefined reports shipped with Argus Insight. These reports are available in the BIP > General folder.

Argus Insight Process Flow

The flowchart in [Figure 1-1](#) depicts the typical steps to generate a *report* in Argus Insight. Refer to your company's guidelines for the exact workflow for generating reports and analyzing data in Argus Insight.

Figure 1-1 Overview of Generating a Report in Argus Insight



[Table 1-1](#) describes the tasks shown in the flowchart.

Table 1-1 Tasks in the Process Flow

Task	Description
Log on to Argus Insight	Log on to the Argus Insight application.
Create a <i>Query</i>	Depending on the complexity of the query, use these Argus Insight components to create a query: <ul style="list-style-type: none"> ■ Query by Example (QBE) — To create simple queries based on the fields in the Argus case <i>form</i> ■ Filters — To create queries based on multiple values in a set of predefined fields ■ Advanced Conditions — To create complex queries by directly selecting data mart (Insight Mart/Argus Mart) fields and applying Boolean and set operations on them
Execute the Query to Generate a Case Series	Execute the query to have the system search the entire data mart (Insight Mart/Argus Mart) and retrieve a list of cases (case series) that match the criteria you specified while creating the query.

Table 1–1 (Cont.) Tasks in the Process Flow

Task	Description
Generate BIP Standard Reports on the Case Series	Select and run a built-in BIP standard report. You can limit this report to only run on the case series.
Generate BIP Custom Reports on the Case Series/Power Queries	Select and run a custom report you created and stored in the BI Tool(s) library. You can limit this report to only run on the Case Series/Power Queries from BI Tool(s).
Query the Data Mart (Insight Mart/Argus Mart)	Use BI Tool(s) to directly query the mart.

Product Compatibility and Upgrade Options

This section describes the compatibility and upgrade options for Argus Insight 8.1.

Compatibility of Argus Insight with Argus Safety

Argus Insight 8.1 is compatible with Argus Safety 8.1.

Compatibility of Argus Insight with Reporting Tools

Argus Insight 8.1 can be used together with a reporting tool, which can be BI Publisher, BusinessObjects, Cognos, or any combination of these three.

Upgrade Paths to Argus Insight 8.1

You can upgrade directly to Argus Insight 8.1 from the following versions of Argus Insight:

- Argus Insight 8.0 (single-tenant to single-tenant installation)
- Argus Insight 8.0 (multi-tenant to multi-tenant installation)

The general steps for upgrading to Argus Insight 8.1 are as follows:

- Upgrade your current Argus Safety application to the Argus Safety 8.1 environment.
- Install the Argus Insight 8.1 application.
- Run the Initial ETL.

For information about upgrading your database to Argus Insight 8.1, see the *Oracle Argus Insight Installation Guide*.

Copy Configuration Utility

Use the Copy Configuration utility to import all the configuration data from the following Argus Insight versions and then export the data to Argus Insight 8.1:

- Argus Insight 8.1 (single-tenant to single-tenant installation).
- Argus Insight 8.1 (multi-tenant to multi-tenant installation). In this case, the utility copies all the enterprise data from one multi-tenant enterprise to another multi-tenant enterprise in Argus Insight, including the enterprises that are marked as *Inactive*.

The Copy Configuration utility:

- Maps the source enterprises to the target enterprises based on the short name of the enterprise.
- Copies the user-specific configuration data *only* for those users in an enterprise who exist in Argus Safety as well for that enterprise.
- Includes the report packaging data for case series, but does not include the report packaging data for frozen case series.
- Does not include the configuration of those enterprises that do not exist in the target system.
- Does not overwrite the configuration of any additional enterprises that exist in target system.

Getting Started

This chapter includes the following topics:

- [About Login Accounts and Access](#)
- [Logging In to the Argus Insight Application](#)
- [Setting Your Personal Options](#)
- [Entering Dates in Argus Insight Date Fields](#)
- [Viewing the Database Name and Argus Insight Release](#)
- [Viewing the Online Help](#)
- [Extending Argus Insight Features](#)
- [Logging Out](#)

About Login Accounts and Access

All users can access Argus Insight directly by using the Argus Insight application URL. Argus Insight checks if the Enterprise ID is already present in the incoming request. If the Enterprise ID exists, the system opens Argus Insight for that enterprise.

System Administrator Account

The Argus Insight installation program creates a system administrator account (Admin) that is synced from Argus Safety through Schema Creation and Initial ETL.

The administrator account cannot be deleted. This restriction ensures that the system administrator can always log in to the system. In a given session, only one system administrator can log in to the system.

You can access Argus Insight through Argus Safety. This feature enables you to use a single login user name and password for all Argus modules. The modules that are enabled when you log in to Argus Safety depend on your access rights to Argus modules.

Single Sign-On Accounts

System administrators can create a user account that allows you to log in to Argus Insight, as well as other Argus applications, using the same user name and password. This type of account is a *single sign-on account*, or SSO account.

For single sign-on accounts, note that:

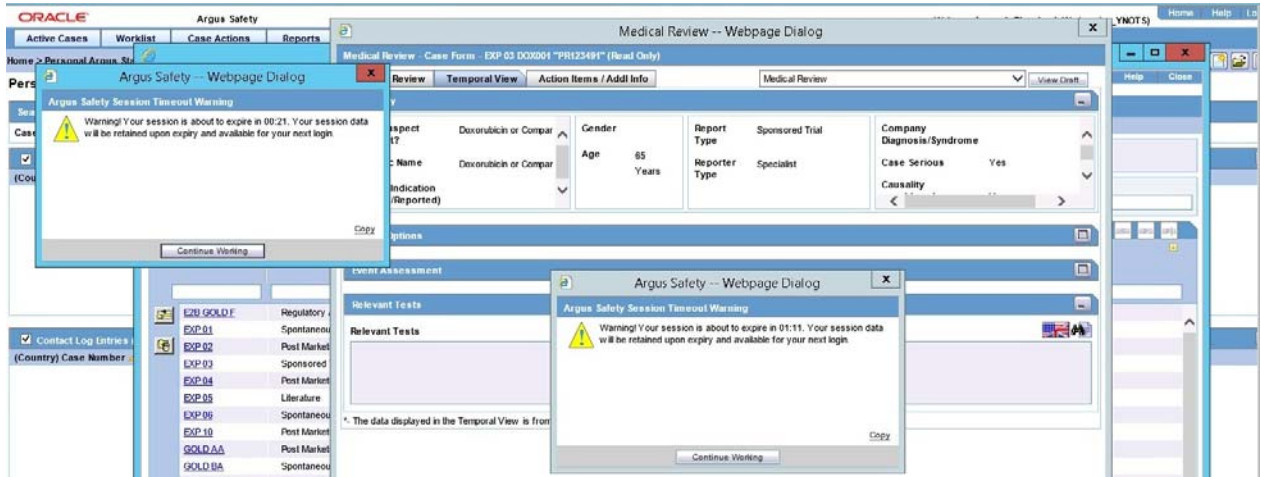
- A user's login authentication is done by a centralized authentication system. Therefore, users do not need to enter their login credentials for each application they access, every single time. Cognos uses the Power Reports namespace.
- The system administrator defines access to the modules in User Maintenance. If you are assigned to more than one group, the system grants you the highest access level.
 - Based on your access rights to modules, the system enables or disables the application buttons access rights in the menus.
 - Group access permissions are assigned in web administration.
- If you have access to Argus Safety or Argus Insight, you can start the application modules. The system does not ask you to enter a password again for the Power Reports or Argus Safety modules. This also applies when you start other applications.
- In User Maintenance, the system administrator can link the Argus Safety database and the Argus Insight data mart. When you log in, the system identifies the available application modules for each Argus instance.
- When you click the application module, the system opens a new window where you can work on the other application (Argus Insight or Argus Safety).
- When you start another application through Argus, or vice versa, the application module buttons **do not appear** in the new windows because you are already logged in to the earlier application.
- The initial login screen is the starting dialog box for all the other modules.
- Logout is available only on the *parent* application dialog box. Logging out of the parent application dialog box closes all child dialog boxes **without** saving information in the child applications.
- Argus Insight Session Timeout

You can now configure a value for session expiry time in Argus Safety, based on which the idle session for the configured time is handled. When **Single Sign On** or **Load Balancer** is enabled in Argus Safety and Argus Insight, Argus Insight extends the session timeout in Argus Safety, and you may continue the work.

If both Argus Safety and Argus Insight are idle for the configured time, a warning message appears in Argus Safety stating whether you want to continue the work or not. If you do not click on **Continue**, the session expires, and Argus Insight is closed.

However, when Argus Insight > Medical Review screen is opened through Argus Safety, Argus Safety treats this time as idle and a warning message appears.

If the Medical Review screen is left idle as well, then two separate dialog boxes appears for both Argus Safety and Argus Insight > Medical Review screen.



Logging In to the Argus Insight Application

To start Argus Insight and log in to the application:

1. Open Microsoft Internet Explorer.
2. Type the Argus Insight Universal Resource Locator (URL) in the address bar.

If you do not know the URL, contact your system administrator configures the URL.

The system uses Secure Socket Layers (SSL) to support third-party digital certificates for secure transmissions at the system level.

3. Press Enter.

Argus Insight Login screen appears.

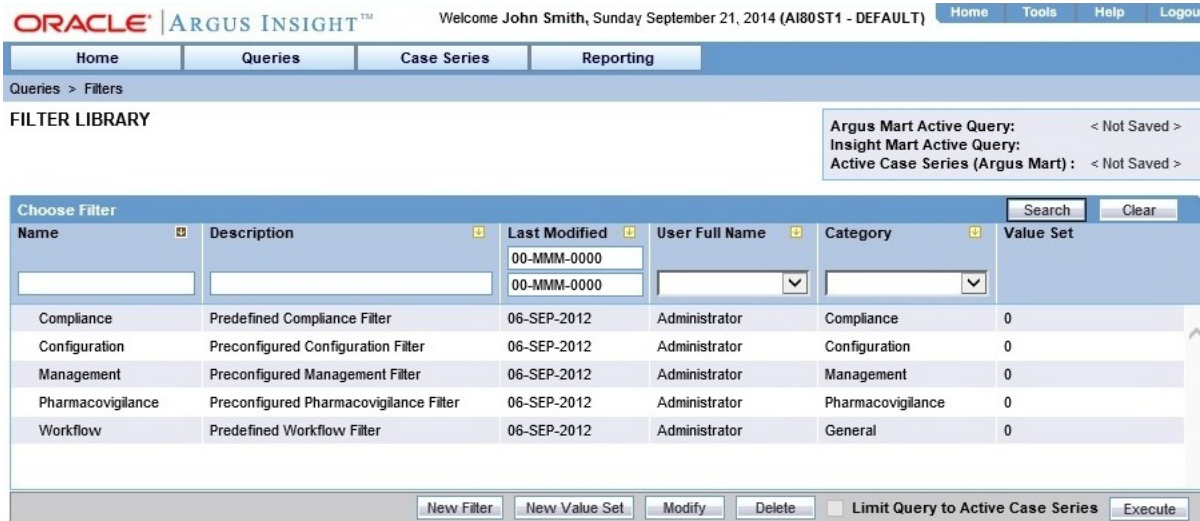


4. Enter user name and password in the respective fields.
5. Click **Login**.

The FILTER LIBRARY page appears. (Default, see [Figure 2-1](#))

To make another page as your default Home page, refer to "[Changing the Default Home Page](#)" on page 2-5.

Figure 2-1 Argus Insight Default Home Page

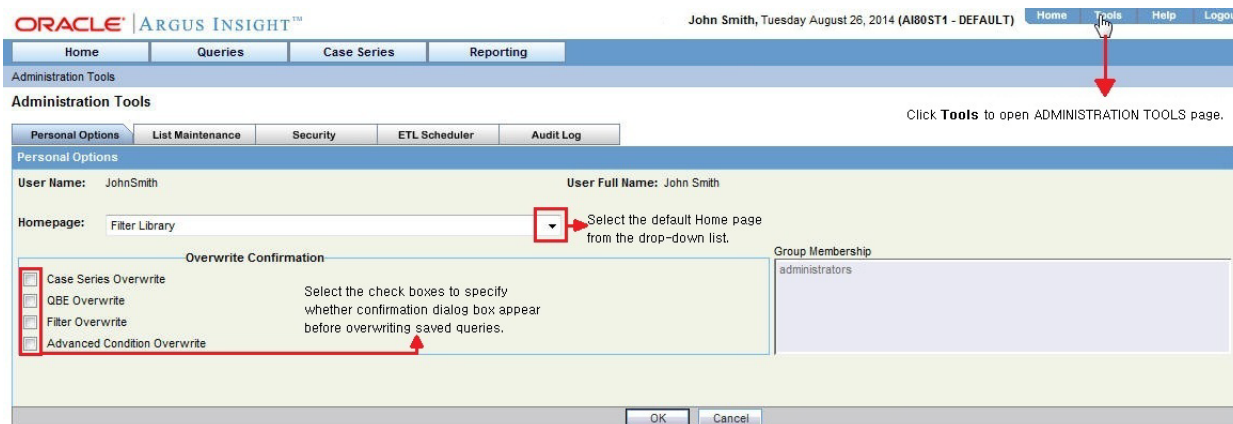


Setting Your Personal Options

Using the Personal Options tab on the ADMINISTRATION TOOLS page (see [Figure 2-2](#)), you can:

- Specify the default Home page for Argus Insight
- Specify whether the system prompts you for confirmation before overwriting saved case series or queries
- View the groups for which you are a member

Figure 2-2 Personal Options Tab on the ADMINISTRATION TOOLS Page



Note: The options available in the Overwrite Confirmation section may vary based on the Argus Insight Data Source (Insight Mart/Argus Mart/Both).

Changing the Default Home Page

The default Argus Insight Home page is the FILTER LIBRARY page.

To change the default Home page:

1. Click **Tools** on the global toolbar.

The ADMINISTRATION TOOLS page appears with the Personal Options tab in focus.

2. In the **Homepage** field, select a page from the drop-down list.



3. Click **OK**.

The default Home page is updated as per the selection, and a confirmation dialog box appears.

4. Click **OK** to close the dialog box.

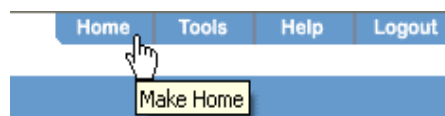
You return to the Personal Options tab.

The next time you click **Home** or log in to Argus Insight, the system displays your selected Home page.

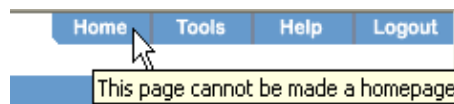


Alternative Method to Selecting a Home Page

Alternatively, click **Home** on the global toolbar to make the current page as your default Home page.



Note that if you cannot make the current page as your Home page, an informational message appears when you hover **Home**.



Changing Your Preferences for Overwrite Confirmation

When you save your modifications to an existing case series, a QBE, a filter, or an advanced condition, Argus Insight saves your changes directly *without* prompting you

to confirm whether you want to overwrite the existing one. This behavior is the default.

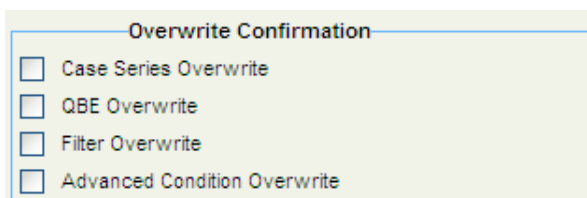
You can choose to have Argus Insight display a confirmation dialog box before overwriting a saved case series or query.

To change whether the system prompts for confirmation:

1. Click **Tools** on the global toolbar.

The ADMINISTRATION TOOLS page appears with the Personal Options tab in focus.

2. In the Overwrite Confirmation section, select the check boxes to define your preferences, and click **OK**.



The confirmation dialog box appears.

3. Click **OK** to close the dialog box.

You return to the Personal Options tab.

Viewing Group Memberships

The **Group Membership** list on the Personal Options tab displays the names of the groups to which you belong.

Group memberships are managed from the Security tab on the ADMINISTRATION TOOLS page. Only a system administrator can manage users and groups.

Entering Dates in Argus Insight Date Fields

Several fields in Argus Insight are date fields. Some date fields require a *full* date; other date fields accept a *partial* date.

Entering a Full Date

For fields that require a *full* date, you must enter the date in the following format:

dd-mmm-yyyy

where:

dd = Day of the month.

mmm = 3-letter abbreviation for the month. For example, FEB or AUG.

You may also enter a valid month number. In this case, the system converts the number to the 3-letter abbreviation for the corresponding month. For example, the system converts 12 to DEC.

yyyy = 4-digit year. For example, 1998 or 2012.

Entering Today's Date

To enter today's date in a date field, press the = (equals) key.

Entering a Partial Date

For fields that accept a *partial* date, Argus Insight displays ??-??-0000 in the field.

See [Figure 2–3](#) for several examples.

Figure 2–3 Examples of Date Fields that Accept Partial Dates

The screenshot shows the 'General Information' tab of an Argus Insight form. It contains several date-related fields:

- Report Type:** A text input field.
- Country:** A dropdown menu.
- Initial Receipt Date:** A date input field containing the partial date '??-??-0000'.
- Follow-up Received:** A date input field containing the partial date '??-??-0000'.
- Safety Received:** A date input field containing the partial date '??-??-0000'.
- Significant:** A checkbox.

For reporting purposes, missing days of the month are approximated to the 15th of the month and missing months are approximated to the month of June.

Valid partial dates must comprise either a year, or a year and a month. If you enter the day, you also need to enter the month.

To enter a date that includes only the month and year (for example, March 2012), you may enter any one of the following sequences:

- /MAR2012
- /32012
- /312
- 00MAR2012
- 0032012
- 00312
- ??MAR2012
- ??32012
- ??312

To enter a date that includes only the year (for example 2012), you may enter any one of the following sequences:

- //2012
- //12
- 00002012
- 000012
- ?? ??2012
- ?? ???12
- ??2012
- ??12

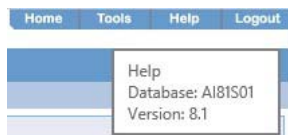
[Table 2–1](#) lists the fields in the tabs on the QUERY BY EXAMPLE page, which is similar to the Argus case form, that accept partial dates.

Table 2–1 QBE Fields that Accept a Partial Date

QBE Tab	Section Name	Field Name
General	General Information	Initial Receipt Date, Central Receipt Date, Follow-up Received, Safety Received, Aware Date
	Study Information	Unblinding Date
Patient, Patient	Patient Details	Date of Birth, Date of LMP
	Lab Data	Date
	Other Relevant History	Start, Stop Date
Patient, Parent	Parent Information	Date of Birth, Date of LMP
	Other Relevant History	Start, Stop Date
Products	Dosage Regimens	Start Date/Time, Stop Date/Time, Expiration Date
	Product Details	First Dose, Last Dose, Date, Start Date/Time, Stop Date/Time
Events	Event Information	Onset Date/Time, Receipt Date, Stop Date/Time
Activities	Contact Log	Date, Date Start
	Action Items	Date Open, Due, Completed
	Case Lock/ Archive	Lock Date, Closure Date

Viewing the Database Name and Argus Insight Release

To view the name of the database and the release of Argus Insight that you are using, position the cursor over **Help** on the global toolbar:



Viewing the Online Help

To view the online help, click **Help** on the global toolbar.

Depending on your privileges, the system opens either the user's guide or the administrator's guide in HTML format. Use the **Contents**, **Next**, and **Previous** links, as well as the links on the Contents page and throughout the document, to navigate to topics and pages in the guide.

Extending Argus Insight Features

For instructions on creating custom reports, as well as customizing code lists and the ETL, refer to the *Oracle Argus Insight 8.1 Extensibility Guide*.

Logging Out

1. Click **Logout** on the global toolbar.
A confirmation dialog box appears.
2. Click **OK**.
The Argus Insight login screen appears.

Creating Queries by Example

In Argus Insight, you use queries to search the data mart and retrieve a *set of cases* (known as a *case series*) with similar attributes. Based on your reporting requirements, your querying criteria may be as simple as a few Argus Safety case *form* fields with specific values or as complex as a SQL query that uses Boolean and Set operations between data mart fields.

Argus Insight provides several tools that you can use to enter, modify, and save queries. This chapter, which describes how to use the *Query by Example (QBE)* tool, includes the following topics:

- [Overview of the Query by Example Tool](#)
- [Starting a New QBE](#)
- [Query By Example Page — Input Fields](#)
- [Assigning Group-Level Permissions to a Saved QBE](#)
- [Working with the Last Modified or Executed QBE](#)
- [Working with Saved QBEs](#)
- [Using QBEs with Advanced Conditions](#)

In addition to the QBE tool, Argus Insight provides the following query tools:

- [Filters](#) (see [Chapter 4, "Using Filters to Create Queries"](#))
- [Advanced Conditions](#) (see [Chapter 5, "Using Advanced Conditions to Create Queries on Insight Mart"](#))
- [Library](#) (see [Chapter 6, "Using Advanced Conditions to Create Point-in-Time Queries on Argus Mart"](#))

Overview of the Query by Example Tool

If you are familiar with the Argus Safety case form, you may want to use *Query by Example (QBE)* to create simple queries. For a QBE, the querying criteria consists of specific values that you enter in the fields on the QUERY BY EXAMPLE page, which looks substantially like the Argus Safety case form. See [Figure 3-1](#).

Note: Query By Example is NOT supported, if target data source is set as Argus Mart only.

Figure 3–1 QUERY BY EXAMPLE Page

QUERY BY EXAMPLE Page — Tab Description

The QUERY BY EXAMPLE page has a tab-based interface consisting of eight multiple section tabs.

Each tab on the QUERY BY EXAMPLE page lets you enter query criteria about a specific aspect of a case:

- **General tab** — Specify general, *study*, reporter, and literature information about the case.
- **Patient tab** — Specify information about the patient, lab data, other relevant history, and the patient's parent.
- **Products tab** — Specify product information and dosage regimens.
- **Events tab** — Specify event information and its seriousness criteria.
- **Analysis tab** — Specify information about case analysis and imputability.
- **Activities tab** — Specify case activity information, such as contact logs, action items, and case lock/archive dates.
- **Additional Info tab** — Specify additional information about the case such as reference type, ID, and notes.
- **Advanced Conditions tab** — Integrate a QBE with an advanced condition stored in Argus Insight. The advanced conditions based on Insight Mart only are displayed.

In addition, you can convert a QBE into an advanced condition. For more information, see [Chapter 5, "Using Advanced Conditions to Create Queries on Insight Mart."](#)

Example of a QBE

For example, your QBE may consist of values in the following fields:

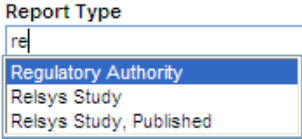
Tab Name	Field Name	Value
General	Country of Incidence	United States
Products	Product Name	Algoheal Injection
Events	Event Description to be Coded	Injection site rash
	Seriousness Criteria	Hospitalized

When you execute this QBE, the system retrieves only those cases in the United States where the patient was given an algoheal injection, and then broke out in a rash due to the injection and was hospitalized.

Using the Type-Ahead Feature in Input Fields

Argus Insight provides *type-ahead* functionality for some fields in the QUERY BY EXAMPLE page.

When you begin to type a value into a field that supports type-ahead functionality, Argus Insight displays a list of valid values that match your entry. You can then select one of the suggested values from the list. For example:



Alternatively, you can double-click any field that supports type-ahead functionality. In this case, Argus Insight displays a complete list of the valid values for the field. You can then select a value from the list. For example:



Table 3–1 lists the input fields in the QUERY BY EXAMPLE page that support the type-ahead feature.

Table 3–1 Fields that Support the Type-Ahead Feature

Accidental Exposure	Action Taken	Action Type
Age Group	Age Units	Case Outcome
Classification	Code (Activities: Action Items)	Code (Activities: Contact Log)

Table 3–1 (Cont.) Fields that Support the Type-Ahead Feature

Condition Type	Dosage Frequency	Dosage Units
Ethnicity	Event Frequency	Event Intensity
Event Outcome (Outcome of Event)	Formulation	Gender
Group (Activities: Action Items)	Group (Activities: Contact Log)	Intermediary
Locked or Closed By	Manufacturer	Occupation
Pack Units	Product Units	References Type
Report Media	Report Type	Reporter Type
Route of Administration (Patient and Parent)	User (Activities: Action Items)	User (Activities: Contact Log)

Starting a New QBE

This section describes the tasks for creating a new QBE:

- [Entering Your Search Criteria and Executing the QBE](#)
- [Reviewing the Results of Your QBE](#)
- [Reviewing and Modifying the Criteria for an Executed QBE](#)
- [Saving the QBE](#)

Entering Your Search Criteria and Executing the QBE

To enter your criteria for a QBE and execute the QBE:

1. Navigate to **Queries > Query by Example**, and select **New**.

The QUERY BY EXAMPLE page appears with the **General** tab in focus.

2. Specify the criteria for your query.

You may enter values into any of the fields on any of the QBE tabs, as appropriate.

Note: The field labels are displayed as per the field labels configured in Argus Safety.

For a description of each field and for additional information about entering values into certain fields, see the following sections:

- [General Tab](#)
- [Patient Tab](#)
- [Products Tab](#)
- [Events Tab](#)
- [Analysis Tab](#)
- [Activities Tab](#)
- [Additional Info Tab](#)

Tip: When you are entering criteria for your query:

- To clear all the values you entered on the current tab only, click **Clear Tab**.
- To clear all the values you entered on all the tabs, click **Clear All**.

3. Click **Execute** to run your query.

The system searches for cases that match your query, begins to build the case series, and displays a progress message during the process.

4. Wait until the system completes the search.

See "[Reviewing the Results of Your QBE](#)" on page 3-5, for information about how to continue.

Reviewing the Results of Your QBE

When you click **Execute** to run a QBE, the system searches for all the cases that match your query criteria and builds a *case series*.

- If the system finds cases that match your query criteria, the ACTIVE CASE SERIES page displays the results.

See [Figure 3–2](#) for an example.

Examine the results in the ACTIVE CASE SERIES page:

- If the case series is too large, you may want to modify your query by specifying additional field values in the QBE form to narrow down the case series.

For more information, see "[Reviewing and Modifying the Criteria for an Executed QBE](#)" on page 3-6.

- If the case series is appropriate, you may want to save your QBE. For more information, see "[Saving the QBE](#)" on page 3-7.

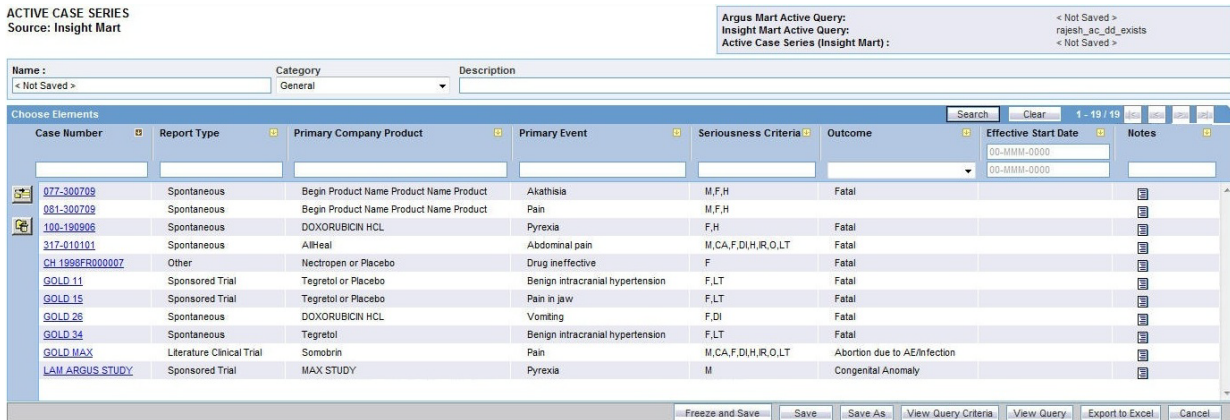
- If the system does not find any cases that match your query criteria, the ACTIVE CASE SERIES page displays the following message:

No Cases found!

You probably want to modify your query and then execute the QBE again.

For more information, see "Reviewing and Modifying the Criteria for an Executed QBE" on page 3-6.

Figure 3–2 ACTIVE CASE SERIES Page



Reviewing and Modifying the Criteria for an Executed QBE

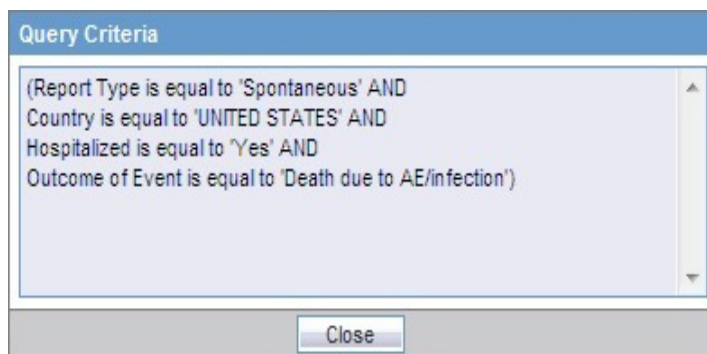
The ACTIVE CASE SERIES page displays the results of your QBE. When you review the results, you may want to modify your query and execute the QBE again.

For example, perhaps the results are too limiting and you want to remove some of the query criteria.

From the ACTIVE CASE SERIES page, you have several options:

- To open a dialog box and review the criteria that you specified for the active case series, click **View Query Criteria**.

For example:



- To return to the QBE form and modify your query, click **View Query**.

The ACTIVE QUERY BY EXAMPLE page appears.

Note that the page retains all the values you entered for your query.

When you execute a QBE or save modifications to a QBE, the system assigns the *active* status to the QBE. Therefore, when you click **View Query** to return to the QBE form, note that the page title changes to ACTIVE QUERY BY EXAMPLE.

See "[Working with the Last Modified or Executed QBE](#)" on page 3-34 for details on active QBEs.

- To cancel the current QBE and return to the QUERY BY EXAMPLE page, click **Cancel**.

You can continue to modify the QBE, execute the QBE again, and review the results.

Saving the QBE

To save a QBE:

1. View your QBE on the ACTIVE QUERY BY EXAMPLE page.

ACTIVE QUERY BY EXAMPLE

		Argus Mart Active Query: < Not Saved >
		Insight Mart Active Query: test qbe
		Active Case Series (Insight Mart): < Not Saved >

Name :	Category	Description
US	General	US

2. Use the **Category** field to assign a category to the QBE.

The category indicates the reporting aspect to which your QBE pertains.

For example, Case Processing, Compliance, Configuration, General, Management, or Pharmacovigilance. Specifying the category helps you when searching for relevant QBEs from a list of all the QBEs saved in the system.

3. Use the **Description** field to enter summary information about the QBE.

For example, you can describe the type of cases the QBE retrieves.

4. Click **Save As**.

The **Save QBE As** dialog box appears.

5. Enter the name of the QBE.

Note: Names cannot contain these characters: % " ' \$ ^ ~ , ' / ; | #

6. Click **OK**.

Note that:

- The page title changes to QUERY BY EXAMPLE.
- The Active Query Name field in the upper-right corner of the page now displays the name you specified when saving the QBE.
- The Category and Description fields display the information you entered before you saved the QBE.

ACTIVE QUERY BY EXAMPLE

		Argus Mart Active Query: < Not Saved >
		Insight Mart Active Query: test qbe
		Active Case Series (Insight Mart): < Not Saved >

Name :	Category	Description
test qbe	General	Study 101, Site 9294, AE MI, Fatal

Note: The QUERY BY EXAMPLE LIBRARY page lists all the QBEs saved to the system. See "[Working with Saved QBEs](#)" on page 3-35 for more information.

Tip: If you make modifications to the field values after you saved the QBE to the system, click **Save** to save the changed field values.

Query By Example Page — Input Fields

When you enter criteria for a QBE, you can enter values into any of the fields in any of the tabs on the QUERY BY EXAMPLE page.

This section summarizes the contents of each tab, describes each field, and provides additional information about entering values into certain fields.

General Tab

In the **General** tab (see [Figure 3-3](#)), you can:

- Specify only one follow-up date.
- Specify only one case classification.
- Specify information only about one reporter.
- Scroll the page to view all the fields available.

Figure 3-3 QUERY BY EXAMPLE Page — General Tab

The screenshot displays the Oracle Argus Insight interface for the 'QUERY BY EXAMPLE' page, specifically the 'General' tab. The page is titled 'QUERY BY EXAMPLE' and includes a navigation bar with 'Home', 'Queries', 'Case Series', and 'Reporting'. The main content area is divided into several sections:

- General Information:** Includes fields for 'TEST Report Type', 'Country of Incidence', 'Initial Receipt Date', 'Central Receipt Date', 'Case Status', 'Follow-up Received', 'Safety Received', 'Date for Reports', and 'Classification'.
- Study Information:** Includes fields for 'Project ID', 'Study ID', 'Center ID', 'Other ID', 'Study Type', 'Week #', 'Visit #', 'Blinding Status', and 'Unblinding Date'.
- Reporter Information:** Includes fields for 'Sal.', 'First Name', 'Middle Name', 'Last Name', 'Suffix', 'Health Care Professional', 'Occupation', 'Address', 'Institution', 'Department', 'City', 'State/Province', 'Postal Code', 'Country', 'Phone Number', 'Alternate Phone', 'FAX Number', 'Reporter ID', 'Reporter's Reference #', 'Email Address', 'Reporter Type', 'Report Media', and 'Intermediary'.
- Literature Information:** Includes fields for 'Author', 'Year', 'Title', 'Vol', 'Journal', and 'Page'.

At the bottom of the page, there are buttons for 'Save', 'Save As', 'Convert to Advanced Condition', 'Clear Tab', 'Clear All', and 'Execute'.

[Table 3-2](#) describes the fields in the **General** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Table 3–2 QUERY BY EXAMPLE Page > General Tab — Field Description

Section	Field or Check Box	Description
General Information	Report Type	Select the case source that the query looks for in cases.
	Country	Select the country of incidence that the query looks for in cases.
	Initial Receipt Date	Enter the date when your company first became aware of the case.
	Central Receipt Date	Enter the date on which Central Safety received the case.
	Case Status	Select the workflow state that the query looks for in cases.
	Follow-up Received	Enter the follow-up information receipt date.
	Safety Received	Enter the date on which follow-up information was received by Central Safety.
	Significant	Select this check box to retrieve cases that had a significant follow-up.
	Aware Date	Enter the most recent significant follow-up date or initial receipt date (if there are no follow-ups) that the query looks for in cases.
Classification	Select the classification that the query looks for in cases.	
Study Information	Project ID Study ID Center ID	Click the Select button associated with these fields to select the Project ID, the Study ID, and the Center ID. See " Selecting the Study Information " on page 3-10 for details.
	Other ID	Enter any other ID that can be relevant to the study.
	Study Type	Select the study type to include in the query.
	Week #	Enter the week number of the study during which the adverse event occurred. The query will only look for such cases.
	Visit #	Enter the visit number of the study during which the adverse event occurred. The query will only look for such cases.
	Blinding Status	Select the study blinding status that the query looks for in cases.
	Unblinding Date	Enter the date on which the study was broken. The query will only look for cases with matching study broken date.
Reporter Information	Sal.	Enter the reporter's salutation that the query looks for in cases.
	First Name	Enter the reporter's first name to look for in cases.
	Middle Name	Enter the reporter's middle name to look for in cases.
	Last Name	Enter the reporter's last name to look for in cases.
	Suffix	Enter the reporter's suffix to look for in cases.
	Health Care Professional	Select an option from the list to include a query criterion based on whether the reporter is a health care professional.
	Occupation	Select the reporter's occupation that the query looks for in cases.
	Address	Enter the report address that the query looks for in cases.
	Institution	Enter the reporter's institution that the query looks for in cases.
	Department	Enter the reporter's department that the query looks for in cases.
	City	Enter the reporter's city that the query looks for in cases.
	State/Province	Enter the reporter's state that the query looks for in cases.
	Postal Code	Enter the reporter's postal code that the query looks for in cases.

Table 3–2 (Cont.) QUERY BY EXAMPLE Page > General Tab — Field Description

Section	Field or Check Box	Description
	Country	Enter the reporter's country ID that the query looks for in cases.
	Phone Number	Enter the reporter's phone number that the query looks for in cases.
	Alternate Phone	Enter the reporter's alternate phone number that the query looks for in cases.
	FAX Number	Enter the reporter's fax number that the query looks for in cases.
	Reporter ID	Enter the reporter's ID that the query looks for in cases.
	Reporter's Reference #	Enter the reporter's reference number that the query looks for in cases.
	Email Address	Enter the reporter's email address that the query looks for in cases.
	Reporter Type	Select the reporter type that the query looks for in cases.
	Report Media	Select the report media that the query looks for in cases.
	Intermediary	Select the intermediary that the query looks for in cases.
	Report Sent to Regulatory Authority by Reporter?	Select the Yes , No , Unknown , or Ignore option, as appropriate, to indicate whether the query looks for cases where the reporter has already informed a regulatory authority about the event.
	Protect Confidentiality	Select this check box to have the query retrieve only those cases where reporter information is specified as confidential.
	Primary Reporter	Select this check box to have the query retrieve only those cases where the reporter is marked as the primary reporter.
	Correspondence Contact	Select this check box to have the query retrieve only those cases where the reporter is marked as a correspondence contact.
Literature Information	Author	Enter the literature author name that the query looks for in cases.
	Title	Enter the literature title that the query looks for in cases.
	Journal	Enter the literature journal name that the query looks for in cases.
	Vol	Enter the literature volume that the query looks for in cases.
	Year	Enter the literature publication year that the query looks for in cases.
	Pgs	Enter the journal page number in which the article appeared. The query will look for this information in cases.

Selecting the Study Information

In the Study Information section, Argus Insight populates the Project ID, Study ID, and Center ID fields when you select a study from the Clinical Study Lookup dialog box.

To select a clinical study:

1. Click the **Select** button associated with the **Study ID** field.

The Clinical Study Lookup dialog box appears.

The diagram illustrates the workflow. At the top, the 'Study Information' dialog box contains three input fields: 'Project ID', 'Study ID', and 'Center ID'. A 'Select' button with a magnifying glass icon is positioned between the 'Study ID' and 'Center ID' fields. A mouse cursor is shown clicking this button. An arrow points down to the 'Clinical Study Lookup' dialog box. This dialog has three input fields: 'Project', 'Study', and 'Center'. To the right of these fields are 'Search' and 'Clear' buttons. Below the input fields is a table titled 'Clinical Studies' with a status '0 - 0 / 0' and navigation icons. At the bottom of the dialog are 'Select' and 'Cancel' buttons.

2. Enter the first few letters of the project name, study ID, or study center name in their respective text boxes.

Tip: Alternatively, if you are not sure about the information you are looking for, click **Search** to list the project name, study, and center for all the clinical studies.

3. Click **Search**.

The Clinical Study Lookup dialog box appears with the search results in tabular format.

The screenshot shows the 'Clinical Study Lookup' dialog box with the 'Project' field containing 'CURE'. The 'Clinical Studies' table displays the following results:

Project	Study	Center	
CURE	CURE ALL PL 001	Sweden	0
CURE	CURE ALL PL 001	Spain	0
CURE	CURE ALL PL 001	Poland	0
CURE	CURE ALL PL 001	Norway	0
CURE	CURE ALL PL 001	Netherland	0
CURE	CURE ALL PL 001	Luxemburg	0
CURE	CURE ALL PL 001	Latvia	0
CURE	CURE ALL PL 001	Italy	0
CURE	CURE ALL PL 001	Ireland	0
CURE	CURE ALL PL 001	Hungary	0
CURE	CURE ALL PL 001	Greece	0
CURE	CURE ALL PL 001	Great Britain	0
CURE	CURE ALL PL 001	Germany	0
CURE	CURE ALL PL 001	France	0

The table has a status '1 - 248 / 248' and navigation icons. At the bottom of the dialog are 'Select' and 'Cancel' buttons.

4. Select a clinical study row from the list, and click **Select**.

You return to the QUERY BY EXAMPLE page, where the selected information is populated into the Project ID, Study ID, and Center ID fields in the Study Information section.

Study Information		
Project ID	Study ID	Center ID
CURE	CURE ALL PL 001	Ireland

Note: The Study ID and Center ID are optional fields.

Patient Tab

The **Patient** tab has two views: **Patient** and **Parent**.

Patient View

In the **Patient** view (see [Figure 3-4](#)), you can:

- Specify information only about one lab data element
- Specify details of only one relevant history
- Scroll the page to view all the fields available.

Figure 3-4 QUERY BY EXAMPLE Page > Patient Tab > Patient View

[Table 3-3](#) describes the fields in the **Patient** view of the **Patient** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Table 3–3 QUERY BY EXAMPLE > Patient Tab > Patient View — Field Description

Section	Field or Check Box	Description
Patient Information	Sponsor Identifier	Enter the <i>study</i> sponsor's ID. The query will look for this information in cases.
	Pat. ID	Enter the patient number that the query looks for in cases.
	Randomization #	Enter the patient randomization number that the query looks for in cases.
	Initials	Enter the patient's initials that the query looks for in cases.
	First Name	Enter the patient's first name that the query looks for in cases.
	MI	Enter the patient's middle initials that the query looks for in cases.
	Last Name	Enter the patient's last name that the query looks for in cases.
	Protect Confidentiality	Select this check box to retrieve those cases where patient information is marked as confidential.
	Address	Enter the patient's address that the query looks for in cases.
	City	Enter the patient's city that the query looks for in cases.
	Country	Enter the patient's country that the query looks for in cases.
	State/Province	Enter the patient's state that the query looks for in cases.
	Postal Code	Enter the patient's postal code that the query looks for in cases.
Patient Details	Date of Birth	Enter the patient's date of birth that the query looks for in cases.
	Age	Enter the patient's age that the query looks for in cases.
	Units	Select the age unit for the value you specified in the Patient Age field.
	Age Group	Select the patient age group that the query looks for in cases.
	Ethnicity	Select the patient's ethnicity that the query looks for in cases.
	Occupation	Select the patient occupation that the query looks for in cases.
	Gender	Select the patient gender that the query looks for in cases.
	Pregnant	Select the Yes , No , Unknown , N/A , or Ignore option, as appropriate, to indicate whether the query looks for cases where the patient's pregnancy status is specified. This field is available only if you specify the patient gender as Female.
	Date of LMP	Enter the date of the patient's last menstrual period (LMP) that the query looks for in cases.
	Patient Weight	Enter the patient weight that the query looks for in cases. Select the lbs or kg option, as appropriate.
	Patient Height	Enter the patient's height that the query looks for in cases. Select the in or cm option, as appropriate.
	Number of Patients	Enter the number of patients.

Table 3–3 (Cont.) QUERY BY EXAMPLE > Patient Tab > Patient View — Field Description

Section	Field or Check Box	Description
Lab Data	Test Name	Click the associated Select button to select the lab test that the query looks for in cases. See " Selecting a Lab Test " on page 3-15 for more information.
	Results	Enter the lab data results that the query looks for in cases.
	Norm Low	Enter the lab data normal low value that the query looks for in cases.
	Date	Enter the lab test date that the query looks for in cases.
	Units	Enter the unit for the value you specified in the Results field in the Lab Data section.
	Norm High	Enter the lab data normal high value that the query looks for in cases.
Other Relevant History	Start	Enter the relevant history start date that the query looks for in cases.
	Condition Type	Select the relevant history condition type that the query looks for in cases.
	Notes	Enter the relevant history notes that the query looks for in cases.
	Stop Date	Enter the relevant history stop date that the query looks for in cases.
	Coded PT	Click the associated Encode button to select the relevant history condition by using the MedDRA Browser. The query will look for the encoded term. See " Using the MedDRA Browser " on page 3-16 for more information.
	Ongoing	Select this check box to retrieve cases where the relevant history condition is continuing/ongoing.
	Patient Relevant Tests	Enter the relevant patient tests that the query looks for in cases.

Parent View

In the **Parent** view (see [Figure 3–5](#)), you can:

- Specify details of only one relevant history.
- Specify details of only one medical history.

Figure 3–5 QUERY BY EXAMPLE Page > Patient Tab > Parent View

Table 3–4 describes the fields in the **Parent** view of the **Patient** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

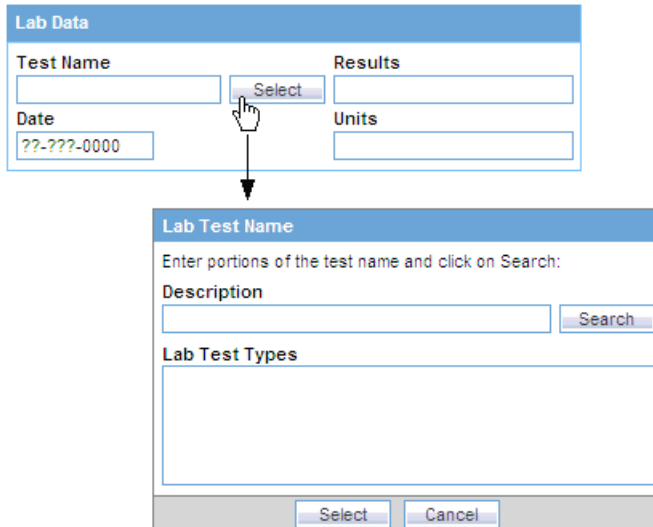
Table 3–4 QUERY BY EXAMPLE Page > Patient Tab > Parent View — Field Description

Section	Field or Check Box	Description
Parent Information	Parent Initials	Enter the parent's initials that the query looks for in cases.
	Date of Birth	Enter the parent's data of birth that the query looks for in cases.
	Age	Enter the parent's age that the query looks for in cases.
	Units	Select the age unit for the value you specified in the Age field.
	Gender	Select the parent gender that the query looks for in cases.
	Date of LMP	Enter the date of the parent's last menstrual period (LMP) that the query looks for in cases. This field is available only if the parent gender is specified as Female.
	Parent Weight	Enter the parent's weight that the query looks for in cases. Select the lbs or kg option, as appropriate.
	Parent Height	Enter the parent's height that the query looks for in cases. Select the in or cm option, as appropriate.
	Parent Breastfeeding	Select this check box to retrieve cases where parent is breast feeding.
Other Relevant History	Start	Enter the relevant history start date that the query looks for in cases.
	Condition Type	Select the relevant history condition type that the query looks for in cases.
	Notes	Enter the relevant history notes that the query looks for in cases.
	Stop Date	Enter the relevant history stop date that the query looks for in cases.
	Coded PT	Click the associated Encode button to select the relevant history condition by using the MedDRA Browser. The query will look for the encoded term. See " Using the MedDRA Browser " on page 3-16 for more information.
	Ongoing	Select this check box to retrieve cases where the relevant history condition is continuing / ongoing.

Selecting a Lab Test

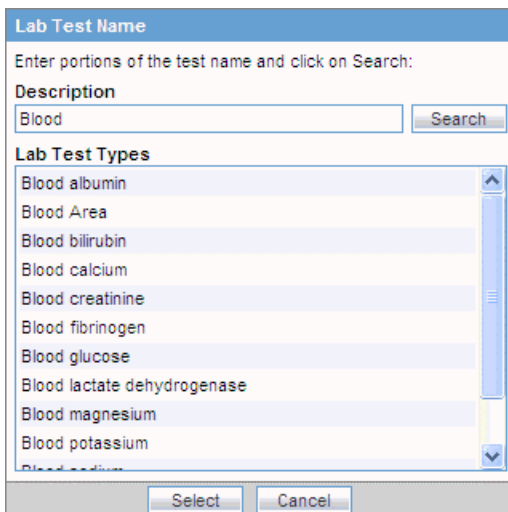
To select a lab test:

1. Navigate to the QUERY BY EXAMPLE page.
2. Click the **Patient** tab.
The Patient view appears, by default.
3. In the Lab Data section, click **Select** associated with the **Test Name** field.
The Lab Test Name dialog box appears.



4. Search for a lab test:
 - To find only those lab tests that match your criteria, enter one or more letters of the test name in the **Description** field, and click **Search**.
 - To display all lab tests, leave the **Description** field blank, and click **Search**.

The search results appears in the Lab Test Types section.



5. Select the required test name, and click **Select**.
The selected test is populated in the **Test Name** field.

Using the MedDRA Browser

To use the MedDRA Browser to search and select MedDRA terms for an event:

1. Click the **Encode** associated with the QBE tabs to start the MedDRA Browser.
The MedDRA Browser dialog box appears.

SOC	HLGT	HLT	PT	LLT
<input type="checkbox"/> SOC	10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
<input type="checkbox"/> HLGT	10029209	Nervous system neoplasms benign		
<input type="checkbox"/> HLT	10029312	Neuromas		
<input checked="" type="checkbox"/> PT	10017709	Ganglioneuroma		
<input type="checkbox"/> LLT				

Note: The output returned by the MedDRA Browser for the **Patient**, **Product** and **Analysis** tabs of QBE is the **Preferred Term (PT)**. The **Events** tab of QBE provides output for multiple options. You can select and search the required term(s), based on the **Seriousness Criteria**.

2. Enter the first few letters of the SOC, HLGT, HLT, PT, or LLT term in the respective text box.

If you want the system to search for the specified word in the entire event term, select the **Full Search** check box.

Note: The Special Category drop-down list displays all the SMQs that can be selected. The selected SMQ searches across PT and LLT levels of the MedDRA dictionary.

The Special Category drop-down list is hidden in MedDRA 10. The MedDRA SMQs drop-down list is hidden in versions lesser than MedDRA 9.

3. Press Tab.

The MedDRA Browser appears with the search results (for the specified word in the event terms) in a *column* below the text box in which you entered the text string.

MedDRA Browser
 Current Coding Version: 12.0 MedDRA SMQ: (N) SMQ_PT_LLT_CHLSMQPL Full Search

NOTE: The QBE only supports single selection in the MedDRA Browser

SOC	HLGT	HLT	PT	LLT
			Ganglioneuroma	No Rows Returned

<input type="checkbox"/> SOC	10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
<input type="checkbox"/> HLGT	10029209	Nervous system neoplasms benign
<input type="checkbox"/> HLT	10029312	Neuromas
<input checked="" type="checkbox"/> PT	10017709	Ganglioneuroma
<input type="checkbox"/> LLT		

4. Select the required event term from the search results.

The **SOC**, **HLGT**, **HLT**, **PT**, and **LLT** fields in the MedDRA Browser display the respective terms for the selected event.

Note that:

- Fields highlighted in yellow indicate the selected hierarchy is the primary SOC path.
- Fields highlighted in gray indicate the selected hierarchy is not the primary SOC path.

MedDRA Browser
 Current Coding Version: 12.0 MedDRA SMQ: (N) SMQ_PT_LLT_CHLSMQPL Full Search

NOTE: The QBE only supports single selection in the MedDRA Browser

SOC	HLGT	HLT	PT	LLT
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Nervous system disorders	Nervous system neoplasms benign	Neuromas	Ganglioneuroma	Gangliocytoma Ganglioneuroma Neurocytoma

<input type="checkbox"/> SOC	10029104	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
<input type="checkbox"/> HLGT	10029209	Nervous system neoplasms benign
<input type="checkbox"/> HLT	10029312	Neuromas
<input checked="" type="checkbox"/> PT	10017709	Ganglioneuroma
<input type="checkbox"/> LLT		

5. Select the **SOC**, **HLGT**, **HLT**, **PT**, and **LLT** check boxes to populate the corresponding fields in the QBE form.

6. Click **Add & Close**.

The selected codes for the selected event appears in the respective fields in the QBE form.

Products Tab

In the **Products** tab (see [Figure 3–6](#)), you can:

- Enter information only about one product.
- Specify details of only one dosage regimen.
- Scroll the page to view all the fields available.

Figure 3–6 QUERY BY EXAMPLE Page — Products Tab

The screenshot displays the 'Products' tab in a query-by-example interface. It is divided into two main sections: 'Product Information' and 'Dosage Regimens'. The 'Product Information' section contains various input fields and radio buttons for specifying product details. The 'Dosage Regimens' section includes fields for dates, durations, and dosages, along with a 'Calculate...' button. The bottom of the window features a row of action buttons: Save, Save As, Convert to Advanced Condition, Clear Tab, Clear All, Permissions, and Execute.

[Table 3–5](#) describes the fields in the **Products** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Table 3–5 QUERY BY EXAMPLE Page > Products Tab — Field Description

Section	Field or Check Box	Description
Product Information	Product Name	Click the associated Select button to use the Product Browser to specify product information for your query criteria. Selecting the product name populates the Product Name, Generic Name, Company Drug Code, Formulation, Concentration, and Units fields with the details of the product you selected. See "Using the Product Browser" on page 3-22 for details. Alternatively, click the associated Encode button to use the Drug Coding Browser to specify the WHO drug name as the query criteria. See "Using the WHO Drug Browser" on page 3-24 for details.
	Drug Type	Select the Suspect, Concomitant, Treatment, or Ignore option, as appropriate, to indicate whether the query looks for cases where drug type is specified.
	Generic Name	Click the Select button associated with the Product Name field to select a generic name that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	Product Indication PT	Click the associated Encode button to use the MedDRA Browser to specify the drug primary indication event term as the query criteria. See "Using the MedDRA Browser" on page 3-16 for details.
	Company Product	Click the associated Select button to select the company product that the query looks for in cases.
	Study Drug	Click the associated Select button to use the Study Drug Lookup dialog box to specify the study drug name as the query criteria. Use this field to retrieve clinical trial cases with the selected study drug. See "Using the Study Drug Lookup" on page 3-26 for details.
	Company Drug Code	Click the Select button associated with the Product Name field to select the company drug code that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	Drug Code	Enter the drug code that the query looks for in cases.
	Manufacturer	Enter the product manufacturer that the query looks for in cases.
	Formulation	Click the Select button associated with the Product Name field to select a drug formulation that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	WHO DRUG ATC CODE	Enter the Anatomical, Therapeutic, Chemical (ATC) classification code that the query looks for in cases.
	WHO DRUG ATC DESCRIPTION	Enter the Anatomical, Therapeutic, Chemical (ATC) classification description that the query looks for in cases.
	Concentration	Click the Select button associated with the Product Name field to select a drug concentration that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	Units	Click the Select button associated with the Product Name field to select the units that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	Interaction?	Select the Yes, No, Unknown, or Ignore option, as appropriate, to indicate whether the query looks for cases where drug interaction status is specified.
	Contraindicated?	Select the Yes, No, or Ignore option, as appropriate, to indicate whether the query looks for cases where drug contraindication status is specified.

Table 3–5 (Cont.) QUERY BY EXAMPLE Page > Products Tab — Field Description

Section	Field or Check Box	Description
Dosage Regimens	Ongoing	Select this check box to retrieve cases where the dosage regimen is ongoing.
	Outside Therapeutic Range	Select this check box to retrieve cases where the dosage regimen is outside therapeutic range. This means that the drug has not been used in accordance with the label or has been used for outside the Therapeutic Range. Consult with your administrator for further company-specific information about the use of this field.
	Start Date/Time	Enter the dosage regimen start date that the query looks for in cases.
	Stop Date/Time	Enter the dosage regimen start date that the query looks for in cases.
	Duration of Regimen	Enter the dosage regimen duration (specified in minutes) as the query criteria. You can click Calculate to view the Duration Calculator dialog box. You can enter the time in hours, days, weeks, months, or years, and then convert the time to minutes. Alternatively, you can select a duration band and value if available. A system administrator must define the bands.
	Dose Number	Enter the drug dose number as the query criteria.
	Dose	Enter the drug dose received by the patient as the query criteria.
	Units	Specify the units for the value you specified in the Dose field.
	Dose Description	Enter the dose description based on the values you specified in Dose , Dose Units , and Frequency fields.
	Daily Dosage	Enter the daily dose based on the values you specified in Dose and Frequency fields.
	Regimen Daily Dosage Unit	Select the same option you selected in the Dose Units field.
	Regimen Dosage	Daily dose, duration, and frequency.
	Regimen Dosage Unit	Select the total dose regimen unit based on the values you specified in Dose , Dosage Regimen Duration , and Frequency fields.
	Patient Route of Administration	Select the route of dosage administration as the query criteria.
	Frequency	Specify the dosage frequency as the query criteria.
	Expiration Date	Enter the product expiration date as the query criteria.
	Accidental Exposure	Select the area of accidental exposure as the query criteria.
	Package ID	Enter the package ID as the query criteria.
	Pack Units	Enter the package units.
	Batch/Lot #	Enter the batch/lot number as the query criteria. Alternatively, click the associated Select button to view the Batch/Lot #s dialog box, enter search criteria to find the batch/ lot number you need, and make your selection.
Parent Route of Administration	Select the route of dosage administration of the parent as the query criteria.	

Table 3–5 (Cont.) QUERY BY EXAMPLE Page > Products Tab — Field Description

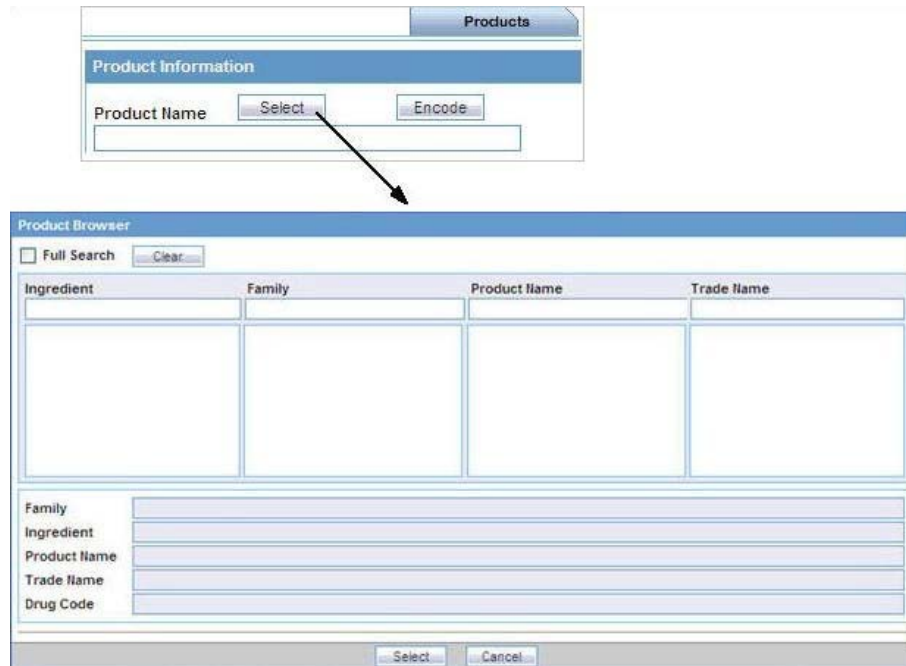
Section	Field or Check Box	Description
Product Details	First Dose	Enter the earliest dosage regimen start date as the query criteria.
	Last Dose	Enter the latest regimen stop date as the query criteria.
	Duration of Administration	Enter the duration of drug administration as the query criteria. This duration is the difference between the first and last dose for all dosage regimens. You can click Calculate to view the Duration Calculator dialog box. You can enter the time in hours, days, weeks, months, or years, and then convert the time to minutes. Alternatively, you can select a duration band and value if available. A system administrator must define the bands.
	Date	Enter the date on which the drug dechallenge was carried out. Note that this date is the same as the Drug Dechallenge Date.
	Other Information	Select the Abuse, Overdose, and Tampering check boxes.
	Time between First Dose / Primary Event	Enter the time between the event onset and the first dose.
	Time between Last Dose / Primary Event	Enter the time between the event onset and the last dose.
	Total Dose to Primary Event	Enter the total dose for the drug.
	Action Taken	Select the action taken to mitigate the adverse event.
	Dechallenge Results	Select the Yes, No, Unknown, N/A, or Ignore option, as appropriate, to indicate whether the query looks for cases where drug dechallenge status is specified.
	Drug Dechallenge Date	Enter the date on which the drug dechallenge was carried out.
	Total Dosage	Enter the total drug usage duration as the query criteria.
	Units	Enter the total dosage unit as the query criteria. This is based on the daily dose, duration and frequency.
	Start Date/Time	Enter the rechallenge start date as the query criteria.
	Stop Date/Time	Enter the rechallenge stop date as the query criteria.
	Taken Previously/Tolerated	Select the Yes, No, Unknown, or Ignore option, as appropriate, to indicate whether the query looks for cases where drug was taken previously.
Rechallenge Results	Select the Yes, No, Unknown, N/A or Ignore option, as appropriate, to indicate whether the query looks for cases where drug rechallenge status is specified.	

Using the Product Browser

To select a product by using the Product Browser:

1. On the QUERY BY EXAMPLE page, select the **Products** tab.
2. Click the **Select** button associated with the **Product Name** field.

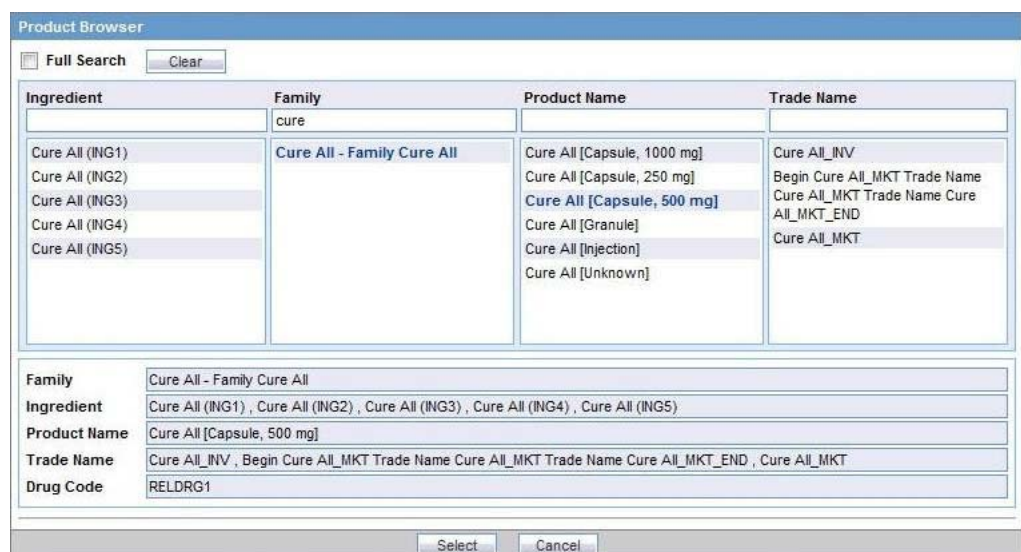
The Product Browser dialog box appears.



3. Enter the first few letters (text string) of the product ingredient, family name, product name, or trade name in the respective field.
 - To search for the specified string in the entire product information, select the **Full Search** check box.
 - To remove your search criteria and start over, click **Clear**.
4. Press Tab (or click another field in the dialog box) to begin the search.
5. Select an item from the search results list.

The Product Browser appears with the search results (for the specified text string) in the column below the field in which you entered the search string.

The details for the selected item are displayed in all the Product Browser fields.



6. Select the required product name or trade name, and click **Select**.

The Product Name, Generic Name, Company Drug Code, Formulation, Concentration, and Units fields with the details of the selected product are populated on the Products tab.

The screenshot shows the 'Products' tab of a software interface. The 'Product Information' section is highlighted. The fields are as follows:

- Product Name:** Cure All_MKT
- Generic Name:** Cure All (ING1), Cure All (ING2), Cure All (ING3), Cure All (ING4), Cure All (ING5)
- Company Drug Code:** RELDRG1
- Formulation:** undefined
- Concentration:** 1000
- Units:** undefined

Using the WHO Drug Browser

To select a WHO drug product by using the WHO Drug Browser:

1. On the QUERY BY EXAMPLE page, select the **Products** tab.
2. Click the **Encode** button associated with the **Product Name** field.

The WHO Drug Browser dialog box appears.

The screenshot shows the 'Drug Coding (WHO-DRUG)' dialog box. The search criteria are:

- Product Type:** All
- ATC Code:** [Empty]
- Drug Code:** [Checked]
- Trade Name:** [Checked]
- Ingredient:** [Unchecked]
- Formulation:** [Unchecked]
- Country:** [Empty]
- Full Search:** [Unchecked]

The table below has the following columns: Trade Name, Formulation / Strength, Sales Country, Generic?.

The 'Drug Details' section includes the following fields:

- Trade Name
- MAH
- Drug Code
- ATC Code
- ATC Description
- Medicinal Product ID
- Ingredients

Note: The WHO Drug Browser that appears depends on the configuration settings defined for your account by the administrator.

The browser categories (B or C) are not displayed in the browser window.

The primary difference between the two browsers is the availability of the following fields in WHO Drug Browser:

- **Product Type**
- **MAH** (name of the manufacturer)
- **Medicinal Prod ID**
- **Ingredients** (product substance name)

3. Use the fields at the top of the WHO Browser dialog box to define your search criteria. You may enter values in one, several, or all fields.

The screenshot shows the 'Drug Coding (WHO-DRUG 2008-MAR)' dialog box. It features a blue header bar. Below the header, there are several search criteria fields: 'Product Type' (a dropdown menu with 'All' selected and a list of options including 'Medicinal product', 'Herbal remedy', 'Vaccine', 'Veterinary product', 'Homeopathic remedy', 'Dietary supplement', 'Radio-pharmaceutical', 'Blood product', and 'Diagnostic agent'), 'ATC Code' (a text input field), 'Drug Code' (a radio button, selected), 'Medicinal Prod ID' (a radio button), 'Trade Name' (a radio button, selected), 'Ingredient' (a radio button), 'Formulation' (a text input field), and 'Country' (a text input field). To the right of these fields is a 'Full Search' checkbox and two buttons: 'Clear' and 'Search'.

- a. In the **Product Type** field, select the type of product.
You may include all products or a single product. The default value is **All**.
 - b. In the **ATC Code** field, type all or part of the Anatomical Therapeutic Chemical (ATC) classification code.
 - c. Select either the **Drug Code** or the **Medicinal Prod ID** option as one of the search criterion, and then enter the appropriate search string in the text box below the options.
The default option is **Drug Code**.
 - d. Select either the **Trade Name** or **Ingredient** option as one of the search criterion, and then enter the appropriate search string in the text box below the options.
The default selection is **Trade Name**.
 - e. Enter the **Formulation** and **Country** details for the drug to be searched.
 - f. Select the **Full Search** check box if you want the system to search for the specified string in the entire product information.
4. Click **Search**.
The WHO Drug Browser appears with the search results (for the specified drug products) in a grid format.
 5. Select the required WHO drug.

The WHO Drug Browser highlights the selected drug and populates the fields in the Drug Details section.

The screenshot shows the 'Drug Coding (WHO-DRUG)' interface. At the top, there are search filters for Product Type, ATC Code, Drug Code, Medicinal Prod ID, Trade Name, Ingredient, Formulation, Country, and Full Search. Below this is a table of drug results. The 'Acetasol' row is highlighted in yellow. Below the table is the 'Drug Details' section, which contains the following information:

Trade Name	Acetasol
MAH	Barre drug. co., inc.
Drug Code	013018.01.001
ATC Code	S02AA
ATC Description	Antiinfectives
Medicinal Product ID	46730
Ingredients	Propylene glycol diacetate

6. Click **Select**.

The Product Name, Generic Name, Drug Code, WHO DRUG ATC CODE, and WHO DRUG ATC DESCRIPTION fields for the selected WHO drug are populated in the **Products** tab.

Note that the **Generic Name** field displays all the ingredients for the selected WHO drug.

The screenshot shows the 'Product Information' form. Several fields are highlighted with red boxes:

- Product Name:** ACETASOL
- Generic Name:** ACETIC ACID, BENZETHONIUM CHLORIDE, PROPYLENE GLYCOL DIACETATE, SODIUM ACETATE
- Drug Code:** 013018.01.001
- WHO DRUG ATC CODE:** S02AA
- WHO DRUG ATC DESCRIPTION:** ANTIINFECTIVES

Using the Study Drug Lookup

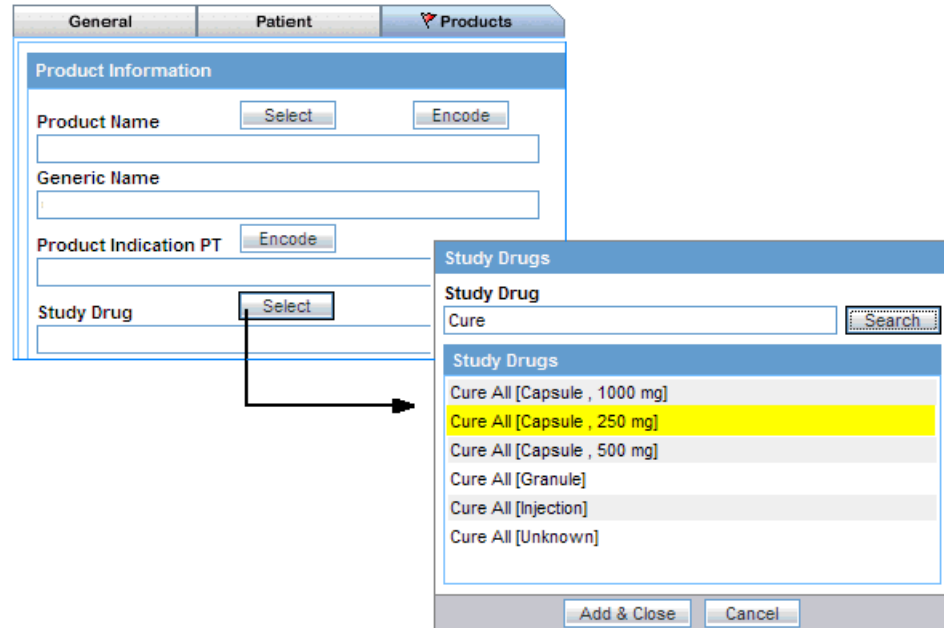
To select a study drug:

1. On QUERY BY EXAMPLE page, select the **Products** tab.
2. Click the **Select** button next to the **Study Drug** field.

The **Study Drugs Lookup** dialog box appears.

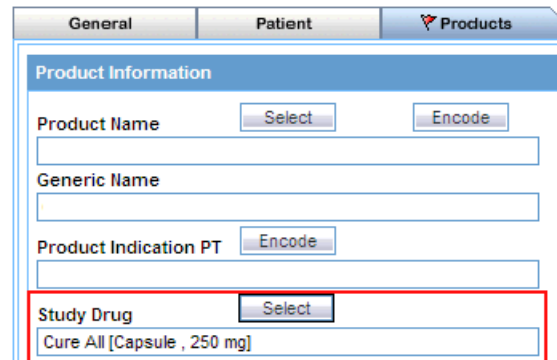
3. In the **Study Drug** field, enter the first few letters of the study drug name.
4. Click **Search**.

The search results based on the specified search string appears.



5. Select the required study drug from the list, and click **Add & Close**.

You return to the PProducts tab and the **Study Drug** field is populated with the selected.



Events Tab

In the **Events** tab (see [Figure 3-7](#)) the details of only one event can be specified at a time.

Figure 3–7 QUERY BY EXAMPLE Page — Events Tab

Table 3–6 describes the fields in the **Events** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Table 3–6 QUERY BY EXAMPLE Page > Events Tab — Field Description

Section	Field or Check Box	Description
Event Information	Diagnosis	Select the Yes , No , or Ignore option, as appropriate, to indicate whether the query looks for cases where event diagnosis flag is set.
	Description as Reported	Enter the reported event description that the query looks for in cases.
	Description to be Coded	Tab out of this field to use the MedDRA Browser to specify an event term as query criteria. See " Using the MedDRA Browser " on page 3-16 for more information. The MedDRA event terms for the selected term are displayed in the Seriousness Criteria section. The query is restricted to the terms displayed.
	Onset Date/Time	Enter the event onset date that the query looks for in cases.
	Duration	Enter the event duration that the query looks for in cases.
	Onset From Last Dose	Enter the event onset duration from last dose as the query criteria.
	Onset Latency	Enter the event onset latency duration that the query looks for in cases.
	Time to Onset from First Dose	Enter the duration from first dose to the event onset as the query criteria. Alternatively, click the associated Calculate button to view the Duration Calculator dialog box and make your selection.
	Receipt Date	Enter the event receipt date that the query looks for in cases.
	Term Highlighted by Reporter	Select the Yes , No , or Ignore option, as appropriate, to indicate whether the query looks for cases where case seriousness status is specified.
Patient Has Prior History?	Select the Yes , No , Unknown , or Ignore option, as appropriate, to indicate whether the query looks for cases where event past history is specified.	

Table 3–6 (Cont.) QUERY BY EXAMPLE Page > Events Tab — Field Description

Section	Field or Check Box	Description
	Treatment Received?	Select the Yes , No , Unknown , or Ignore option, as appropriate, to indicate whether the query looks for cases where patient received treatment for the event.
	Time to Onset from Last Dose	Enter the duration from last dose to the event onset as the query criteria. Alternatively, click the associated Calculate button to view the Duration Calculator dialog box and make your selection.
	Progression of Disease	Select this check box to retrieve cases where Event Progression of Disease is selected.
	Adverse Drug Withdrawal Reaction	Select this check box to retrieve cases where Event Withdrawal Reaction is selected.
	Stop Date/Time	Enter the event stop date that the query looks for in cases.
	Intensity	Select the event intensity option that the query looks for in cases.
	Frequency	Select the event frequency option that the query looks for in cases.
	Lack of Efficacy	Select Yes from the drop-down list to retrieve cases where Event Lack of Efficacy is selected, else select No .
	Related to <i>Study</i> Conduct? (As Reported)	Select the Yes , No , Unknown , or N/A from the drop-down list, to indicate whether the query looks for cases where the event is related to a study.
	Outcome of Event	Enter the event outcome that the query looks for in cases.
	Nature of Event	Enter the nature of the event that the query looks for in cases.
Event Coding	System Organ Class (SOC) High Level Group Term High Level Term Preferred Term Lower Level Term	Click the associated Encode button to use the MedDRA Browser to specify event terms as query criteria. See " Using the MedDRA Browser " on page 3-16 for details.
Seriousness Criteria	Seriousness Criteria check boxes	Select one or more check boxes to specify the seriousness criteria that the query looks for in cases. The available values are: <ul style="list-style-type: none"> ■ Death ■ Medically Significant ■ Hospitalized ■ Life-threatening ■ Disability ■ Intervention Required ■ Congenital Anomaly ■ Other

Analysis Tab

The **Analysis** tab (see [Figure 3–8](#)) has two views: **Case Analysis** and **AFSSaPS**.

Analysis information about Regulatory Information (notification log), MedWatch Information, BfArM Information, and EU devices is not available. For more sophisticated queries, use filters or advanced conditions.

Figure 3–8 QUERY BY EXAMPLE Page — Analysis Tab

Table 3–7 describes all the fields in the **Case Analysis** view. The field values you specify are used as the *query* criteria to retrieve matching cases.

Table 3–7 QUERY BY EXAMPLE Page > Analysis Tab > Case Analysis View — Field Description

Section	Field or Check Box	Description
Narrative	Narrative	Enter the case narrative that the query looks for in cases.
	Case Comment	Enter the case comment that the query looks for in cases.
	Local Evaluator Comment	Enter the local evaluator' comment that the query looks for in cases.
	Company Comment	Enter the company's comment that the query looks for in cases.
	Abbreviated Narrative	Enter the abbreviated case narrative that the query looks for in cases.
	Evaluation in light of similar events in the past	Enter the evaluation comment that takes in to consideration similar events that have occurred in the past. The query will look for the specified text in cases.

Table 3–7 (Cont.) QUERY BY EXAMPLE Page > Analysis Tab > Case Analysis View — Field Description

Section	Field or Check Box	Description
Other Information	Case Serious	Select the Yes , No , or Ignore option, as appropriate, to indicate whether the query looks for cases where case seriousness status is specified.
	Notes	Enter the case seriousness notes that the query looks for in cases.
	Company Agent Causal	Select the Yes , No , Unknown , or Ignore option, as appropriate, to indicate whether the query looks for cases where the company agent causality status is specified.
	Notes	Enter the company agent causality notes that the query looks for in cases.
	Listedness Determination	Select the case listedness status that the query looks for in cases.
	Notes	Enter the case assessment listedness notes that the query looks for in cases.
	Case Outcome	Select the case outcome that the query looks for in cases.
	Company Diagnosis/Syndrome	Click the associated Encode button to use the MedDRA Browser to specify the company diagnosis as query criteria. See " Using the MedDRA Browser " on page 3-16 for more information.
	Notes	Enter the company diagnosis/syndrome notes that the query looks for in cases.

[Table 3–8](#) describes all the fields in the **AFSSaPS** view. The field values you specify are used as the query criteria to retrieve matching cases.

Table 3–8 QUERY BY EXAMPLE Page > Analysis Tab > AFSSaPS View — Field Description

Section	Field	Description
Case Event Imputability Details	Preferred Term	Click the associated Select button to use the MedDRA Browser to specify the Event Preferred Term as query criteria. See " Using the MedDRA Browser " on page 3-16 for more information.
	Agent	Click the associated Select button to choose the <i>suspect product</i> that the query looks for in cases.
	Chronology	Select the imputability chronology code that the query looks for in cases.
	Semiology	Select the imputability semiology code that the query looks for in cases.
	Bibliography	Select the imputability bibliography code that the query looks for in cases.
	Imputability	Select the imputability score that the query looks for in cases.

Activities Tab

In the **Activities** tab (see [Figure 3–9](#)), you can:

- Specify information only about one contact log.
- Specify information only about one action item.

Note that routing search is not applicable in Argus Insight.

Figure 3–9 QUERY BY EXAMPLE Page — Activities Tab

Table 3–9 describes all the fields in the **Activities** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Table 3–9 QUERY BY EXAMPLE Page > Activities Tab — Field Description

Section	Field	Description
Contact Log	Date	Enter the contact log date that the query looks for in cases.
	Code	Select the contact log code that the query looks for in cases.
	Group	Select the contact log group that the query looks for in cases.
	Date Sent	Enter the sent date for the contact.
	Description	Enter the contact log description that the query looks for in cases.
	User	Select the user responsible for the contact log. The query will look for the user name you select.
Action Items	Date Open	Enter the action item opening date that the query looks for in cases.
	Code	Select the action type that the query looks for in cases.
	Group	Select the responsible group that the query looks for in cases.
	Due	Enter the action item due date that the query looks for in cases.
	Description	Enter the action item description that the query looks for in cases.
	User	Select the user responsible for the action item. The query looks for the specified user name.
	Completed	Enter the action item completion date that the query looks for in cases.
Case Lock/Archive	Lock Date	Enter the case lock date that the query looks for in cases.
	Locked or Closed By	Enter the user who locked or closed the case.
	Closure Date	Enter the date when the case was closed.

Additional Info Tab

In the **Additional Info** tab (see [Figure 3–10](#)):

- You can specify information only about one note.

- Attachments are not permitted.
- You can specify information only about one reference.

Figure 3–10 QUERY BY EXAMPLE Page — Additional Info Tab

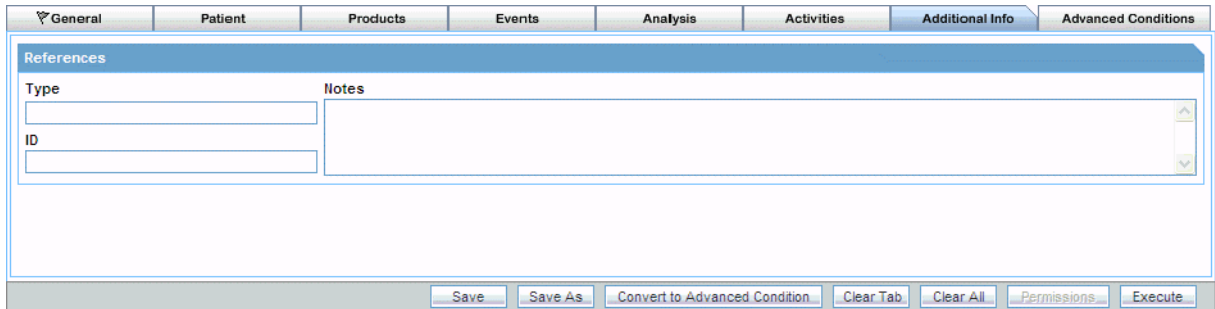


Table 3–10 describes all the fields in the **Additional Info** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Table 3–10 QUERY BY EXAMPLE Page > Additional Information Tab — Field Description

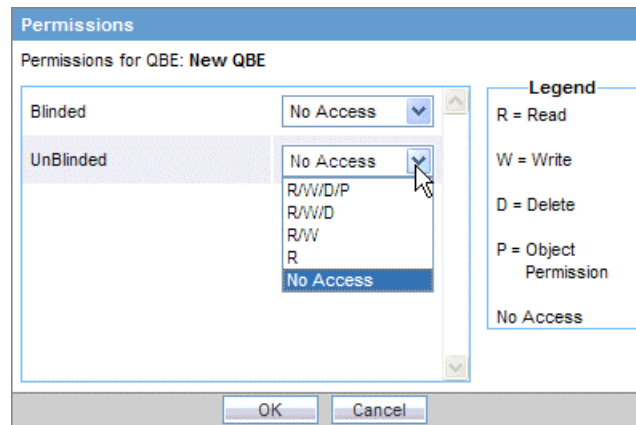
Section	Field	Description
References	Type	Enter the reference type that the query looks for in cases.
	ID	Enter the referenced case ID that the query looks for in cases.
	Notes	Enter the reference notes that the query looks for in cases.

Assigning Group-Level Permissions to a Saved QBE

To assign group-level permissions to a saved QBE:

1. Click **Permissions**.

The **Permissions** dialog box appears with the names of all the groups (except the **Administrator** group) that the system administrator has created.



2. Use the drop-down list next to a group name to assign permissions to the group members on the QBE you have created. The available options are:

Permission	Description
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the QBE.
R/W/D	Group members will be able to view, modify, and delete the QBE.
R/W	Group members will be able to view and modify the QBE.
R	Group members will be able to only view the QBE.
No Access (Default)	No group members will be able to access the QBE.

3. Click **OK**.

The permission settings are saved.

Working with the Last Modified or Executed QBE

This section describes how to view the QBE that you last modified or executed.

The system assigns the *active* status to a QBE when you save modifications to it or execute it. Unless you save the modifications to another QBE or execute another QBE, the last QBE you modified or executed remains active. This is helpful in situations when you want to access a frequently used QBE.

To view an active QBE:

1. Navigate to **Queries > Query by Example > Active**.

The ACTIVE QUERY BY EXAMPLE page appears with the QBE *form* for the last QBE you executed. For example:

- If the active QBE was saved to the system before executing, both the **Active Query Name** field and the **Name** field appears with the name of the QBE.

- If the active QBE was not saved before executing, the Active Query Name field displays the following text:

<Not Saved>

You may enter the name of the QBE in the **Name** field, and click **Save**.

2. To rename an already saved QBE, enter the new name in the **Name** field, and click **Save**.

Modifying the Description and Values for the Active QBE

To change the description of the active QBE, add or modify the text in the **Description** field.

In addition, you may modify the value of any field on any of the QBE tabs (that is, the QBE form).

When you modify the values of a QBE:

- To clear all the values for the current tab, click **Clear Tab**.
- To clear all the values specified in all the tabs for this active QBE, click **Clear All**.

Saving the Active QBE

You have two options for saving the active QBE:

- To save any changes or updates you make to the active QBE, click **Save**.
The Save button is enabled for a saved active QBE only.
- To save the active QBE with a different name, click **Save As**.

The QUERY BY EXAMPLE LIBRARY page lists all the QBEs saved to the system.

See "[Working with Saved QBEs](#)" on page 3-35 for more information.

Converting the Active QBE to an Advanced Condition

To convert the QBE to an Advanced Condition, click **Convert to Advanced Condition**.

See "[Using QBEs with Advanced Conditions](#)" on page 3-38 for more information.

Assigning Permissions

To set the group-level access permissions on the QBE, click **Permissions**.

The **Permissions** button is only available for saved active QBEs.

See "[Assigning Group-Level Permissions to a Saved QBE](#)" on page 3-33 for more information.

Executing the Active QBE

To generate a case series by using the active QBE, click **Execute**.

Modifying the field values in the QBE form for an active QBE or saving the active QBE with a different name changes the active QBE to reflect the most recent changes. The active QBE also changes if you modify the field values in the QBE form and execute the QBE without saving the QBE form modifications.

Working with Saved QBEs

The QUERY BY EXAMPLE LIBRARY page lists all the QBEs saved to the system.

To view the list of saved QBEs, navigate to **Queries > Query by Example > Library**.

The QUERY BY EXAMPLE LIBRARY page appears (See Figure 3–11) with the following information about the saved QBE:

- Name of the QBE that was entered when the query was saved.
- Description of the QBE that was entered in the Description field on the QBE form.
- Date when the QBE was last modified.
- Full name of the user who created the QBE.
- Category that was selected on the QBE form and assigned to the query.

Figure 3–11 QUERY BY EXAMPLE LIBRARY Page

Name	Description	Last Modified	User Full Name	Category
		00-MMM-0000		
		00-MMM-0000		
QBE_An		21-JUL-14	anishap	General
test qbe		21-JUL-14	rajeshs	General

Searching for a Saved QBE

To search for a saved QBE:

1. Perform one of the following to specify the search criteria:
 - To search for a QBE by its name, type the QBE name in the **Name** field.
 - To search for a QBE by its description, type the first few words of the description in the **Description** field.
The system searches for the specified search string in all QBE descriptions.
 - To search for a QBE by its date of modification, enter the modification date in the first **Last Modified** date field.
You may also specify a date range by typing the start and end dates in the first and second date fields, respectively.
 - To search for a QBE by its author, select the author name from the **User Full Name** drop-down list.
 - To search for a QBE by its category, select the category from the **Category** drop-down list.

Note: If you search for a text comprising an underscore, it is treated as a wildcard and is replaced by a letter in the displayed results. For example, If you have queries with names - CURE, CORE, and CARE and you search for C_RE, all three queries are displayed in the result.

2. Click **Search**.

The search results appear in a list based on the search criteria.

- To sort search results, click the sort icon next to the column headers in the list.
- To clear the search results and display all the saved QBEs in the list, click **Clear**.

Creating a New QBE

To create a new QBE, navigate to **Queries > Query By Example > New**.

Alternatively, click **New** in the QUERY BY EXAMPLE LIBRARY page to open a new QBE form directly.

Modifying a Saved QBE

To modify a saved QBE:

1. On the QUERY BY EXAMPLE LIBRARY page, select a QBE from the list of QBEs.
2. Click **Modify**.

The QBE form for the selected QBE appears.

3. Modify the field values in the QBE form, and save the changes.
 - To save the current query, click **Save**.
 - To save the current query by another name, click **Save As**.

Deleting a Saved QBE

To delete a saved QBE:

1. On the QUERY BY EXAMPLE LIBRARY page, select a QBE from the list of QBEs.
2. Click **Delete**.

A confirmation dialog box appears.

3. Click **OK**.

Executing a Saved QBE

To execute a saved QBE:

1. Navigate to **Queries > Query by Example > Library**.

The QUERY BY EXAMPLE LIBRARY page appears.

2. Select a QBE from the list.
3. Click **Execute**.

When execution is complete, the ACTIVE CASE SERIES page appears.

After generating the case series, you may add cases to or delete cases from the series, freeze the case series, or export the case series results into a Microsoft Excel file.

For more information, see [Chapter 7, "Working with Case Series."](#)

Executing a Saved QBE on the Active Case Series

Just as the system assigns the *active* status to a QBE when you save modifications to it or execute it, the last saved or generated case series becomes the *active* case series.

You may want to run an existing QBE on an active case series instead of creating and running a new QBE on the entire data mart and generating a new case series.

To narrow down the list of cases in the active case series:

1. Generate the case series on which you want to run another QBE as follows:
 - If the case series on which you want to run another QBE is not yet generated or active, you can either create a new QBE and execute it, or execute a saved QBE as explained in ["Executing a Saved QBE"](#) on page 3-37.

This case series becomes the active case series and remains so until you execute another query to generate a different case series.

- Alternatively, if the case series on which you want to run another QBE is already saved in the system, navigate to **Case Series > Open Case Series > Library**.

When the CASE SERIES LIBRARY page opens, select the case series, and click **Make Active**.

2. Navigate to **Queries > Query by Example > Library**.

The QUERY BY EXAMPLE LIBRARY page appears.

3. Select a query to run on the active case series that was generated in Step 1.
4. Select the **Limit Query to Active Case Series** check box.
5. Click **Execute**.

The selected QBE is executed on the active case series and the ACTIVE CASE SERIES appears.

Note that the case series you just generated becomes the active case series.

Using QBEs with Advanced Conditions

Advanced conditions let you create complex queries that involve Boolean and set operations among fields.

To create advanced conditions, use the Advanced Conditions Editor, which uses a spreadsheet-like approach for adding *query* conditions (fields and their values) and conditional operators (Boolean or set).

In Argus Insight, QBEs are integrated with advanced conditions to let you perform the following tasks:

- [Converting a QBE to an Advanced Condition](#)
- [Integrating a QBE with an Advanced Condition](#)

Converting a QBE to an Advanced Condition

You can use an existing QBE to start to build an advanced condition that uses Boolean or set operations between QBE form fields that have specific values. When you convert a QBE to an advanced condition, all the QBE form fields in which you entered values are listed on the ACTIVE ADVANCED CONDITIONS EDITOR page as *advanced condition attributes*.

To convert a QBE to an advanced condition:

1. Open a QBE form by either starting a new QBE, opening the active QBE, or opening a saved QBE.
2. Verify the *field* values you specified in the tab pages in the QBE form.
3. Click **Convert to Advanced Condition**.

The ACTIVE ADVANCED CONDITIONS EDITOR page appears.

All the fields in which you specified values in the QBE form are listed as advanced condition attributes.

ACTIVE ADVANCED CONDITIONS EDITOR

Argus Mart Active Query: < Not Saved >
 Insight Mart Active Query: TestTW
 Active Case Series (Insight Mart): < Not Saved >

Name: < Not Saved > Category: Pharmacovigilance Description:

(Attributes	Condition	Value)	Operator
(Report Type	equal to	Spontaneous)	AND
	Country	equal to	US)	AND
	Hospitalized	equal to	Yes)	
	Outcome of Event	equal to	Death due to AE/infection)	AND

Save Execute

4. Build your *query* further by:
 - Adding additional attributes (fields) and specifying their values.
 - Adding another advanced condition as an attribute.
 - Placing runtime parameters in attributes.
 - Placing parentheses to determine the query execution order.
 - Specifying conditions for attributes values.
 - Specifying Boolean and set operators to join the attributes.

See [Chapter 5, "Using Advanced Conditions to Create Queries on Insight Mart"](#) for detailed information about using the Advanced Conditions Editor.

Integrating a QBE with an Advanced Condition

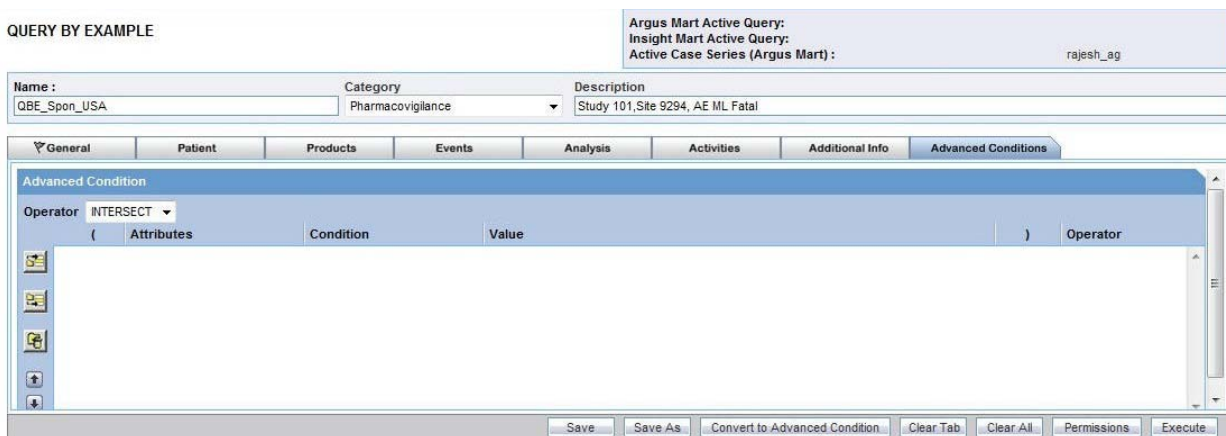
You can integrate a new, active, or saved QBE with an existing advanced condition through these set operators:

- INTERSECT
- MINUS
- UNION

If required, you can integrate your QBE with multiple advanced conditions that can have Boolean or set operations between them.

To integrate a QBE with existing advanced conditions:

1. Open a QBE form by either starting a new QBE, opening the active QBE, or opening a saved QBE.
2. Verify the *field* values you specified in the tab pages in the QBE form.
3. Click the **Advanced Conditions** tab.



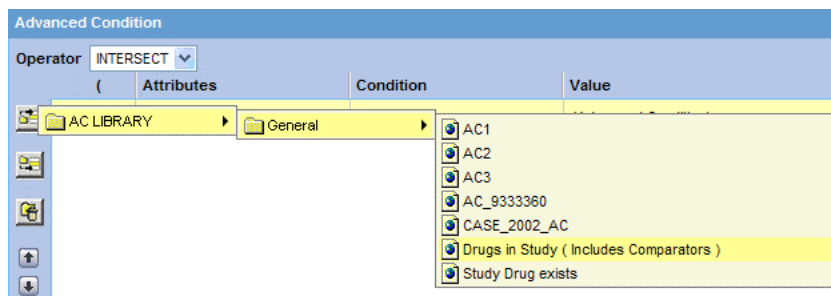
4. In the **Operator** field, select a set operator to integrate the QBE and the advanced condition.

You may select **INTERSECT**, **MINUS**, or **UNION**.

5. Select the advanced condition to integrate with the QBE as follows:

- a. Click the **Add Advanced Condition Above** icon on the left bar to open the Advanced Conditions menu.

This menu lists all the advanced conditions (based on Insight Mart only) that are stored in the system and accessible to you. The conditions are organized by categories.



- b. Browse to the appropriate category, and select the required advanced condition.

The selected row is added in the Advanced Conditions Editor.

Operator	(Attributes	Condition	Value)	Operator
INTERSECT	(Drugs in Study (Includes Comparators)		(Advanced Condition))	INTERSECT
	(AC1		(Advanced Condition))	

- c. Click the **Add Advanced Condition Above** icon, or the **Add Advanced Condition Below** icon to insert another advanced condition above or below the existing advanced condition.

Tip: To change the structure of the *query* by changing the order of the rows, select a row and then click the arrow icons to move the row up or down.

6. Enter parentheses in the (and) columns to determine the order of execution for the selected advanced conditions.
7. In the **Operator** column, specify the set operation to perform between the selected advanced conditions.
8. Click **Save As** to save your integrated query.
 - To run the integrated QBE and generate the case series, click **Execute**.
The ACTIVE CASE SERIES page appears with the case series.
See [Chapter 7, "Working with Case Series"](#) for more information.
 - To convert the integrated QBE and advanced condition into a single advanced condition, click **Convert to Advanced Condition**.
See ["Converting a QBE to an Advanced Condition"](#) on page 3-39 for more information.

For detailed information about using the Advanced Conditions Editor, see [Chapter 5, "Using Advanced Conditions to Create Queries on Insight Mart."](#)

Using Filters to Create Queries

Filters let you create queries by specifying multiple values or a range of values (in numeric or date fields) for each field in a set of fields displayed on a single page. Therefore, you may choose filters in situations when the querying criteria is based on multiple values or a range of values in fields.

Note: Filters are NOT supported, if target data source is set as Argus Mart only.

This chapter, which describes how to work with filters, includes the following topics:

- [About Filters](#)
- [Using Predefined Filters](#)
- [Creating Custom Filters](#)
- [Working with the Last Modified or Executed Value Set](#)
- [Working with Saved Filters and Value Sets](#)
- [Using Filters with Advanced Conditions](#)

In addition to filters, Argus Insight provides the following query tools:

- QBEs (see [Chapter 3, "Creating Queries by Example"](#))
- Advanced Conditions (see [Chapter 5, "Using Advanced Conditions to Create Queries on Insight Mart"](#))

About Filters

Argus Insight provides five predefined filters. Each predefined *filter* comprises of a set of specific data mart fields called filter elements. [Table 4-1](#) lists the five predefined filters and the elements associated with them.

Note: The field labels for each filter are displayed as per the field labels configured in Argus Safety.

Table 4–1 Argus Insight Predefined Filters and Elements

Predefined Filter	Associated Filter Elements (Fields)	
Compliance	Advanced Conditions Case Initial Receipt Date Country of Incidence Family Name Product Related to Study Conduct? (As Reported) Report Form Reporting Group	Case Followup Receipt Date Case Report Type Event Listedness/Lic Country Owned by Site Project/Study/Center Report Agency Report Submission Date
Configuration	Advanced Conditions Product	Country of Incidence Project/Study/Center
Management	Advanced Conditions Case Followup Receipt Date Case Report Type Case Status Has Followup Product Workflow Group	Case Delayed/Open Case Initial Receipt Date Case Seriousness Country of Incidence Owned by Site Reports Pending
Pharmacovigilance	Advanced Conditions BMI Case Comment Case Initial Receipt Date Case Outcome Company Comment Dosage Regimen Route of Administration Drug Duration of Administration Event Diagnosis Flag Event Term Onset Latency (minutes) Patient Age (In Years) Patient Ethnicity Patient Relevant Tests Product Type Rechallenge/Dechallenge Reporter Type/HCP Time to Onset from First Dose	ATC Code Case Abbreviated Narrative Case Followup Receipt Date Case Narrative Case Seriousness Country of Incidence Dose Evaluation in Light of Similar Events Event Seriousness Local Evaluator Comment Outcome of Event Patient Age Group Patient Gender/Pregnancy Product Project/Study/Center Relevant History Condition Study Blinding Status Time to Onset from Last Dose
Workflow	Advanced Conditions Case Followup Receipt Date Case Report Type Case Status Event Term Has Followup Product Workflow Group	Case Delayed/Open Case Initial Receipt Date Case Seriousness Event Listedness/Lic Country Family Name Owned by Site Project/Study

Argus Insight also lets you define custom filters by letting you select a set of elements (data mart fields) and saving the selection as your own filter.

To create a filter using queries:

1. Select a predefined or custom filter.
2. Specify values (multiple or range) in the desired filter elements associated with the filter.
3. To generate a case series, execute this query (value set).

The set of values you specify in the elements associated with a filter is called a value set. For example, a particular filter may have this value set:

Filter Element	Values Specified
Country of Incidence	United States and Germany
Product Name	CureAll Injection and CureAll Capsule
Coded Event Description	Injection site rash and aggravated nausea
Seriousness Criteria	Hospitalized and intervention required
Patient Age	25 to 65 years
	Note that ranges can only be specified for fields that have numeric values.

Argus Insight lets you save value sets. Therefore, each filter can have multiple value sets. The advantage of saving value sets is that this enables you to execute a value set later without having to select a filter and then entering values in the associated elements.

Using Predefined Filters

This section describes the following tasks:

- [Selecting a Predefined Filter](#)
- [Creating a Value Set for the Predefined Filter](#)
- [Executing a Value Set](#)

Selecting a Predefined Filter

To select a predefined filter:

1. Navigate to **Queries > Filters > New Value Set**.

The Select Filter for New Value Set dialog box appears.



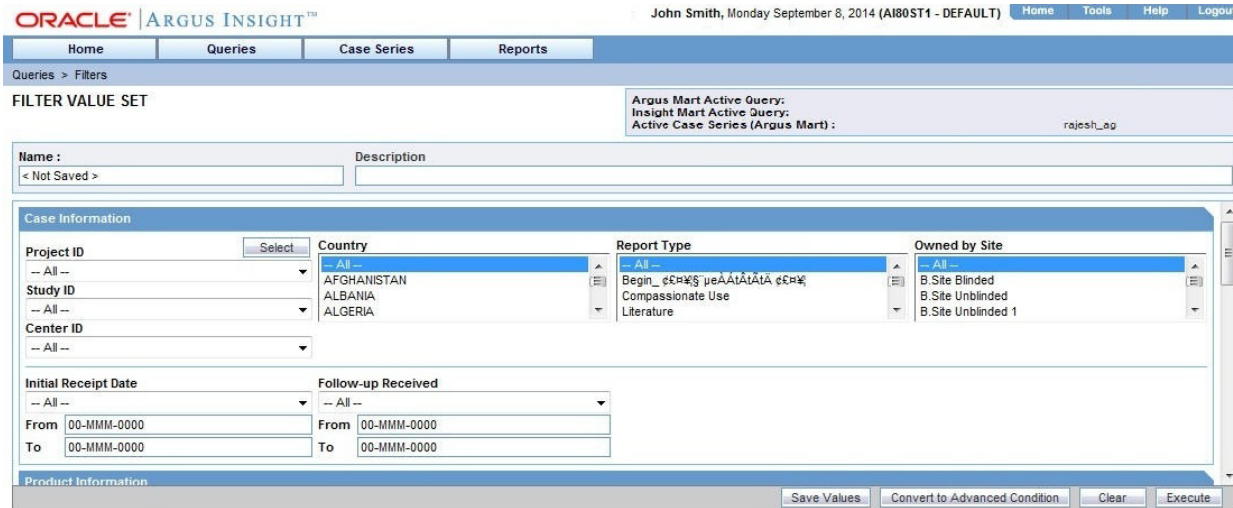
Note: The **Select Filter for New Value Set** dialog box displays a list of all the predefined as well as custom filters and their associated elements. Use the scroll bar to view all the filters in the list.

2. Select a predefined filters (**Compliance, Configuration, Management, Pharmacovigilance, or Workflow**).

If custom filters are saved to the system, you may select a custom filter instead.

3. Click **OK**.

The **FILTER VALUE SET** page appears.



Note: In the **FILTER VALUE SET** page, all the elements associated with the filter are organized in sections. You need to scroll the page to view all the sections. All the predefined value sets contain the **Advanced Condition** section. You can use the options in this section to select an existing advanced condition and integrate your value set with it. See ["Integrating a Value Set with an Advanced Condition"](#) on page 4-23 for details. To convert the entire value set to an advanced condition, see ["Converting a Value Set to an Advanced Condition"](#) on page 4-22 for details.

Creating a Value Set for the Predefined Filter

To create a value set for the predefined filter:

1. Specify values for the filter elements in the sections.

Depending on the filter you selected, the **FILTER VALUE SET** page may contain these sections:

Sections in the New FILTER VALUE SET Page	Associated Elements (Fields)
Case Information	Case Followup Receipt Date Case Report Type Family Name Product
	Case Initial Receipt Date Event Listedness/Lic Country Owned by Site Project/Study

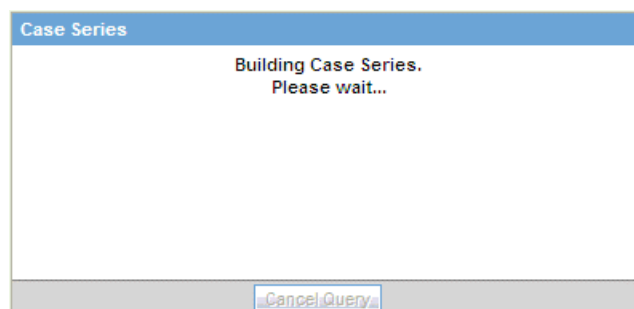
Sections in the New FILTER VALUE SET Page	Associated Elements (Fields)	
Patient Information	BMI Patient Age (In Years) Patient Ethnicity	Patient Age Group Patient Gender/Pregnancy
Product Information	ATC Code Product Regimen Daily Dose Total Regimen Dosage	Drug Primary Indication Code <i>Rechallenge/Dechallenge</i> Total Drug Dosage
Event Information	Event Seriousness Event Listedness/Lic Country Outcome of Event	Event Term Onset Latency (minutes) Related to Study Conduct? (As Reported)
Workflow Information	Case Delayed/Open Has Followup	Case Status Workflow Group
Miscellaneous Information	Lab Results	Lab Test/Assessment
Report Information	Report Agency Report Submission Date Reporting Group	Report <i>Form</i> Reports Pending

Note: To access the MedDRA Browser from the Pharmacovigilance or Workflow filters, navigate to **Queries > Filters > New Value Set**. The MedDRA Browser for the Pharmacovigilance and Workflow filters support the following options specific to filters:

- **All hierarchy** option — Use this option to enable a query search based on all/selected hierarchical terms in MedDRA. The search output captured depends on the check boxes selected in the MedDRA Browser window.
- **Term only** option — Use this option to select multiple terms within a specific AE term. Click on the term(s) you want to include in your search criteria. These terms are highlighted in yellow. The output based on the term(s) selected in the MedDRA Browser is populated in the relevant section of the filter.

2. Examine the value set results.
3. Click **Execute**.

While the system searches for matching cases, the following dialog box appears:



Tip: To cancel the query execution at this point and return to the FILTER VALUE SET page, click **Cancel Query**.

If the system finds cases that match the query criteria, the list of cases appear on the ACTIVE CASE SERIES page.

4. Examine the case series. If the case series is too large, you may want to modify the value set to narrow down the case series.

Alternatively, if you find the case series to be appropriate, you can save the value set to the system.

5. Click **View Query** in the ACTIVE CASE SERIES page to return to the FILTER VALUE SET page.

Note: When you save the modifications to a value set or execute a value set, the system assigns the active status to the value set. Therefore, when you return to the VALUE SET page, the **Active Query Name** label displays the name of the filter.

6. If required, modify the value set and examine the results again or proceed to save the value set.

7. Save the value set to the system.

8. In the **Description** field, enter a description of the value set.

For example, you may describe the type of cases the value set retrieves.

9. Click **Save Values**.

The Save Value Set dialog box appears.

10. In the **Name** field, enter the name of the value set.
11. Click **OK** to close the dialog box and refresh the FILTER VALUE SET page.

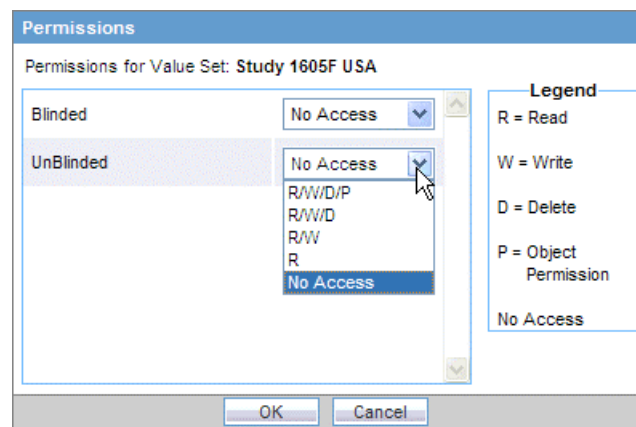
Note that:

- The **Name** label displays the name of the value set you specified.
- The **Save Values As** button and the **Permissions** button are now enabled.

Note: The FILTER LIBRARY page displays all the value sets saved to the system. See "[Working with Saved Filters and Value Sets](#)" on page 4-18 for more information.

Tip: If you make modifications to the field values after you saved the value set to the system, click **Save Values** to save the changed field values. To save the value set by another name, click **Save Values As**. To clear all the field values in the FILTER VALUE SET page, click **Clear**.

12. To assign group-level permissions on the saved value set, click **Permissions**.
The **Permissions** dialog box appears with the names of all the groups (except the **Administrator** group) that the system administrator has created.



13. To assign permissions to the group members on the value set you have created, use the drop-down list next to a group name.

The available options are:

Permission	Description
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the value set.
R/W/D	Group members will be able to view, modify, and delete the Value Set.
R/W	Group members will be able to view and modify the value set.
R	Group members will be able to only view the value set.
No Access (Default)	No group members will be able to access the value set.

14. Click **OK** to save the permission settings.

Note: The author of the value set always has the highest level of permission (R/W/D/P) on it. For example, suppose you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a value set that you create. In this case, you will continue to have the highest level of permission on your value set; other members in your group cannot access your value set.

Executing a Value Set

To execute a value set, on the FILTER VALUE SET page, click **Execute**.

The ACTIVE CASE SERIES page appears with the cases that match the value set criteria.

ACTIVE CASE SERIES
Source: Insight Mart

Argus Mart Active Query: rajesh test smoke
Insight Mart Active Query: Management
Active Case Series (Insight Mart): < Not Saved >

Name: < Not Saved > Category: General Description:

Choose Elements Search Clear 1 - 50 / 938

Case Number	Report Type	Primary Company Product	Primary Event	Seriousness Criteria	Outcome	Effective Start Date	Notes
0019_MP_TEST_DEVICE	Spontaneous	MP TEST DEVICE	Rash	M		00-MMM-0000 00:00:00	
002_GLOBAL_ONLY	Spontaneous	CROOIN (US)	Pain	M		00-MMM-0000 00:00:00	
003_GLOBAL_LOCAL	Spontaneous	CROOIN (US & JP)	Rash	M			
004_GLOBAL_LOCAL_F	Spontaneous	CROOIN (US & JP)	Rash	M			
006_GLOBAL_LOCAL_L	Spontaneous	CROOIN (US & JP)	Rash	M			
077-300709	Spontaneous	Begin Product Name Product Name Product	Alkathisia	M,F,H	Fatal		
078-010108	Spontaneous	Tegretol	Rigors	M			
079-300709	Spontaneous	DOXORUBION HCL	Pyrexia	D,I,R			
080-150808	Spontaneous	Rabipur		N/A			
081-300709	Spontaneous	Begin Product Name Product Name Product	Pain	M,F,H			
082-010108	Spontaneous	Tegretol	Rigors	M			
083-160808	Sponsored Trial	Doxorubicin or Placebo		N/A			
084-010108	Spontaneous	Tegretol	Rigors	M			
085-060809	Sponsored Trial	Begin Product Name Product Name Product	Pyrexia	Non Serious			
086-060809	Sponsored Trial	Begin Product Name Product Name Product	Pyrexia	Non Serious			
087-060809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
088-060809	Literature	GB Test IM/ Product	Pyrexia	M	Unchanged		
089-070809	Sponsored Trial	DOXORUBION HCL	Pyrexia	Non Serious			
090-070809	Sponsored Trial	DOXORUBION HCL	Pyrexia	Non Serious			
091-070809	Sponsored Trial	DOXORUBION HCL	Asthma	Non Serious			
092-050102	Sponsored Trial	DOXORUBION HCL	Cardiac arrest	H			
093-050102	Sponsored Trial	DOXORUBION HCL	Cardiac arrest	H			
094-100809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
095-030101	Spontaneous	Sombrin	Blester	Non Serious			
096-100809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
097-100809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
098-110809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
099-110809	Sponsored Trial	DOXORUBION HCL	Hepatic failure	M			
100-190906	Spontaneous	DOXORUBION HCL	Pyrexia	F,H	Fatal		

Freeze and Save Save Save As View Query Criteria View Query Export to Excel Cancel

After generating the case series, you may manually modify or save the series.

See [Chapter 7, "Working with Case Series"](#) for more information.

Creating Custom Filters

This section includes the following topics:

- [Creating a Custom Filter](#)
- [Creating a Value Set for a Custom Filter](#)

Creating a Custom Filter

To create a custom filter:

1. Navigate to **Queries > Filters > Library**.

The **FILTER LIBRARY** page appears.

This page lists the predefined as well as custom filters and their value sets in a control tree format.

Name	Description	Last Modified	User Full Name	Category	Value Set
Compliance	Predefined Compliance Filter	06-SEP-2012	Administrator	Compliance	2
Configuration	Preconfigured Configuration Filter	06-SEP-2012	Administrator	Configuration	3
CustomFilter		05-JAN-2016	rajesh	General	0
CustomFilter		20-OCT-2015	Administrator	General	0
CustomSQL AC integrated with Customfilter	desc	21-OCT-2015	igow da_RW	Compliance	3
Custom_filter_sprint 4		21-OCT-2015	igow da_RW	Pharmacovigilance	1
Management	Preconfigured Management Filter	06-SEP-2012	Administrator	Management	7
Pharmacovigilance	Preconfigured Pharmacovigilance Filter	06-SEP-2012	Administrator	Pharmacovigilance	0
qc_sprint4_Filter		16-OCT-2015	igow da_R	General	1
santosh customfilter		01-DEC-2015	rajesh	General	2
Workflow	Predefined Workflow Filter	06-SEP-2012	Administrator	General	1

2. Click **New Filter**.

The **FILTER ELEMENTS** page appears.

FILTER ELEMENTS

Argus Mart Active Query: < Not Saved >
 Insight Mart Active Query: test qbe
 Active Case Series (Insight Mart): < Not Saved >

Name: < Not Saved > Category: General Description:

Choose Elements

Available Elements:	Selected Elements:
Abbreviated Narrative	
Advanced Conditions	
Age	
Age Group	
BMI	
Blinding Status	
Case Comment	
Case Delayed/Open	
Case Outcome	
Case Serious	
Case Status	
Co-Drug Code w Study	
Coded PT	
Company Comment	
Country	
Daily Dosage	
Data Sheet	
Diagnosis	
Dose	
Drug Type	
Duration of Administration	
Ethnicity	
Evaluation in light of similar events in the past	
Event Listedness/Lic Country	
Event Onset Latency	
Event Seriousness	
Event Term	
Follow-up Received	
Has Followup	
Initial Receipt Date	
Lab Test/Assessment	
Local Evaluator Comment	
Narrative	
Outcome of Event	
Owned by Site	
Patient Gender/Pregnancy	
Patient Relevant Tests	
Patient Route of Administration	
Preferred Term	
Product	
Product Indication PT	

Buttons: >, >>, <, <<

Buttons: Save, Continue

3. From the **Available Elements** list, select an element to associate with the custom filter.

- Click the right arrow (>) button to associate the selected element with the custom filter.

The selected element appears in the **Selected Elements** list.

Tip: To add all the elements in **Available Elements** list to the **Selected Elements** list, click the >> button.

To remove an element from the **Selected Elements** list, click the < button.

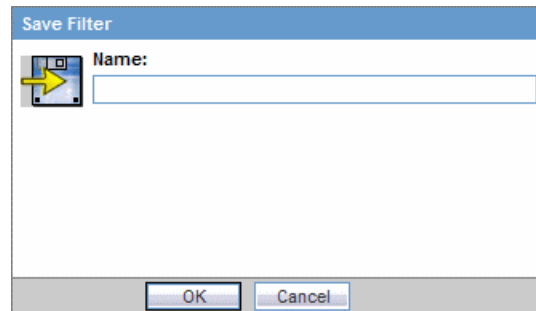
To remove all the elements from the **Selected Elements** list, click << the button.

- Save the filter.
- To assign a category to the custom filter, use the **Category** drop-down list.

A category indicates the reporting aspect to which your filter pertains: **Compliance, Configuration, General, Management, or Pharmacovigilance**. Specifying the category also helps you in searching the relevant filters from a list of all the filters saved in the system.

- In the **Description** field, enter a description of the custom filter.
- Click **Save**.

The Save Filter dialog box appears.



9. Enter a name for the custom filter.
10. Click **OK** to save the custom filter and refresh the FILTER ELEMENTS page.

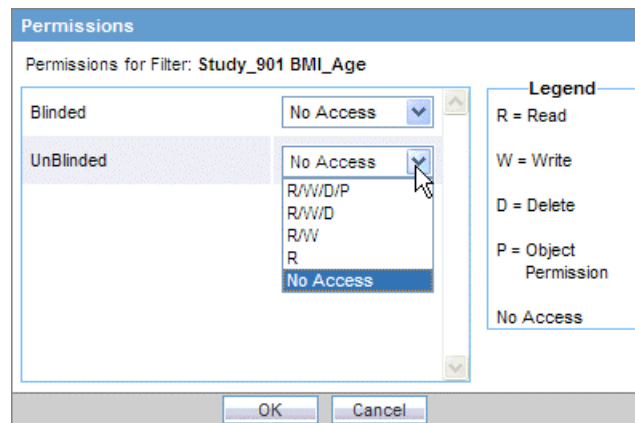
Note that:

- The **Name** label displays the name of the saved filter.
- The **Active Query Name** label in the upper-right corner of the page now displays the name of the filter you specified.
- The **Save As** button and the **Permissions** button are now enabled.

Note: If you make modifications to the filter elements after you saved the filter to the system, click **Save** to save the changes. To save the filter by another name, click **Save As**.

11. To assign group-level permissions on the filter, click **Permissions**.

The Permissions dialog box appears with the names of all the groups (except the **Administrator** group) that the system administrator has created.



12. To assign permissions to the group members on the filter you have created, use the drop-down list next to a group name. The available options are:

Permission	Description
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the filter.
R/W/D	Group members will be able to view, modify, and delete the filter.
R/W	Group members will be able to view and modify the filter.
R	Group members will be able to only view the filter.
No Access (Default)	No group members will be able to access the filter.

Note: The author of the filter always has the highest level of permission (R/W/D/P) on the filter. For example, suppose you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a filter that you create. In this case, you will continue to have the highest level of permission on your filter; other members in your group cannot access the filter.

13. Click **OK** to save the permission settings.

Creating a Value Set for a Custom Filter

To create a value set for a custom filter:

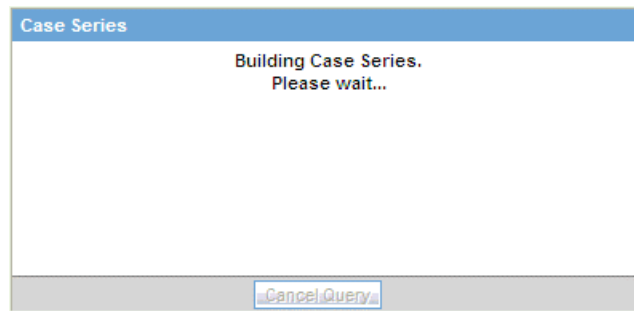
1. On the FILTER ELEMENTS page, click **Continue**.

The FILTER VALUE SET page appears.

Note: In the FILTER VALUE SET page, all the elements associated with the filter are organized in sections. You need to scroll the page to view all the sections. If you included the advanced condition element while creating your filter in Step 2, the FILTER VALUE SET page displays an additional Advanced Conditions section. You can use the options in this section to create an advanced condition and integrate your value set with it. See ["Integrating a Value Set with an Advanced Condition"](#) on page 4-23 for details. To convert the entire value set to an advanced condition, see ["Converting a Value Set to an Advanced Condition"](#) on page 4-22 for details.

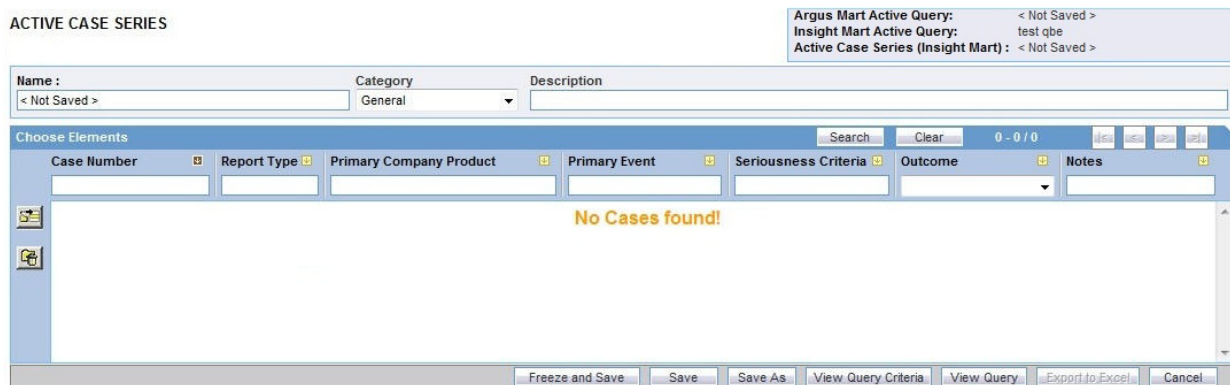
2. Specify values for the filter elements.
See ["Using Predefined Filters"](#) on page 4-3 for details.
3. Examine the value set results.
4. Click **Execute**.

While the system searches for matching cases, the following dialog box appears:



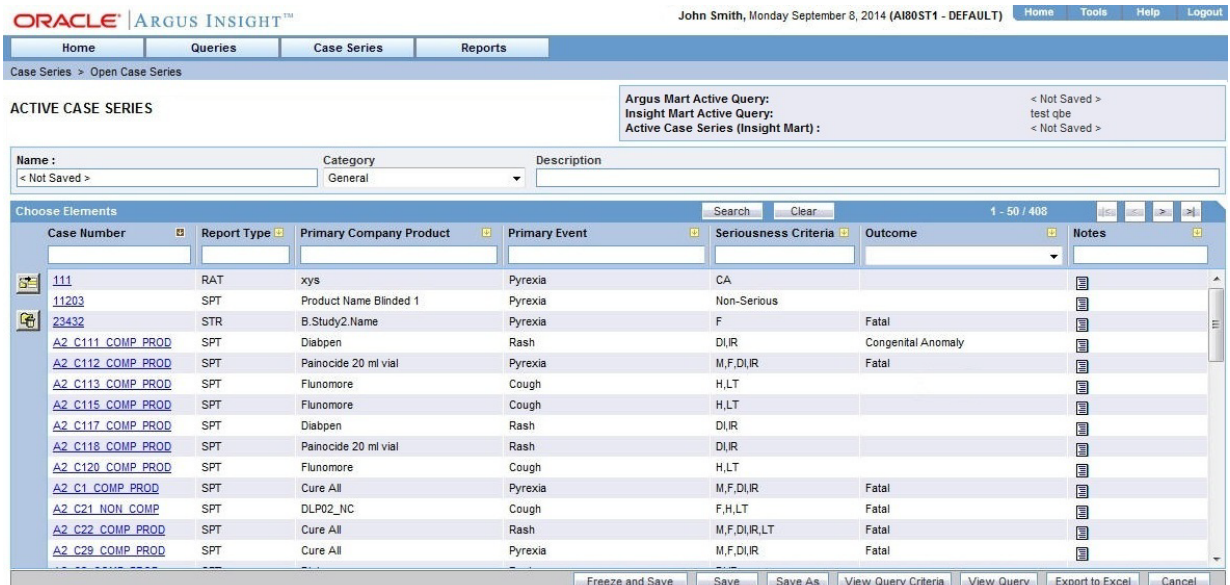
Note: To cancel the query execution at this point and return to the FILTER VALUE SET page, click **Cancel Query**.

- If the system does not find any cases that match the querying criteria, the following dialog box appears:



Click **OK** in this dialog box to return to the Value Set *form*, modify the criteria, and execute the value set again

- If the system finds cases that match the query criteria, a list of such cases appears in the ACTIVE CASE SERIES page.



- Examine the case series. If the case series is too large, you may want to add additional elements to the filter or modify the value set.

Alternatively, if you find the case series to be appropriate, you can save the value set to the system.

- Click **View Query** to return to the FILTER VALUE SET page.

- Modify the value set, if required, and examine the results again or proceed to save the value set.

- Save the value set to the system.

- In the **Description** field, enter a description of the value set.

For example, you may describe the type of cases the value set retrieves.

- Click **Save Values**.

The Save Value Set dialog box appears.

- Enter a name for the value set.

Note: The name cannot contain following characters: % " ' ^ ~ ; | #`

- Click **OK**.

The FILTER VALUE SET page refreshes.

Note that the **Save Values As** button and the **Permissions** button are now enabled.

FILTER VALUE SET

Argus Mart Active Query: < Not Saved >
 Insight Mart Active Query: test qbe
 Active Case Series (Insight Mart): < Not Saved >

Name: sdvsdv Description:

Case Information

Project ID: CURE
 Study ID: CURE ALL US 001
 Center ID: -- All --

Country: -- All --
 AFGHANISTAN
 ALBANIA
 ALGERIA

Product Information

Company Product w/o Study: -- All --

Advanced Conditions

Operator	Attributes	Condition	Value	Operator
(AC1		(Advanced Condition)	UNION
	Study Drug exists		(Advanced Condition)	
)				

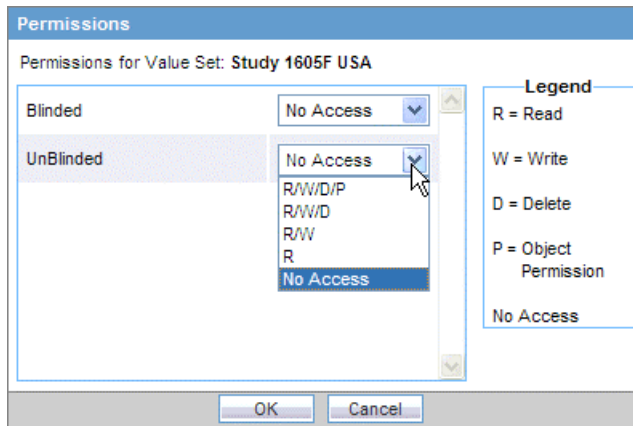
Buttons: Save Values, Convert to Advanced Condition, Clear, Execute

Note: The FILTER LIBRARY page displays the custom as well as predefined filters and their value sets in a control tree format. From this page, you can select a value set and directly execute it. See ["Working with Saved Filters and Value Sets"](#) on page 4-18 for more information. The saved filters also appear in the **Select Filter for New Value Set** dialog box from where you can select the desired filter, enter values in the NEW VALUE SET page and execute. See ["Using Predefined Filters"](#) on page 4-3 for more information.

Tip: If you make modifications to the field values after you saved the value set to the system, click **Save Values** to save the changed field values. To save the value set by another name, click **Save Values As**. To clear all the field values in the FILTER VALUE SET page, click **Clear**.

15. To assign group-level permissions on the saved value set, click **Permissions**.

The Permissions dialog box appears with the names of all the groups (except the **Administrator** group) that the system administrator has created.



16. To assign permissions to the group members on the value set you have created, use the drop-down list next to a group name. The available options are:

Permission	Description
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the value set.
R/W/D	Group members will be able to view, modify, and delete the Value Set.
R/W	Group members will be able to view and modify the value set.
R	Group members will be able to only view the value set.
No Access (Default)	No group members will be able to access the value set.

Note: The author of the value set always has the highest level of permission (R/W/D/P) on it. For example, suppose you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a value set that you create. In this case, you will continue to have the highest level of permission on your value set; other members in your group cannot access your value set.

17. Click **OK** to save the permission settings.

18. Click **Execute**.

The ACTIVE CASE SERIES page appears with the cases that match the value set criteria.

After generating the case series, you may manually modify or save the series. See [Chapter 7, "Working with Case Series"](#) for more information.

Working with the Last Modified or Executed Value Set

The system assigns the *active* status to a value set when you save modifications to it or execute it. Unless you save the modifications to another value set or execute it, the last value set you modified or executed remains active. This is helpful in situations when you want to access a frequently used value set.

To view an active value set:

1. Navigate to **Queries > Filters > Active**.

The FILTER VALUE SET page appears with the value set you executed or modified last.

FILTER VALUE SET

Argus Mart Active Query: < Not Saved >
 Insight Mart Active Query: test qbe
 Active Case Series (Insight Mart): < Not Saved >

Name: edvsdv Description

Case Information

Project ID: CURE Country: -- All --
 Study ID: CURE ALL US 001
 Center ID: -- All --

Product Information

Company Product w/lo Study: -- All --

Advanced Conditions

Operator	Attributes	Condition	Value	Operator
(AC1		(Advanced Condition)	UNION
	Study Drug exists		(Advanced Condition)	
)				

Buttons: Save Values, Convert to Advanced Condition, Clear, Execute

- If the value set was saved to the system before executing, the name of the value set appears in the **Name** field.
 In addition, the name of the filter appears next to the **Active Query Name** label.
 To rename an already saved value set, enter the new name in the **Name** field, and click **Save Values**.
- If the value set was not saved to the system before executing, the text <Not Saved> is displayed in the **Name** field.
 You may enter the name of the value set in the **Name** field, and click **Save**.
- From the ACTIVE FILTER VALUE SET page, you can perform the following tasks:

Task	Description
Modify the Active Value Set	If required, you can modify the value set by changing the <i>field</i> values. While entering field values, if you want to remove all the values you entered, click Clear . Click Save Values to save the changed field values. This button is only available for a saved value set.
Save the Active Value Set by another name	Click Save Values As to save the active value set by a different name. The FILTER LIBRARY page displays all the value sets you saved to the system. See " Working with Saved Filters and Value Sets " on page 4-18 for more information.
Convert Active Value Set to Advanced Condition	Click Convert to Advanced Condition to convert the active value set to an advanced condition. See " Converting a Value Set to an Advanced Condition " on page 4-22 for more information.
Assign Permissions on the Active Value Set	Click Permissions to set the group-level access permissions. The Permissions button is only available for saved value sets.

Task	Description
Change the Description of the Active Value Set	You can change the description of the active value set by modifying the text displayed in the Description field. Click Save Values to store the changed description.
Execute the Active Value Set	Click Execute to generate a case series by using the active value set.

Note: When the field values for an active value set are modified or the active value set is saved by a different name, the changes in the active value set reflect the most recent changes. The active value set also changes in case you modify the field values and execute the value set without saving the modifications.

Working with Saved Filters and Value Sets

The FILTER LIBRARY page lists all the predefined as well as saved custom filters and their value sets in a control tree format.

To access this page, navigate to **Queries > Filters > Library**.

To view the value sets associated with a filter, expand the control tree for a filter. The saved value sets are displayed below each filter.

The descriptions of the columns in the FILTER LIBRARY page follow.

Column	Description
Name	Displays the name of the filters and value sets.
Description	Displays the description of the filters and value sets.
Last Modified	Displays the date when the filters/value set was last modified.
User Full Name	Displays the name of the user who created the filter/value set.
Category	Displays the filter category.
Value Set	Displays the number of value sets created for a filter.

Searching Saved Filters and Value Sets

To search for a saved filter or value set:

1. Specify the search criteria, as appropriate:
 - To search for a filter/value set by its name, type the filter/value set name in the **Name** text box.
 - To search for a filter/value set by its description, type the first few words of the description in the **Description** text box. The system searches for the specified search string in all filter/value set descriptions.
 - To search for a filter/value set by its date of modification, enter the modification date in the first **Last Modified** date *field*. You can specify a date range by typing the start and end dates in the first and second date fields, respectively.
 - To search a filter/value set by its author, select the author name from the **User Full Name** drop-down list.
 - To search for a filter by its category, select the category from the **Category** drop-down list.

Note: If you search for a text comprising an underscore, it is treated as a wildcard and is replaced by a letter in the displayed results. For example, If you have queries with names - CURE, CORE, and CARE and you search for C_RE, all three queries are displayed in the result.

2. Click **Search**.
The search results appear in a list based on the search criteria.
3. To sort the search results list, click the sort icon next to the column headers in the list.

Creating a New Filter

On the FILTER LIBRARY page, click **New Filter**.

See "[Creating a Custom Filter](#)" on page 4-9 for details.

Creating a New Value Set

To create a new value set, navigate to **Queries > Filters > New Value Set**.

Alternatively, on the FILTER LIBRARY page, click **New Value Set**.

You may create value sets for predefined as well as custom filters by using this method.

See "[Using Predefined Filters](#)" on page 4-3 for details.

Modifying a Filter or Value Set

To modify a filter or value set:

1. On the FILTER LIBRARY page, select the value set or the filter from the list.
2. Click **Modify**.
 - If you selected a filter, the FILTER ELEMENTS page appears.

- If you selected a value set, the FILTER VALUE SET page appears.
3. Make your modifications to the filter or value set.
 4. Click **Save** to save the modifications you made in the FILTER ELEMENTS page.
If you modified a value set, click **Save Values** in the FILTER VALUE SET page to save the changes.

Deleting a Filter or Value Set

You may delete the value sets for predefined as well as custom filters. You may also delete custom filters. However, you cannot delete the predefined filters. When you delete a filter, all its associated value sets are also deleted.

To delete a value set or a custom filter:

1. Navigate to the FILTER LIBRARY page.
2. Select the value set or custom filter that you want to delete.
3. Click **Delete**.

A confirmation dialog box appears.

4. Click **OK**.

The system deletes the selected filter/value set, and returns to the FILTER LIBRARY page.

Executing a Value Set

To execute a value set:

1. Navigate to the FILTER LIBRARY page.
2. Select a value set from the list.
3. Click **Execute**.

The system executes the value set, and the ACTIVE CASE SERIES page appears.

ACTIVE CASE SERIES
Source: Insight Mart

Argus Mart Active Query: rajesh test smoke
Insight Mart Active Query: Management
Active Case Series (Insight Mart): < Not Saved >

Name: < Not Saved > Category: General Description:

Choose Elements Search Clear 1 - 50 / 938

Case Number	Report Type	Primary Company Product	Primary Event	Seriousness Criteria	Outcome	Effective Start Date	Notes
0019_MP_TEST_DEVICE	Spontaneous	MP TEST DEVICE	Rash	M		00-MMM-0000 00:00:00	
002_GLOBAL_ONLY	Spontaneous	CROCIN (US)	Pain	M		00-MMM-0000 00:00:00	
003_GLOBAL_LOCAL	Spontaneous	CROCIN (US & JP)	Rash	M			
004_GLOBAL_LOCAL_F	Spontaneous	CROCIN (US & JP)	Rash	M			
006_GLOBAL_LOCAL_L	Spontaneous	CROCIN (US & JP)	Rash	M			
077-300709	Spontaneous	Begin Product Name Product Name Product	Akathisia	M,F,H	Fatal		
078-010108	Spontaneous	Tegretol	Rigors	M			
079-300709	Spontaneous	DOXORUBION HCL	Pyrexia	DI,R			
080-150808	Spontaneous	Rabipur		N/A			
081-300709	Spontaneous	Begin Product Name Product Name Product	Pain	M,F,H			
082-010108	Spontaneous	Tegretol	Rigors	M			
083-160808	Sponsored Trial	Doxorubicin or Placebo		N/A			
084-010108	Spontaneous	Tegretol	Rigors	M			
085-060809	Sponsored Trial	Begin Product Name Product Name Product	Pyrexia	Non Serious			
086-060809	Sponsored Trial	Begin Product Name Product Name Product	Pyrexia	Non Serious			
087-060809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
088-060809	Literature	GB Test IM/ Product	Pyrexia	M	Unchanged		
089-070809	Sponsored Trial	DOXORUBION HCL	Pyrexia	Non Serious			
090-070809	Sponsored Trial	DOXORUBION HCL	Pyrexia	Non Serious			
091-070809	Sponsored Trial	DOXORUBION HCL	Asthma	Non Serious			
092-050102	Sponsored Trial	DOXORUBION HCL	Cardiac arrest	H			
093-050102	Sponsored Trial	DOXORUBION HCL	Cardiac arrest	H			
094-100809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
095-030101	Spontaneous	Sombrin	Blister	Non Serious			
096-100809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
097-100809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
098-110809	Sponsored Trial	DOXORUBION HCL	Pyrexia	M			
099-110809	Sponsored Trial	DOXORUBION HCL	Hepatic failure	M			
100-100809	Spontaneous	DOXORUBION HCL	Pyrexia	F,H	Fatal		

Freeze and Save Save Save As View Query Criteria View Query Export to Excel Cancel

- If a report is associated with the saved QBE, click **Execute**.

The ACTIVE CASE SERIES page and PRE FILTER page of the associated report is displayed.

- Enter the prompts value in the PRE FILTER page.
- Click **Execute** to generate the report.

After generating the case series, you can manually modify it or save it. See [Chapter 7, "Working with Case Series"](#) for more information.

Executing a Saved Value Set on the Active Case Series

Just as the system assigns the active status to a value set when you save modifications to it or execute it, the last saved or generated case series becomes the active case series.

You may want to run a value set on an active case series.

To narrow down the list of cases in the active case series:

- Generate the case series to run another value set:
 - You may generate the case series by using predefined filters or creating custom filters and executing a value set. This case series becomes the active case series and remains so until you execute another query to generate a different case series.
 - Alternatively, if the case series on which you want to run another value set is already saved in the system, navigate to **Case Series > Open Case Series > Library**.

When the CASE SERIES LIBRARY page appears, select the case series, and click **Make Active**.

2. Navigate to **Queries > Filters > Library**.

The FILTER LIBRARY page appears.

3. Select the value set to run on the active case series you generated in Step 1.
4. Select the **Limit Query to Active Case Series** check box.
5. Click **Execute**.

The system runs the selected value set on the active case series and displays the ACTIVE CASE SERIES page.

Note that the case series you just generated becomes the active case series.

Using Filters with Advanced Conditions

Advanced conditions let you create complex queries that involve Boolean and set operations among fields. To create advanced conditions, you use the Advanced Conditions Editor, which uses a spreadsheet-like approach for adding *query* conditions (fields and their values) and conditional operators (Boolean or set).

In Argus Insight, filters are integrated with advanced conditions to let you perform the following tasks:

- [Converting a Value Set to an Advanced Condition](#)
- [Integrating a Value Set with an Advanced Condition](#)

Converting a Value Set to an Advanced Condition

You can use an existing *filter value set* to start to build an advanced condition that uses Boolean or set operations between elements that have multiple values. When you convert a value set to an advanced condition, all the fields in which you entered values are listed on the ACTIVE ADVANCED CONDITIONS EDITOR page as *advanced condition attributes*.

To convert a value set to an advanced condition:

1. Create a new value set by either using predefined filters or creating custom filters.
Alternatively, from the FILTER LIBRARY page, open a saved value set (see "[Working with Saved Filters and Value Sets](#)" on page 4-18).
2. Verify the *field* values specified in the fields in the value set.
3. Click **Convert to Advanced Condition**.

The ACTIVE ADVANCED CONDITIONS EDITOR page appears.

All the fields in which the values were specified are listed as advanced condition attributes. The fields with multiple values are repeated.

ACTIVE ADVANCED CONDITIONS EDITOR

Argus Mart Active Query: < Not Saved >
 Insight Mart Active Query: test qbe
 Active Case Series (Insight Mart): < Not Saved >

Name: < Not Saved > Category: Pharmacovigilance Description:

(Attributes	Condition	Value)	Operator
(Report Type	equal to	Spontaneous)	AND
	Country	equal to	US)	AND
	Hospitalized	equal to	Yes)	
	Outcome of Event	equal to	Death due to AE/infection)	AND

Save Execute

4. Build your *query* further by:
 - Adding additional attributes (fields) and specifying their values
 - Adding another advanced condition as an attribute
 - Placing runtime parameters in attributes
 - Placing parentheses to determine the query execution order
 - Specifying conditions for attributes values
 - Specifying Boolean and set operators to join the attributes

See [Chapter 5, "Using Advanced Conditions to Create Queries on Insight Mart"](#) for detailed information about using the Advanced Conditions Editor.

Integrating a Value Set with an Advanced Condition

You can integrate a value set with an existing advanced condition through these set operators:

- INTERSECT
- MINUS
- UNION

If required, you can integrate the value set with multiple advanced conditions that can have Boolean or set operations between them.

Note: Only those value sets that have the **Advanced Condition** element can be integrated with advanced conditions. All value sets that you create for predefined filters contain the **Advanced Condition** element. If you want to convert a *custom filter value set* to an advanced condition, make sure you select the **Advanced Condition** element when creating the custom filter.

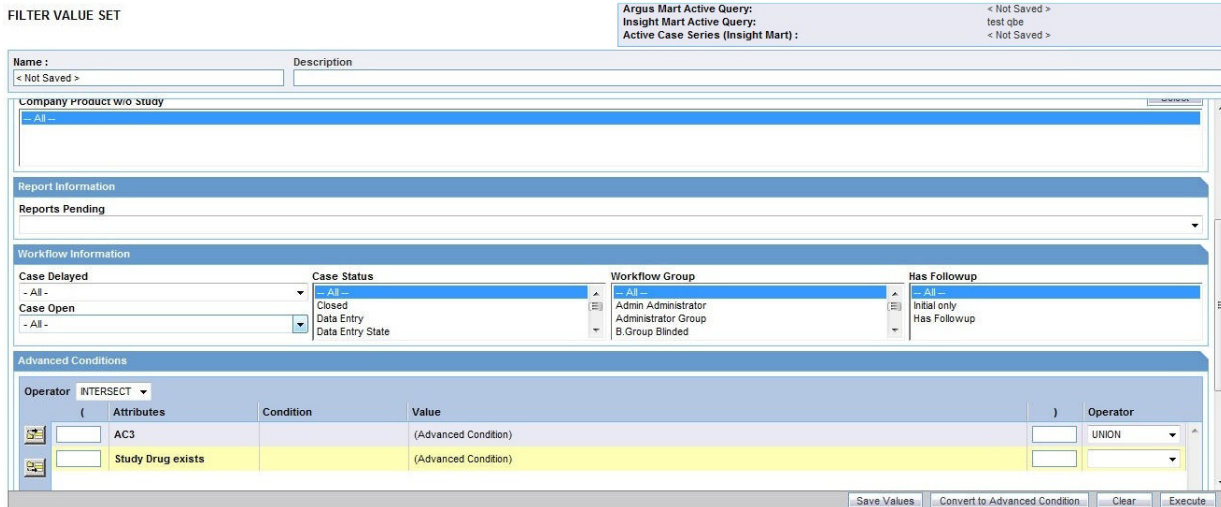
To integrate a value set with an existing advanced conditions:

1. Create a new value set by either using predefined filters or creating custom filters.

Alternatively, from the FILTER LIBRARY page, open a saved value set (see ["Working with Saved Filters and Value Sets"](#) on page 4-18).

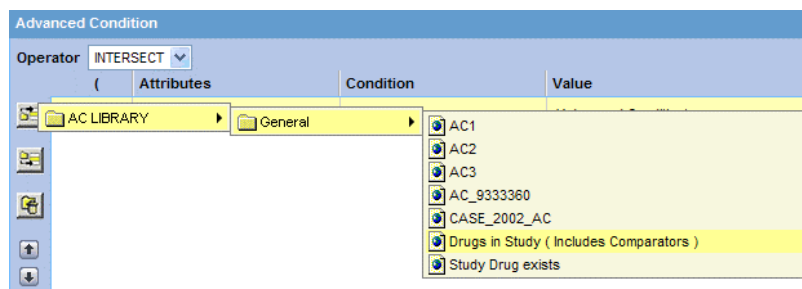
If you create a custom value set, make sure you include the Advanced Condition element.

2. Verify the *field* values specified for the value set.
3. On the FILTER VALUE SET page, scroll to the **Advanced Condition** section.

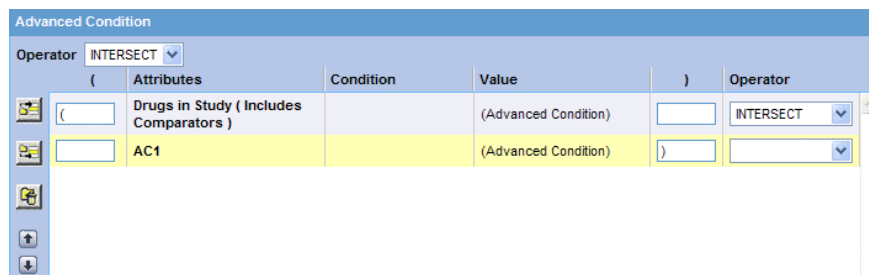


4. To enter the operator to use to integrate the value set and the advanced condition, use the **Operator** field.
You may select **INTERSECT**, **MINUS**, or **UNION**.
5. Select the advanced condition to integrate with the value set as follows:
 - a. Click the **Add Advanced Condition Above** icon on the left bar.

The Advanced Conditions menu lists the advanced conditions that are stored in the system and available to you. The conditions are organized by categories.



- b. Browse to a category and select the required advanced condition.
The selection is added as a row in the Advanced Conditions Editor.



- c. Click the **Add Advanced Condition Above** icon or the **Add Advanced Condition Below** icon to insert another advanced condition above or below the existing advanced condition.

Tip: To change the structure of the *query* by reordering of the rows, select a row and click the arrow icons to move the row up or down.

6. Type parentheses in the (and) columns to determine the order of execution for the selected advanced conditions.
7. To specify the set operation to perform between the selected advanced conditions, use the field in the **Operator** column.
8. Click **Save As** to save your integrated value set.
 - To run the integrated value set and generate the case series, click **Execute**.
The ACTIVE CASE SERIES page appears with the case series.
See [Chapter 7, "Working with Case Series"](#) for more information.
 - To convert the integrated value set and advanced condition into a single advanced condition, click **Convert to Advanced Condition**.
See ["Converting a Value Set to an Advanced Condition"](#) on page 4-22 for more information.

For detailed information about using the Advanced Conditions Editor, see [Chapter 5, "Using Advanced Conditions to Create Queries on Insight Mart."](#)

Using Advanced Conditions to Create Queries on Insight Mart

The *advanced conditions* querying tool is designed to allow the greatest flexibility in designing the most advanced queries. You can use advanced conditions to create complex queries that involve Boolean and Set operations and use Structured Query Language (SQL).

You create advanced conditions in the Advanced Conditions Editor, which employs a spreadsheet-like approach for adding query conditions (fields and their values) and conditional operators (Boolean or Set).

Besides, Argus Insight also supports queries for analysis of the historical case data based on specific date/time through Argus Mart. To enable access to this data in Argus Mart, you need to set specific attributes.

See [Chapter 6, "Using Advanced Conditions to Create Point-in-Time Queries on Argus Mart."](#)

Note: The labels for the advanced conditions field are displayed as per the field labels configured in Argus Safety.

This chapter includes the following topics:

- [Creating a New Advanced Condition](#)
- [Working with the Last Modified or Saved Advanced Condition](#)
- [Working with Saved Advanced Conditions](#)

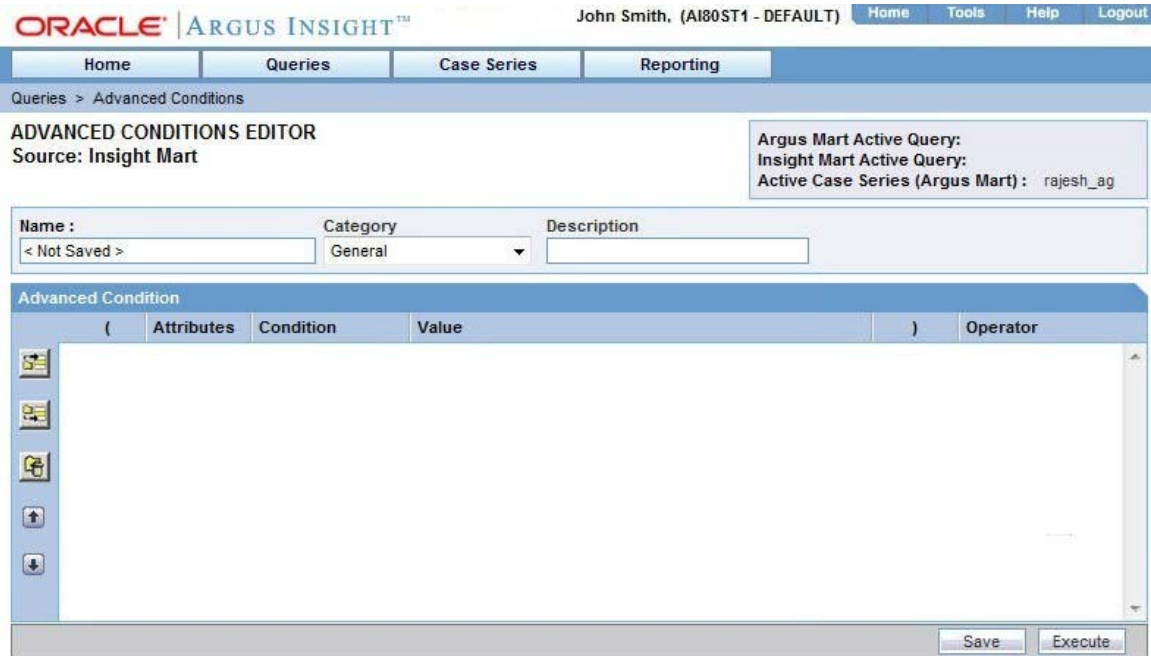
In addition to advanced conditions, Argus Insight provides the following query tools:

- QBEs (see [Chapter 3, "Creating Queries by Example"](#))
- Filters (see [Chapter 4, "Using Filters to Create Queries"](#))

Creating a New Advanced Condition

To start a new Insight Mart advanced condition:

1. Navigate to **Queries > Advanced Conditions > New (Insight Mart)**.
The ADVANCED CONDITIONS EDITOR page appears with the data source.



Note: You may also start an advanced condition by converting a QBE or a filter value set to an advanced condition. See "[Converting a QBE to an Advanced Condition](#)" on page 3-39 and "[Converting a Value Set to an Advanced Condition](#)" on page 4-22 for details.

2. Enter the attributes (fields and values) for the advanced condition.
3. Click the context menu icon (Add Advanced Condition Element Above/Below icon).

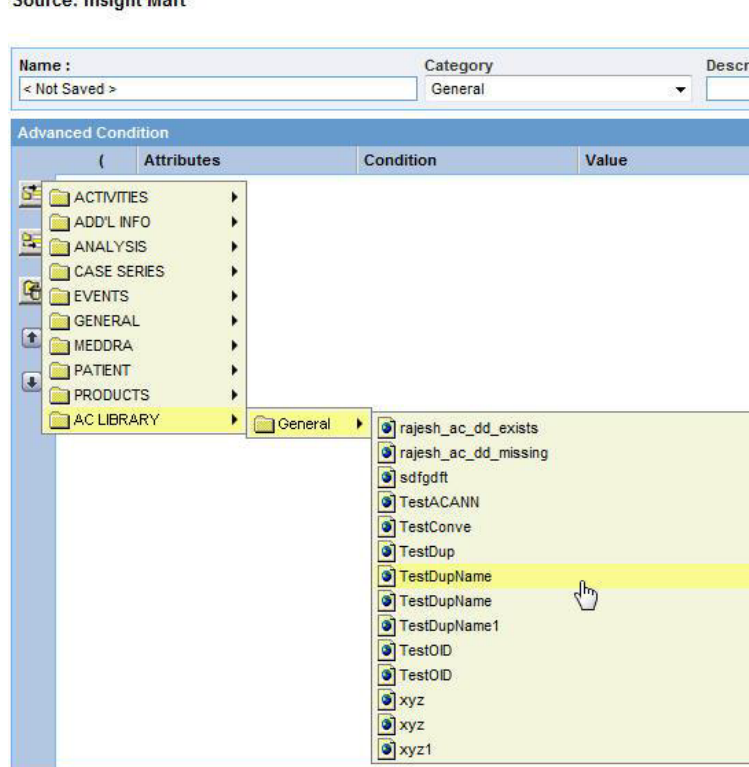
In the context menu, the categories (Activities, Additional Info, Analysis, Events, General, Patients, and Products) represent the Argus case form tabs. In these categories, the data mart fields that pertain to case information are organized in this hierarchy:

- Argus case form tab
- Sections within the tab
- Fields within the section

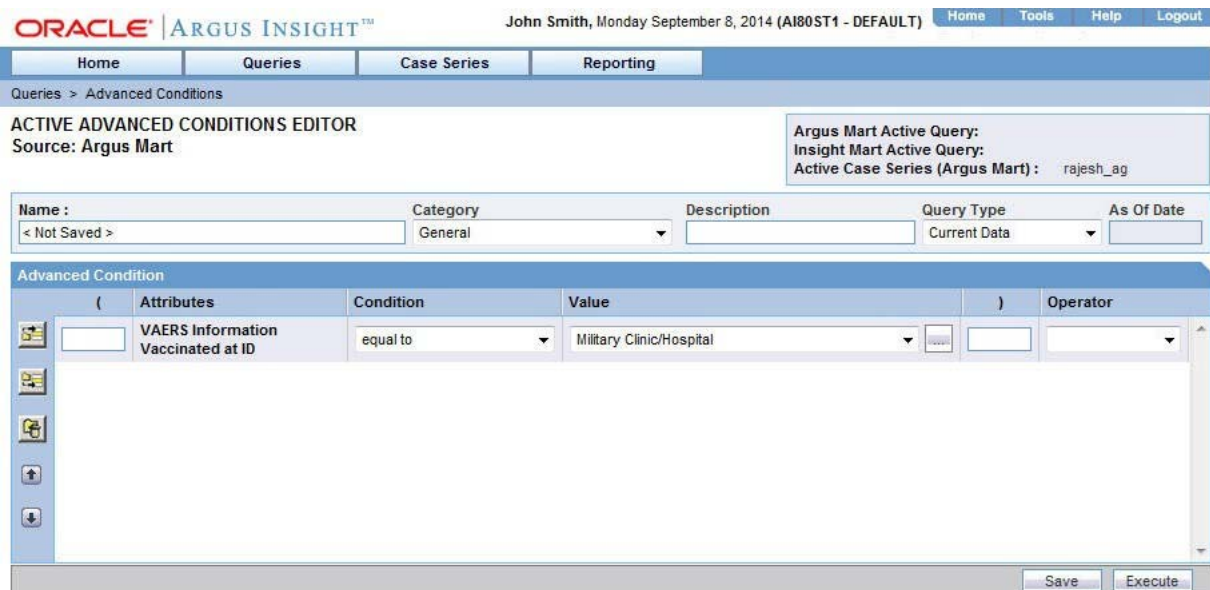
You may browse through the appropriate hierarchy and select the required *field* as an advanced condition attribute.

The **AC Library** category lists all the advanced conditions stored in the system. You may browse through the **AC Library** category and select a stored advanced condition as an attribute for the new advanced condition.

ADVANCED CONDITIONS EDITOR
Source: Insight Mart



4. Browse through a category hierarchy, and select the required attribute.
The selected attribute appears as a row in the editor.



Note: The user defined fields in Argus Safety which have been converted as a look up are also available as attributes for the advanced condition search.

5. In the **Value** field, enter the value for the selected attribute.

Depending on the type of the selected attribute, the **Value** field populates a:

- Drop-down list to select from a set of predefined values
- Text box to enter text strings or numerals
- Date field to enter dates
- Browser to select MedDRA dictionary terms, company products, WHO drugs, clinical *study* IDs, Drugs in Study (incl. Comparators) and Investigational Drugs.

To use a browser to populate the **Value** field, click the ellipsis button next to the **Value** field. From the context menu, select the option corresponding to the browser you want to start. For example, you can start the MedDRA Browser and enter criteria to search for a preferred term based on a specific code or description. You can add a selected term to the **Value** field.

6. Click the **Conditions** field, and select a condition for the attribute value.

See [Table 5–1](#) for a description of each condition. The availability of the conditions depends on the selected attribute.

Table 5–1 Conditions for Defining an Advanced Condition

Condition	Select this option if you want to...
equal to	Retrieve cases where the selected attribute's value is equal to what the Value field specifies
not equal to	Retrieve cases where the selected attribute's value is not equal to what the Value field specifies
greater than	Retrieve cases where the selected attribute's value is greater than what the Value field specifies
greater than or equal to	Retrieve cases where the selected attribute's value is greater than or equal to what the Value field specifies
less than	Retrieve cases where the selected attribute's value is less than what the Value field specifies
less than or equal to	Retrieve cases where the selected attribute's value is less than or equal to the Value that the field specifies
missing	Retrieve cases where the selected attribute's value has not been specified
exists	Retrieve cases where the selected attribute has any value
begins with	Retrieve cases where the selected attribute's value begins with what the Value field specifies
contains	Retrieve cases where the selected attribute's value contains what the Value field specifies
does not contain	Retrieve cases where the selected attribute's value does not contain what the Value field specifies
in	Retrieve cases where the selected attribute's value exists in what the Value field specifies
not in	Retrieve cases where the selected attribute's value does not exist in what the Value field specifies

Tip: To change the structure of the *query* by changing the order of the attribute rows, select a row and then click the arrow icons to move the row up or down. To delete a row from the editor, select the row and click the Delete icon.

7. Specify the operator.

Use the **Operator** drop-down list to specify the Boolean or Set operator to join the attribute with another attribute.

8. To add more attributes to your advanced condition, click the icons on the left bar to insert another attribute above or below the existing attribute.

9. Specify runtime parameters.

Note: Argus Insight lets you create advanced conditions which when executed, ask for user-specified values for certain attributes to generate the case series. For example, you may create an advanced condition in which the Case Number or the Product name may be specified only at the time of execution. In this case, the advanced condition would only retrieve those cases where the Case Number/Product Name is as specified at the time of execution.

Creating an advanced condition using same field name multiple times requires to change the Parameter name so that while executing the advanced condition different parameters values can be entered.

10. Identify the attribute row to specify runtime parameters.

11. Click the ellipsis button next to the **Value** field, and then select **Parameters** from the menu.

Attributes	Condition	Value)	Operator
VAERS Information Vaccinated at ID	equal to	Military Clinic/Hospital	⋮	Parameters

12. Click **Parameter**.

The Parameter dialog box appears.

The image shows a dialog box titled "Parameter". It contains an information icon on the left. The main text reads "New Parameter Name:" followed by a text input field containing the word "Type". Below this, it says "or Select from Existing Parameter Names:" followed by a dropdown menu. At the bottom, there is a checked checkbox labeled "Multi Select". At the very bottom of the dialog are "OK" and "Cancel" buttons.

13. To pass multiple runtime values for a single attribute, select the **Multi Select** check box.

For example, you might want to pass more than one case number or product name as runtime parameters.

14. Click **OK**.

If the field is configured to accept single runtime parameter, the field you configured as a runtime parameter is displayed in the **Value** text box enclosed within % symbol. For example, %Product Type%.

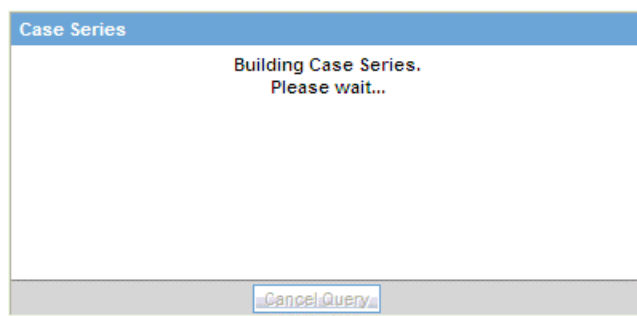
If the field is configured to accept multiple runtime parameters, the field name appears in the **Value** text box enclosed within %% symbol. For example, %%Product Type%%.

15. To determine the order of execution for the selected advanced conditions, enter parentheses in the (and) columns.

16. Examine the advanced condition results.

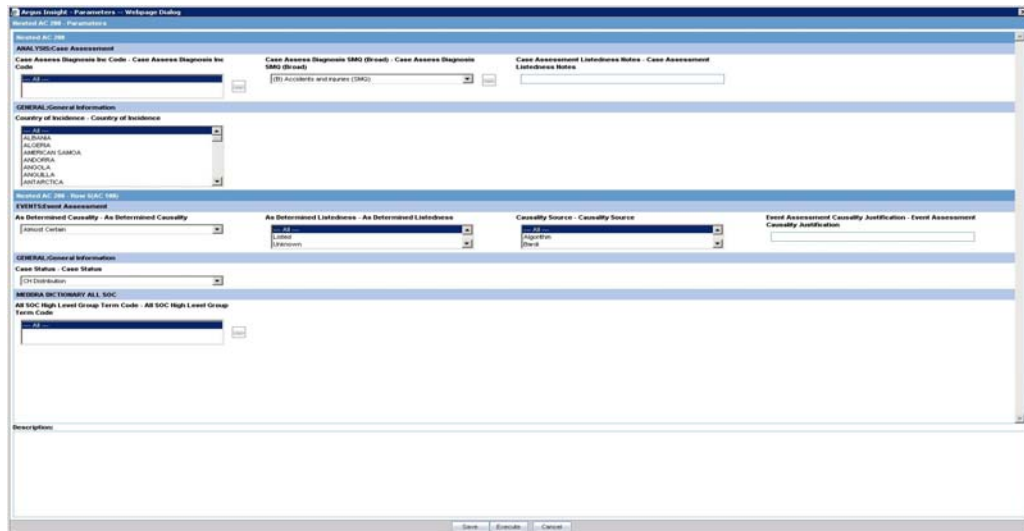
17. Click **Execute**.

The following dialog box appears:



Tip: To cancel the query execution at this point and return to the Advanced Conditions Editor, click **Cancel Query**.

- If any runtime parameter is configured, the **Parameters** dialog box appears with all the fields available based on the categorization of different fields from the tree view.



- Specify the parameter values by using the options in the dialog box, and click **Execute**.

Select at least one parameter for query execution.

The ACTIVE CASE SERIES page appears with the matching cases from the data mart.

Tip: If you select one runtime parameter and execute the search, you must enter a field.

If you select multiple runtime parameters and execute the search, you have the option to ignore the runtime parameters.

- To ignore the field criteria for query execution, select **All**.
- To save the selected values on the Advanced Condition Parameters screen, click **Save**.

Note:

- When the **Save** button is clicked, the values of the current Advance Condition only are saved, and not for the Nested Advance Conditions.
- The **Save** button is enabled only when Advance Condition is saved, and not when the Advanced Condition is executed from Query By Example, Filter, or Advance Condition Library page.

You may enter value for one or more parameters.

If no value is selected for any parameter that is if you try to save a parameterized advanced condition without providing any value, then an error message appears as '*You must select values in order to save.*'

All the fields where value is been provided are stored for the future use.

- Upon execution of these advanced conditions again, the previously selected values will appear by default on the Advanced Condition Parameters page.

Note: On the Advanced Condition Editor page, the parameterized advanced conditions appears in their original structure, and the saved parameter values are not available. These values appear only while executing the advanced condition.

-
-
- Query criteria for the case series generated using such advanced conditions will only display fields for which values for the parameter were provided.
 - The selective use of parameters can also be used while converting existing filters into advanced conditions.
 - If no cases are found that match the querying criteria, the following screen appears.



Click **View Query** to return to the Advanced Conditions Editor, modify the criteria and execute again.

- If the cases that match the query criteria are found, the ACTIVE CASE SERIES page appears with the list of such cases.
18. Examine the case series. If the case series is too large, you may want to modify the advanced condition by specifying additional attributes or changing values.

Alternatively, if you find the case series to be appropriate, you can save the advanced condition to the system.

The system retrieves the matching cases from the data mart and displays them in the ACTIVE CASE SERIES page.

Note: If the Argus Insight case series are created by using the Argus Mart advanced condition, then these case series records only case IDs, case revision effective start dates, and query criteria (as a text string).

Returning to the Advanced Conditions Editor

To return to the Advanced Conditions Editor:

1. On the ACTIVE CASE SERIES page, click **View Query**.

The ACTIVE ADVANCED CONDITIONS EDITOR page appears.

Note: When you save the modifications to an advanced condition or execute it, the system assigns the active status to the advanced condition. Therefore, when you return to the editor after executing the advanced condition, the page title changes to ACTIVE ADVANCED CONDITIONS EDITOR. The field values you specified in the editor before executing are retained. See "[Working with the Last Modified or Saved Advanced Condition](#)" on page 5-16 for details.

2. If required, modify the advanced condition and examine the results again or proceed to save the advanced condition.
3. Save the advanced condition.

Assigning a Category to an Advanced Condition

A category indicates the reporting aspect to which your advanced condition pertains:

- Case Processing
- Compliance

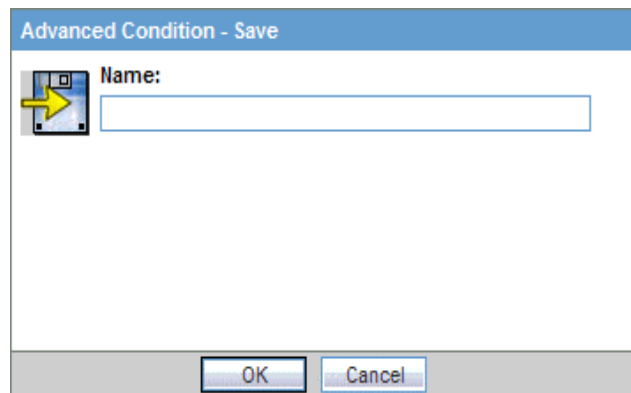
- Configuration
- General
- Management
- Pharmacovigilance

Specifying the category also helps in searching the relevant advanced conditions from a list of all the advanced conditions saved in the system.

To assign a category to an advanced condition:

1. On the ACTIVE ADVANCED CONDITIONS EDITOR page, from the **Category** drop-down list, select a category.
2. In the **Description** field, enter a description of the advanced condition.
For example, you may describe the type of cases the advanced condition retrieves.
3. Click **Save**.

The Advanced Condition - Save dialog box appears.



4. In the **Name** field, enter the name of the advanced condition.
5. Click **OK** to save the advanced condition and refresh the ACTIVE ADVANCED CONDITIONS EDITOR page.

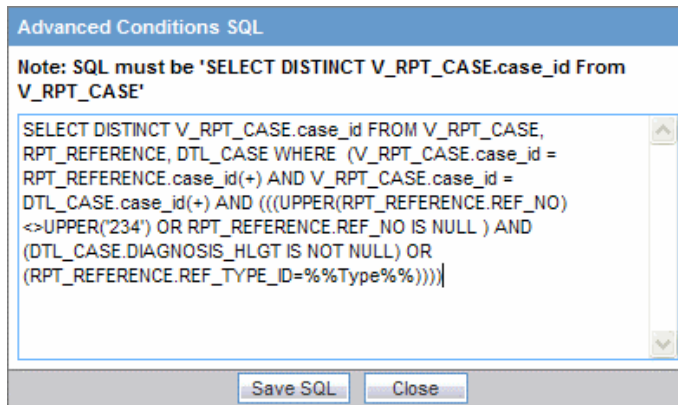
Note that:

- The **Active Query Name** field in the upper-right corner of the page now displays the name of the advanced condition you specified while saving the advanced condition.
- The **Save As**, **View SQL**, and **Permissions** buttons are now enabled.

Note: The ADVANCED CONDITION LIBRARY page lists all the advanced conditions saved to the system. See "[Working with Saved Advanced Conditions](#)" on page 5-17 for more information.

Tip: If the field values are modified after saving the advanced condition to the system, click **Save** to save the changed field values.

6. Click **View SQL** to view the underlying SQL query for the advanced condition.



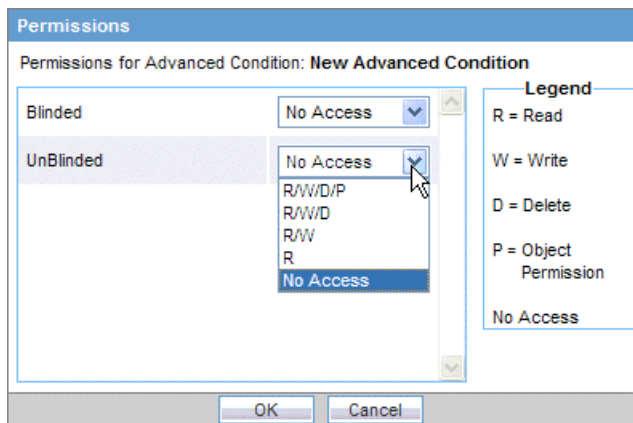
- a. Modify the SQL, if necessary.
- b. Click **Save SQL** after editing the query.

Note: When using the Save SQL functionality, the advanced condition can be executed only from the ADVANCED CONDITIONS LIBRARY page.

Tip: **Revert to Original** lets you to revert back to the original advanced condition. This button is enabled only when you edit the SQL.

- c. Click **Close**.
7. To assign group-level permissions on the saved advanced condition, click **Permissions**.

The **Permissions** dialog box appears with the names of all the groups (except the **Administrator** group) that the system administrator has created.



8. To assign permissions to the group members on the advanced condition you have created, use the drop-down list next to a group name. The available options are:

Permission	Description
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the advanced condition.

Permission	Description
R/W/D	Group members will be able to view, modify, and delete the advanced condition.
R/W	Group members will be able to view and modify the advanced condition.
R	Group members will be able to only view the advanced condition.
No Access (Default)	No group members will be able to access the advanced condition.

Note: The author of the advanced condition always has the highest level of permission (R/W/D/P) on it. For example, suppose you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on an advanced condition that you create. In this case, you will continue to have the highest level of permission on your advanced condition; other members in your group cannot access your advanced condition.

9. Click **OK** to save the permission settings.
10. Click **Execute** to generate the case series.
 - The ACTIVE CASE SERIES page appears with the matching cases from the data mart.
 - If any runtime parameters are configured, the Parameters dialog box appears. Specify the parameter values by using the options in the dialog box, and click **Execute**.
The ACTIVE CASE SERIES page appears with the matching cases from the data mart.
See [Chapter 7, "Working with Case Series"](#) for more information.

Using and Ordering Advanced Condition Operators

Use the following order of precedence for the operators you can select when creating an advanced condition.

Order	Operator	Use
1	AND	Use with all fields available in an advanced condition.
2	OR	Use with all fields available in an advanced condition.
3	INTERSECT	Use between queries (AC Library Attributes)
4	MINUS	Use between queries (AC Library Attributes)
5	UNION	Use between queries (AC Library Attributes)

Using an **INTERSECT**, **MINUS**, or **UNION** operator results in the creation of two separate select clauses. Therefore, use these operators between different queries.

Be sure to use correct PL/SQL syntax:

```
SELECT
table1.common_column
FROM
```

```

Table1, table2, table3
WHERE
Table1.column2 = table2.column2
AND
Table2.column3 = table3.column3
INTERSECT
SELECT
Table4.common_column
FROM
Table4, table5, table6
WHERE
Table4.column2 = table5.column2
AND
Table5.column3 = table6.column3
    
```

Advanced Condition Example

Suppose you want to create an advanced condition as follows:

```

WHERE Country = "Australia" AND Co-Drug Code w Study = "LAS + TAB" OR Co-Drug Code w Study = "LAS+" AND Overdose = "Yes" AND Interaction? = "Yes"
    
```

AND

You want to INTERSECT the results of this advanced condition with the existing advanced condition:

```

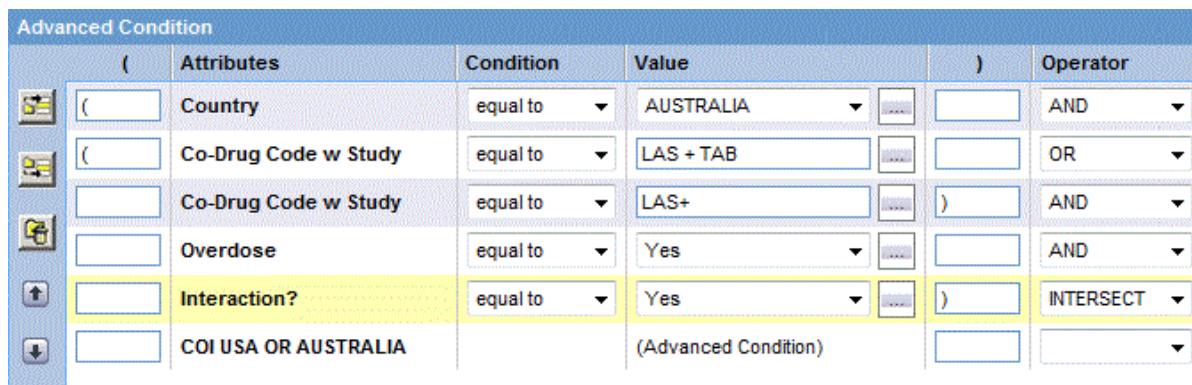
WHERE Country = "United States" OR Country = "Australia"
    
```

Table 5–2 lists the values that you enter to create the advanced condition specified in the previous example. Figure 5–1 shows the same example advanced condition in Argus Insight.

Table 5–2 Values Entered for the Advanced Condition Example

(Attributes	Condition	Value)	Operator
(Country	equal to	AUSTRALIA		AND
(Co-Drug Code w Study	equal to	LAS + TAB		OR
	Co-Drug Code w Study	equal to	LAS+)	AND
	Overdose	equal to	Yes		AND
	Interaction?	equal to	Yes)	INTERSECT
	COI USA OR AUSTRALIA		(Advanced Condition)		

Figure 5–1 Insight Mart Advanced Condition Example in Argus Insight



You do not need to include the parentheses if the PL/SQL syntax, the order and precedence of operators are correct.

Sample SQL Generated

The following SQL is generated for the previous example:

```

SELECT DISTINCT v_rpt_case.case_id
FROM v_rpt_case, rpt_product
WHERE v_rpt_case.case_id = rpt_product.case_id
AND ( (v_rpt_case.country_id = 13)
AND ( UPPER (rpt_product.co_drug_code) = 'LAS+TAB'
OR (pat_exposure IN (
SELECT product_id
FROM lm_product
WHERE UPPER (lm_product.drug_code) = 'LAS+TAB'))
OR (UPPER (rpt_product.co_drug_code) = 'LAS+'
OR (pat_exposure IN (SELECT product_id FROM lm_product
WHERE UPPER (lm_product.drug_code) = 'LAS+'))
AND (rpt_product.is_overdose = 1)
AND (rpt_product.interaction = 1))
INTERSECT
SELECT DISTINCT v_rpt_case.case_id
FROM v_rpt_case
WHERE v_rpt_case.case_id IN (
SELECT DISTINCT v_rpt_case.case_id
FROM v_rpt_case
WHERE (v_rpt_case.country_id = 13)
OR (v_rpt_case.country_id = 223))

```

Note: While creating a new **Advanced Condition** using the saved **Advanced Condition**, always enclose the saved Advanced Condition within the parenthesis as using **Union**, **Minus**, or **Intersect** will create different select statements and if you use parenthesis with the saved **Advanced Condition** with new fields, wrong SQL will be generated.

This is the desired and correct SQL.



The following SQL gets generated in this case.

```
(SELECT DISTINCT v_rpt_case.case_id
FROM v_rpt_case
WHERE v_rpt_case.case_id IN (
SELECT DISTINCT v_rpt_case.case_id
FROM v_rpt_case
WHERE (v_rpt_case.case_num IS NOT NULL)))
UNION
(SELECT DISTINCT v_rpt_case.case_id
FROM v_rpt_case, rpt_event, rpt_product
WHERE v_rpt_case.case_id = rpt_event.case_id
AND v_rpt_case.case_id = rpt_product.case_id
AND ((rpt_event.agent_seq_num = 1)))
```

Below Query will execute fine but parenthesis will not be at right place. Following is the SQL generated.

ORACLE ARGUS INSIGHT™ John Smith (AI80ST1 - DEFAULT) Home Tools Help Logout

Home Queries Case Series Reporting

Queries > Advanced Conditions

ACTIVE ADVANCED CONDITIONS EDITOR
Source: Insight Mart

Argus Mart Active Query: < Not Saved >
Insight Mart Active Query: TestTW
Active Case Series (Insight Mart): < Not Saved >

Name : TestTW Category: Management Description:

(Attributes	Condition	Value)	Operator
	Co-Drug Code w Study	equal to	RELVAC1		OR
	Co-Drug Code w Study	equal to	C_Test Drug 1		INTERSECT
{	COI Germany		(Advanced Condition)		UNION
{	Follow-up Received Query		(Advanced Condition)		UNION
)	Case Status	equal to	Data Entry)	OR
)	Primary Reporter	equal to	Yes)	

Save Save As View SQL Permissions Execute

```

SELECT DISTINCT v_rpt_case.case_id
FROM v_rpt_case, rpt_product
      WHERE v_rpt_case.case_id = rpt_product.case_id
      AND ( (UPPER (rpt_product.co_drug_code) = 'RELVAC1'
            OR (pat_exposure IN (
                SELECT product_id
                FROM lm_product
                WHERE UPPER (lm_product.drug_code) = 'RELVAC1')
            )
          )
        OR ( UPPER (rpt_product.co_drug_code) = 'C_TEST DRUG 1'
          OR (pat_exposure IN (
                SELECT product_id
                FROM lm_product
                WHERE UPPER (lm_product.drug_code) = 'C_TEST DRUG 1')
          )
        )
      )
INTERSECT
(SELECT DISTINCT v_rpt_case.case_id
 FROM v_rpt_case
  WHERE (v_rpt_case.country_id = 81)
UNION
SELECT DISTINCT v_rpt_case.case_id
 FROM v_rpt_case, rpt_followup
  WHERE v_rpt_case.case_id = rpt_followup.case_id
        AND (( TRUNC (rpt_followupreceipt_date) =
TO_DATE ('17-MAR-2009', 'DD-MON-YYYY')
        )
        AND rpt_followup.seq_num > 0
        )
        )
UNION
SELECT DISTINCT v_rpt_case.case_id

```

```

FROM v_rpt_case, rpt_reporters
WHERE v_rpt_case.case_id = rpt_reporters.case_id
      AND ((v_rpt_case.state_id = 3))
      OR (rpt_reporters.primary_contact = 1)

```

Note: Parenthesis shown in red are not at correct place as compared to AC created. Last parenthesis will come only after complete query creation.

Working with the Last Modified or Saved Advanced Condition

The system assigns an active status to a advanced condition when you modify and save it or when you execute it. Unless you save the modifications to another advanced condition or execute another advanced condition, the last advanced condition you modified or executed remains active. This is helpful in situations when you want to access a frequently used advanced condition.

To work with last modified or saved advanced condition:

- For Argus Insight database, select Active (Insight Mart)
- For Argus Mart database, select Active (Argus Mart)

To view an active advanced condition:

1. Navigate to **Queries > Advanced Condition > Active (Insight Mart)**.

The ACTIVE ADVANCED CONDITIONS EDITOR page appears with data source and the advanced condition you executed or modified last.

The screenshot displays the 'ACTIVE ADVANCED CONDITIONS EDITOR' interface. At the top, there's a navigation bar with 'Home', 'Queries', 'Case Series', and 'Reporting'. Below it, the current path is 'Queries > Advanced Conditions'. The main area shows the editor for an active advanced condition. The 'Name' field is 'TestTW', 'Category' is 'Management', and 'Description' is empty. A table titled 'Advanced Condition' has columns for 'Attributes', 'Condition', 'Value', and 'Operator'. It contains two rows: one for 'Case Number Exists' with value '(Advanced Condition)' and operator 'UNION', and another for 'Test 21' with value '(Advanced Condition)'. On the right, there are status indicators for 'Argus Mart Active Query', 'Insight Mart Active Query', and 'Active Case Series (Insight Mart)', all showing '<Not Saved>'. At the bottom right, there are 'Save' and 'Execute' buttons.

2. If the active advanced condition was saved to the system before executing, the name of the advanced condition appears next to the **Active Query Name** and in the **Name** field.

However, if the active advanced condition was not saved to the system before executing, the text <Not Saved> is displayed next to the **Active Query Name** label.

You can enter the name of the advanced condition in the **Name** field and click **Save**.

To rename an already saved advanced condition, in the **Name** field, enter the new name, and click **Save**.

From the ACTIVE ADVANCED CONDITION page, you can perform the following tasks:

Task	Description
Modify the attributes in the Advanced Conditions Editor	<p>If required, you can modify the attributes (fields and values) in the Advanced Conditions Editor. See "Creating a New Advanced Condition" on page 5-1 for more information.</p> <p>Click Save to save the changed <i>field</i> values. This button is only available for a saved active advanced condition.</p>
Save Active Advanced Condition with another name	<p>Click Save As to save the active advanced condition by a different name.</p> <p>The ADVANCED CONDITIONS LIBRARY page lists all the advanced conditions saved to the system. See "Working with Saved Advanced Conditions" on page 5-17 for more information.</p>
View the Advanced Condition in SQL	<p>Click View SQL to view the underlying SQL query for the advanced condition.</p> <p>In this SQL, manually replace the V_RPT_CASE with RPT_CASE. This is required to execute the query in the Oracle database.</p>
Assign Permissions	<p>Click Permissions to set the group-level access permissions on the advanced condition. See "Creating a New Advanced Condition" on page 5-1 for more information.</p> <p>The Permissions button is only available for saved active advanced conditions.</p>
Change the Description of the Active Advanced Condition	<p>You can change the description of the active advanced condition by modifying the text displayed in the Description field.</p> <p>Click Save to store the changed description.</p>
Execute the Active Advanced Condition	<p>Click Execute to generate a case series by using the active advanced condition.</p>

Note that modifying the field values in the Advanced Conditions Editor for an active advanced condition or saving the active advanced condition by a different name changes the active advanced condition to reflect the most recent changes. The active advanced condition also changes in case you modify the field values in the Advanced Conditions Editor and execute the advanced condition without saving the modifications.

Working with Saved Advanced Conditions

The ADVANCED CONDITIONS LIBRARY page lists all the advanced conditions saved to the system.

To access this page, navigate to **Queries > Advanced Conditions > Library**.

The ADVANCED CONDITIONS LIBRARY page appears (See [Figure 5-2](#).) with the following information about each saved advanced condition:

- Name of the advanced condition.
- Description of the advanced condition.
- Date when the advanced condition was last modified.
- Full name of the user who created the advanced condition.
- Category assigned to the advanced condition.

- Data source (Insight Mart/Argus Mart) of the advanced condition.
- Query type and Date (Current/Historical) for Argus Mart data source only.

Figure 5–2 ADVANCED CONDITIONS LIBRARY Page

The screenshot displays the 'ADVANCED CONDITIONS LIBRARY' page in Oracle Argus Insight. At the top, there is a navigation bar with 'Home', 'Queries', 'Case Series', and 'Reporting' tabs. Below this, a breadcrumb trail shows 'Queries > Advanced Conditions'. The main content area features a table titled 'Choose Advanced Condition' with the following columns: Name, Description, Last Modified, User Full Name, Category, Source, Query Type, and As of Date. The table contains several rows of saved conditions, including 'As of Date', 'At Lock', 'Current Data', and 'Last Locked Revision for a Version in a Period'. A search bar is located at the top right of the table, and a 'Clear' button is next to it. At the bottom of the table, there are buttons for 'Modify', 'Delete', 'Limit Query to Active Case Series', and 'Execute'.

Searching Saved Advanced Conditions

To search for a saved advanced condition:

1. Specify the search criteria:
 - To search for an advanced condition by its name, type the advanced condition name in the **Name** text box.
 - To search for an advanced condition by its description, type the first few words of the description in the **Description** text box. The system searches for the specified search string in all advanced condition descriptions.
 - To search for an advanced condition by its date of modification, enter the modification date in the first **Last Modified** date *field*. You can specify a date range by typing the start and end dates in the first and second date fields, respectively.
 - To search for an advanced condition by its author, select the author name from the **User Full Name** drop-down list.
 - To search for an advanced condition by its category, select the category from the **Category** drop-down list.

Note: If you search for a text comprising an underscore, it is treated as a wildcard and is replaced by a letter in the displayed results. For example, If you have queries with names - CURE, CORE, and CARE and you search for C_RE, all three queries are displayed in the result.

2. Click **Search**.

The search results appear based the search criteria.

- To sort the search results, click the sort icon next to the column headers in the list.
- To clear the search results and display all the advanced conditions in the list, click **Clear**.

Creating a New Advanced Condition

See "Creating a New Advanced Condition" on page 5-1 for details.

Modifying an Advanced Condition

To modify an advanced condition:

1. Navigate to the ADVANCED CONDITIONS LIBRARY page.
2. Select the advanced condition you want to modify.
3. Click **Modify**.
4. Make your modifications to the advanced condition.
5. Click **Save** to save your changes.

Alternatively, click **Save As** to save the modified advanced condition by another name.

Modifying the SQL of an Advanced Condition

To modify the SQL of an advanced condition:

1. Navigate to the ADVANCED CONDITIONS LIBRARY page.
2. Select the advanced condition.
3. Click **Modify**.

The ACTIVE ADVANCED CONDITIONS EDITOR page appears.

ORACLE | ARGUS INSIGHT™ John Smith, Monday September 8, 2014 (AI80ST1 - DEFAULT) Home Tools Help Logout

Home Queries Case Series Reporting

Queries > Advanced Conditions

ADVANCED CONDITIONS EDITOR
Source: Insight Mart

Argus Mart Active Query: < Not Saved >
Insight Mart Active Query: TestTW
Active Case Series (Insight Mart): < Not Saved >

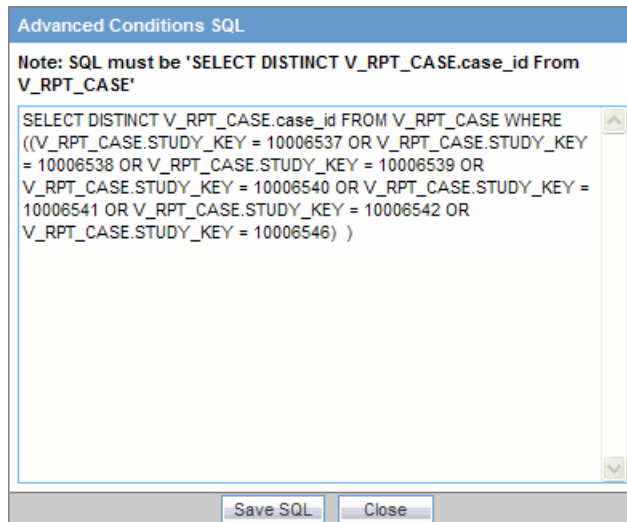
Name: rajesh_ac_dd_exists Category: General Description:

(Attributes	Condition	Value)	Operator
	Death Date	exists			

Save Save As View SQL Permissions Execute

4. Click **View SQL**.

The Advanced Conditions SQL dialog appears.



5. Modify the SQL as per your requirement.
6. Click **Save SQL** to save your changes.
7. Click **Close** to return to the ADVANCED CONDITIONS LIBRARY page.
8. Select the modified advanced condition.
9. Click **Execute**.

The search results appear based on your modified SQL.

Note: You cannot modify an advanced condition once you have added user defined SQL in that, you can modify SQL but cannot add new items in advanced condition.

If you want to add new items, you have to revert the SQL to original by clicking **Revert to Original**.

Deleting an Advanced Condition

To delete an advanced condition:

1. Navigate to the ADVANCED CONDITIONS LIBRARY page.
2. Select the advanced condition you want to delete.
3. Click **Delete**.

A confirmation dialog box appears.

4. Click **OK**.

Executing an Advanced Condition

To execute an advanced condition:

1. Navigate to the ADVANCED CONDITIONS LIBRARY page.
2. Select an advanced condition.
3. Click **Execute**.

The ACTIVE CASE SERIES page appears with the results of the executed advanced condition.

The screenshot displays the Oracle Argus Insight 'ACTIVE CASE SERIES' page. At the top, the Oracle Argus Insight logo is visible on the left, and the user information 'John Smith, Monday September 8, 2014 (AR05T1 - DEFAULT)' is on the right. Below the logo, there are navigation tabs for 'Home', 'Queries', 'Case Series', and 'Reporting'. The main content area shows the 'ACTIVE CASE SERIES' page with a source of 'Insight Mart'. A search bar is present with fields for 'Name', 'Category', and 'Description'. Below this is a 'Choose Elements' section with a table of case series results. The table has columns: Case Number, Report Type, Primary Company Product, Primary Event, Seriousness Criteria, Outcome, Effective Start Date, and Notes. The table contains 19 rows of data. At the bottom of the page, there is a status bar with buttons: 'Freeze and Save', 'Save', 'Save As', 'View Query Criteria', 'View Query', 'Export to Excel', and 'Cancel'.

Case Number	Report Type	Primary Company Product	Primary Event	Seriousness Criteria	Outcome	Effective Start Date	Notes
077-300709	Spontaneous	Begin Product Name Product Name Product	Akathisia	M,F,H	Fatal	00-MMM-0000	
081-300709	Spontaneous	Begin Product Name Product Name Product	Pain	M,F,H	Fatal	00-MMM-0000	
100-190908	Spontaneous	DOXORUBICIN HCL	Pyrexia	F,H	Fatal		
317-010101	Spontaneous	AlHeal	Abdominal pain	M,CA,F,DI,H,R,O,LT	Fatal		
CH 1998FR000007	Other	Nectropen or Placebo	Drug ineffective	F	Fatal		
GOLD 11	Sponsored Trial	Tegretol or Placebo	Benign intracranial hypertension	F,LT	Fatal		
GOLD 15	Sponsored Trial	Tegretol or Placebo	Pain in jaw	F,LT	Fatal		
GOLD 28	Spontaneous	DOXORUBICIN HCL	Vomiting	F,DI	Fatal		
GOLD 34	Spontaneous	Tegretol	Benign intracranial hypertension	F,LT	Fatal		
GOLD MAX	Literature Clinical Trial	Somobrin	Pain	M,CA,F,DI,H,R,O,LT	Abortion due to AE/Infection		
LAM ARGUS STUDY	Sponsored Trial	MAX STUDY	Pyrexia	M	Congenital Anomaly		
MAX-CASE	Literature	Begin Product Name Product Name Product	Pyrexia	M,DI,R,O	Resolved		
MAX CASE	begin Report Type Report	begin Study name Study name Study name		N/A	Fatal		
PLATINUM CASE 044B	Sponsored Trial	Tegretol or Placebo	Cardiac failure	F,LT	Fatal		
PLATINUM CASE 44	Sponsored Trial	Tegretol or Placebo	Cardiac failure	F,LT	Fatal		
PLATINUM CASE 44A	Sponsored Trial	Tegretol or Placebo	Cardiac failure	F,LT	Fatal		
PLATINUM CASE 44R	Sponsored Trial	Tegretol or Placebo	Cardiac failure	F,LT	Fatal		
US 1997US000003	Epidemiological Study	Placebo	Culture urine negative	M,F,H,O	Fatal		
	Spontaneous	AlHeal	Abdominal pain	M,CA,F,DI,H,R,O,LT	Fatal		

After generating the case series, you can manually modify it or save it. See [Chapter 7, "Working with Case Series"](#) for more information.

Executing a Saved Advanced Condition on the Active Case Series

Just as the system assigns the *active* status to an advanced condition when you save modifications to it or execute it, the last saved or generated case series becomes the *active* case series.

You may want to run an advanced condition on an active case series.

To narrow down the list of cases in the active case series:

1. Generate the case series to run another Value Set:
 - You may generate the case series by either using QBE, filters, or advanced conditions. This case series becomes the active case series and remains so until you execute another query to generate a different case series.
 - Alternatively, if the case series on which you want to run another Value Set is already saved in the system, navigate to **Case Series > Open Case Series > Library**.

The CASE SERIES LIBRARY page appears.

Select the case series, and click **Make Active**.

2. Navigate to **Queries > Advanced Conditions > Library**.

The ADVANCED CONDITIONS LIBRARY page appears.

3. Select the advanced condition to run on the active case series you generated in Step 1.
4. Select the **Limit Query to Active Case Series** check box.

Note: The **Limit Query to Active Case Series** check box is enabled only when the selected active case series and advance condition are of same type (Insight Mart/Argus Mart).

5. Click *Execute*.

The ACTIVE CASE SERIES page appears with the execution results of the selected advanced condition on the active case series.

Note that the case series you just generated becomes the active case series.

Using Advanced Conditions to Create Point-in-Time Queries on Argus Mart

Argus Insight also supports point-in-time queries for analysis of the historical case data based on specific date/time through Argus Mart.

To enable access to this data in Argus Mart, you need to set specific attributes.

See [Table 12-1, "Common Profile Switches"](#), for more information on these attributes.

Benefits of running queries on Argus Mart:

- Enables you to create the advanced condition queries using the list of fields configured in the common fields table for Argus Mart data source. These advanced condition can be executed to generate case series.
- Displays the Effective Start Date of the case revision in the resultant case series for all the case series generated on Argus Mart data.
- Supports different type of queries for fetching the historical data while executing queries on Argus Mart data source.
 - Current Data Queries—Provides a consistent view of the most recent revisions available in Argus Safety regardless of whether the cases are locked or unlocked. These queries and query results are same as the existing queries created on Argus Insight data source that is, case data for cases present in the case series will be refreshed if a case changes in Argus Safety. Any reporting done on such case series/queries will always return the latest data related to cases in the case series.
 - As of Date (Historical Data)—Refers to the data that was *current* at some point in the past. This query type allows the use of an As of Date that is earlier than the most recent ETL high water mark and later than ETL low water mark. These queries uses the Effective Start Date and End Date of the locked and unlocked revisions.

Note:

- ETL High Watermark — Date when ETL was executed for the last time.
 - ETL Low Watermark — Date when ETL was executed for the first time.
-
-

- At Lock—Provides the case data at one or more user lock actions. A typical use case for an At Lock query displays the data that was provided to local affiliates for review and possible submission. The query returns the revisions at the time of the user lock action. That is, the post-lock revisions are not included. The list of lock dates (and times) is provided by Argus Safety tables that record the user lock action. These queries use the valid Start Date and End Date of the locked revisions.
 - Last Locked Revision as of a Point in Time—Provides a consistent view of the most recent locked revisions that were committed to the database on or before the as-of date. The as-of date can be arbitrary (a date that may not correspond to any actual transaction). When there are post-lock revisions, the query returns any post-lock revision data valid at the given point-in-time. These queries return only a single revision of each case. The as-of date is the same for all cases (a single value for the query). These queries use the valid Start Date and End Date of the locked revisions.
 - Last Locked Revision for a Version in a Period—Provides a consistent view of the most recent locked revision for case versions in a time period. You can choose between Case Creation Date, Case Receipt Date, and Case Lock Date for determining the versions in a period. Regardless of the kind of date used for determining *in period*, the key point of this type of query is that the revision may have been committed to the database outside the period. However, revisions that belong to later versions of a case not included in the period are not returned. These queries return only a single revision of each case. The as-of date may vary by case (no single as-of date will be sufficient to return the needed revisions across all cases). These queries use the valid Start Date and End Date of the locked revisions.
 - Aggregate Queries—Provides a consistent view of the most recent locked revision for case versions for a specific time period based on the Case Receipt Date. You may also view the most recent unlocked revision with this type of query.
- Enables saving the advanced conditions along with query type and As of Date for future use.
 - Supports all the existing features of advanced conditions with Argus Mart data source and point in time queries. For example, View SQL, Parameterized queries, and etc.

This chapter includes the following topics:

- [Creating a New Advanced Condition](#)
- [Working with the Last Modified or Saved Advanced Condition](#)
- [Working with Saved Advanced Conditions](#)

Creating a New Advanced Condition

To start a new Argus Mart advanced condition:

1. Navigate to **Queries > Advanced Conditions > New (Argus Mart)**.

The ADVANCED CONDITIONS EDITOR page appears with the data source.

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John Smith, Monday October 20, 2014 (A180MT) Home Tools Help Logout

Home Queries Case Series Reporting

Queries > Advanced Conditions

ADVANCED CONDITIONS EDITOR
Source: Argus Mart

Argus Mart Active Query:
Insight Mart Active Query:
Active Case Series (Argus Mart): Aggregate_Report_User1(Cumulative Case Series)

Name: < Not Saved > Category: General Description: Query Type: Current Data As Of Date:

Advanced Condition					
(Attributes	Condition	Value)	Operator

Save Execute

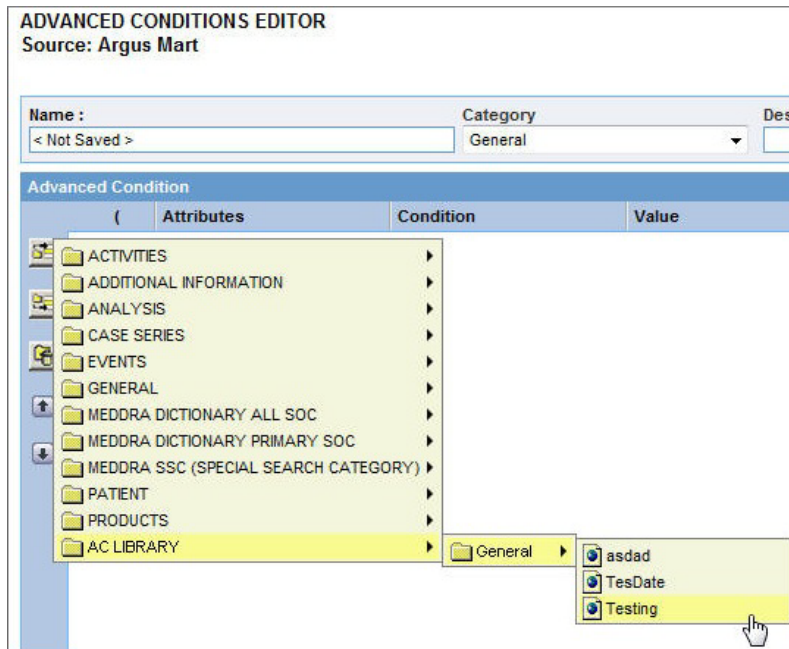
2. Enter the attributes (fields and values) for the advanced condition.
3. Click the context menu icon (Add Advanced Condition Element Above/Below icon).

In the context menu, the categories (Activities, Additional Info, Analysis, Events, General, Patients, and Products) represent the Argus case form tabs. In these categories, the data mart fields that pertain to case information are organized in this hierarchy:

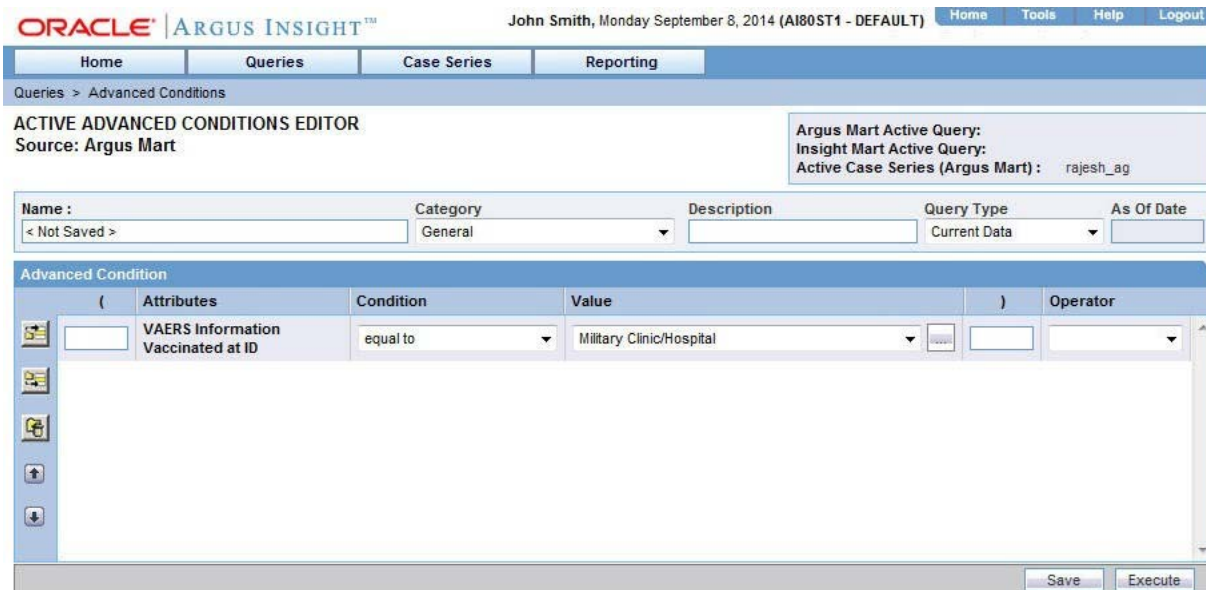
- Argus case form tab
- Sections within the tab
- Fields within the section

You may browse through the appropriate hierarchy and select the required *field* as an advanced condition attribute.

The **AC Library** category lists all the advanced conditions stored in the system. You may browse through the **AC Library** category and select a stored advanced condition as an attribute for the new advanced condition.



4. Browse through a category hierarchy, and select the required attribute.
The selected attribute appears as a row in the editor.



Note: The user defined fields in Argus Safety which have been converted as a look up are also available as attributes for the advanced condition search.

5. In the **Value** field, enter the value for the selected attribute.
Depending on the type of the selected attribute, the **Value** field populates a:
 - Drop-down list to select from a set of predefined values
 - Text box to enter text strings or numerals

- Date field to enter dates
- Browser to select MedDRA dictionary terms, company products, WHO drugs, clinical *study* IDs, Drugs in Study (incl. Comparators) and Investigational Drugs.

To use a browser to populate the **Value** field, click the ellipsis button next to the **Value** field. From the context menu, select the option corresponding to the browser you want to start. For example, you can start the MedDRA Browser and enter criteria to search for a preferred term based on a specific code or description. You can add a selected term to the **Value** field.

6. Click the **Conditions** field, and select a condition for the attribute value.

See [Table 6–1](#) for a description of each condition. The availability of the conditions depends on the selected attribute.

Table 6–1 Conditions for Defining an Advanced Condition

Condition	Select this option if you want to...
equal to	Retrieve cases where the selected attribute's value is equal to what the Value field specifies
not equal to	Retrieve cases where the selected attribute's value is not equal to what the Value field specifies
greater than	Retrieve cases where the selected attribute's value is greater than what the Value field specifies
greater than or equal to	Retrieve cases where the selected attribute's value is greater than or equal to what the Value field specifies
less than	Retrieve cases where the selected attribute's value is less than what the Value field specifies
less than or equal to	Retrieve cases where the selected attribute's value is less than or equal to the Value that the field specifies
missing	Retrieve cases where the selected attribute's value has not been specified
exists	Retrieve cases where the selected attribute has any value
begins with	Retrieve cases where the selected attribute's value begins with what the Value field specifies
contains	Retrieve cases where the selected attribute's value contains what the Value field specifies
does not contain	Retrieve cases where the selected attribute's value does not contain what the Value field specifies
in	Retrieve cases where the selected attribute's value exists in what the Value field specifies
not in	Retrieve cases where the selected attribute's value does not exist in what the Value field specifies

Tip: To change the structure of the *query* by changing the order of the attribute rows, select a row and then click the arrow icons to move the row up or down. To delete a row from the editor, select the row and click the Delete icon.

7. Specify the operator.

Use the **Operator** drop-down list to specify the Boolean or Set operator to join the attribute with another attribute.

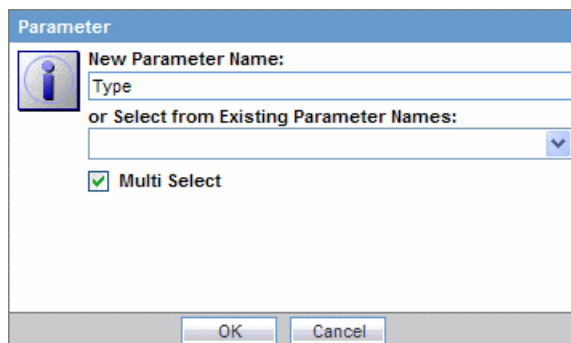
8. To add more attributes to your advanced condition, click the icons on the left bar to insert another attribute above or below the existing attribute.
9. Specify runtime parameters.

Note: Argus Insight lets you create advanced conditions which when executed, ask for user-specified values for certain attributes to generate the case series. For example, you may create an advanced condition in which the Case Number or the Product name may be specified only at the time of execution. In this case, the advanced condition would only retrieve those cases where the Case Number/Product Name is as specified at the time of execution.

Creating an advanced condition using same field name multiple times requires to change the Parameter name so that while executing the advanced condition different parameters values can be entered.

10. Identify the attribute row to specify runtime parameters.
11. Click the ellipsis button next to the **Value** field, and then select **Parameters** from the menu.
12. Click **Parameter**.

The Parameter dialog box appears.



13. To pass multiple runtime values for a single attribute, select the **Multi Select** check box.

For example, you might want to pass more than one case number or product name as runtime parameters.

14. Click **OK**.

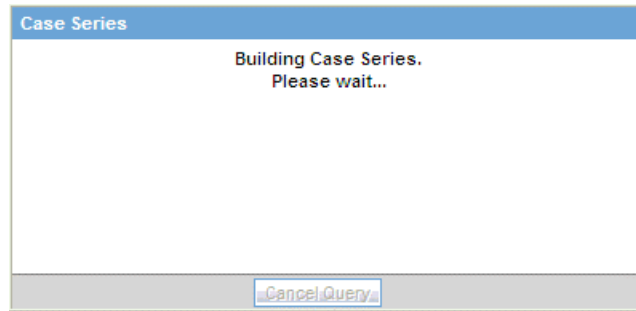
If the field is configured to accept single runtime parameter, the field you configured as a runtime parameter is displayed in the **Value** text box enclosed within % symbol. For example, %Product Type%.

If the field is configured to accept multiple runtime parameters, the field name appears in the **Value** text box enclosed within %% symbol. For example, %%Product Type%%.

15. To determine the order of execution for the selected advanced conditions, enter parentheses in the (and) columns.

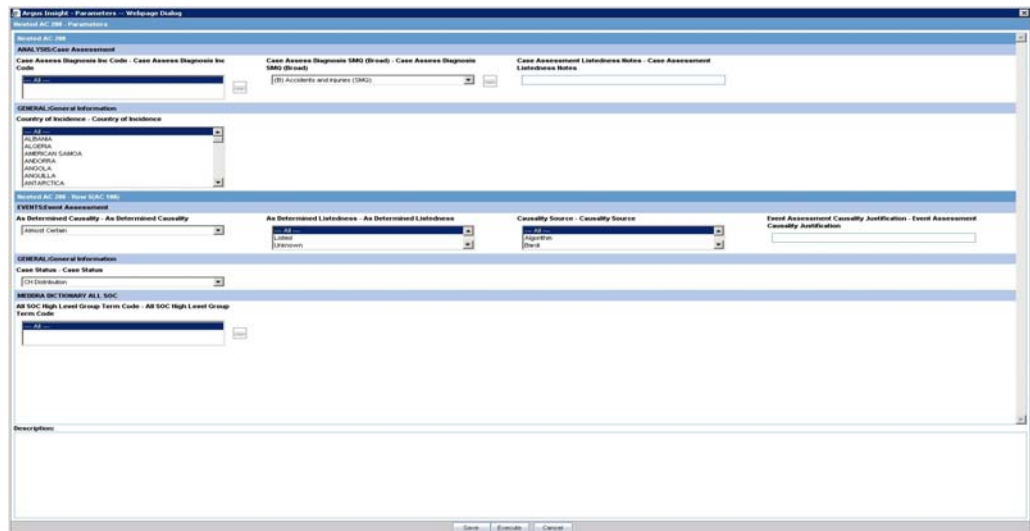
16. Examine the advanced condition results.
17. Click **Execute**.

The following dialog box appears:



Tip: To cancel the query execution at this point and return to the Advanced Conditions Editor, click **Cancel Query**.

- If any runtime parameter is configured, the **Parameters** dialog box appears with all the fields available based on the categorization of different fields from the tree view.



- Specify the parameter values by using the options in the dialog box, and click **Execute**.

Select at least one parameter for query execution.

The ACTIVE CASE SERIES page appears with the matching cases from the data mart.

Tip: If you select one runtime parameter and execute the search, you must enter a field.

If you select multiple runtime parameters and execute the search, you have the option to ignore the runtime parameters.

- To ignore the field criteria for query execution, select **All**.

- To save the selected values on the Advanced Condition Parameters screen, click **Save**.

Note:

- When the **Save** button is clicked, the values of the current Advance Condition only are saved, and not for the Nested Advance Conditions.
- The **Save** button is enabled only when Advance Condition is saved, and not when the Advanced Condition is executed from Query By Example, Filter, or Advance Condition Library page.

You may enter value for one or more parameters.

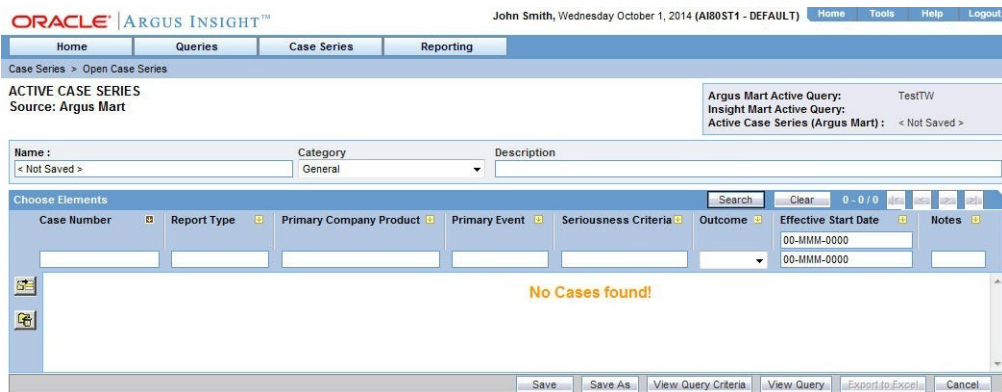
If no value is selected for any parameter that is if you try to save a parameterized advanced condition without providing any value, then an error message appears as 'You must select values in order to save.'

All the fields where value is been provided are stored for the future use.

- Upon execution of these advanced conditions again, the previously selected values will appear by default on the Advanced Condition Parameters page.

Note: On the Advanced Condition Editor page, the parameterized advanced conditions appears in their original structure, and the saved parameter values are not available. These values appear only while executing the advanced condition.

- Query criteria for the case series generated using such advanced conditions will only display fields for which values for the parameter were provided.
- The selective use of parameters can also be used while converting existing filters into advanced conditions.
- If no cases are found that match the querying criteria, the following screen appears.



Click **View Query** to return to the Advanced Conditions Editor, modify the criteria and execute again.

- If the cases that match the query criteria are found, the ACTIVE CASE SERIES page appears with the list of such cases.
18. Examine the case series. If the case series is too large, you may want to modify the advanced condition by specifying additional attributes or changing values.

Alternatively, if you find the case series to be appropriate, you can save the advanced condition to the system.

The system retrieves the matching cases from the data mart and displays them in the ACTIVE CASE SERIES page.

Note: If the Argus Insight case series are created by using the Argus Mart advanced condition, then these case series records only case IDs, case revision effective start dates, and query criteria (as a text string).

Saving and Providing Point-in-Time Query Date

1. On the ACTIVE ADVANCED CONDITIONS EDITOR page, from the **Category** drop-down list, select a category.
2. In the **Description** field, enter a description of the advanced condition.
For example, you may describe the type of cases the advanced condition retrieves.
3. In the Query Type field:
 - a. To execute the query based on current data, select **Current Data**.
The **As of Date** field is disabled.
 - b. To execute the query based on historical data, select **As of Date**.
 - c. To execute the query based on one or more user lock actions, select **At Lock**.
 - d. To view the most recent locked revisions that were committed to the database on or before As of Date, select **Last Locked Revision as of a Point in Time**.

For steps 3b to 3d, the **As of Date** field is enabled.

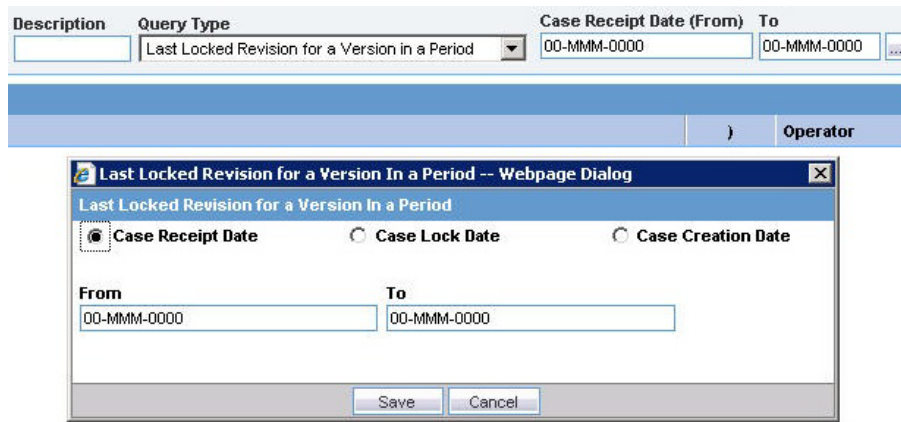
In the **As of Date** field, enter the date based on which advanced condition will be executed.

Note: **As of Date** field contains date-time, populated with ETL high water mark as the default value for all query types.

As of Date cannot be greater than ETL high watermark or less than ETL low watermark.

- e. To view the most recent locked revision for case versions in a time period, select **Last Locked Revision for a Version in a Period**.

The Last Locked Revision for a Version In a Period dialog box appears.



- i. To execute the query based on the receipt date, select **Case Receipt Date** (default), and enter dates in the **From** and **To** fields. Click **Save**.
 - ii. To execute the query based on the lock date, select **Case Lock Date**, and enter dates in the **From** and **To** fields. Click **Save**.
 - iii. To execute the query based on the creation date, select **Case Creation Date**, and enter dates in the **From** and **To** fields. Click **Save**.
- f. To view the most recent locked revision for case versions for a specific time period, select **Aggregate Queries**.

The Aggregate Queries dialog box appears.

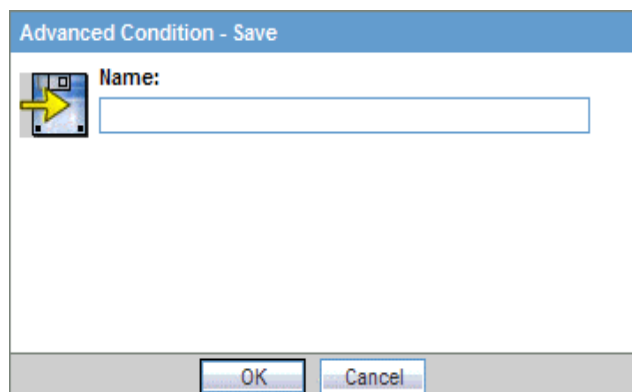
- i. Enter the date range for the Case Receipt Date in **From** and **To** fields, and click **Save**.

Based on the selected date range, only the last locked revision of a case for the version falling in that period based on initial/follow-up receipt date are displayed. Post lock revisions are also displayed

- ii. To view the latest unlocked revision of the cases, select **Include Unlocked Cases**.

4. Click **Save**.

The Advanced Condition - Save dialog box appears.



- 5. In the **Name** field, enter the name of the advanced condition.
- 6. Click **OK** to save the advanced condition and refresh the ACTIVE ADVANCED CONDITIONS EDITOR page.

Note that:

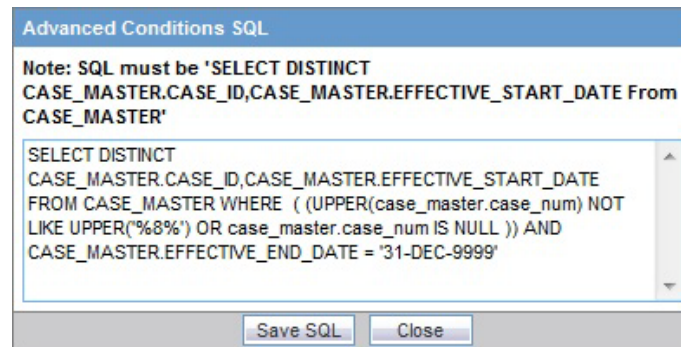
- The **Active Query Name** field in the upper-right corner of the page now displays the name of the advanced condition you specified while saving the advanced condition.
- The **Save As**, **View SQL**, and **Permissions** buttons are now enabled.

Note: The ADVANCED CONDITION LIBRARY page lists all the advanced conditions saved to the system. See "[Working with Saved Advanced Conditions](#)" on page 6-15 for more information.

Tip: If the field values are modified after saving the advanced condition to the system, click **Save** to save the changed field values.

7. Click **View SQL** to view the underlying SQL query for the advanced condition.

Note that the creation of advanced conditions custom SQL on Argus Mart requires the use of CASE_MASTER table instead of V_RTP_CASE, and additional EFFECTIVE_START_DATE in the query.



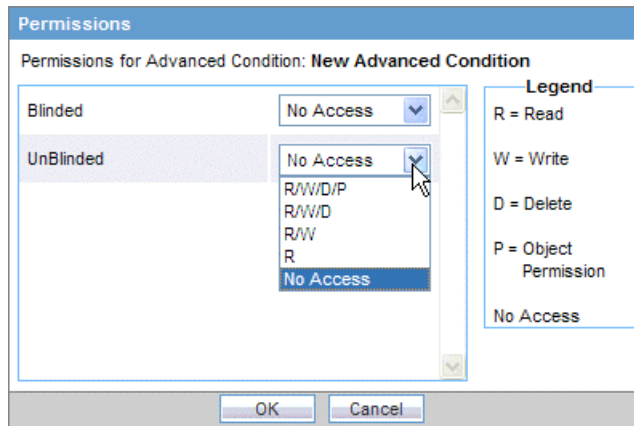
- a. Modify the SQL, if necessary.
- b. Click **Save SQL** after editing the query.

Note: When using the Save SQL functionality, the advanced condition can be executed only from the ADVANCED CONDITIONS LIBRARY page.

Tip: **Revert to Original** lets you to revert back to the original advanced condition. This button is enabled only when you edit the SQL.

- c. Click **Close**.
8. To assign group-level permissions on the saved advanced condition, click **Permissions**.

The **Permissions** dialog box appears with the names of all the groups (except the **Administrator** group) that the system administrator has created.



9. To assign permissions to the group members on the advanced condition you have created, use the drop-down list next to a group name. The available options are:

Permission	Description
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the advanced condition.
R/W/D	Group members will be able to view, modify, and delete the advanced condition.
R/W	Group members will be able to view and modify the advanced condition.
R	Group members will be able to only view the advanced condition.
No Access (Default)	No group members will be able to access the advanced condition.

Note: The author of the advanced condition always has the highest level of permission (R/W/D/P) on it. For example, suppose you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on an advanced condition that you create. In this case, you will continue to have the highest level of permission on your advanced condition; other members in your group cannot access your advanced condition.

10. Click **OK** to save the permission settings.
11. Click **Execute** to generate the case series.
 - The ACTIVE CASE SERIES page appears with the matching cases from the data mart.
 - If any runtime parameters are configured, the Parameters dialog box appears. Specify the parameter values by using the options in the dialog box, and click **Execute**.
The ACTIVE CASE SERIES page appears with the matching cases from the data mart.

Note: The case series generated using Argus Mart data source also displays EFFECTIVE_START_DATE/LOCKED_DATE in the Case Series Editor page.

See [Chapter 7, "Working with Case Series"](#) for more information.

Returning to the Advanced Conditions Editor

Refer to [Chapter 5 > "Returning to the Advanced Conditions Editor"](#).

Assigning a Category to an Advanced Condition

Similar to assigning categories to Insight advanced conditions, you may assign categories to advanced conditions created on Argus Mart.

For more details, refer to [Chapter 5 > "Assigning a Category to an Advanced Condition"](#).

Using and Ordering Advanced Condition Operators

Each SQL generated on Argus Mart contains EFFECTIVE_START_DATE for supporting point-in-time querying.

The following is the syntax of PL/SQL generated on Argus Mart:

```

SELECT
table1.common_column
FROM
Table1, table2, table3
WHERE
Table1.column2 = table2.column2
AND
Table2.column3 = table3.column3
INTERSECT
SELECT
Table4.common_column
FROM
Table4, table5, table6
WHERE
Table4.column2 = table5.column2
AND
Table5.column3 = table6.column3

```

For more details, refer to [Chapter 5 > "Using and Ordering Advanced Condition Operators"](#).

Working with the Last Modified or Saved Advanced Condition

The system assigns an active status to a advanced condition when you modify and save it or when you execute it. Unless you save the modifications to another advanced condition or execute another advanced condition, the last advanced condition you modified or executed remains active. This is helpful in situations when you want to access a frequently used advanced condition.

To work with last modified or saved advanced condition:

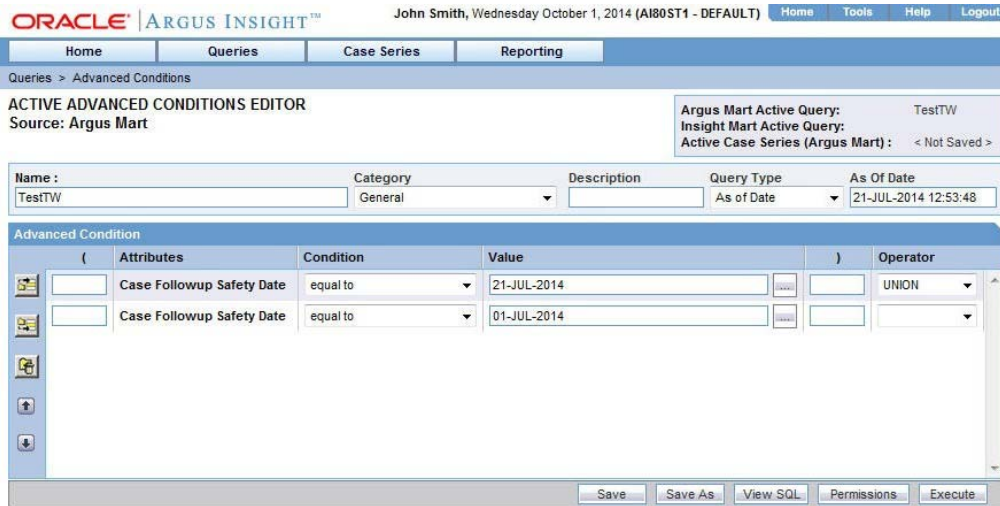
- For Argus Insight database, select Active (Insight Mart)

- For Argus Mart database, select Active (Argus Mart)

To view an active advanced condition:

1. Navigate to **Queries > Advanced Condition > Active (Argus Mart)**.

The ACTIVE ADVANCED CONDITIONS EDITOR page appears with data source and the advanced condition you executed or modified last.



2. If the active advanced condition was saved to the system before executing, the name of the advanced condition appears next to the **Active Query Name** and in the **Name** field.

However, if the active advanced condition was not saved to the system before executing, the text <Not Saved> is displayed next to the **Active Query Name** label.

You can enter the name of the advanced condition in the **Name** field and click **Save**.

To rename an already saved advanced condition, in the **Name** field, enter the new name, and click **Save**.

From the ACTIVE ADVANCED CONDITION page, you can perform the following tasks:

Task	Description
Modify the attributes in the Advanced Conditions Editor	If required, you can modify the attributes (fields and values) in the Advanced Conditions Editor. See "Creating a New Advanced Condition" on page 6-2 for more information. Click Save to save the changed <i>field</i> values. This button is only available for a saved active advanced condition.
Save Active Advanced Condition with another name	Click Save As to save the active advanced condition by a different name. The ADVANCED CONDITIONS LIBRARY page lists all the advanced conditions saved to the system. See "Working with Saved Advanced Conditions" on page 6-15 for more information.
View the Advanced Condition in SQL	Click View SQL to view the underlying SQL query for the advanced condition.

Task	Description
Assign Permissions	Click Permissions to set the group-level access permissions on the advanced condition. See " Creating a New Advanced Condition " on page 6-2 for more information. The Permissions button is only available for saved active advanced conditions.
Change the Description of the Active Advanced Condition	You can change the description of the active advanced condition by modifying the text displayed in the Description field. Click Save to store the changed description.
Execute the Active Advanced Condition	Click Execute to generate a case series by using the active advanced condition.

Note that modifying the field values in the Advanced Conditions Editor for an active advanced condition or saving the active advanced condition by a different name changes the active advanced condition to reflect the most recent changes. The active advanced condition also changes in case you modify the field values in the Advanced Conditions Editor and execute the advanced condition without saving the modifications.

Working with Saved Advanced Conditions

Refer to [Chapter , "Working with Saved Advanced Conditions"](#).

Searching Saved Advanced Conditions

Refer to [Chapter 5 > "Searching Saved Advanced Conditions"](#).

Creating a New Advanced Condition

See "[Creating a New Advanced Condition](#)" on page 6-2 for details.

Modifying an Advanced Condition

To modify an advanced condition:

1. Navigate to the ADVANCED CONDITIONS LIBRARY page.
2. Select the advanced condition you want to modify.
3. Click **Modify**.
4. Make your modifications to the advanced condition.
5. Click **Save** to save your changes.

Alternatively, click **Save As** to save the modified advanced condition by another name.

Modifying the SQL of an Advanced Condition

To modify the SQL of an advanced condition:

1. Navigate to the ADVANCED CONDITIONS LIBRARY page.
2. Select the advanced condition.
3. Click **Modify**.

The ACTIVE ADVANCED CONDITIONS EDITOR page appears.

4. Click **View SQL**.

The Advanced Conditions SQL dialog appears.

5. Modify the SQL.
6. Click **Save SQL** to save your changes.
7. Click **Close** to return to the ADVANCED CONDITIONS LIBRARY page.
8. Select the modified advanced condition.
9. From the **Query Type** drop-down list, select:
 - **Current Data**—Executes the custom SQL based on the current data and returns the latest revisions of the cases.
 - **As of Date**—Executes the modified SQL based on the historical date.
 - **At Lock**—Executes the modified SQL based on one or more user lock actions.
 - **Last Locked Revision as of a Point-in-Time**—Executes the modified SQL to display the most recent locked revisions that were committed to the database on or before As of Date.
 - **Last Locked Revision for a Version in a Period**—Executes the modified SQL to display the most recent locked revision for case versions in a time period based on Case Receipt Date, Case Lock Date, or Case Creation Date.

- **Aggregate Queries**—Executes the most recent locked revision for case versions for a specific time period.

You cannot edit the date for an Advanced Condition with Custom SQL from the library.

Once executed the query criteria displays the custom SQL as-is, and does not mention the Query Type.

Note: The custom SQL should begin with:

```
SELECT DISTINCT CASE_MASTER.CASE_ID, CASE_MASTER.EFFECTIVE_START_
DATE FROM CASE_MASTER
```

10. Click **Execute**.

The search results appear based on your modified SQL.

Note: You cannot modify an advanced condition once you have added user defined SQL in that, you can modify SQL but cannot add new items in advanced condition.

If you want to add new items, you have to revert the SQL to original by clicking **Revert to Original**.

Deleting an Advanced Condition

Refer to [Chapter 5 > "Deleting an Advanced Condition"](#).

Executing an Advanced Condition

Refer to [Chapter 5 > "Executing an Advanced Condition"](#).

Executing a Saved Advanced Condition on the Active Case Series

Just as the system assigns the *active* status to an advanced condition when you save modifications to it or execute it, the last saved or generated case series becomes the *active* case series.

You may want to run an advanced condition on an active case series.

To narrow down the list of cases in the active case series:

1. Generate the case series to run another Value Set:
 - You may generate the case series by either using QBE, filters, or advanced conditions. This case series becomes the active case series and remains so until you execute another query to generate a different case series.
 - Alternatively, if the case series on which you want to run another Value Set is already saved in the system, navigate to **Case Series > Open Case Series > Library**.

The CASE SERIES LIBRARY page appears.

Select the case series, and click **Make Active**.

2. Navigate to **Queries > Advanced Conditions > Library**.

The ADVANCED CONDITIONS LIBRARY page appears.

3. Select the advanced condition to run on the active case series you generated in Step 1.
4. Select the **Limit Query to Active Case Series** check box.

Note: The **Limit Query to Active Case Series** check box is enabled:

- When the selected active case series and advance condition are of same type (Insight Mart/Argus Mart).
 - When Argus Aggregate case series is active.
-

5. Click **Execute**.

The ACTIVE CASE SERIES page appears with the execution results of the selected advanced condition on the active case series.

Note that the case series you just generated becomes the active case series.

Working with Case Series

When you execute a QBE, a filter, or an advanced condition, Argus Insight generates a list of cases that match the querying criteria. This list of cases is called a *case series*. Argus Insight displays the case series in a listing format on the ACTIVE CASE SERIES page.

The case series is the communication foundation between all modules of Argus Insight.

If the Argus Insight case series are created by using the Argus Mart advanced condition, then these case series records only case IDs, case revision effective start dates, and query criteria (as a text string).

This chapter includes the following topics:

- [Working with the Active Case Series](#)
- [Working with Case Series Saved in the Library](#)
- [Sharing Case Series with Argus Safety Web](#)
- [Exporting a Case Series to Microsoft Excel](#)
- [Freezing and Unfreezing Case Series Data](#)
- [Using the Link to Argus Safety Medical Review](#)

Note: The case series might become obsolete each time the data mart is refreshed by running an ETL because new cases with similar attributes might get added to the data mart.

Working with the Active Case Series

This section provides information about working with the active case series and includes the following topics:

- [Viewing the Active Case Series](#)
- [Saving the Active Case Series](#)
- [Viewing the Criteria that Generated the Active Case Series](#)
- [Assigning Group-Level Access Permissions](#)
- [Adding an Annotation to a Case](#)
- [Adding a Case to a Case Series](#)
- [Deleting a Case from a Case Series](#)

Viewing the Active Case Series

The system assigns the *active* status to the case series that was last generated by executing a *query*. Only one case series can be active at a time. The last case series generated remains active until you:

- Generate another case series.
- Save modifications to an existing case series.
- Manually assign the active status to a case series that has been saved to the case series library.

See "[Making a Case Series Active](#)" on page 7-12 for details.

To view the active case series, navigate to **Case Series > Open Case Series > Active**.

The ACTIVE CASE SERIES page appears with the last case series that is executed, modified, or manually made active. See [Figure 7-1](#).

Figure 7-1 Viewing the Active Cases Series

The screenshot shows the Oracle Argus Insight interface. The top navigation bar has 'Home', 'Queries', 'Case Series', and 'Reporting'. A dropdown menu is open under 'Case Series', with 'Active' selected. The main content area shows 'ACTIVE CASE SERIES' with 'Source: Argus Mart'. Below this, there are search filters for Name, Category, and Description. A table titled 'Choose Elements' displays a list of case series with columns: Case Number, Report Type, Primary Company Product, Primary Event, Seriousness Criteria, Outcome, Locked Date, and Notes. The table contains 10 rows of data. At the bottom, there are buttons for 'Save', 'Save As', 'View Query Criteria', 'View Query', 'Export to Excel', and 'Cancel'.

Case Number	Report Type	Primary Company Product	Primary Event	Seriousness Criteria	Outcome	Locked Date	Notes
003 GLOBAL LOC	Spontaneous	CROCI (US & JP)	Rash	M		18-FEB-2015	
004 GLOBAL LOC	Spontaneous	CROCI (US & JP)	Rash	M		16-FEB-2015	
006 GLOBAL LOC	Spontaneous	CROCI (US & JP)	Rash	M		16-FEB-2015	
078-010108	Spontaneous	Tegretol	Rigors	M		31-JUL-2009	
079-300709	Spontaneous	DOXORUBICIN HCL	Pyrexia	DI,R		30-JUL-2009	
080-150808	Spontaneous	Rabipur	cough	NA		31-JUL-2009	
081-300709	Spontaneous	Begin Product Name Product Name	Pain	M,F,H	Fatal	07-AUG-2009	
084-010108	Spontaneous	Tegretol	Rigors	M		04-AUG-2009	
086-060809	Sponsored Trial	Begin Product Name Product Name	Pyrexia	Non Serious		15-JAN-2015	
091-070809	Sponsored Trial	DOXORUBICIN HCL	Asthma	Non Serious		07-AUG-2009	
093-050102	Sponsored Trial	DOXORUBICIN HCL	Cardiac arrest	H		07-AUG-2009	
099-110809	Sponsored Trial	DOXORUBICIN HCL	Hepatic failure	M		11-AUG-2009	

The ACTIVE CASE SERIES page displays different fields based on the type of the point-in-time query used to generate the case series.

- The **Effective Start Date** field appears for **Current Data**, and **As of Date** queries with the most recent revisions available in Argus Safety regardless of whether the cases are locked or unlocked, and historical data respectively.
- The **Locked Date** field appears for **At Lock**, **Last Locked Revision as of a Point in Time**, and **Last Locked Revision for a Version in Period** queries with locked date for all the case revisions which are returned in the case series.

The tool tip for this field also displays <Locked Date> (<Effective Start Date>) values for each row.

Active Case Series and Active Query Names

On the ACTIVE CASE SERIES page, note that:

- The **Active Query Name** label displays the name of the saved query (QBE, filter, or advanced condition) that generated the case series. If the query was not saved, the label displays the text <Not Saved>.

Now, Argus Insight supports two Active Queries: **Active Query for Argus Mart** and **Active Query for Insight Mart**.

- The **Active Case Series** label displays the text <Not Saved> until you save the case series by a name. Similarly, the **Name** field displays the text <Not Saved> until you save the case series by a name.

You can enter the name of the case series in the **Name** field, and click **Save**.

To rename an already saved case series, enter the new name in the **Name** field, and click **Save**.

Sorting, Searching, and Navigating

On the ACTIVE CASE SERIES page, use the tools in the table header (see [Figure 7-2](#)) to sort, search, and navigate through the list of cases.

- To sort the list by a specific column, click the arrow icon next to a column heading.
- To filter the list, enter search criteria into one or more of the fields below the column headings, and then click **Search**.

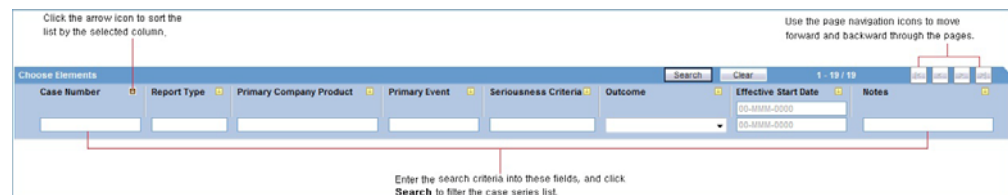
Note: If you search for a text comprising an underscore, it is treated as a wildcard and is replaced by a letter in the displayed results. For example, If you have queries with names - CURE, CORE, and CARE and you search for C_RE, all three queries are displayed in the result.

- To move forward and backward through the pages of case series, click the Page Navigation icons. A page displays 50 cases.

When you export the data to a Microsoft Excel file, the system retains any changes you made to the sorting and filtering order.

See "[Exporting a Case Series to Microsoft Excel](#)" on page 7-16 for more information.

Figure 7-2 *Sorting, Searching, and Navigating the List of Cases*



Note: The ACTIVE CASE SERIES page displays different fields (Effective Start Date/Locked Date) based on the type of the point-in-time query used to generate the case series.

Saving the Active Case Series

Before you can save a case series, you must enter a description for the case series in the **Description** field.

If you have not saved the active case series to the system yet, click either **Save** or **Save As** to assign a name to the case series and save it to the Case Series library.

If you are modifying a case series that is already saved, click **Save** to save your modifications or click **Save As** to save the case series by another name.

Note: All the Argus Aggregate Case Series will be saved under **Compliance** category by default after copying these from Argus Safety database through ETL process.

Besides, the **Save As** option for Aggregate Case Series will save the case series as Argus Mart case series.

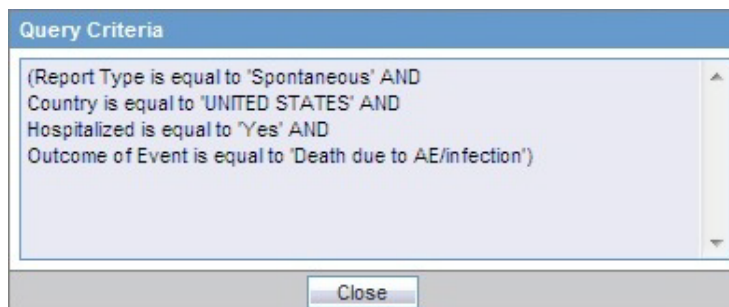
Viewing the Criteria that Generated the Active Case Series

Use one of the following options to view the query criteria that generated the active case series:

- To return to the appropriate *Queries* page (QUERY BY EXAMPLE page, FILTER VALUE SET page, or ADVANCED CONDITIONS EDITOR page) and view the query criteria that generated the case series, click **View Query**.

The **View Query** button is enabled *only if* the active case series is not yet saved to the system.

- To view the query criteria in a statement format, click **View Query Criteria**. The Query Criteria dialog box opens and displays the query. For example:



Assigning Group-Level Access Permissions

You can assign group-level access permissions for the case series. These permissions determine which user groups will be able to view, modify, or delete a case series.

Note: You can set permissions only on case series you saved to the system.

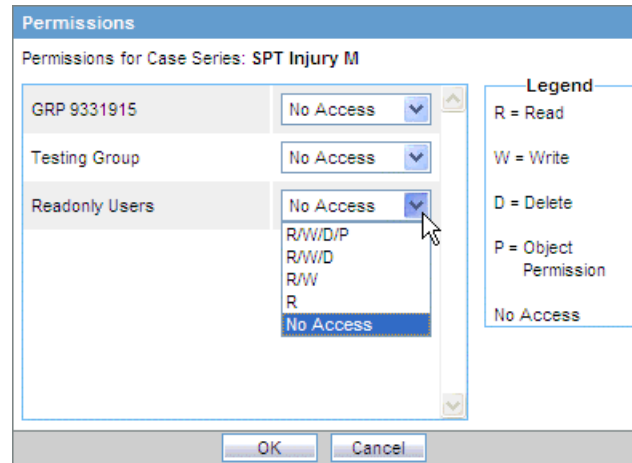
To set case series permissions:

1. Navigate to **Case Series > Open Case Series > Active**.

The ACTIVE CASE SERIES page appears.

2. To assign group-level permissions on the saved case series, click **Permissions**.

The **Permissions** dialog box appears with the names of all the groups (except the **Administrator** group) that the system administrator has created.



Note: For Argus Aggregate case series, the **Permission** button will be enabled if you have permission to share case series in Case Editor page.

For example, if Argus Aggregate case series is shared to any Argus Insight group (Group_1) using the Permission settings, then the shared aggregate case series will be available to all the users belonging to that group (Group_1). This permission will not be effected by Argus Mart ETL.

3. To assign permissions to the group members on the case series you have created, use the drop-down list next to a group name. The available options are:

Permission	Description
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the case series.
R/W/D	Group members will be able to view, modify, and delete the case series.
R/W	Group members will be able to view and modify the case series.
R	Group members will be able to only view the case series.
No Access (Default)	No group members will be able to access the case series.

Note: The author of the case series always has the highest level of permission (R/W/D/P) on the case series. For example, suppose you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a case series that you generate. In this case, you will continue to have the highest level of permission on your case series; other members in your group cannot access your case series.

4. Click **OK** to save the permission settings.

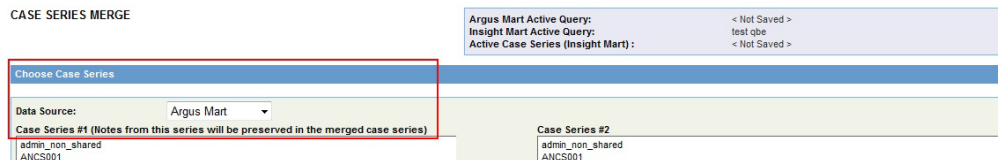
Adding an Annotation to a Case

A *case annotation* is the addition of notes to a case. For example, you may want to add explanatory notes, critical comments about the case, or updates for the reporter. Adding relevant and important information about a case makes for better understanding of that case.

About Case Annotations

A case annotation:

- Supports a maximum of 200 characters.
- Is saved with the case series. Once entered, an annotation is saved for the case series. You do not need to explicitly save a case series to save the annotations.
- Is applicable for the case in only the same case series where it was saved. It is not applicable even for the same case if the case is in a different case series.
- Is frozen along with a frozen case series. Therefore, you cannot edit, add, or delete an annotation in a frozen case series.
- Is copied to a new case series if the case series where it was created is also copied.
- Is exported to Microsoft Excel when you use the Export to Excel feature.
- Is kept with a case if the case series is subsetted.
- Is retained when the case series merges with another case series. As shown in the following graphic, the Case Series #1 section title on the CASE SERIES MERGE page includes a statement that the notes from this series will be preserved in the merged case series:



If you can access a case series, you can access its corresponding case annotations.

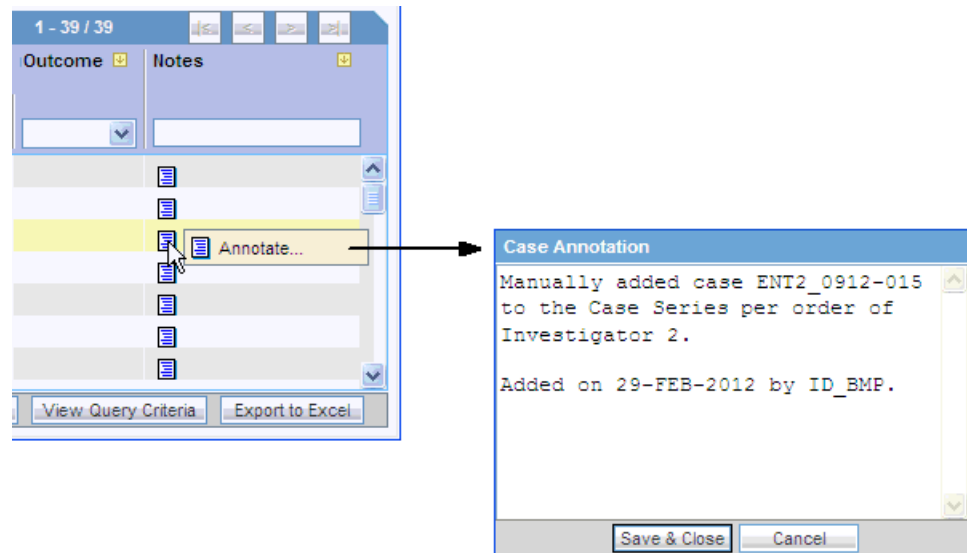
Annotations in the Active Case Series

For any case in the active case series, you may include an annotation with the case.

To add an annotation to a specific case:

1. Navigate to the ACTIVE CASE SERIES page.
2. Select the case that you want to annotate.
3. In the Notes column, click the **Annotate** icon.
4. From the drop-down menu, select **Annotate**.

The Case Annotation dialog box appears.

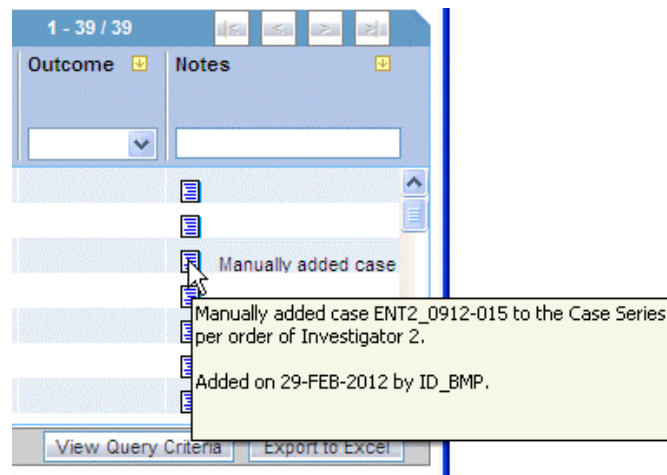


5. Enter notes, comments, or remarks about the case.

6. Click **Save & Close**.

The selected case is updated with the annotation. In addition, the Notes column displays the beginning text of the annotation.

To view the complete annotation, position the cursor over the Annotate icon.



To modify or delete an existing annotation, open the Case Annotation dialog box, edit the text, and save your changes.

Annotations in Advanced Conditions


To use annotations when you create an advanced condition, navigate to **Case Series, Cases**, and select **Case Annotations**. This field is a freehand text field and supports single select only.

This note is not available in Argus Safety and does not impact the case series in Argus Safety.

Adding a Case to a Case Series

If required, you can modify the case series by adding cases manually.

To add a case to the case series:

1. Navigate to the ACTIVE CASE SERIES page.
2. Click the **Add Case** icon  on the left bar.

The Add Case to Case Series dialog box appears.

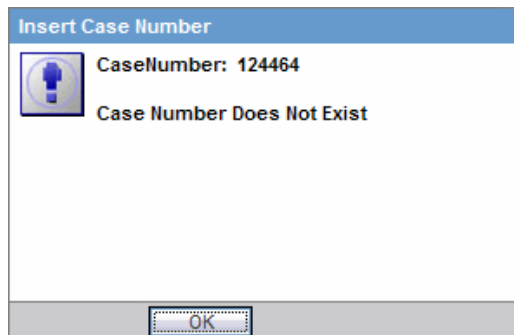


3. Enter the case number to add to the case series manually.
4. To select the reason to modify the case series, click the **Justification** field.

Alternatively, you may type your own justification text to explain why you are modifying the case series.

In addition, you may define the choices that Argus Insight lists for the Justification field by using the Case Series Modification Justification option in the List Maintenance tab on the ADMINISTRATION TOOLS page.


5. Click **OK**.
 - If the case number you specified exists in the data mart, the system adds the case to the case series and saves the changes. A message dialog box reports that the case number was successfully inserted.
 - If the case number you specified does not exist in the data mart, the system displays an error message. For example:



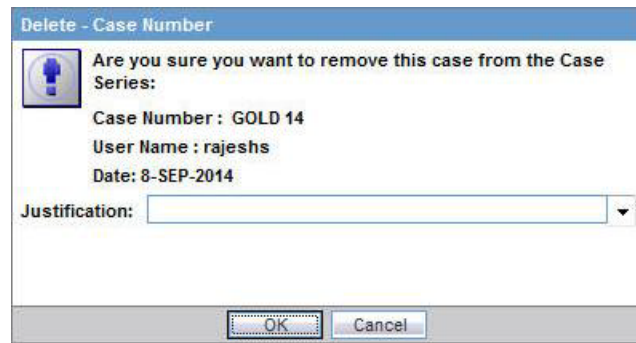
6. Click **OK** to close the message dialog box.

Deleting a Case from a Case Series

To delete a case from the case series:

1. Navigate to the ACTIVE CASE SERIES page.
2. Select the case you want to delete.
3. Click the **Delete Case** icon  on the left bar.

The Delete Case Number dialog box appears.



4. To select the reason to delete the case, click the **Justification** field.

Alternatively, you may type your own justification text to explain why you are deleting the case.

In addition, you may define the justification choices that Argus Insight lists for the Justification field by using the Case Series Modification Justification option in the List Maintenance tab on the ADMINISTRATION TOOLS page.

5. Click **OK** to delete the case from the case series and saves the changes.

Working with Case Series Saved in the Library

When you execute a QBE, a filter, or an advanced condition, Argus Insight generates a list of cases that match your query criteria. This list of cases is called a *case series*.

You can choose to save a case series for future reference. You provide a brief description and a unique name for the case series; the system stores all saved case series in the Case Series library.

This section provides information about working with saved case series and includes the following topics

- [Opening the CASE SERIES LIBRARY Page](#)
- [Searching for a Saved Case Series in the Library](#)
- [Making a Case Series Active](#)
- [Modifying a Case Series](#)
- [Merging Case Series](#)
- [Importing a Case Series from an External Source](#)
- [Deleting a Case Series from the Library](#)
- [Viewing the Query Criteria that Generated the Case Series](#)

Opening the CASE SERIES LIBRARY Page

The CASE SERIES LIBRARY page, shown in [Figure 7-3](#), lists all the case series saved to the system.

To open the CASE SERIES LIBRARY page, navigate to **Case Series > Open Case Series > Library**.

The CASE SERIES LIBRARY page displays the following information for each case series:

- Name of the case series.
- Brief description of the case series.
- Date when the case series was last modified.
- Name of the user who generated the case series.
- Category assigned to the case series.
For example, Compliance, General, Management, or Pharmacovigilance.
- Source of the case series.
 - **Argus Insight** indicates the case series was generated using Argus Insight querying tools.
 - **Argus Mart** indicates the case series was generated using Argus Mart querying tools.

Note: To import Argus Insight or Argus Mart based case series, see ["Importing a Case Series from an External Source"](#) on page 7-14.

- **Argus Aggregate** indicates the case series was imported into Argus Insight (for Argus Mart data source only) from Argus Safety via ETL process. These case series belongs to Argus periodic/aggregate reporting.

Access permission for all the Aggregate Case Series are brought over from Argus Safety database to Argus Insight. You may access Aggregate Case Series, only when you have access to Argus Safety or Argus Insight, assigned from Argus Insight Group Permissions.

For more information in Group Permissions, see [Assigning Group-Level Access Permissions](#).

All Aggregate Case Series fetched from Argus Safety will have query criteria as **Argus Aggregate Case Series**.

To view all these case series, select **Include Aggregate Case Series** check box. This check box is disabled if there are either no Aggregate Case Series in Argus Insight database or you do not have access to any of the Aggregate Case Series. This check box is not available when application is running on Insight Mart data source only.

- Number of cases in the case series.

In addition, the Cases column displays the following icons:



- **For Argus Insight Case Series**—A snowflake icon  if the case series is frozen. Positioning the cursor over the icon displays the date and time the case series was frozen.
- **For Argus Mart Case Series**—A snowflake icon  along with the case counts for all case series other than Current Data. Positioning the cursor over the icon displays the type of the case series.

Figure 7-3 CASE SERIES LIBRARY Page

CASE SERIES LIBRARY							
Argus Mart Active Query: rajesh test smoke Insight Mart Active Query: Management Active Case Series (Insight Mart): < Not Saved >							
<input type="checkbox"/> Include Aggregate Case Series							
Choose Case Series							
Name	Description	Last Modified	User Full Name	Category	Source	Cases	
(SPR11_ATLOCK UNION SPR11_CURRENTDATA)	(SPR11_ATLOCK UNION SPR11_CURRENTDATA)	04-MAR-2016	igow da_R	Compliance	Argus Mart	25	
20810001	desc	25-FEB-2016	Administrator	General	Insight Mart	972	
< Not Saved >Filter_CS	sdf of dsfd	23-SEP-2015	igow da_RW	General	Insight Mart	977	
< Not Saved >QC_CS1_QBE	as dsdad	23-SEP-2015	igow da_RW	General	Insight Mart	221	
AIB1_agg_cs1	dfedrererer	01-MAR-2016	igow da_RW	General	Argus Mart	21	
AIB1_Agg_query_CS	AIB1_Agg_query_CS	28-JAN-2016	igow da_RW	General	Argus Mart	19	
AIB1_Agg_query_CS SAVE AS	AIB1_Agg_query_CS	02-MAR-2016	Administrator	General	Argus Mart	19	
AIB1_Agg_query_CS_Savaas	AIB1_Agg_query_CS	28-JAN-2016	igow da_RW	General	Argus Mart	20	
AIB1_AS of date	desc	01-MAR-2016	igow da_RW	General	Argus Mart	25	
AIB1_AS of date 245	desc	02-MAR-2016	Administrator	General	Argus Mart	25	
AIB1_AsofDate_CS	AIB1_AsofDate_CS	28-JAN-2016	igow da_RW	General	Argus Mart	99	
AIB1_AsofDate_CS saveas	AIB1_AsofDate_CS	02-MAR-2016	Administrator	General	Argus Mart	99	
AIB1_AsofDate_CS sdf	AIB1_AsofDate_CS	02-MAR-2016	Administrator	General	Argus Mart	99	
aib1_atlock_CS	aib1_atlock_CS	28-JAN-2016	igow da_RW	Management	Argus Mart	159	
aib1_atlock_CS 123	aib1_atlock_CS	02-MAR-2016	Administrator	Management	Argus Mart	159	
aib1_atlock_CS UNION AIB1_current_cs	(aib1_atlock_CS UNION AIB1_current_cs)	28-JAN-2016	igow da_RW	General	Argus Mart	1102	
aib1_atlock_CS- saved as	aib1_atlock_CS	01-MAR-2016	Administrator	Management	Argus Mart	159	
AIB1_atlock_CS1	desc	01-MAR-2016	igow da_RW	General	Argus Mart	27	
AIB1_current_cs	AIB1_current_cs	28-JAN-2016	igow da_RW	General	Argus Mart	1101	

Searching for a Saved Case Series in the Library

You can search a saved case series by its name, description, modified date, author, category, and source. You can enter a value for one, several, or all search fields to find a saved case series.

To search for a saved case series:

1. Navigate to the CASE SERIES LIBRARY page.
2. Enter search criteria into one or more of the fields below the column headings.

CASE SERIES LIBRARY							
Argus Mart Active Query: < Not Saved > Insight Mart Active Query: test qbe Active Case Series (Insight Mart): < Not Saved >							
<input checked="" type="checkbox"/> Include Aggregate Case Series							
Choose Case Series							
Name	Description	Last Modified	User Full Name	Category	Source	Cases	
		00-MMM-0000					
		00-MMM-0000					

To search for a case series:

- By its name, type the name of the case series in the **Name** field.
- By its description, type part of the description in the **Description** field. The system searches for the specified text string in all case series descriptions.
- By its date of modification, enter the modification date in the first **Last Modified** date field. To specify a date range, type the start and end dates in the first and second date fields, respectively.
- By its author, select the author name from the **User Full Name** field.
- By its category, select the category from the **Category** field.
- By its source, select the source from the **Source** field.

Note: If you search for a text comprising an underscore, it is treated as a wildcard and is replaced by a letter in the displayed results. For example, If you have queries with names - CURE, CORE, and CARE and you search for C_RE, all three queries are displayed in the result.

3. Click **Search**.

The search results appear based on the specified criteria.

- To sort the search results, click the sort icon next to a column header.
- To clear the search results and list all the saved case series, click **Clear**.

Making a Case Series Active

To make a case series active:

1. Navigate to the CASE SERIES LIBRARY page.
2. To view Argus Aggregate Case Series, select **Include Aggregate Case Series** check box.
3. Select a case series to make active.
4. Click **Make Active**.

The **Active Case Series** label in the upper-right corner of the CASE SERIES LIBRARY page displays the name of the case series you made active.

Modifying a Case Series

You may want to modify an existing case series by adding cases to it or deleting existing cases. You can also change the group-level access permissions on the case series.

To modify a case series:

1. Navigate to the CASE SERIES LIBRARY page.
2. Select the case series you want to modify.
3. Click **Modify**.

See "[Working with the Active Case Series](#)" on page 7-1 for detailed information about making modifications to the case series and setting permissions.

Merging Case Series

Argus Insight lets you create a new case series by merging two case series through a *set operator*. The set operator you select works on the case numbers. The case numbers included in the merged case series depend on the type of set operator you use:

- **Union** — Creates a new case series that contains all the cases in both case series; common case numbers are included, and are listed only once.
- **Intersect** — Creates a new case series that contains only those case numbers that exist in both case series.
- **Minus** — Creates a new case series that contains only those case numbers that are present in the first case series, but are not present in the second case series.

To generate a merged case series:

1. Navigate to the CASE SERIES LIBRARY page.
2. Click **Merge**.

The CASE SERIES MERGE page appears.

CASE SERIES MERGE

Argus Mart Active Query: ragesh test smoke Management
 Insight Mart Active Query: <Not Saved>

Choose Case Series

Data Source: Argus Mart

Case Series #1 (Notes from this series will be preserved in the merged case series)

(SFR11_ATLOOK UNION SFR11_CURRENTDATA)
 20865710_combined_sql_CS
 AB1_agg_cs1
 AB1_Agq_query_CS
 AB1_Agq_query_CS SAVEAS
 AB1_Agq_query_CS_Savaas
 AB1_AS of date
 AB1_AS of date 245
 AB1_AsofDate_CS
 AB1_AsofDate_CS saveas
 AB1_AsofDate_CS sdf
 ab1_atlook_CS
 ab1_atlook_CS 123
 ab1_atlook_CS UNION AB1_current_cs
 ab1_atlook_CS- saved as
 AB1_atlook_CS1
 AB1_current_cs
 AB1_current_cs UNION AB1_AsofDate_CS
 AB1_current_data
 AB1_Last_touched revision for a point in time
 AB1_Pt_CS
 ab1_pt_cs1
 ab1_test_vid
 ab1_test_vid_test

Description
 AB1_AsofDate_CS

Author
 igow da_RW

Merge Type: Current Data Show Locked Date

Action
 Union
 Intersect
 Minus

Case Series #2

(SFR11_ATLOOK UNION SFR11_CURRENTDATA)
 20865710_combined_sql_CS
 AB1_agg_cs1
 AB1_Agq_query_CS
 AB1_Agq_query_CS SAVEAS
 AB1_Agq_query_CS_Savaas
 AB1_AS of date
 AB1_AS of date 245
 AB1_AsofDate_CS
 AB1_AsofDate_CS saveas
 AB1_AsofDate_CS sdf
 ab1_atlook_CS
 ab1_atlook_CS 123
 ab1_atlook_CS UNION AB1_current_cs
 ab1_atlook_CS- saved as
 AB1_atlook_CS1
 AB1_current_cs
 AB1_current_cs UNION AB1_AsofDate_CS
 AB1_current_data
 AB1_Last_touched revision for a point in time
 AB1_Pt_CS
 ab1_pt_cs1
 ab1_test_vid
 ab1_test_vid_test

Description
 desc

Author
 igow da_RW

Merge Cancel

3. From the **Data Source** drop-down list, select a data source (Insight Mart/ Argus Mart).

Based on the selected data source, the list of case series in both the columns Case Series #1 and Case Series #2 are updated.

Note: Argus Aggregate case series are available for merging only when Data Source from the drop-down list is selected as Argus Mart. Beside, merged aggregate case series will be reflected as Argus Mart.

4. Select the two case series to merge:
 - a. From the **Case Series # 1** list, select the first case series.
 - b. From the **Case Series # 2** list, select the second case series.

Note that the system populates the Description and Author fields for each selected case. You may modify the information if necessary.

5. Select the **Action** (set operator) to merge the two selected case series.

As described previously, you can select one of the following actions:

- **Union** — Creates a new case series that contains all the cases in both case series; common case numbers are included, and are listed only once.
- **Intersect** — Creates a new case series that contains only those case numbers that exist in both case series.
- **Minus** — Creates a new case series that contains only those case numbers present in the first case series, but not present in the second case series.

6. For **Data Source** as **Argus Mart**, from **Merge Type** drop-down list, select:
 - **Current Data**—To save single revision per case after UNION/INTERSECT/MINUS. Every time you open the saved case series, the latest data in case series is displayed.
 - **Latest Revision**—To save single revision per case after UNION/INTERSECT/MINUS. Saved Revision will be the highest revision of the case at the time of operation. Every time you open the saved case series, data as per saved revision is displayed.
 - **All Revisions from Source**—To save all the revisions after UNION/INTERSECT/MINUS. Every time you open saved case series, the data as per saved revision is displayed.

To view **Locked Date** in the Case Series Editor page for the merged case series, select **Show Locked Date**.

7. Click **Merge**.

The ACTIVE CASE SERIES page appears with the resultant case series.

Importing a Case Series from an External Source

You can import a case series from an external source into Argus Insight. The requirements are as follows:

- The external source file can be a text (TXT) file or a comma-separated values (CSV) file.
- Each case number in the file must be on a new line.
- Each case number must be separated by a line return (Enter) or a semicolon (;).

To import a case series from an external source into Argus Insight:

1. Navigate to the CASE SERIES LIBRARY page.
2. Click **Import**.

The Select File For Import dialog box appears.

3. From the **Target Data Source** drop-down list, select a data source (Insight Mart/Argus Mart).
4. To locate and select the external case series source file, click **Browse**.
Alternatively, in the **File** field, enter the file name with its complete system path.

5. Verify if the first row in your TXT or CSV file has the column headings. If so, be sure to select the **First row contains column header(s)** check box.
6. Click **OK**.

The Import Case Series dialog box appears with the status of the import operation.

Note: To view the import operation log, click **View Log**.

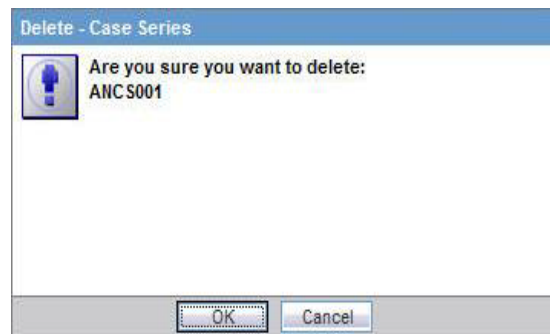
7. Click **OK** to display the imported case series on the ACTIVE CASE SERIES page.

Deleting a Case Series from the Library

To delete an existing case series:

1. Navigate to the CASE SERIES LIBRARY page.
2. Select **Include Aggregate Case Series** check box.
3. Select the case series to delete.
4. Click **Delete**.

A confirmation dialog box appears.



5. Click **OK**.

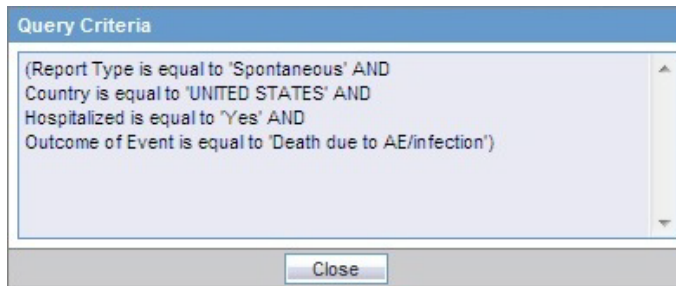
You return to the CASE SERIES LIBRARY page.

Note: When Argus Aggregate Case Series is deleted from Argus Insight, it will be re-populated if that case series is still available in Argus Safety. Beside, when any Aggregate Case Series is deleted from Argus Safety then it will also be deleted from Argus Insight.

Viewing the Query Criteria that Generated the Case Series

To view the details of the query that generated a case series:

1. Navigate to the CASE SERIES LIBRARY page.
2. Select a case series.
3. Click **Query Criteria** to open the Query Criteria dialog box and display the query in an SQL-statement format. For example:



Note: For a *saved* case series, you can view the query details only in a SQL-statement format in the Query Criteria dialog box.

However, for an active case series that *is not yet saved* to the system, you can view the query details within the query tool interface as well as in the SQL-statement format. See "[Viewing the Criteria that Generated the Active Case Series](#)" on page 7-4 for more information.

Sharing Case Series with Argus Safety Web

You can share cases between Argus Safety Web and Argus Insight.

To enable case sharing between these two applications, you need a common user name (ID) and password for Argus Safety Web and Argus Insight. If you do not have a valid user ID in Argus Safety Web, the system displays the following error message:

Your user ID is not present in Argus.

Note: **Import from Argus Safety** option is available only when the target data source is selected as Insight Mart or Both (Insight Mart and Argus Mart).

To share cases between Argus Insight and Argus Safety Web:

1. Log in to Argus Insight.
2. Navigate to **Case Series > Open Case Series > Import from Argus Safety**.

The list of active case series appears from Argus Safety Web.

The active case series present in Argus Safety are now the active case series in Argus Insight.

Note: An error message appears if there are no cases present in the active series of Argus Safety.

3. Click **Save** or **Save As** to save the case series.

Exporting a Case Series to Microsoft Excel

To export a case series to a Microsoft Excel file:

1. Create a new query using a QBE, a filter, or an advanced condition, or open a saved query from the Query library.

2. Click **Execute** to open the ACTIVE CASE SERIES page with the list of cases.
3. Make adjustments to the listing, if necessary. You can sort the list or enter search criteria to filter the list. The system retains the sorting and filtering order when you export the data to a Microsoft Excel file.
4. Click **Export to Excel**. The File Download dialog box opens and prompts you to open or save the Microsoft Excel file.
 - To open the Excel file and view the case series results, click **Open**.
 - To save the Excel file to your system, click **Save**.

The system prompts for the location to save the file. Once the file is saved, you can open the file and view the case series results.

The Excel spreadsheet has two tabs:

- The **Case Series** tab provides information about each case in the case series, including the case number, report type, primary company product, primary event, seriousness criteria, and outcome. See in [Figure 7-4](#).
- The **Case Series Details** tab provides information about the entire case series, including the name specified when the case series was saved, the total number of cases in the series, the description specified when the case series was saved, and the query criteria (in SQL-statement format) used to generate the case series.

Figure 7-4 Sample Case Series Exported to an Excel Spreadsheet

	A	B	C	D	E	F	G	H	I
1	Case Number	Report Type	Primary Company Product	Primary Event	Seriousness Criteria	Outcome	Notes	Effective Start Date	Locked Date
2	QC_VIP02_09AUG	Sponsored Trial	Tegretol or Placebo	Cardiac failure	LT			9/10/2015 2:52:53 PM	9/10/2015 11:15:32 AM
3	QC_VIP1_09AUG	Sponsored Trial	Tegretol or Placebo	Cardiac failure	LT			9/10/2015 2:52:38 PM	
4	QC_VIP1_CASE4	Sponsored Trial	Tegretol or Placebo	Cardiac failure	LT			9/11/2015 11:49:21 AM	
5	QC_VIP1_CASE5	Sponsored Trial	Tegretol or Placebo	Cardiac failure	LT			9/15/2015 11:09:07 PM	9/11/2015 12:22:22 PM
6	QC_VIP1_LOCK1	Literature Clinical Trial	UpgradeA	Cardiac failure	LT			9/21/2015 5:22:57 PM	
7	QC_VIP1_LOCK2	Sponsored Trial	Tegretol or Placebo	Cardiac failure	LT			9/17/2015 2:36:45 PM	9/16/2015 12:13:03 AM
8	QC_VIP1_LOCK3	Spontaneous	Tegretol	Cardiac failure	LT			9/15/2015 11:35:55 PM	9/15/2015 11:31:06 PM
9	QC_VIP1_LOCK4	Spontaneous	Tegretol	Cardiac failure	LT			9/15/2015 11:52:51 PM	9/15/2015 11:48:01 PM
10	QC_VIP1_LOCK5	Spontaneous	Tegretol	Cardiac failure	LT			9/17/2015 2:36:59 PM	9/16/2015 12:34:36 AM
11	QC_VIP1_POSTLOCK1	Spontaneous	Tegretol	Cardiac failure	LT			11/4/2015 10:08:18 AM	9/16/2015 12:18:21 AM
12	QC_VIP1_POSTLOCK2	Spontaneous	Tegretol	Cardiac failure	LT			9/18/2015 5:13:30 PM	9/16/2015 12:29:35 AM
13	QC_VIP1_POSTLOCK3	Spontaneous	UpgradeB	Cardiac failure	LT			9/21/2015 10:16:11 AM	9/18/2015 1:27:28 PM
14	QC_VIP1_POSTLOCK4	Spontaneous	Tegretol	Cardiac failure	LT			9/17/2015 2:38:00 PM	9/16/2015 12:28:11 AM
15	QC_VIP1_POSTLOCK5	Spontaneous	Tegretol	Cardiac failure	LT			9/17/2015 2:38:09 PM	9/16/2015 12:33:00 AM
16	QC_VIP1_UNLOCK1	Spontaneous	Tegretol	Cardiac failure	LT			9/15/2015 11:55:04 PM	
17	QC_VIP1_UNLOCK2	Spontaneous	Tegretol	Cardiac failure	LT			9/17/2015 2:37:15 PM	
18	QC_VIP1_UNLOCK3	Spontaneous	Tegretol	Cardiac failure	LT			9/16/2015 12:05:54 AM	
19	QC_VIP1_UNLOCK4	Spontaneous	Tegretol	Cardiac failure	LT			9/16/2015 12:08:09 AM	
20	QC_VIP1_UNLOCK5	Spontaneous	Tegretol	Cardiac failure	LT			9/17/2015 2:37:25 PM	

Freezing and Unfreezing Case Series Data

This section includes the following topics:

- [Before Freezing the Data in a Case Series](#)
- [Freezing a Case Series](#)
- [Unfreezing Case Series Data](#)

Note: The Freeze and Unfreeze functionality is available for Insight Mart only. Argus Mart case series cannot be frozen. The Freeze and Unfreeze buttons are not available for Argus Mart.

Before Freezing the Data in a Case Series

Before you freeze the data in a case series, review the information in this section to understand the restrictions and usage for frozen case series.

Access Rights

System administrators define the freeze and unfreeze access rights when creating user groups.

You can freeze and unfreeze case series *only if* you have the access rights (privileges).

Working with Frozen Case Series

When you work with frozen case series, note that:

- You cannot insert cases into a frozen case series.
- You cannot share a frozen case series with Argus Safety.
- You can delete cases from a frozen case series.
- When you run a query or an advanced condition against a frozen case series, Argus Insight uses the frozen data.
- The link to the Medical Review dialog box accesses the latest data for the case.
- The following Argus Insight features **do not** require all case data to be frozen:
 - Copy Configuration utility
 - Derivation rules

List Maintenance Items and Derivation Rules in a Frozen Case Series

- List Maintenance items are not frozen. Therefore, some reports will have a mismatch of List Maintenance items and the frozen case series data.
- The derivation rules operate against current case data if the List Maintenance rules are modified. The frozen case series are shown if there is a change in the case data resulting from the derivation rules.
- If suppress condition is checked in the derivation rule, then List Maintenance records related to the derivation rule will not be deleted in cases used in the frozen case data table.

Freezing a Case Series

You can freeze a custom case series when editing the case series from the CASE SERIES LIBRARY page.

To freeze the existing cases in a case series:

1. Navigate to the CASE SERIES LIBRARY page.
2. Select a case series.
3. Click **Freeze Case Series**.

The Freeze Case Series dialog box appears.





4. Enter a name for this frozen case series.
5. Click **OK**.

The system freezes and saves the case series with the specified name.

Recognizing a Frozen Case Series

To indicate that a case series is frozen, the Cases column on the CASE SERIES LIBRARY page displays a snowflake icon. Positioning the cursor over the snowflake icon displays the date and time the selected case series was frozen.

Category	Source	Cases
General	Insight Mart	514
Compliance	Insight Mart	19
General	Insight Mart	 532
General	Insight Mart	 532
Compliance	Argus Mart	Frozen on 8/13/2014 12:12:42 PM

Freezing and Saving Case Series

You can freeze any system-generated case series (active or inactive) (for example, using Argus Insight queries, filters, and advanced conditions) by clicking **Freeze and Save**.

The system freezes the case series and then displays the standard Case Series Save dialog box. You must enter a name for the saved case series.

If you have not yet saved the case series from the ACTIVE CASE SERIES page, and you click **Freeze and Save**, the system saves only one copy of the frozen case in the library. The frozen case series is now the active case series.

On the CASE SERIES LIBRARY page, you can position the cursor over the snowflake icon in the Cases column to view the date and time the selected case series was frozen.

Unfreezing Case Series Data

On the CASE SERIES LIBRARY page, you have the option to unfreeze a currently frozen case series. Unfreezing a case series forces Argus Insight to retrieve the latest information for all the cases in the series.

When you unfreeze a case series, you must provide a justification, or reason, for this action. You can either type a new justification or select a preconfigured justification.

If you have access rights to the List Maintenance tab on the ADMINISTRATION TOOLS page, use the **Case Series Un-Freezing Justification** option to configure one or more justifications that can be selected when you unfreeze a case series. You can add new justifications, modify existing justifications, or delete an existing justification.

To unfreeze a case series that is currently frozen:

1. Navigate to the CASE SERIES LIBRARY page.
2. Select the frozen case series to unfreeze.

If a case series is frozen, the Cases column displays a snowflake icon for that series.

The **Un-freeze Case Series** button is enabled *only if* you select a case series that is frozen.

3. Click **Un-freeze Case Series**.

The Un-freeze Case Series dialog box appears.

4. From the **Justification** drop-down list, select the reason to unfreeze the case series.

Alternatively, you may enter your own justification text to explain why you are unfreezing the case series.

In addition, you may define the choices that Argus Insight lists for the Justification field if you have access rights to the Case Series Un-freezing Justification option in the List Maintenance tab on the ADMINISTRATION TOOLS page.

5. Click **OK**.

The system retrieves the latest information for all the cases in the series, refreshes the CASE SERIES LIBRARY page, and displays the updated case series in the list.

In addition, system removes the snowflake icon from the Cases column because the case series is no longer frozen.

Using the Link to Argus Safety Medical Review

On the ACTIVE CASE SERIES page, you can click a link in the Case Number column to access Argus Safety and open the Medical Review dialog box in read-only mode.

All reports that can be executed from the Medical Review dialog box are available to you.

ACTIVE CASE SERIES

Name :
Study_429F

Choose Elements

Case Number	Report Type
ENTO_1998DE000020	RAT
ENTO_1998DE000037	STR
ENTO_2002DE000005	SPT
ENTO_2003DE000003	SPT

You may not be able to link successfully to the Medical Review dialog box for the following reasons:

- If you do not have access to the case from an Argus Safety perspective, the system displays the following message:
`user_name` does not have access to the case in Argus Safety.
- If you try to access a case that has been deleted since the last ETL, the system displays the following message:
This case has been deleted in Argus Safety since the last ETL.
- If Oracle Access Manager (OAM) is not enabled in Argus Safety and Argus Insight, *and* you log in to Argus Insight without logging through Argus Safety, the system displays the following message:
`user_name` is not logged into Argus Safety.

Generating and Scheduling Standard Reports - BIP

Argus Insight provides built-in Reports that you can run on active case series to analyze your company's safety, workflow, and product data.

This chapter includes the following topics:

- [About BIP Standard Reports](#)
- [Working in the Reports Page](#)
- [Generating Reports](#)
- [Scheduling and Associating Reports Against a Query or Case Series](#)

In addition to the preformatted and predefined BIP standard reports, you can create custom reports using the BI Publisher tool. For more information, see [Chapter 9, "Creating Custom Reports - BIP."](#)

About BIP Standard Reports

Although BIP standard reports are predefined reports, you can define pre-filters before generating a BIP standard report to have the report output display information only about specific types of cases. Pre-filters let you narrow down the case series further so that the system runs the report only on those cases that conform to the pre-filter criteria.

For example, suppose your case series consists of cases that were reported in *all countries* for a particular product. However, you only want information about cases reported in the *United States*. In this case, you can specify a pre-filter such that the report output includes only those cases that were reported in the United States.

Case Series, ETL, and Association

Because a case series might become obsolete each time the data mart is refreshed by running an ETL, you may need to generate the case series again before generating a BIP standard report.

Alternatively, you can directly associate a *query* (QBE, filter, or advanced condition) to a BIP standard report to avoid manual generation of the case series.

Browser Configuration

Before using Argus Insight to generate reports, configure the browser as defined in the *Oracle Argus Insight Installation Guide*.

Report Cover Page

Figure 8–1 shows a sample cover page of the report when it is generated in PDF format. The report cover page has three main sections:

- Page header
- Page contents
- Page footer

You can customize some of the information on the report cover page. The sections that follow provide more information about each component of the cover page.

Figure 8–1 Sample Report Cover Page

The figure shows a sample report cover page with the following structure:

- Page Header:** Contains the Oracle logo, the text "Page Header", a "General" tab, and the date/time "23-NOV-2012 02:57 GMT-8".
- Page Contents:** Includes the report title "Report2", category "COI US", "Report Filters/Prompts:", "Start Time of Last ETL Run:" (23-nov-2012 02:02:00 GMT-8), "Case Count:" (Total Count of Cases in Hist: 519), "Case Series Name:" (CaseSeries1_A1702_RW4), and "Case Series Criteria:" (COI is equal to 'UNITED STATES').
- Page Footer:** Contains "a1702_rw4 - Ent2new", "Confidential", and "Page 1 of 74".

Page Header

The page header of the report cover page includes the following information:

- Company logo. The upper-left box is a placeholder for a logo. You can configure your company logo to print in this space.
- Name of the category to which the selected report belongs. For example, Compliance, Management, or Pharmacovigilance.
- Date and time (Greenwich Mean Time [GMT]) that the report was run.

Page Contents

The page contents of the report cover page includes the following information:

- Title of the selected report.

- Report subtitle. You configure the subtitle when you run the report. Subtitles are useful in further defining the contents of the report. For example, 01-JAN-2000 to 31-DEC-2012.
- Filters defined for the selected report.
- Start date and time (GMT) of the last successful ETL run.
- Count of the total number of unique cases in the case series.
- Name of the saved case series on which the report has been executed.
 - Reports that are run on frozen case series data include the following text next to the case series name on the report:

The data in this report was frozen as of *date_and_time*.

Time is the database system time with the GMT offset.
 - Reports that are run on normal case series data include the following text next to the case series name on the report:

The case series was last modified on *date_and_time*.
- Query criteria to get case series on which the report has been executed.

Page Footer

The page footer of the report cover page includes the following information:

- Name of the user who executed the report.
- Confidential text. You can configure the text that prints in the center of the page footer.
- Page number (Page *x* of *y*).

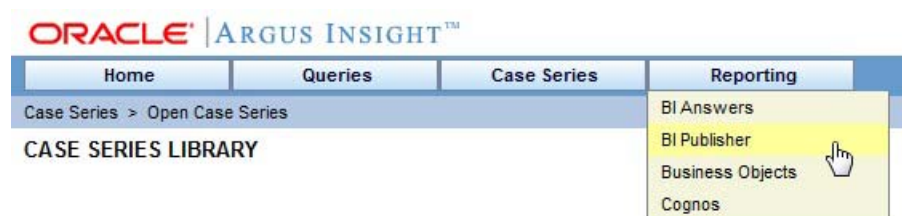
In addition, some reports include a placeholder in the footer for another logo. You can configure the image for the logo.

Working in the Reports Page

The Reports page, lists all the BI Publisher reports built in to Argus Insight.

To display the Reports page:

1. Select **Reporting > BI Publisher**.



The BIP login page appears in new window.

2. Log on to the BI Publisher tool.

The BIP Home page appears.
3. Click **Catalog**.
4. In the **Folders** section, navigate to **Shared Folders > Argus Insight > General > Reports**.

The **Generic Line Listing Report** in **LE** and **RTF** formats appears in the right pane.



Generating Reports

To generate a report using the BI Publisher tool:

1. Click the **Report** link or **Open** on the **Reports** page.

The **Generic Line Listing Report-LE** page appears.



2. Enter the values for all the fields and select the Output Type.



3. Click **Apply**.

The values entered are displayed in the generated report.



For more information on Viewing Reports using the BI Publisher tool, refer to the **Viewing a Report** section of the *Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Publisher*.

Scheduling and Associating Reports Against a Query or Case Series

You may refer to the **Creating Report Jobs** and **Viewing and Managing Report Jobs** sections of the *Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Publisher* for information on Scheduling and Associating Reports against a query or a case series.

Creating Custom Reports - BIP

In addition to the preformatted BIP standard reports, the BI Publisher tool also enables you to create custom reports.

This chapter, which explains how to use the custom report tools, includes the following topics:

- [Creating a New Report](#)
- [Editing Reports](#)
- [Changing the Report Layout](#)

Creating a New Report

Creating a new report using the BI Publisher tool comprises two parts:

- Creating Reports
- Creating Data Models

For information on creating reports using the BI Publisher tool, refer to the **Creating Reports and Layouts** section of the *Oracle Fusion Middleware Report Designer's Guide for Oracle Business Intelligence Publisher*.

For information on creating Data Models, refer to the *Oracle Fusion Middleware Data Modeling Guide for Oracle Business Intelligence Publisher*.

Editing Reports

For information on editing reports, refer to the **Creating and Editing Reports** section of the *Oracle Fusion Middleware Report Designer's Guide for Oracle Business Intelligence Publisher*.

Changing the Report Layout

For information on changing the Report Layout, refer to the following sections of *Oracle Fusion Middleware Report Designer's Guide for Oracle Business Intelligence Publisher*:

- Creating BI Publisher Layout Templates
- **Creating RTF Templates**
- Creating RTF Templates Using the Template Builder for Word

In addition, you may also refer to the following sections of the *Oracle Argus Insight Extensibility Guide*:

- **Extend Current Data Model** — This section explains the steps to extend the existing report.
- **Add New Data Set** — This section explains the steps to add new data set in BIP data model.
- **BIP Report Templates** — This section explains the steps to add or modify existing layout or report templates.

Generating OBIEE Answers and Working on Aggregate Analysis - Sample Dashboard

Argus Insight provides an out-of-the-box RPD for analyzing the data of aggregated reports generated through Argus Safety or BI Publisher.

Note: Analysis can be done on the RPD once the Argus Mart ETL has brought all the necessary data from BIP Enabled Argus Safety.

This chapter includes the following topics:

- [Argus Insight Catalog](#)
- [About OBIEE Aggregate Analysis - Sample Dashboard](#)
- [Working on BI Answers](#)

Argus Insight Catalog

The following components are available as part of the Argus Insight Catalog:

- Aggregate Analysis - Sample Dashboard — Provides Dashboard and Page Level prompts, and displays data on Sample Report based on these prompts.
- Dashboard Prompt — Enables selection of the Enterprise ID.
- Page Prompts — Comprises three-level page prompts: Aggregate Configuration Name, Report Form Name and Report Type.
- Sample Line Listing — Generates as Sample Line Listing Report comprising the following dimensions:
 - Case Number
 - Product Name
 - Event Reported
 - Event Seriousness
 - Event Listedness
 - As Reported Causality
- Sample Report — Generates as Sample Report comprising the following dimensions:
 - Initial Receipt Year

- Product Name
- Event Reported
- Event Seriousness
- Case Count

About OBIEE Aggregate Analysis - Sample Dashboard

To view OBIEE Aggregate Analysis - Sample Dashboard:

1. From Argus Insight, navigate to Reporting > BI Answers.

The OBIEE URL is opened in a new window as configured in the Argus Insight > List Maintenance > Profile Switch.

The screenshot shows the Oracle Argus Insight Administration Tools interface. At the top, there is a navigation bar with tabs for Home, Queries, Case Series, and Reporting. Below this is a sub-navigation bar with Administration Tools and BI Answers. The main content area is titled Administration Tools and contains several sub-sections: Personal Options, List Maintenance (selected), Security, ETL Scheduler, and Audit Log. The List Maintenance section is further divided into List Maintenance Items and Attributes. The List Maintenance Items list includes Profile Switches (highlighted), EU Countries, Workflow Management, Categories, Duration Value Bands, Derivation Functions, Case Series Modification Justification, and Case Series Un-Freezing Justification. The Attributes list includes various system parameters such as ARGUS INSIGHT APPLICATION DATA SOURCE, ARGUS MART DB NAME, ARGUS MART USER NAME, ARGUS MART USER PASSWORD, BI ANSWERS WEB URL, BIP WEB URL, BO WEB URL, COGNOS AUTHENTICATION ENTERPRISE, COGNOS SINGLE SIGN ON ENABLED, COGNOS WEB URL, CUSTOM HELP URL, CUSTOM ROUTINE AFTER INCREMENTAL ETL, CUSTOM ROUTINE BEFORE INCREMENTAL ETL, EMAIL SENDER ADDRESS, ETL DATA EXCLUSION, ETL EMAIL RECEIVER ADDRESS, ETL EMAIL SETUP, FAILED RECIPIENTS STATUS EMAIL ADDRESS, FORCE SECURE COOKIES, KEEP REPORT DATA, and LEGACY REPORTS CONFIGURATION.

2. Go to Dashboard > Aggregate Analysis - Sample Dashboard.

A sample dashboard as available in Argus Insight catalog, will generate a report based on the selected prompt values.

Figure 10–1 Aggregate Analysis - Sample Dashboard

Aggregate Analysis - Sample Dashboard

Home Catalog Favorites Dashboards New Open Signed In As admin

Dashboard Prompt

Enterprise: 1

Apply Reset

Page level Prompts

Aggregate Configuration Name: PMAR AN TEST DRJ Report Form Name: PMAR Report Type: Draft

Apply Reset

Aggregate Analysis - Sample Report

Sample Report
Time run: 11/21/2014 3:33:56 PM

Initial Receipt Year	Product Name	Event Reported	Event Seriousness	# Case
2012	Retrovector	Pyrexia	Serious	1
2013	Begin this is blinded name maximized END	Asthma	Non-serious	1
		Cardiac stress test abnormal	Non-serious	1
		Pain	Serious	1
	Tegretol	Asthma	Non-serious	1
		Cardiac stress test abnormal	Non-serious	1
		Pain	Serious	1

Enterprise ID is equal to 1
and Report Configuration Name is equal to PMAR AN TEST DRAFT
and Report Form Name is equal to PMAR
and Report Type (D/F) is equal to Draft

The Sample Report displays the data based on the prompts available on the dashboard, such as:

- Enterprise ID
- Aggregate Configuration Name
- Report Form Name
- Report Type

Figure 10-2 Sample Report

ORACLE Business Intelligence

Sample Report

Sample Report
Time run: 11/21/2014 2:45:47 PM

Initial Receipt Year	Product Name	Event Reported	Event Seriousness	# Case
1997	CALCIUM	ANAPHYLACTIC SHOCK	Serious	1
		Headache NOS	Non-serious	1
		Nausea	Non-serious	1
		Pruritus NOS	Serious	1
		Pyrexia	Non-serious	1
		Urticaria NOS	Non-serious	1
	Doxorubicin HCL	ANAPHYLACTIC SHOCK	Serious	1
	Doxorubicin or Comparator	ANAPHYLACTIC SHOCK	Serious	1
		Headache NOS	Non-serious	1
		Nausea	Non-serious	1
		Pruritus NOS	Serious	1
		Pyrexia	Non-serious	1
		Urticaria NOS	Non-serious	1
	HERACLIN	ANAPHYLACTIC SHOCK	Serious	1
		Headache NOS	Non-serious	1
		Nausea	Non-serious	1
		Pruritus NOS	Serious	1
		Pyrexia	Non-serious	1
		Urticaria NOS	Non-serious	1
	IBUPROFEN	ANAPHYLACTIC SHOCK	Serious	1
		Headache NOS	Non-serious	1
		Nausea	Non-serious	1
		Pruritus NOS	Serious	1
		Pyrexia	Non-serious	1
		Urticaria NOS	Non-serious	1

Rows 1 - 25

You may drill-down based on the Case Count Dimension.

Note: By default, the drill-down option is available only for Sample Dashboard. For Custom Dashboards, add the drill-down option manually.

- To view the Sample Line Listing Report, click the **case count**.

Figure 10–3 Sample Line Listing Report

ORACLE Business Intelligence

Sample Line Listing

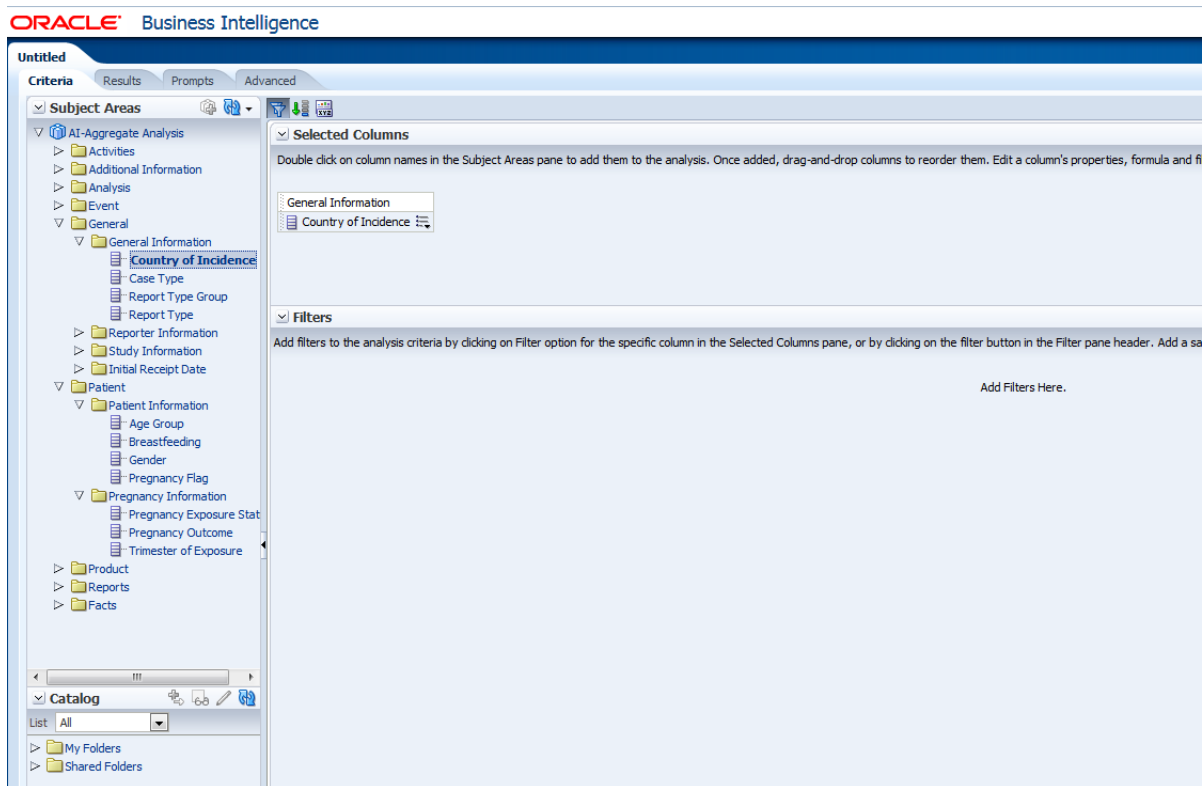
Time run: 11/21/2014 3:01:00 PM

Case Number	Product Name	Event Reported	Event Seriousness	Event Listedness	As Reported Causality	
09US000000001	Ampicillin	Post procedural vomiting	Non-serious	Unlisted	Unknown	
09US000000005	200 MAX Ingredient Added	Pain	Non-serious	Unknown	Unknown	
		Pyrexia	Non-serious	Unknown	Unknown	
	Activase	Pain	Non-serious	Unknown	Unknown	
		Pyrexia	Non-serious	Unknown	Unknown	
COPY CASE E2B CHILD	Tegretol	Premature baby	Serious	Unlisted	Unknown	
E2B CHILD	Tegretol	Premature baby	Serious	Unlisted	Unknown	
E2B DUP 1	Nutropin	Arrhythmia	Serious	Unlisted	Possible	
		Atrial fibrillation	Serious	Unlisted	Possible	
		Atrial flutter	Serious	Unlisted	Unknown	
		Blood potassium decreased	Serious	Unlisted	Unknown	
		Loss of consciousness	Serious	Unlisted	Possible	
		Pulse absent	Serious	Unlisted	Unknown	
		Respiratory arrest	Serious	Unlisted	Unknown	
		Retrograde amnesia	Serious	Unlisted	Possible	
		Ventricular fibrillation	Serious	Unlisted	Possible	
		Sucrose	Arrhythmia	Serious	Unlisted	Unknown
			Atrial fibrillation	Serious	Unlisted	Unknown
			Atrial flutter	Serious	Unlisted	Unknown
	Blood potassium decreased		Serious	Unlisted	Unknown	
	Loss of consciousness		Serious	Unlisted	Unknown	
	Pulse absent		Serious	Unlisted	Unknown	
	Respiratory arrest		Serious	Unlisted	Unknown	
	Ventricular fibrillation		Serious	Unlisted	Unknown	

Working on BI Answers

To create new Analysis or Answers, navigate to New > Analysis, and select the dimensions from the **Subject Area**.

Figure 10–4 BI Answers — Home Page



The **Subject Area** displays all the dimensions created in the RPD.

For more information on these dimensions, refer to *Oracle Argus Insight Extensibility Guide > Appendix: Dimensions and their Mapping*.

Adding filters in Analysis

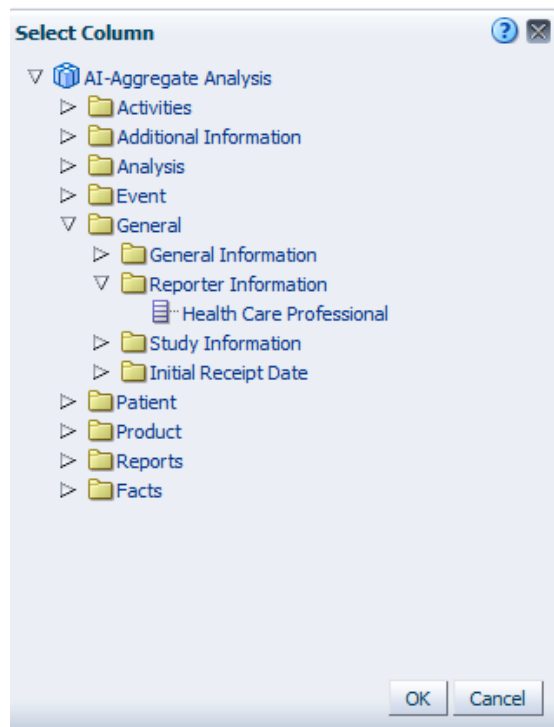
To add filters in the Answers, select a dimension, and click **Create a Filter**.

Figure 10–5 Adding Filters



To add filter on the non-selected columns, click **More Columns**.

A list of all the available dimensions appears.

Figure 10–6 Adding Filters — More Columns

Go to the Results tab, to view the result of the analysis based on the dimensions and filters.

Note: For more information on each dimension, refer to *Oracle Argus Insight Extensibility Guide > Appendix: Dimensions and Mappings*.

For more information on each field description, refer to *Oracle Argus Safety BIP Aggregate Reporting Extensibility Guide > Appendix A: Data Model*.

Working in a Multi-Tenant Environment

This chapter describes the unique features and key differences for running Argus Insight in a multi-tenant environment versus a single-tenant environment.

This chapter includes the following topics:

- [Assumptions and Constraints](#)
- [Data Segregation](#)
- [Login and Navigation](#)
- [Global Homepage](#)
- [Power Queries and Case Series](#)
- [Common Profile Switches](#)
- [ETL Scheduler](#)

Assumptions and Constraints

This section lists the assumptions and constraints with which the Argus Insight application works in a multi-tenant environment:

- **Single Sign-On Account (SSO)** — To have the capability to switch client context and to open Argus Insight from the Application Access Portlet, you must have a SSO account enabled.

When Argus Insight is configured for SSO, Cognos still uses the PowerReports namespace.
- **Accessing Argus Insight directly by using URL** — It is expected that customers will pass the internal enterprise ID as a URL parameter for the Argus Insight application to open with the appropriate enterprise context. If the enterprise ID is not passed, the system validates the user against the default enterprise.
- **Global User Management** — To apply updates to the *Synchronizable* fields for all the enterprises in the system, you must maintain some administrative users in Argus Insight. Use the User and Group Administration options in the Security tab on the ADMINISTRATION TOOLS page to modify user accounts and enable access for all enterprises in the system.
- **User-Enterprise Association** — To copy a user account from one enterprise to another, you must have already set up the appropriate user groups in the target enterprise. Otherwise, the user association will fail with an appropriate error message.

- **New User Creation/Association** — Argus Insight lets you use the same user ID to create different users across multiple enterprises. However, use this feature *only if* you do not expect to share the users across enterprises.

If you expect to share users across multiple enterprises, do not use the same user ID to create different users across different enterprises. Instead, create the user in one enterprise, and then use Global User Management to associate the user to other enterprises.

- **New Enterprise Setup** — It is expected that you will create and choose appropriate enterprises with generic configuration data that can be used as a source for copying the configuration data to create new enterprises.

Power Queries used within any configuration item is recommended to ensure that the values being copied from the source enterprise are appropriate for the newly created enterprise.

The following items are common for all enterprises:

- MedDRA and WHO dictionaries
- Default enterprise

- **Post-Database Upgrade Considerations** — There are no post-database upgrade considerations for existing users.

Data Segregation

Having a system that can partition client data within a single, access-driven database significantly reduces operational and ownership costs for the client. Argus Insight achieves this objective through database segregation.

The entire Argus Insight application, including all its components and data, have been partitioned by an enterprise ID. This ID is a unique, customer-specified identifier.

Module-Wise Impact

[Table 11–1](#) describes the modules in Argus Insight as per their data segregation status in Clinical Research Organization mode (CRO mode) and hosting installations.

Table 11–1 Data Segregation Status for Argus Insight Modules

Module	Data Segregation	Notes
Power Query	Yes	Displays QBEs, filters, and advanced conditions only for one enterprise at a time, to the logged-in user. The type of display is based on the selected enterprise.
Case Series	Yes	Retrieves cases only from the logged-in enterprise. The Case Series library displays the case series belonging to the logged-in enterprise only.
MedDRA Dictionary and SMQs	No	Each enterprise can configure a specific version of the MedDRA dictionary. A single copy of each version is to be shared by the enterprises.
WHO Dictionary	No	Each enterprise can configure a specific version of WHO Drug dictionaries (B2 as well as C formats). A single copy of each version is to be shared by the enterprises.
ETL	No	The ETL schedule is universal across all enterprises. Any user with administrator privileges who has access to this portlet can view and modify the ETL schedule. When an enterprise is added to an existing CRO setup, the Initial ETL can also run for individual new enterprises. The Initial/Reinitial/Incremental ETL cannot be run in parallel at any point of time in the application.
BI Tool	No	A single BI Tool supports all the enterprises. When you log in to BI Tool directly, you can see all the common objects as well as the enterprise-specific objects that are accessible to you. When you run a report, you can access the cases for a specific enterprise only. For reports that you can access, you can run the report against any enterprise data for which you have access.

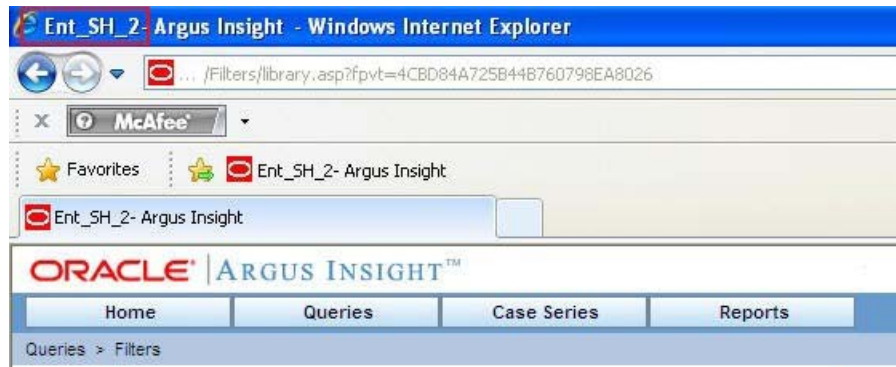
Enterprise Short Name in Argus Insight

The *Enterprise Short Name* is an abbreviated, unique name of a client. You can configure Argus Insight to display the Enterprise Short Name in the title bar for the Argus Insight application.

The **Display Enterprise Short Name in Application Header** check box in Global Enterprise Management controls the display of the Enterprise Short Name.

If this check box is selected, the Enterprise Short Name is displayed in the Argus Safety header along with database name (*DB_Name – Enterprise_Short_Name*), where *Enterprise_Short_Name* is the unique short name of the enterprise.

In addition, the Argus Insight application displays the Enterprise Short Name in the title bar. For example, the following illustration shows **ABC Pharma**, which is a sample Enterprise Short Name, in the title bar:



If the **Display Enterprise Short Name in Application Header** check box is not selected, Argus Insight does not display the Enterprise Short Name in the title bar.

Login and Navigation

Clinical Research Organization (CRO) users can operate on only specific enterprises. Users have access to only certain Argus Insight modules.

Note: The default enterprise in Argus Insight is the same as the default enterprise configured in Argus Safety.

Single Sign-On Accounts

Having a single sign-on account (SSO account) for the modules that you have access to and providing navigation to these modules simplifies your login and authentication process.

With a SSO account, your login authentication is done using a centralized authentication system. Therefore, you do not need to enter your login credentials for each application you access, every single time.

In multi-tenant installations, Global Homepage and Argus Insight are two different applications that are available to you, other users, and CRO/Hosting administrators.

Using Separate URLs to Access the Applications

The Global Homepage and Argus Insight web applications have separate URLs, which can be accessed independent of each other.

When you enter the URL of either the Global Homepage or Argus Insight application, the SSO module authenticates your credentials and allows access to these applications without asking for any user credentials.

- For Global Homepage, if the SSO authentication fails for your account, the system displays an appropriate error message.
- For Argus Insight, if the SSO authentication fails for your account, the system displays an appropriate error message in the Argus Insight login screen.

In this scenario, Argus Insight does not display Argus Safety buttons on the top navigation bar because the system expected you to access these applications from the Application Access Portlet on the Global Homepage. These applications are available to be opened in separate windows.

Opening Argus Insight from Other Applications

To access Argus Insight from other applications, you can either:

- Open Global Homepage and select the Application Access Portlet
- Open Argus Safety and click the Argus Insight link

In this scenario, Argus Insight opens in a separate browser window for either the enterprise you selected in the Application Access Portlet or the enterprise you selected in the Argus Safety.

- When you log out of Argus Insight, the system closes Argus Insight and its child windows after prompting you to save any unsaved changes. The Global Homepage window is not affected when you log out of Argus Insight.
- When you click **Close** in the Global Homepage application, only the Global Homepage closes. The Argus Insight window is not affected when you close Global Homepage.

If Argus Insight is defined as the default application in Argus Console for your account and you try to log in to Argus Safety by using the direct Safety link, the Argus Insight application opens. Argus Insight displays the Argus Safety button in the top navigation bar, based on whether you logged in using a SSO account and have access to Argus Safety.

Enterprise Switching

The capability to switch enterprises within the same session gives you significant usability benefits.

You must have a SSO account enabled if you want to switch enterprise context and open Argus Insight from within the Argus Safety application or the Application Access Portlet on the Global Homepage.

The system lets you open Argus Insight in a separate window with the context set to a specific active enterprise from Argus Safety and Application Access Portlet on the Global Homepage.

You can switch the context to a different enterprise from Global Homepage without logging out.

If Argus Insight is already opened for an enterprise and you switch to a different enterprise from the Application Access Portlet, the system displays a message before switching.

Direct Access

You can access Argus Insight directly by using the Argus Insight application URL. The system checks if the enterprise ID is already present in the URL request. If the enterprise ID exists, the system opens Argus Insight for that enterprise.

Global Homepage

Argus Insight provides a Global Homepage that can host multiple portlets. With this feature, CRO users can now access different views of their work items for Argus Safety.

A CRO can access the following modules from the Global Homepage:

- [Application Access Portlet](#) (which allows access to Argus Insight for different enterprises)

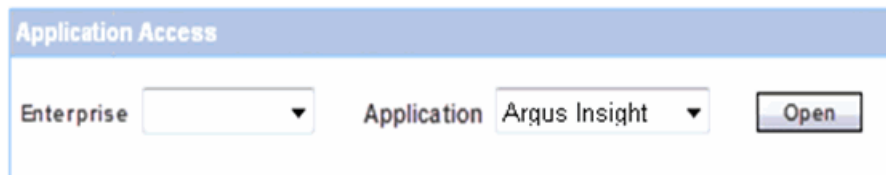
- [Global Enterprise Management Portlet](#)
- [Global User Management Portlet](#)

Application Access Portlet

You can use the Applications Access portlet within the Global Homepage to start Argus applications for any enterprise to which you have access privileges.

If you have access to both Argus Safety and Argus Insight, this portlet lets you select between Argus Safety and Argus Insight.

Use the **Enterprise** and **Application** fields to make your selections, and then click **Open** to access the selected application.



Global Enterprise Management Portlet

The Global Enterprise Management portlet lets you define and manage enterprises easily, as per the configuration of the already existing enterprises. You can access this portlet from the Global Homepage provided you have the proper privileges.

From the Global Enterprise Management portlet, you can:

- Copy the enterprise created in Argus Safety to Argus Insight
- Copy the configuration data from an existing enterprise in Argus Insight

Note: The Argus Insight module is available in the Global Enterprise Management portlet *only if* the **Safety to Insight** database link is set up in the database.

If this link is not created, the **Copy Enterprise to Insight** button does not appear on the Global Enterprise Management screen.

Oracle recommends that when you click **Copy Enterprise to Insight**, you select the same enterprise as the source enterprise with which the Argus Safety enterprise has been created.

Overview of the Global Enterprise Management Page Layout

The Global Enterprise Management portlet, see [Figure 11-1](#), has two panes:

- The left pane lists all the enterprises of the portal user, in a tree-view structure.
- The right pane, by default, loads as blank, in disabled mode.

When you select an enterprise from the left pane, the right pane refreshes and displays the details for the selected enterprise.

Figure 11–1 Global Enterprise Management Portlet

The screenshot displays the Global Enterprise Management Portlet interface. On the left, a 'Browser' pane shows a tree view of 'Enterprises' with sub-items 'PF1', 'Amgen', and 'Novartis'. The main area is titled 'PF1' and contains the following sections:

- Enterprise Name:** 'Pfizer' (text input), Active (checkbox).
- Enterprise Short Name:** 'PF1' (text input).
- Contact Information:**
 - Title:** 'Dr' (text input)
 - First Name:** 'B' (text input)
 - Middle Name:** (text input)
 - Last Name:** 'Williams' (text input)
 - Address:** (text area)
 - City:** (text input)
 - State/Province:** (text input)
 - Postal Code:** (text input)
 - Country:** (text input)
 - Department:** '228-987-0213' (text input)
 - Phone:** (text input)
 - FAX:** (text input)
 - Email Address:** (text input)
 - Notes:** (text area)
- Associate Users:**
 - Select Users From:** 'Baseline' (dropdown)
 - Available Users to Copy:** List containing 'atsushi', 'baraj', 'barajv', 'bikannusa', 'charlie', 'charlej'.
 - Users associated to this Enterprise:** List containing 'de reporting 1', 'de reporting 2', 'fuji', 'fukao', 'hiroki'.
 - Buttons: 'Add >', '< Remove', 'Add All >>', '<< Remove All'.

At the bottom, there are buttons for 'Add New Enterprise', 'Copy Enterprise to Insight', 'Save', and 'Print'.

Adding a New Enterprise

To create a new enterprise in Argus Insight, click **Add New Enterprise**.

Note: You can create a new enterprise in Argus Insight only after the enterprise and its details are entered and saved in Argus Safety.

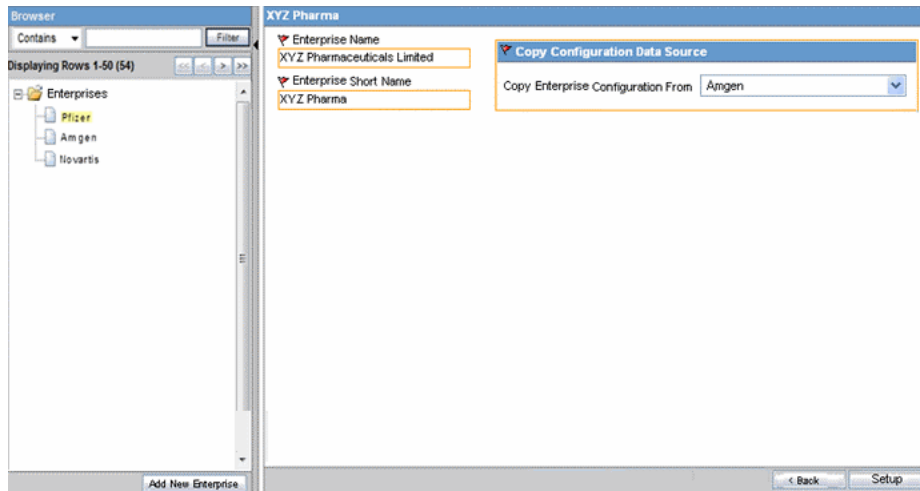
Copying an Enterprise

To copy an enterprise to Argus Insight:

1. Open the Global Enterprise Management portlet.
2. Click **Copy Enterprise to Insight**.

Note: The **Copy Enterprise to Insight** button is disabled for the default enterprise.

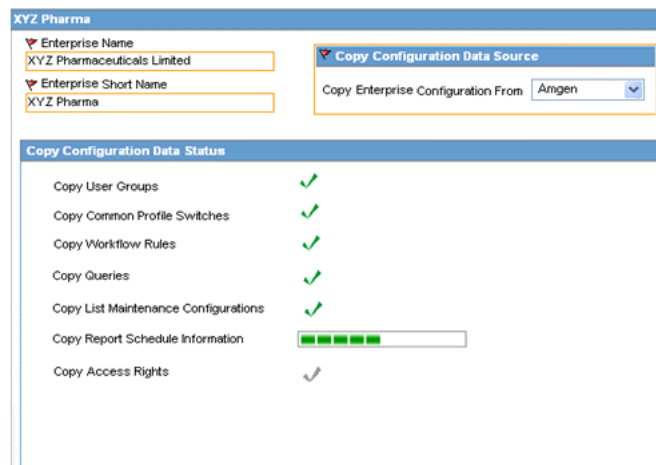
The system updates the right pane and displays information about the enterprise to copy. The details in the Enterprise Name and Enterprise Short Name fields are read-only.



3. From the **Copy Enterprise Configuration From** field, select an enterprise.
4. Click **Setup**.

(The **Setup** button is enabled only after you specify all mandatory enterprise information.)

The system copies all the configuration data from the enterprise that you selected and reports status information throughout the process.



When enterprise creation is completed for an enterprise, the **Copy Enterprise to Insight** button is disabled for that enterprise because enterprise creation in Argus Insight is a one-time operation.

Note: The **Copy Enterprise to Insight** button can be created in Argus Insight only after the enterprise and its details have been entered and saved in Argus Safety.

Once all the configuration data has been successfully copied, the user who is setting up the new enterprise is associated as a new user in Enterprise Manager, to the newly created enterprise partition.

The user attributes of the user get copied from the source enterprise.

See the *Oracle Argus Safety Administrator's Guide* for additional details about the Global Enterprise Management portlet.

Global User Management Portlet

The Global User Management portlet within the Global Homepage lets you associate yourself to multiple enterprises, and keep your user attributes consistent across all the enterprises.

All the Argus Insight users are created from Argus Safety Console only. See the *Oracle Argus Safety Administrator's Guide* for additional details.

Power Queries and Case Series

Power queries include QBEs, filter value sets, and advanced conditions.

In a multi-tenant environment, power queries and case series work as follows:

- A new power query/case series created and saved stores the value of the enterprise along with the other details.
 - The value for the enterprise is derived from the logged-in enterprise.
 - The Query and Case Series libraries display only the power query/case series specific to the logged-in enterprise.
 - The Active function retrieves the active power query/case series for the user within the enterprise.
- You can grant permissions on a power query/case series to the groups that belong to the currently logged-in enterprise. The Permissions dialog box displays the User Groups that are associated with the logged-in enterprise.
- The power query/case series created by users that are currently disabled or has been disassociated from the enterprise through which the power query/case series was created, are displayed in the respective library for users who have access to the respective power query/case series.

The power query/case series created by the users are deleted when the user account is deleted.

- When you execute a power query, the results display the cases from the currently logged-in enterprise only.
- All Query and Case Series libraries display the data pertaining to the logged-in enterprise only.
- SSO must be enabled to have the capability to switch client context and to open Argus Insight from the Application Access Portlet.
- There are no post-database upgrade considerations for existing users.

Importing a Case Series

When you import a case series, the system validates whether each case being imported belongs to the logged-in enterprise.

- If the case belongs to the current enterprise, the system imports the case successfully.
- If the case does not belong to the current enterprise, the system rejects the import. The log file displays the following message against the specific case number:

Case Rejected

Modifying a Case Series

When you add a new case number to an existing case series, the system validates whether the case being added belongs to the logged-in enterprise.

- If the case belongs to the current enterprise, the system adds the specified case into the case series.
- If the case does not belong to the current enterprise, the system does not add the case and displays the following error message:

Case Number does not exist.

Deleting a Case Series

Deleting a case from a case series functions the same way in multi-tenant and single-tenant installations.

Exporting a Case Series

When you export a case series to a Microsoft Excel document, the system can include the enterprise as part of the export details.

If you select the **Display Enterprise Short Name in Application Header** check box in Global Enterprise Management, the Case Series Details tab in the Excel document displays the Enterprise Short Name. The system derives the value from the currently logged-in enterprise.

The Enterprise Short Name is displayed in CRO, hosting, and single-tenant mode of an installation.

Common Profile Switches

All the global-level switches are displayed, updated, and audit logged in the default enterprise.

To view or edit Profile Switches:

1. Click **Tools** on the Argus Insight global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Profile Switches**.

The Attributes section is updated with the profile switches that you can configure.

ETL Scheduler

Beginning with Argus Insight 7.0, administrators must assign the ETL Scheduler role to any user who needs to configure the schedule and run an ETL process. The ETL Scheduler role is available across all enterprises at a global level.

Argus Insight administrators can configure the ETL Scheduler role by modifying the user account listed in the Security tab on the ADMINISTRATION TOOLS page.

The ETL Scheduler screen can be displayed, updated, and audit logged from the default enterprise in a multi-tenant installation. However, only those users who have been assigned the ETL Scheduler role can view the ETL Scheduler screen.

Using the Administration Tools

This chapter provides information about using the Argus Insight administration tools. You use the tabs on the ADMINISTRATION TOOLS page to configure, maintain, and secure Argus Insight.

This chapter includes the following topics:

- [Support for Multibyte Characters](#)
- [Using Schema Creation Tool](#)
- [Opening the ADMINISTRATION TOOLS Page](#)
- [Configuring Personal Options](#)
- [Configuring Lists Maintenance](#)
- [Running the Extract, Transform, and Load Process](#)
- [Securing User Accounts, Groups, and Access Rights](#)
- [Viewing the Audit Log](#)

Support for Multibyte Characters

Beginning with Argus 5.1, the database was converted to accommodate multibyte characters. The Argus J structure was merged into Argus Safety 5.1, which included Argus field conversion from VARCHAR to CLOB data type.

To ensure compatibility Argus Safety, Argus Insight 5.1 and later supports the following field changes:

- Schema creation and validation — Data type changed from VARCHAR to CLOB
- Initial ETL and Incremental ETL — Transformation logic changed
- Database upgrade — Data type changed from VARCHAR to CLOB
- Power Queries — QBEs, filters, and advanced conditions validated and modified

Using Schema Creation Tool

Using the Schema Creation Tool (see [Figure 12-1](#)), you create the Argus Insight data mart structure. You create a link between the source Argus Safety database and the new Argus Insight data mart. The Extract Transform and Load (ETL) process uses this link to transfer data from your Argus database to the Argus Insight data mart for reporting purposes.

During the schema creation process, you create four database users: one user for logging in to the Argus Insight application, two other users who are schema owners, and one user for supporting private database links (DB Links).

Figure 12–1 Schema Creation Tool — Main Menu



The Schema Creation Tool provides the following options:

- **Create Schema** — Creates a new database schema for Argus Insight.
- **Schema Validation** — Validates a newly-created database schema.
- **Factory Data** — Loads the factory data into the database.
- **Initial ETL** — Runs the initial process of extracting, transforming, and loading data.
- **DB Upgrade** — Upgrades an existing Argus Insight 8.0 database to an Argus Insight 8.1 database.
- **Export Data** — Exports data.
- **Import Data** — Imports data.
- **Argus DBLink** — Creates a link between Argus Insight and Argus Safety.
- **Argus User Creation** — Lets you create Argus Insight users and roles.
- **Exit** — Exits from the Schema Creation Tool.

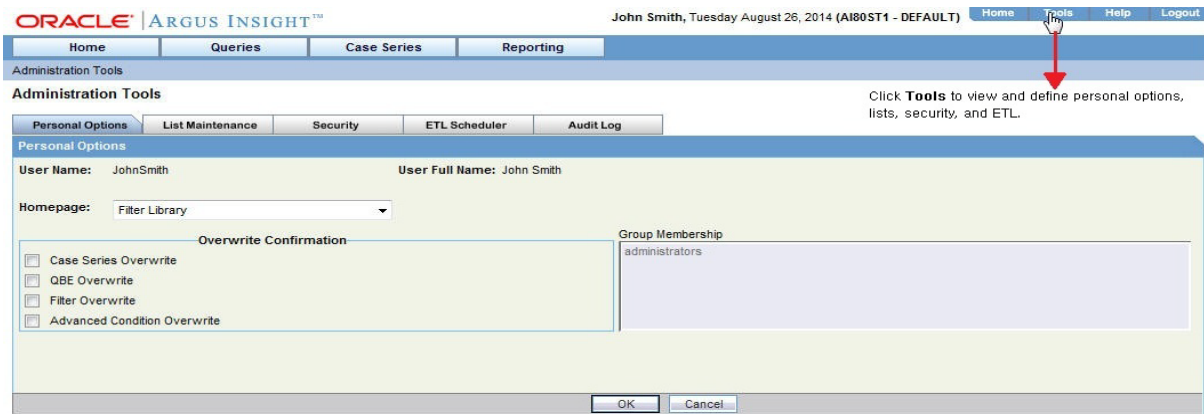
For detailed information about using the Schema Creation Tool to create the Argus Insight data mart structure, including the database link, users, and roles, see the *Oracle Argus Insight Installation Guide*.

Opening the ADMINISTRATION TOOLS Page

To access the Argus Insight administration tools, click **Tools** on the global toolbar in the upper-right corner of the page.

The ADMINISTRATION TOOLS page appears with the Personal Options tab in focus. See [Figure 12–2](#).

Figure 12–2 ADMINISTRATION TOOLS Page



Configuring Personal Options

Using the Personal Options tab on the ADMINISTRATION TOOLS page, you can:

- Specify the default Home page for Argus Insight
- Specify whether the system prompts you for confirmation before overwriting saved case series or queries
- View the groups for which you are a member

By default, the Personal Options tab is in focus when you open the ADMINISTRATION TOOLS page.

The Personal Options tab is available to all users. For more information about using the Personal Options tab, see "[Setting Your Personal Options](#)" on page 2-4.

Configuring Lists Maintenance

This section describes the following tasks that you can perform using the List Maintenance tab on the ADMINISTRATION TOOLS page:

- [Configuring the Argus Insight Application Profile Switches](#)
- [Configuring European Union Countries](#)
- [Mapping Case Workflow States](#)
- [Configuring Categories](#)
- [Configuring Duration Value Bands](#)
- [Configuring Derivation Functions](#)
- [Configuring Case Series Modification Justification](#)
- [Configuring Case Series Un-freezing Justification](#)
- * [Configuring Holiday Schedule Management](#)
- * [Configuring Product Designated Medical Event Configurations](#)
- * [Configuring Measurable Suppliers](#)
- * [Configuring Non-Core Sites](#)
- * [Configuring Acceptable Delay Justifications](#)

Note: * This List Maintenance item is available for configuration, if profile switch BO WEB URL is configured, and profile switch LEGACY REPORTS CONFIGURATION is set to 1.

Besides, when the Argus Insight Application Data Source profile switch is set to Argus Mart, then in the List Maintenance section, only **Profile Switches** and **Case Series Modification Justification** list maintenance items are available.

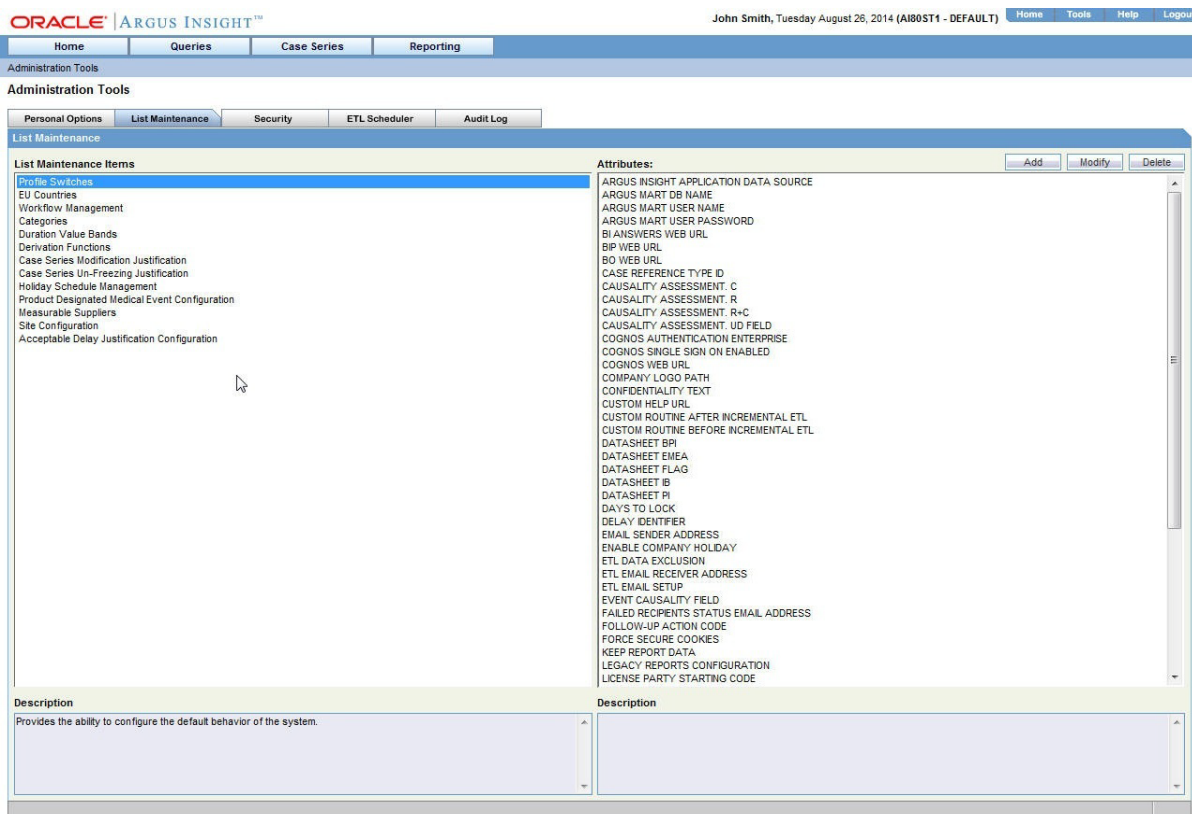
Configuring the Argus Insight Application Profile Switches

Profile switches are a collection of settings that let you configure the default behavior of Argus Insight. The default value of a profile switch can be predefined or based on user input. All profile switch values are case sensitive.

In general, you use the List Maintenance tab on the ADMINISTRATION TOOLS page (see [Figure 12-3](#)) to configure existing profile switches and to add new profile switches.

However, certain profile switches can only be configured through direct SQL statements.

Figure 12-3 List Maintenance Tab — Profile Switches



Consult your company's policies and the terminology used before configuring profile switches.

For detailed information about all the profile switches, see the following documents:

- *Oracle Argus Insight CMN Profile Enterprise Table Guide*

- *Oracle Argus Insight CMN Profile Global Table Guide*

In addition, the documents have a sample SQL for inserting profile switches and updating their values in the database.

Accessing and Modifying the Profile Switches

To access and modify the Argus Insight profile switches:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Profile Switches**.
The Attributes section is updated with the profile switches that you can configure.
4. Select a profile switch, and click **Modify**.
The Modify Attributes dialog box appears.
5. Modify the values, and click **OK**.
The profile switch is updated.

Adding a New Profile Switch

To add a new profile switch:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Profile Switches**.
The Attributes section is updated with the current profile switches.
4. Click **Add**.
The Add New Attribute dialog box appears.
5. Enter the profile switch name, key, and description.
6. Click **OK**.

Listing of the Common Profile Switches

[Table 12–1](#) lists the profile switches that you can configure using the options in the List Maintenance tab. For each profile switch, the table specifies the name of the switch, indicates whether the switch is a global-level or an enterprise-level switch, and provides a brief description.

All the global-level switches are displayed, updated, and audit logged in the default enterprise.

When profile switch ARGUS INSIGHT APPLICATION DATA SOURCE is set to Argus Mart, the following profile switched will NOT be available for configuration:

- KEEP REPORT DATA
- LEGACY REPORT CONFIGURATION (with default value set to 0, so that other reporting switches are no visible)
- POPULATE AFFILATE DATA

- POPULATE BLOB DATA
- POPULATE INTERCHANGE CLOB DATA
- POPULATE INTERCHANGE DATA

For more information about viewing and editing profile switches, see "[Configuring the Argus Insight Application Profile Switches](#)" on page 12-4.

Note: *This profile switch is available for configuration only when profile switch LEGACY REPORTS CONFIGURATION is set to 1.

Table 12–1 Common Profile Switches

Profile Switch	Switch Level	Description
ARUGUS INSIGHT APPLICATION DATA SOURCE	Enterprise	<p>Enables you to configure the data source for Argus Insight. You may run your queries for Argus Insight or Argus Mart depending on the value configured in this switch.</p> <ul style="list-style-type: none"> ■ Argus Mart — Enable queries on Argus Mart data source only. ■ Insight Mart — Enable queries on Argus Insight data source only. ■ Both (Insight Mart and Argus Mart) — You may choose between Insight Mart and Argus Mart data sources for creating and executing your queries. All the queries and case series created on these data sources can be identified in the application.
ARGUSMARTDBNAME	Enterprise	Specify the database instance name for the Argus Mart data mart. This information enables to connect Argus Insight with Argus Mart database.
ARGUS MART USER NAME	Enterprise	Specify the schema user created for Argus Insight in Argus Mart database. This user may perform all the background functions from Argus Insight application to Argus Mart database including querying and reporting.
ARGUS MART USER PASSWORD	Enterprise	Specify the password of the schema user created for Argus Insight in Argus Mart database that is, the password of user configured in ARGUS MART USER NAME.
BIP ANSWERS WEB URL	Global	Specifies the complete BI Answers Web URL for opening up the BI Answers home page. This URL can be for standalone BI Answers server or load balancer URL configured for multiple BI Answers servers. If BI Answers is configured for SSL, please make sure to use https with the URL.
BIP WEB URL	Enterprise	Specifies the URL for accessing the BI Publisher Home page. This URL can be for standalone BI Publisher server, or Load Balancer URL configured for multiple BI Publisher servers. If BI Publisher is configured for SSL, you must use https with the URL.
BO WEB URL	Enterprise	Specifies the complete BusinessObjects Web URL for opening the BusinessObjects Home page. This URL can be for standalone BusinessObjects server, or Load Balancer URL configured for multiple BusinessObjects servers. If BusinessObjects is configured for SSL, you must use https with the URL.
*CASE REFERENCE TYPE ID	Enterprise	Populates the RPT_CASE.FIRST_REF_NO column.

Table 12–1 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
*CAUSALITY ASSESSMENT. C	Enterprise	Used in BIP standard reports for Company Defined Causality.
*CAUSALITY ASSESSMENT. R	Enterprise	Used in BIP standard reports for Reporter Defined Causality.
*CAUSALITY ASSESSMENT. R+C	Enterprise	Used in BIP standard reports for Reporter Defined Causality and Company Defined Causality.
*CAUSALITY ASSESSMENT. UD FIELD	Enterprise	Used in BIP standard reports for user-defined field to determine causality.
COGNOS AUTHENTICATION ENTERPRISE	Global	Defines the short name of the enterprise from which all users are authenticated for Cognos login. All Argus Insight users must be a member of this template enterprise. On the Cognos Server, Cognos security is enabled only after this switch is configured.
COGNOS SINGLE SIGN ON ENABLED	Global	Determines whether Cognos is Single Sign On (SSO) enabled or not. This profile switch has one of the following values: <ul style="list-style-type: none"> ■ 1 — Cognos SSO is enabled ■ 0 — Cognos SSO is disabled (Default)
COGNOS WEB URL	Enterprise	Defines the complete Cognos Web URL for opening the Cognos Home Page. This URL can be Cognos URL for Standalone Cognos Server, or Load Balancer URL configured for multiple Cognos Servers. If Cognos is configured for SSL, you must use https with the URL. Example: http://<server name>/Cognos102 Default Value — Blank
*COMPANY LOGO PATH	Enterprise	Defines the location of the company logo on the local server. This logo prints in the report header.
*CONFIDENTIALITY TEXT	Enterprise	Defines the confidentiality text that prints in the running footer on each page in the report.
CUSTOM HELP URL	Enterprise	Defines the URL for your customized online help. If the URL is not valid, users receive the following error message: Error 404 - Page Not Found.
CUSTOM ROUTINE AFTER INCREMENTAL ETL	Global	Defines the full path of the custom routine (Oracle stored procedure) to be executed <i>after</i> Incremental ETL. If the routine fails or is not found, the administrator receives an email notification.
CUSTOM ROUTINE BEFORE INCREMENTAL ETL	Global	Defines the full path of the custom routine (Oracle stored procedure) to be executed <i>before</i> Incremental ETL. If this routine fails or is not found, then the ETL does not run and the administrator receives an email notification.
*DATASHEET BPI	Enterprise	Configures the user-defined fields for assessment of BPI Datasheet in the Product tab.
*DATASHEET EMEA	Enterprise	Configures the user-defined fields for assessment of EMEA Datasheet in the Product tab.
*DATASHEET FLAG	Enterprise	Sets the flag used during Incremental ETL to determine whether to populate the data in the four <i>DATASHEET</i> fields (DATASHEET BPI, DATASHEET EMEA, DATASHEET IB, DATASHEET PI) for all the cases or for only the modified cases.

Table 12–1 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
*DATASHEET IB	Enterprise	Configures the user-defined fields for assessment of IB Datasheet in the Product tab.
*DATASHEET PI	Enterprise	Configures the user-defined fields for assessment of PI Datasheet in the Product tab.
*DAYS TO LOCK	Enterprise	Configures the number of days to lock for a case.
*DELAY IDENTIFIER	Enterprise	Defines the delay text that ETL uses to populate the RPT_FOLLOWUP.CORE_DELAY_ROUTING_COMMENT field in the Supplier Performance Report and the Process Performance Report - Workflow.
EMAIL SENDER ADDRESS	Enterprise	Defines the email address of the person on whose behalf Argus Insight sends all email messages. If you leave the value blank, then Argus Insight sends no email messages.
ENABLE_AI_PROCESSING	Enterprise	<p>Note: Use Argus Safety Console to enable this profile switch.</p> <p>This profile switch must be set to Yes to link Argus Insight database to Argus Mart database.</p> <ul style="list-style-type: none"> ■ Yes — Enable Argus Insight Processing for Argus Mart. ■ No — Disable Argus Insight Processing for Argus Mart.
*ENABLE COMPANY HOLIDAY	Enterprise	<p>Defines company holiday calendar in due date calculation of Data Entry Performance Over Time Report (0 = Disable and 1 = Enable). This profile switch contains one of the following values:</p> <ul style="list-style-type: none"> ■ 1 — Includes COMPANY holidays in the calculations ■ 0 — Does not include COMPANY holidays in calculations
ETL DATA EXCLUSION	Global	Specifies whether to continue or cancel the ETL process if cases with erroneous data are found.
ETL EMAIL RECEIVER ADDRESS	Global	Defines the email address of each administrator who will receive email status messages of the ETL process. Use a semi-colon to separate each entry. If you leave the value blank, then Argus Insight sends no email messages.
ETL EMAIL SETUP	Global	Defines whether to send an email only after ETL failure, only after ETL success, or in either case.
*EVENT CAUSALITY FIELD	Enterprise	Determines which user defined field of the Event tab is to be displayed in the Case Reporter Type Listing.
FAILED RECIPIENTS STATUS EMAIL ADDRESS	Enterprise	Defines the email address of the user who will receive information regarding undeliverable email messages due to an invalid email ID or other error.
*FOLLOW-UP ACTION CODE	Enterprise	Configures the code that indicates a follow-up action is required.
FORCE SECURE COOKIES	Global	Defines whether the user must enter a SSL-enabled URL (HTTPS) to open the Argus Insight application.
KEEP REPORT DATA	Enterprise	<p>Represents a flag to determine if the Report Log Tables need to be populated or not.</p> <ul style="list-style-type: none"> ■ Y — Populate the Report Log Tables ■ N — Do not populate the Report Log Tables <p>Default Value — N</p>

Table 12–1 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
LEGACY REPORTS CONFIGURATION	Global	Determines if Legacy Report Configuration profile items are visible/invisible. Possible Values are: <ul style="list-style-type: none"> ■ 1 — Configuration Items are visible ■ 0 — Configuration items are not visible Default Value — 0
*LICENSE PARTY STARTING CODE	Enterprise	Configures starting code for a licensing party. Currently, this key is used for Process Performance Report - Notification.
LOG REPORT SQL	Global	Identifies if report SQL is to be logged. Possible Values are: <ul style="list-style-type: none"> ■ 1 — Yes ■ 0 — No Default Value — 0
MAXIMUM EMAIL ATTEMPTS	Global	Defines the maximum number of times the system attempts to send an email.
POPULATE AFFILIATE DATA	Enterprise	Defines whether to bring affiliate data into the data mart.
POPULATE BLOB DATA	Global	Defines whether to bring BLOB data into the data mart.
POPULATE CASE/CONFIGURATION DATA	Global	This profile switch contains one of the following values: <ul style="list-style-type: none"> ■ 1 — Populate all the data (both case and configuration data) ■ 0 — Populate configuration data only
*POPULATE DLL SLL REPORTS TABLE DATA	Enterprise	Defines whether to populate the RPT_CASE_EVENT_PRODUCT table required for DLL and SLL.
POPULATE INTERCHANGE CLOB DATA	Global	Defines whether to bring Interchange CLOB data into the data mart.
POPULATE INTERCHANGE DATA	Enterprise	Defines whether to bring Interchange data into the data mart.
*POPULATE NARRATIVE LANGUAGES TABLES	Enterprise	This profile switch contains one of the following values: <ul style="list-style-type: none"> ■ 1 — Table RPT_CNL_ENGLISH is populated ■ 0 — Table RPT_CNL_ENGLISH is NOT be populated For more information on Report List, refer to CMN_PROFILE_ENTERPRISE document.
*POPULATE RPT_REG_REPORTS COLUMNS	Enterprise	Defines whether to populate the extra columns of the RPT_REG_REPORTS table.
*POPULATE STUDY RECONCILIATION REPORT TABLE DATA	Enterprise	Defines whether to populate the FACT_PROD_LICENSE table required for the Study Reconciliation Report.
*PRODUCT LOGO PATH	Enterprise	Defines the full URL path to the image file of the product logo that prints in the header of certain reports.
*REPORT FOOTER LOGO PATH	Enterprise	Defines the full URL path to the image file of the product logo that prints in the footer of certain reports.
*ROUTING JUSTIFICATION ID	Enterprise	Contains LM_JUSTIFICATIONS.FIELD_ID value. This field fetches the List Maintenance values for Acceptable Routing Justification from the table LM_JUSTIFICATIONS.

Table 12–1 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
*SUBMISSION JUSTIFICATION ID	Enterprise	Contains LM_JUSTIFICATIONS.FIELD_ID value. This field fetches the List Maintenance values for Acceptable Submission Justification from the table LM_JUSTIFICATIONS.
*SUPPLIER FIELD ID	Enterprise	Contains LM_JUSTIFICATIONS.FIELD_ID value. This field fetches the List Maintenance Values for Measurable Suppliers configuration from the table LM_JUSTIFICATIONS.
*UDN COLUMN FOR SUPPLIER NAME	Enterprise	Defines the user-defined name (UDN) of the column in the Argus Safety CASE_MASTER table that contains the SUPPLIER NAME value.

Configuring European Union Countries

From the List Maintenance tab, you can configure the list of European Union countries for reporting purposes. You can add and remove countries as required.

Note: Countries configured as EU Countries are used in the 'Reporting Compliance Listing - Detail' report. EU countries are configured to identify cases for which Country of Incidence is from the list of configured EU countries. All the cases for which Country of Incidence is equal to EU countries appear with a '*' in the report output.

Table 12–2 lists the countries included in the default European Union list.

Table 12–2 Countries Included in the Default European Union List

Austria	Finland	Latvia	Portugal
Belgium	France	Liechtenstein	Romania
Bulgaria	Germany	Lithuania	Slovakia (Slovak Republic)
Cyprus	Greece	Luxembourg	Slovenia
Czech Republic	Hungary	Malta	Spain
Denmark	Iceland	Netherlands	Sweden
Estonia	Ireland	Norway	Switzerland
—	Italy	Poland	United Kingdom

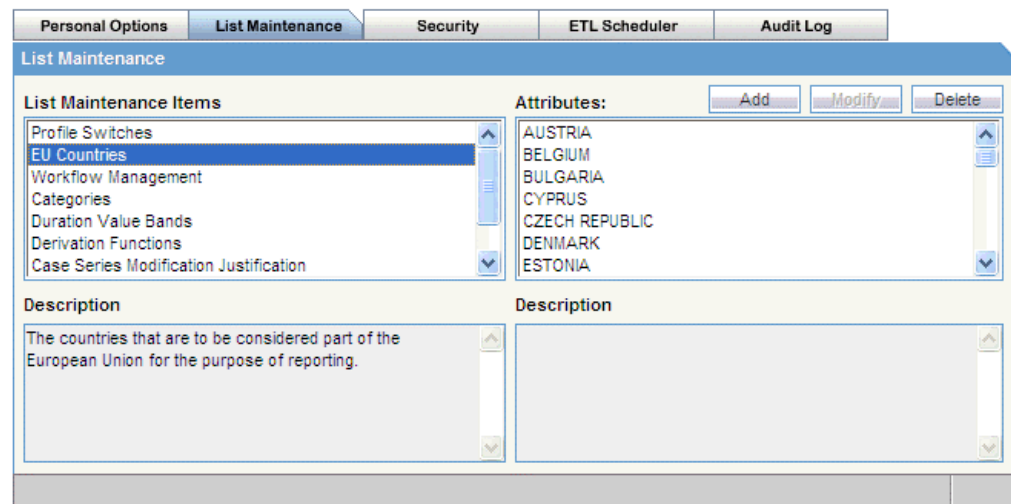
Adding a Country to the European Union List

To add a country to the list of countries in the European Union:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **EU Countries**.

The Attributes section is updated with the countries currently defined in the European Union list.

Administration Tools

4. Click **Add**.

The Add EU Countries dialog box appears.

5. Select one or more countries to add.

- To select more than one country, press and hold the CTRL key when you click each country.
- To select a range of countries, press and hold the SHIFT key when you click the start and end country in the range.

6. Click **OK**.

The specified countries are added to the list of countries in the European Union.

Deleting a Country from the European Union List

To delete a country from the European Union list:

1. Click **Tools** on the global toolbar.

The ADMINISTRATION TOOLS page appears.

2. Click the **List Maintenance** tab.3. From the List Maintenance Items section, select **EU Countries**.

The Attributes section is updated with the countries currently defined in the European Union list.

4. Select the country to delete from the list of European Union countries.

You can delete only one country at a time.

5. Click **Delete**.

A confirmation dialog box appears.

6. Click **OK**.**Mapping Case Workflow States**

Workflow is company-specific and your company may not use all the Workflow states.

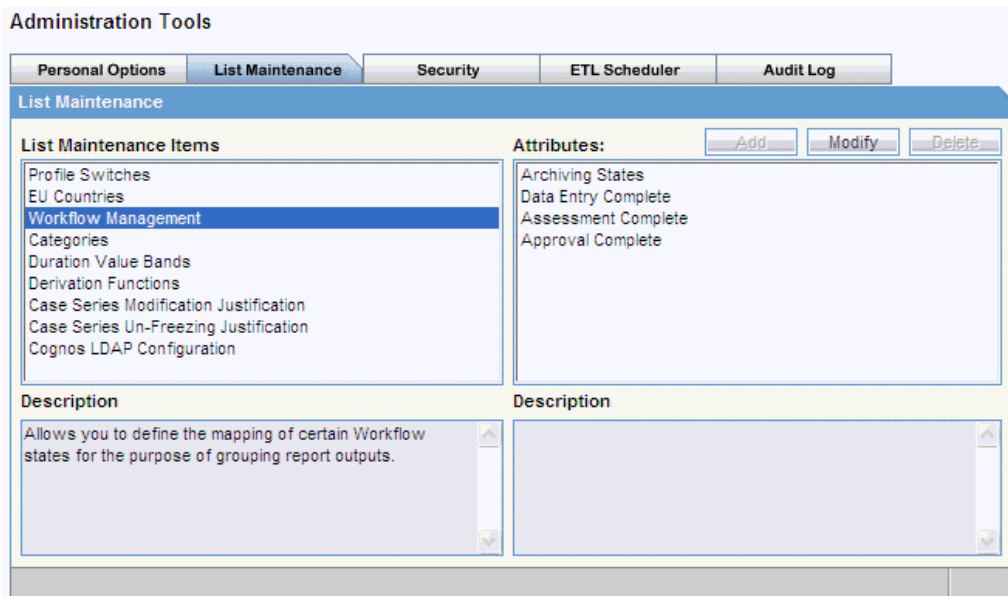
You can map all the site-specific workflow states to the following default groups for the purpose of grouping outputs of certain reports:

- **Archiving States** — All workflow states that are considered as archived/closed in Argus.
- **Data Entry Complete** — All workflow states that indicate completion of data entry in Argus.
- **Assessment Complete** — All workflow states that indicate completion of event assessment in Argus.
- **Approval Complete** — All workflow states that indicate that the case is ready for reporting after being locked in Argus.

Although the workflow mappings are preconfigured during the installation of Argus Insight, you can modify them by adding or removing workflow states from a group as required. However, you cannot add more groups or delete existing ones.

To configure workflow management for the Argus Insight application:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Workflow Management**.
The Attributes section is updated with the existing workflow groups.



4. Select a workflow group to change, and click **Modify**.
The Workflow Metrics - <selected workflow name> dialog box appears.
5. Modify the mappings.
 - To add a new workflow state to the group, select a state from the list on the left and click the right arrow (>).
 - To remove a workflow state from the group, select a state from the list on the right and click the left arrow (<).
6. Click **OK** to save the changes.

Configuring Categories

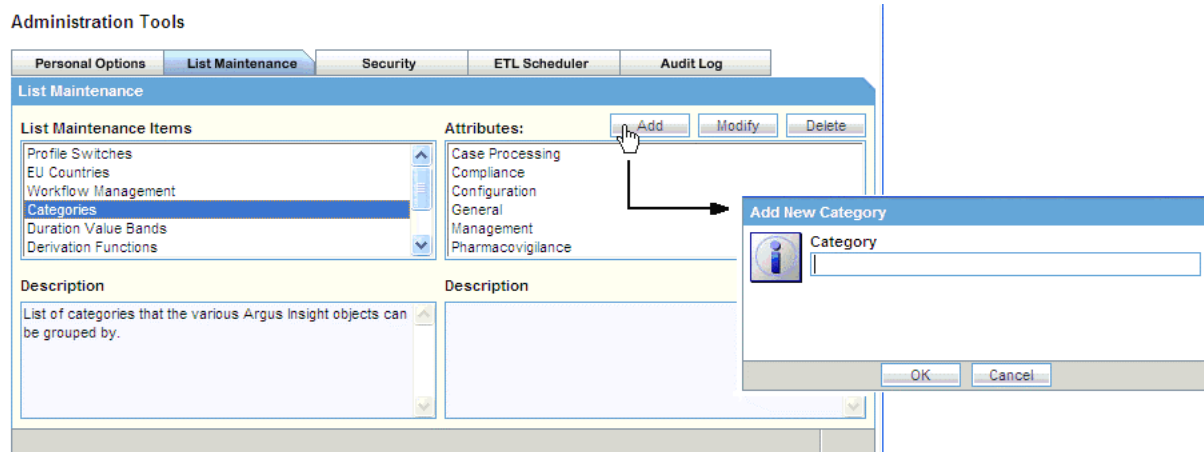
Argus Insight objects, such as queries, case series, and BIP standard reports, can be grouped into one of the following default categories:

- Case Processing
- Compliance
- Configuration
- General
- Management
- Pharmacovigilance

You cannot modify or delete the default categories. You can, however, add one or more custom categories. Once added, you can modify or delete a custom category.

To add, modify, or delete custom categories:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items list, select **Categories**.
The Attributes list is updated with the existing categories.
4. Click **Add**.
The Add New Category dialog box appears.



5. Enter the category name, and click **OK**.
A new category is added to Argus Insight.
6. To change the name of an existing custom category, select the category from the Attributes section, and click **Modify**.
Change the category name, and click **OK**.
7. To delete an existing custom category, select the category from the Attributes section, and click **Delete**.
A confirmation dialog box appears.
Click **OK**.

Configuring Duration Value Bands

In Argus Insight, you can map the following time values (entered in Argus Safety) to specific ranges called Duration Value Bands:

- Time to Onset from First Dose
- Time to Onset from Last Dose

You set the value of these fields in Argus Safety by navigating to Product Tab, Drug Duration of Administration, and Events Tab.

By mapping the time values to Duration Value Bands in Argus Insight, you can specify query criteria for the **Time to Onset from First Dose** field and the **Time to Onset from Last Dose** field based on ranges instead of specific values.

Using the Duration Value Bands item on the List Maintenance tab, you can configure duration value bands in hours, days, weeks, months, and years. For each band, you can specify multiple ranges by entering minimum and maximum values for each range item. Any value that falls within a configured range will map to that range.

Note: Duration Value Band configuration must be done before running the Initial ETL.

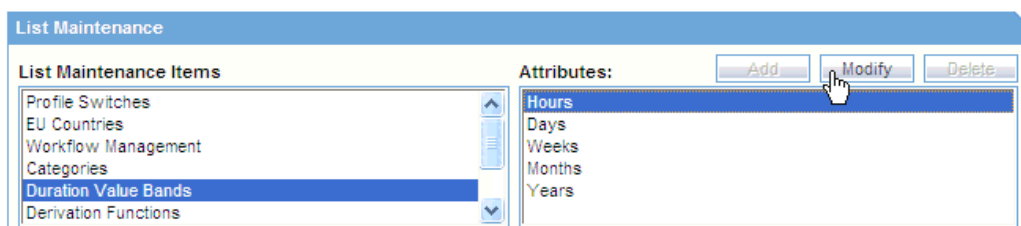
If Duration Value Bands are modified after Initial ETL, you must rerun the Initial ETL.

To modify a duration value band:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Duration Value Bands**.

The Attributes section is updated with the valid bands (Hours, Days, Weeks, Months, and Years).

You can modify the values of these bands. You cannot, however, add more bands or delete an existing band.



4. Select the duration value band (Hours, Days, Weeks, Months, Years) to change, and click **Modify**.

The Duration Value Bands Configuration dialog box appears with the factory-configured ranges.

Note that:

- The Label column represents the name of the range.
- The Lower Range (\geq) and Higher Range ($<$) columns contain the minimum and maximum values, respectively.

- The highest value band includes all values that are greater than the highest range value specified.

Band	Label	Lower Range (>=)	Higher Range (<)
Hours	<1	0	1
	1 to <2	1	2
	2 to <4	2	4
	4 to <6	4	6
	6 to <8	6	8
	8 to <10	8	10
	10 to <12	10	12
	12 to <24	12	24
	>=24	24	

5. Modify the values.

- To modify an existing range, edit the values in the **Lower Range (>=)** and **Higher Range (<)** fields.
- To add a range, scroll to the current highest range and click in the blank **Higher Range (<)** field. Enter a value greater than the current highest range and press **Tab** to add a new row.
- To delete an existing range, click the **Delete** icon next to the row. Note that you cannot delete the lowest band.

If you delete an intermediate range, the system converts the highest value of the deleted range to the lowest value in the next range. However, the system does not change the range labels.

6. Click **OK** to save the changes.

Configuring Derivation Functions

Argus Insight lets you create a new List Maintenance item and derive specific cases to this item based on case attributes. These attributes are supplied to the system as SQL.

For example, you can create a new List Maintenance item called **Report Type 1** and derive to this item all the cases that have the **Report Type** attribute defined as **Spontaneous**, **Literature**, or **Compassionate Use**. As a result, Report Type 1 appears as an option in the query tool interface corresponding to the Report Type attribute. When you select Report Type 1 from the Report Type list and execute your query, the system returns only those cases that have the Report Type attribute specified as Spontaneous, Literature, or Compassionate Use.

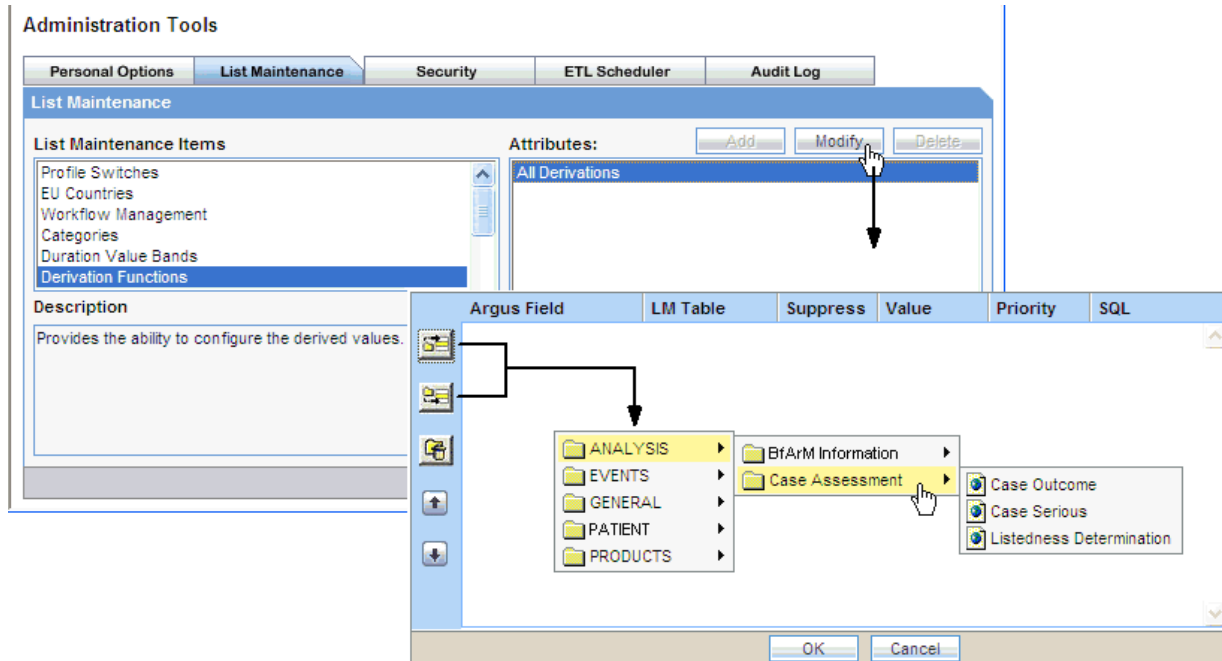
You can specify more than one attribute. For example, you can create a further specialized List Maintenance item called **Report Type 1 US** and derive to this item all the cases that have the **Report Type** attribute defined as **Spontaneous**, **Literature**, or **Compassionate Use**, *and* the **Country of Incidence** attribute defined as **United States**.

Note: There can be situations where two different List Maintenance items you create contain similar attributes in the SQL criteria. In this case, you can assign a priority level to individual List Maintenance items. The priority level determines which List Maintenance item SQL executes first.

Opening the Derivation Fields Dialog Box

To open the Derivation Fields dialog box and configure derivation functions:






1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Derivation Functions**.
4. From the Attributes section, select **All Derivations**, and click **Modify**.
The Derivation Fields dialog box appears.



Icons in the Derivation Fields Dialog Box

Table 12-3 describes the icons in the Derivation Fields dialog box that you can use to add, delete, and reorder derivation field elements (rows).

Table 12-3 *Icons in the Derivation Fields Dialog Box*

Click...	To...
	Add a derivation field element (row) above the currently selected row
	Add a derivation field element (row) below the currently selected row
	Delete the currently selected derivation field element (row)
	Move the selected row up
	Move the selected row down

Field Mapping Derivation Rules

Table 12–4 lists the available field mapping derivation rules for Argus Insight.

Table 12–4 Field Mapping Derivation Rules

Function Category	Function Sub-category	Argus Insight Field
ANALYSIS	BfArM Information	Causality
ANALYSIS	Case Assessment	Case Outcome Case Serious Listedness Determination
EVENTS	Event Information	Lack of Efficacy
GENERAL	General Information	Derived Pregnancy Report Type
PATIENT	Patient Information	Age Group Gender Patient weight BMI desc
PRODUCTS	Product Drug	Derived Drug Abuse Derived Drug Interaction Derived Overdose Last Daily Dose

Note: Causality, Report Type, Age Group, and Last Daily Dose are comma-separated derivation rules. See

Fields and Check Boxes in the Derivation Fields Dialog Box

This section describes the fields and check boxes in the Derivation Fields dialog box.

LM Table The LM Table field is the table name of the selected Argus field (that is, populated).

Suppress The Suppress check box is available for fields associated with the list maintenance data. When suppress is enabled for a field, the corresponding list maintenance values that are not present in any case are deleted and thus not available for querying.

Note: The Suppress check box is applicable *only if* the condition specified in the SQL text box covers all the cases having the selected List Maintenance field.

Value The Value field captures the value for the new derivation field.

For the following four rules, you must enter the new value for the rule as a comma-separated value:

- Causality
- Report Type
- Age Group
- Last Daily Dose

Note: Make sure that you enter the values for these rules as defined in the following sections. Unexpected results and/or ETL errors may result if the values are not entered as specified.

Causality Rule

Parameters: VALUE, REPORTABILITY

where:

VALUE = New value for the rule

REPORTABILITY = Lower value of the group

Example: NewCausality,1

Report Type Rule

Parameters: VALUE, INC_LIT, INC_TRIAL, ABRV

where:

VALUE = New value for the rule

INC_LIT = 1 if Literature Report Type else 0

INC_TRIAL = 1 if Clinical Trial Report Type else 0

ABRV = A 3-letter abbreviation for the Report Type

Example: NewReportType,0,1,NRT

Age Group Rule

Parameters: VALUE, GROUP_LOW, GROUP_HIGH

where:

VALUE = New value for the rule

GROUP_LOW = Lowest value of the age group

GROUP_HIGH = Highest value of the age group

Example: NewAgeGroup,25,50

If you do not want to specify the High Value, then the comma is mandatory in the end.

Example: Unknown,70,

Last Daily Dose Rule

Parameters: VALUE, DAILY_DOSE_SORTING_ORDER

where:

VALUE = New value for the rule

DAILY_DOSE_SORTING_ORDER = 1 or 2 or 3 and so on to define the sorting order if there is more than 1 rule for the Last Daily Dose field

Examples: 1 -> 0to1,1; 2 -> 2to3,2 3 -> 5to8,3

Priority The Priority field captures the priority for a list of derivation rules applied to a single List Maintenance field. Valid values: 1–255.

Note: The priority for derivation rules applicable to a single List Maintenance field must be unique.

SQL

The SQL field specifies the SQL statement to capture the cases for which the derivation rule is applicable.

Note: The SQL statement must follow the correct syntax.

The system does not validate the length of the new values against the database. Make sure that new values being inserted into the data mart do not exceed the limit defined in the database.

Guidelines for correct SQL statement syntax:

- The SQL query configured against a rule cannot contain the table name. It must contain only the primary key column name(s) of the field in the SELECT clause. For example:
Correct: SELECT CASE_ID FROM RPT_CASE WHERE...
Incorrect: SELECT RPT_CASE.CASE_ID FROM RPT_CASE WHERE...
- Make sure that there is only one space after the SELECT clause in the SQL query. For example:
Correct: SELECT CASE_ID, SEQ_NUM FROM RPT_PRODUCT WHERE...
Incorrect: SELECT CASE_ID, SEQ_NUM FROM RPT_PRODUCT WHERE...
- Make sure that no Oracle keyword (such as DISTINCT) is used after the SELECT clause in the SQL query. For example:
Correct: SELECT CASE_ID, SEQ_NUM FROM RPT_PRODUCT...
Incorrect: SELECT DISTINCT CASE_ID, SEQ_NUM FROM RPT_PRODUCT...

Configuring Case Series Modification Justification

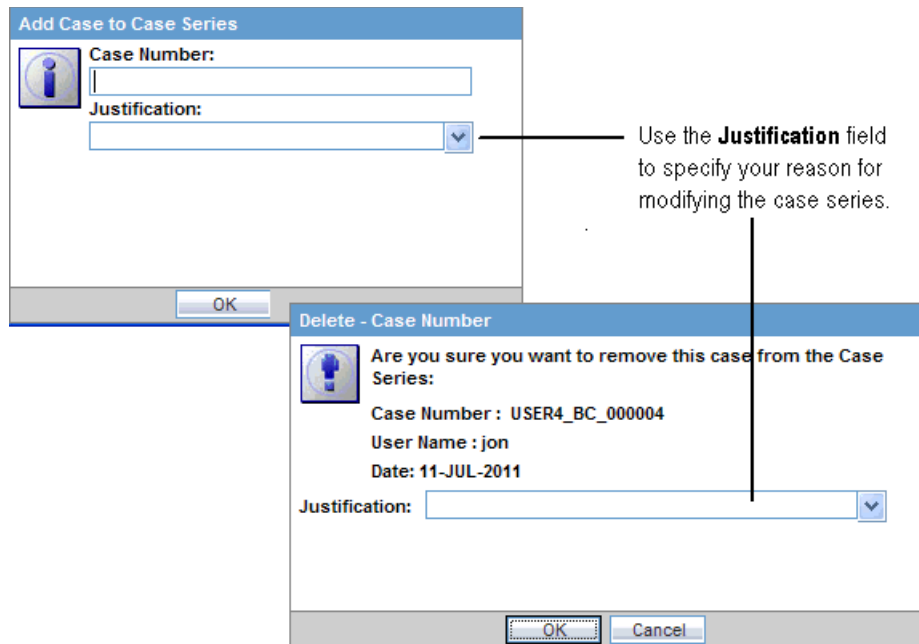
When you modify a case series either by adding a case to the series or by removing a case from the series, Argus Insight prompts for a justification, or reason, for the action. See [Figure 12-4](#).

In the **Justification** field, either enter your own reason or select a reason from the list.

Argus Insight does not provide a default list of justifications. However, you can create a set of standard and relevant reasons for Argus Insight to display in the Justification field. Once you create the list of reasons, users can select one of your defined justifications whenever they modify a case series. In addition, users always have the option to type their own justification.

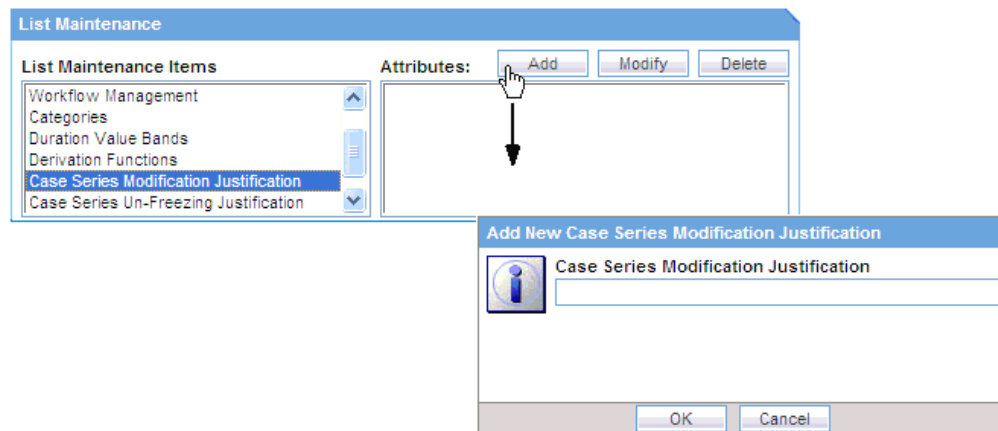
Justifications are important for maintaining the history of a case series.

Figure 12-4 Specifying a Justification when Modifying a Case Series



To create the list of justifications for modifying a case series:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Case Series Modification Justification**.
The Attributes list is updated with the existing configured justifications, if any.
4. Click **Add**.



5. Enter the justification text, and click **OK** to save the justification.
6. To edit an existing justification, select the justification from the Attributes list, and click **Modify**.
7. To delete an existing justification, select the justification from the Attributes list, and click **Delete**.

Configuring Case Series Un-freezing Justification

When you unfreeze a case series, Argus Insight prompts for a justification, or reason, for this action. In the **Justification** field, you can either type your own reason or select a reason from the list. For example:



Argus Insight does not provide a default list of justifications. However, you can create a set of standard and relevant reasons for Argus Insight to display in the Justification field. Once you create the list of reasons, users can select one of your defined justifications whenever they unfreeze a case series. In addition, users always have the option to type their own justification.

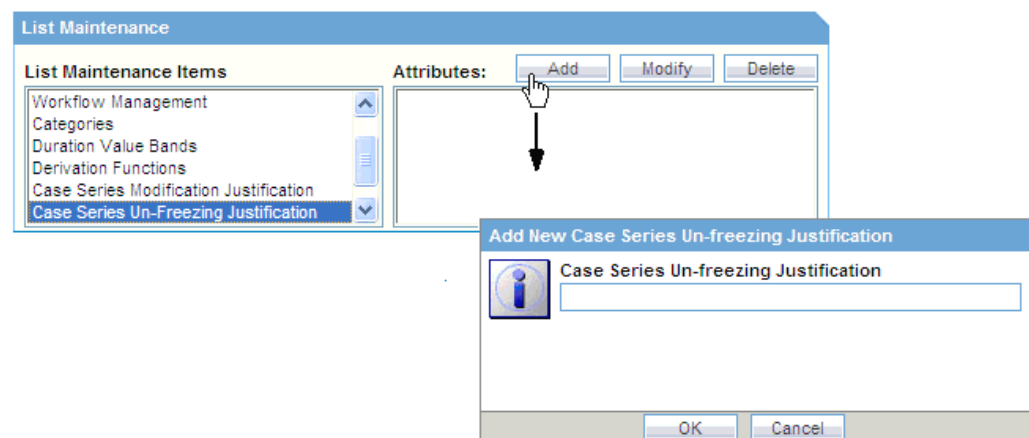
Justifications are important for maintaining the history of a case series.

To create the list of justifications for unfreezing a case series:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Case Series Un-Freezing Justification**.

The Attributes list is updated with the existing configured justification text, if any.

4. Click **Add**.



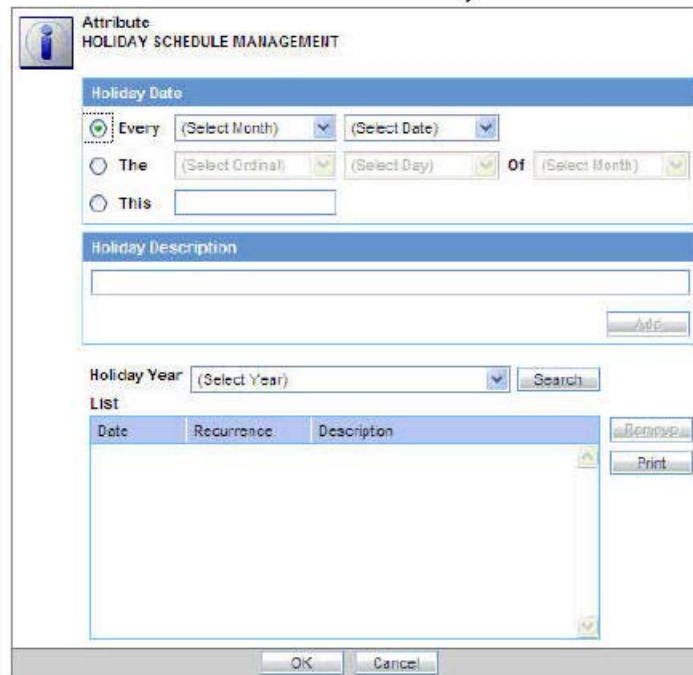
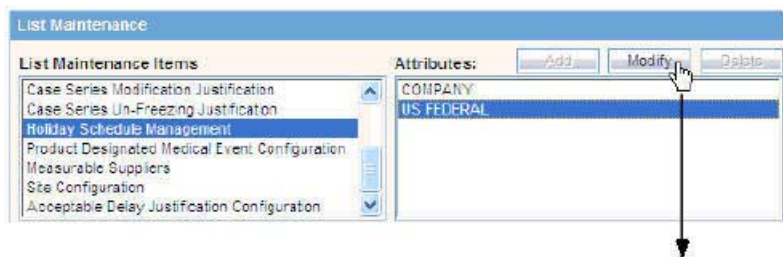
5. Enter the justification text, and click **OK** to save the justification.
6. To edit an existing justification, select the justification from the Attributes list, and click **Modify**.

7. To delete an existing justification, select the justification from the Attributes list, and click **Delete**.

Configuring Holiday Schedule Management

To configure or manage the schedule of a company's holidays or the US federal holidays:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Holiday Schedule Management**.
4. From the Attributes list, select **COMPANY** or **US FEDERAL**.
5. Click **Modify**.



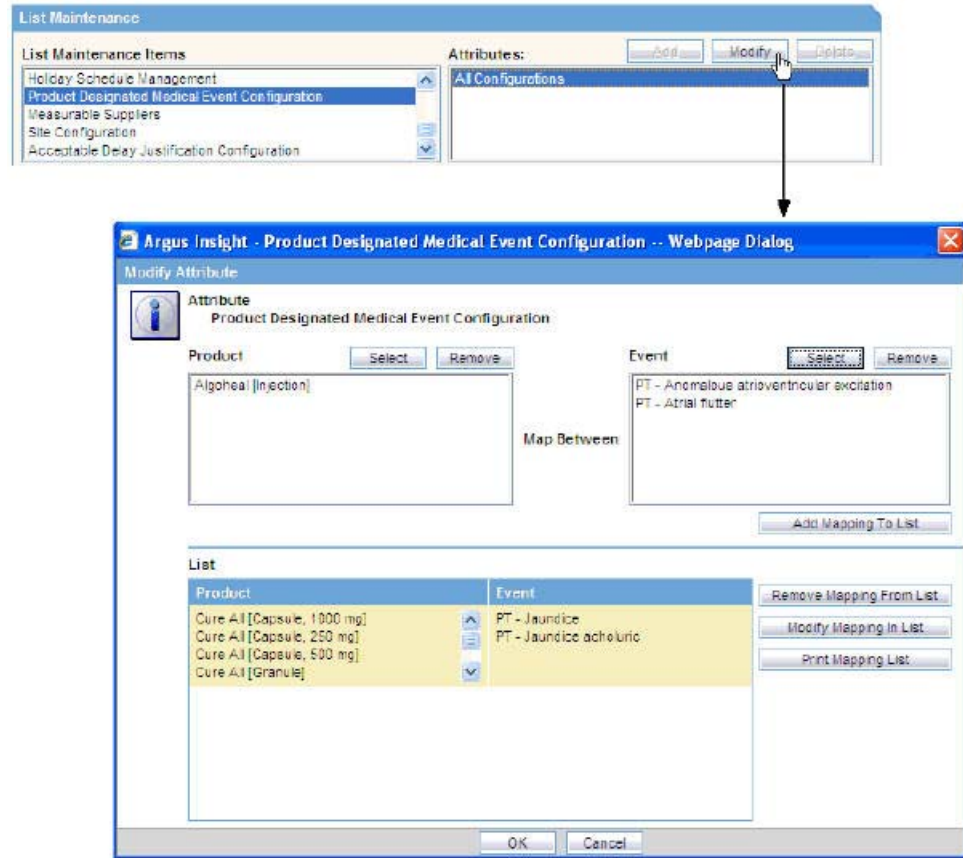
6. Make the required holiday selections, additions, and deletions.
7. Click **OK** to save the holiday schedule.

Configuring Product Designated Medical Event Configurations

To configure or manage Product Designated Medical Event Configurations (PDMEC):

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.

2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Product Designated Medical Event Configuration**.
4. From the **Attributes** list, select **All Configurations**.
5. Click **Modify**.



6. Select the product to map between one or more events, and then add the mapping to the list.

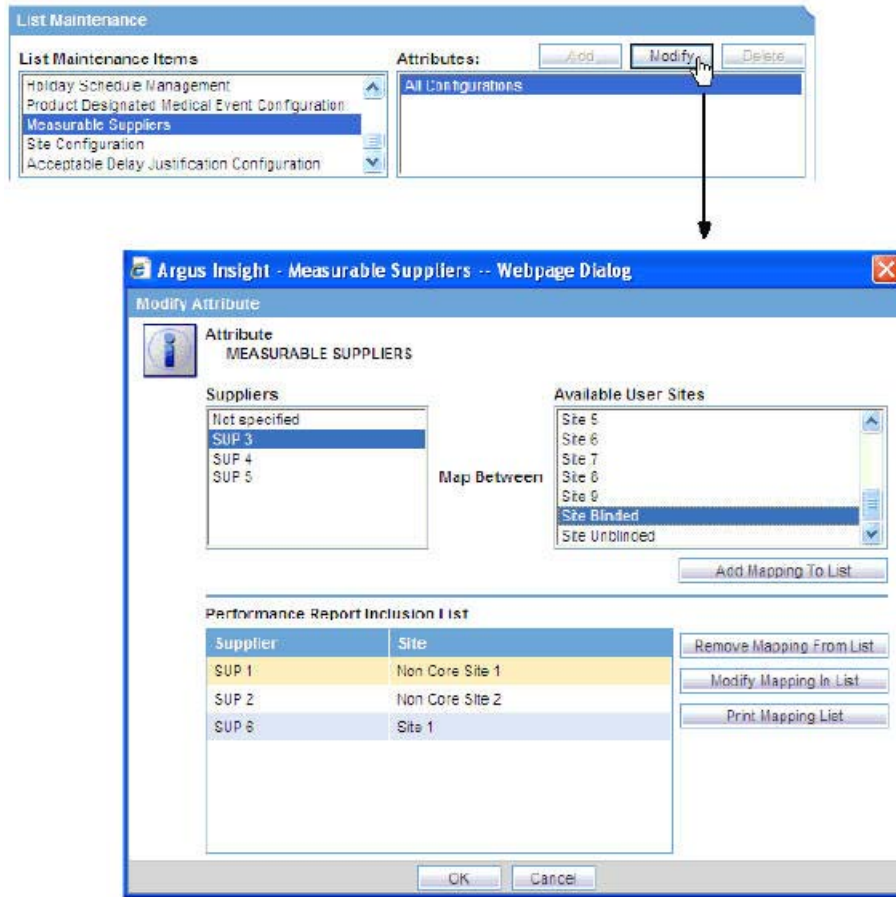
In addition, you can modify an existing mapping in the list, remove a mapping from the list, and print the mapping list.

7. Click **OK** to save the configuration.

Configuring Measurable Suppliers

To configure or manage measurable suppliers:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Measurable Suppliers**.
4. From the Attributes list, select **All Configurations**.
5. Click **Modify**.

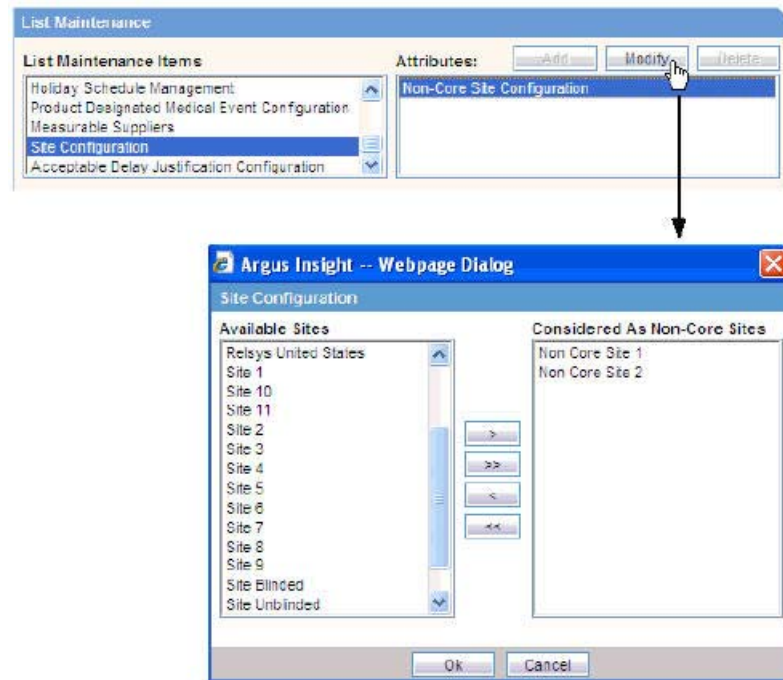


6. Configure the mapping between suppliers and available user sites, and then add the mapping to the list.
 In addition, you can modify an existing mapping in the list, remove a mapping from the list, and print the mapping list.
7. Click **OK** to save the changes.

Configuring Non-Core Sites

To configure the sites in your installation that are considered non-core sites:

1. Click **Tools** on the global toolbar.
 The **ADMINISTRATION TOOLS** page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Site Configuration**.
4. From the Attributes list, select **Non-Core Site Configuration**.
5. Click **Modify**.

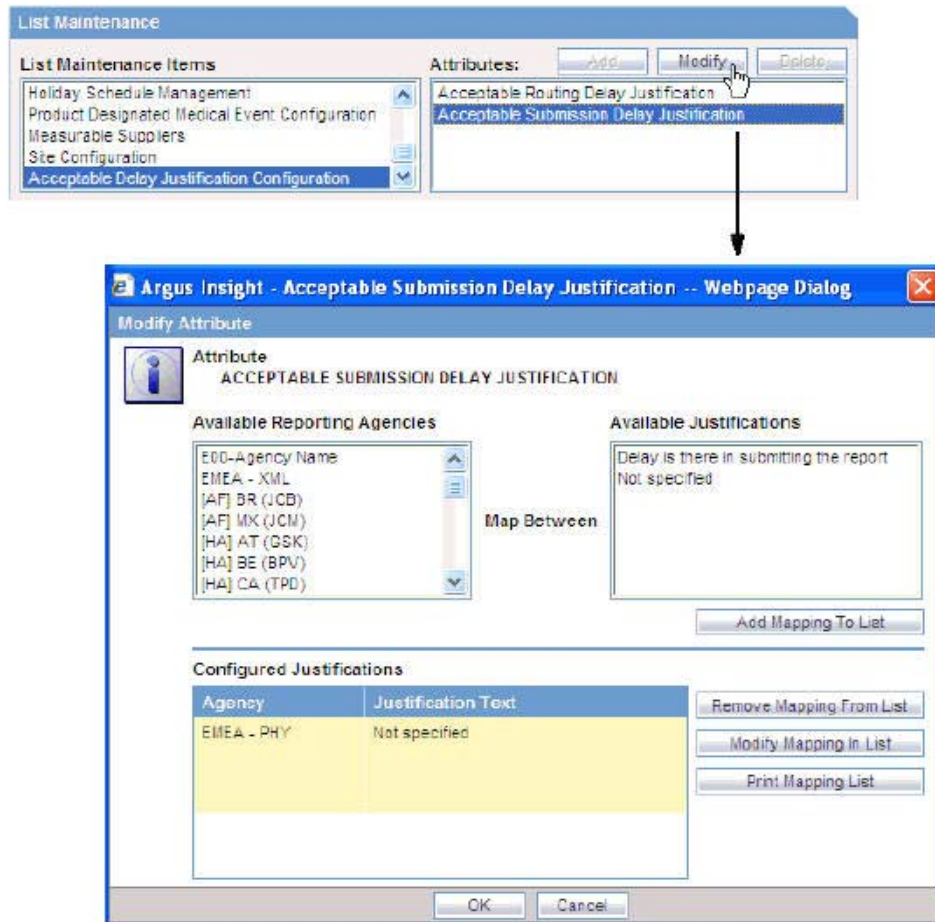


6. Select sites and use the arrow buttons to move sites between the list of available sites and the list of those sites considered to be non-core sites.
7. Click **OK** to save the changes.

Configuring Acceptable Delay Justifications

To configure the justifications for acceptable delays in submission or routing:

1. Click **Tools** on the global toolbar.
The **ADMINISTRATION TOOLS** page appears.
2. Click the **List Maintenance** tab.
3. From the List Maintenance Items section, select **Acceptable Delay Justification Configuration**.
4. From the Attributes list, select one of the following options:
 - To define the justifications for a routing delay, select **Acceptable Routing Delay Justification**.
 - To define the justifications for a submission delay, select **Acceptable Submission Delay Justification**.
5. Click **Modify**.



6. Configure the mapping between available reporting agencies with the available justifications, and then add the mapping to the list.
 In addition, you can modify an existing mapping in the list, remove a mapping from the list, and print the mapping list.
7. Click **OK** to save the changes.

Running the Extract, Transform, and Load Process

The Extract, Transform, and Load (ETL) process enables you to move data from your drug safety database, reformat the data, and then load the data into another database (data mart) for querying, drill-down analysis, and report generation.

Beginning with Argus Insight 7.0, ETL Scheduler is a user role defined in the Security tab on the ADMINISTRATION TOOLS page. This role is available across all enterprises at a global level.

The ETL Scheduler screen can be displayed, updated, and audit logged from the default enterprise in a multi-tenant installation. Only those users who have been assigned the ETL Scheduler role can view this screen.

Argus Insight application has been enhanced to run on Argus Mart database now. With changing time, Argus Mart database may be used as a primary database in future for all querying and reporting purpose as it contains useful information related to different case revisions. With this information, you can create and execute point-in-time queries in Argus Insight for a deep dive into historical data.

If you do not wish to use Argus Insight database along with Argus Mart, a new feature has been introduced in ETL process for copying only configuration tables from Insight database. These configuration tables are still required for proper functioning and use of Argus Insight UI with Argus Mart database. Population of Case tables data can be turned off which will help save the Argus Insight ETL time if its data is not used anymore for querying and reporting purpose. For list of case tables, see [Appendix: Argus Insight Case Tables](#).

To turn off Argus Insight case table population, use profile switch POPULATE CASE/CONFIGURATION DATA.

To fetch Argus Insight specific data in Argus Mart, enable profile switch ENABLE_AI_PROCESSING before running Argus Mart ETL.

For more information, see [Table 12-1, "Common Profile Switches"](#).

Note: The instructions given in this chapter are specific to Argus Insight ETL only and will not populate the Argus Mart database. For instructions on how to run Argus Mart ETL, refer to the *Oracle Argus Mart Installation and Administration Guide*.

Data Integrity Checks Before ETL

Argus must complete the following data integrity checks before performing the ETL:

- Every case must have at least one suspect product.
- Every case must have at least one event where the DESC_REPTD column is not null.
- Every case must have one and only one primary event.
- Every case must have a State record (CASE_MASTER.STATE_ID).
- Every case must have a Report Type record (CASE_MASTER.RPT_TYPE_ID).
- Every case must have a Country of Incidence record (CASE_MASTER.COUNTRY_ID).
- Every case must have a Study record (CASE_STUDY).
- Every case must have an Assessment record (CASE_ASSESS).
- Every product in CASE_PRODUCT must have a record in CASE_PROD_DRUGS.
- If there are reporters on the case, there must be only one primary reporter

Initial ETL Versus Incremental ETL

When Argus Insight is installed, the Initial ETL process is run to populate the data mart for the first time. Subsequently, you need to run Incremental ETL processes at specific intervals to update the data mart with the latest data from your drug safety database.

You cannot execute an Initial ETL and an Incremental ETL simultaneously.

Note: Do not run an Incremental ETL for more than 30000 cases. If the number of cases exceeds 30000, run the Initial ETL again. See the *Oracle Argus Insight Installation Guide* for information about running the Initial ETL.

Scheduling the ETL

The ETL Scheduler tab lets you schedule the Incremental ETL process to run and update the data mart.

Note: Updating reports table must always be followed by an update to the CASE_MASTER.LAST_UPDATE_TIME. (Updating the CASE_MASTER will result in moving the case along with all the reports to the mart schema.)

To schedule the ETL:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the ETL Scheduler tab.

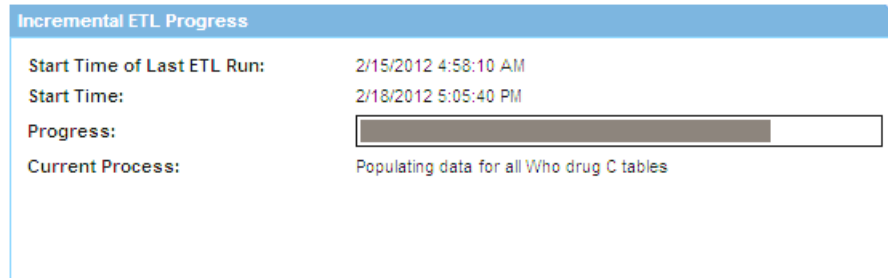
Note: This is Argus Insight ETL only and will not populate the Argus Mart database. For instructions on how to run Argus Mart ETL, refer to the *Oracle Argus Mart Installation and Administration Guide*.

3. Define how often you want to run the ETL by selecting one of the following options:
 - Hourly every so many hours, starting at a specific time
 - Daily at a specific time
 - Weekly at a specific time on a set day of the week
 - Monthly on a set day of the month at a specific time
4. Specify the other parameters, such as the hour of the day when the ETL will run. Use the 24-hour format (HH:MM:SS) when specifying a time value.
5. Click **Save Schedule** to save the settings.

To run the ETL immediately, click **Run ETL Now**. Running the ETL immediately does not affect the scheduled ETL.

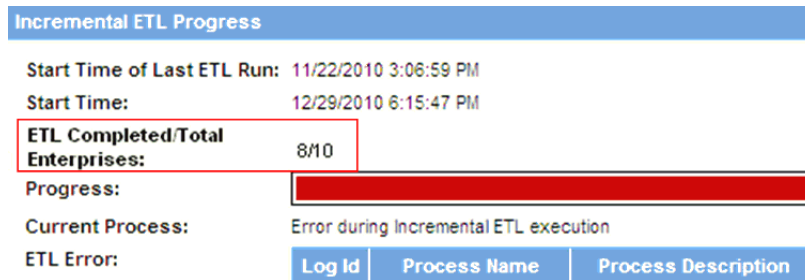
Monitoring the Progress of the ETL

While running the ETL, Argus Insight displays a status bar that shows the progress of Incremental ETL. For example:



The ETL Scheduler screen is only displayed, updated, and audit logged from the default enterprise to the user who is assigned with the ETL Scheduler role.

Beginning with Argus Insight 7.0, the Incremental ETL Progress status screen also displays the ETL Completed/Total Enterprises field. This field displays the number of enterprises for which the ETL has been completed, out of the total number of active enterprises in the system. For example:



If an error occurs during the ETL execution, the ETL stops and the system displays the error message.

- To resume the ETL from the point where the ETL failure occurred, click **Resume ETL**.

Note that Argus Insight enables the **Resume ETL** button *only* when the first commit point is reached, after staging has completed.

Any ETL failure that occurs before the first commit point will start from scratch.

- To start the Incremental ETL from the beginning again, click **Run ETL Now**.

To check the Initial ETL execution, review the balancing log in the database installation folder.

Securing User Accounts, Groups, and Access Rights

The default user name for the Argus Insight application comes from Argus Safety (admin). Its password is the same as the password of that user in Argus Safety.

Beginning with Argus Insight 7.0, you cannot create a user from Argus Insight. Instead, you create, copy, and delete Argus Insight users from the Argus Safety Console application.

In Argus Insight, however, you can create one or more user groups, and then assign access rights to the group. You can modify an existing user account, assign roles to the user, and add the user as a member of one or more groups.

In addition, all the existing Argus Safety user names and their passwords are replicated in Argus Insight.

Note: Any user with access to the custom SQL interface for creating advanced conditions may be able to see any data present in the database. Therefore, restrict the access to this interface to those users who have back-end access or are allowed to see any data from the database.

Creating New User Groups

To create a new user group:

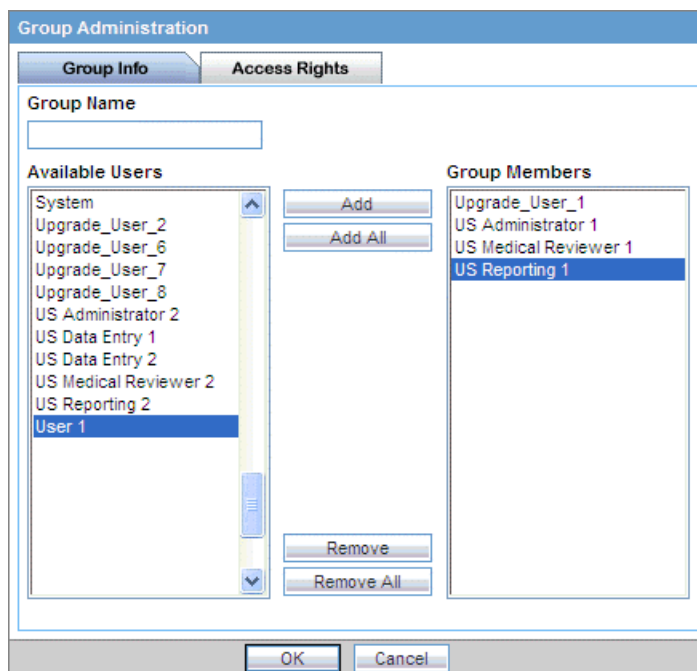
1. Click **Tools** on the global toolbar.

The ADMINISTRATION TOOLS page appears.

2. Click the **Security** tab.

3. In the **Groups** section, click **Add**.

The Group Administration dialog box appears.



4. Click the **Group Name** field and enter a name for this user group.

5. Define the users who are members of this group.

- To add one or more users to the group, select the user name from the Available Users list, and click **Add**.

To add all available users to the group, click **Add All**.

- To delete one or more users from the group, select the user name from the Group Members list, and click **Remove**.

To remove all users from the group, click **Remove All**.

6. Define the access rights for all the members of this group.
 - a. Click the **Access Rights** tab.
 - b. Click **OK** to confirm that you want to create the group.
 - c. Select the appropriate check boxes depending on the access rights you want to assign to this group of users.
7. Click **OK**.

In the Security tab, the list in the **Groups** section displays the name of the newly created group along with the names of the users who are members of the group.

Copying Groups

Once you have created a user group, you can use the Copy functionality to save the existing user group or account by another name while retaining all the access rights, group associations, and user associations. This is useful when you are creating multiple groups or user accounts with similar access rights and associations.

To create a new group or account by copying information from an existing group or account:

1. Click **Tools** on the global toolbar.

The ADMINISTRATION TOOLS page appears.
2. Click the **Security** tab.
3. Select a user name or a group name to copy.
4. In the **Groups** section, click **Copy**.

The Group Administration dialog box appears.
5. In the **Group Name** field, enter a group name.
6. Click **OK**.

Settings from the copied group are carried over to the new group.

Modifying Existing Groups

To modify the details and members of a group:

1. Click **Tools** on the global toolbar.

The ADMINISTRATION TOOLS page appears.
2. Click the **Security** tab.
3. Select a group name to modify.
4. In the **Groups** section, click **Modify**.

The Group Administration dialog box appears.
5. Modify the settings, and click **OK** to save the changes.

Deleting Existing Groups

To delete an existing group:

1. Click **Tools** on the global toolbar.

The ADMINISTRATION TOOLS page appears.

2. Click the **Security** tab.
3. Select the group to delete.
4. Click **Delete**.

A confirmation dialog box appears.

Note: When you delete a user, all the queries and case series that the user saved in Argus Insight are also deleted.

5. Click **Yes** to delete the selected group.

Modifying User Accounts

To modify an existing user account:

1. Click **Tools** on the global toolbar.

The ADMINISTRATION TOOLS page appears.

2. Click the **Security** tab.
3. Select the user account to modify.
4. Click **Modify**.

The User Administration dialog box appears.

The **User Full Name** field, the **User Name** field, the **Use LDAP Authentication** check box, and the **Protect from unblinded information** check box are read-only in Argus Insight, and are synchronized with their values configured in Argus Console.

5. Define the roles for this user.

- To assign a role to this user, select the role from the Available Roles list, and click **Add**.
- To remove an existing role for this user, select the role from the Selected Roles list, and click **Remove**.

Note: The Copy Configuration role appears under Selected Roles in read-only mode for the users having this role. Those Argus Insight users who have access to the Copy Configuration role in Argus Safety can copy all the configuration data from the enterprise where they have this role to any new enterprise that they create through the Global Enterprise Management portlet.

Beginning with Argus Insight 7.0, ETL Scheduler is a user role. This role is only displayed, updated, and audit logged in the default enterprise.

6. Assign the user to be a member of one or more groups.
 - To make this user a member of a group, select the group name from the Available Groups list, and click **Add**.
To make this user a member of all groups, click **Add All**.
 - To revoke this user's membership in a group, select the group name from the Member Groups list, and click **Remove**.
To revoke this user's membership in all groups, click **Remove All**.
7. Click **OK** to save the modifications to the selected user account.

Users who selected the Argus Insight check box (from Argus Console, User Management, Application Access) for an enterprise can access the application for that enterprise.

Viewing the Audit Log

From the **Audit Log** tab, you can view the activities performed by an Argus Insight user or by all users during a particular period.

To view the audit log:

1. Click **Tools** on the global toolbar.
The ADMINISTRATION TOOLS page appears.
2. Click the **Audit Log** tab.

The screenshot shows the 'Audit Log' tab selected in the navigation bar. Below the tabs, there is a search form with the following fields and values:

- Category:** All
- User Full Name:** All
- Date Range From:** 01-JAN-2012
- To:** 01-FEB-2012
- Search:** Search button

3. Enter the criteria to search the audit logs.
 - a. In the **Category** field, select the activity category or select **All**.
 - b. In the **User Full Name** field, select a user name or select **All**.
 - c. In the **Date Range From** and **To** fields, enter the date range.

4. Click **Search**.

The Audit Log tab appears with the list of activities based on the specified criteria.

Administration Tools

The screenshot shows the 'Administration Tools' window with the 'Audit Log' tab selected. At the top, there are navigation tabs: Personal Options, List Maintenance, Security, ETL Scheduler, and Audit Log. Below these are search filters: Category (All), User Full Name (All), Date Range From (01-JAN-2012) To (18-FEB-2012), and a Search button. The main area is a table of activities:

Activity	Category	User Full Name	Date/Time (GMT)
Added	Initial ETL	Windows User	07-FEB-12 15:18:51
Added	Successful Login Record	Administrator	09-FEB-12 07:27:05
Updated	List Maintenance - Profile Switches	Administrator	09-FEB-12 07:32:55
Updated	List Maintenance - Profile Switches	Administrator	09-FEB-12 07:33:49
Updated	List Maintenance - Profile Switches	Administrator	09-FEB-12 07:36:45
Updated	List Maintenance - Profile Switches	Administrator	09-FEB-12 07:40:02
Updated	List Maintenance - Profile Switches	Administrator	09-FEB-12 07:40:33
Updated	List Maintenance - Profile Switches	Administrator	09-FEB-12 07:40:54
Updated	List Maintenance - Profile Switches	Administrator	09-FEB-12 07:41:14
Updated	List Maintenance - Profile Switches	Administrator	09-FEB-12 07:41:35

A 'Print' button is located at the bottom right of the table.

- To sort the list of activities, click a column heading.
- To print the list of activities, click **Print**.
- To view more details about an activity, click the Audit Log Details icon in the Activity column.

The Audit Log Details dialog box appears with additional information about the activity.

To print the activity details, click **Print**.

The screenshot shows the 'Audit Log Details' dialog box. It contains a table with the following data:

Table Name	Field Name	Old Value	New Value	User Full Name	Date / Time (GMT)
RPT_ETL_SCHEDULE_INFO	ETL_RUN	<Added>	ETL Run From UI	Administrator	09-FEB-12 07:47:37

At the bottom of the dialog box, there are 'Close' and 'Print' buttons.

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Appendix: Argus Insight Case Tables

The following is the list of Argus Insight Case tables:

AIR_AUDITLOG_CASES	REA_CAUSALITY_DATA	TMP_ASSOCIATED_SYMPTOM
AIR_AUDITLOG_CASES_LOG	REP_CASE_DETAIL_TMP	TMP_CASE_AGENCY
AIR_CASES_TO_PROCESS	REP_CASE_DETAIL_TP_TMP	TMP_CASE_REFERENCE
AIR_CASES_TO_PROCESS_CHUNK	REP_CASE_LOG	TMP_DQI
AIR_FREEZE_CASES_TO_PROCESS	REP_CASE_TMP	TMP_DTL_CASE
AIR_MANUAL_LOG_CASES	REP_EVENT_LOG	TMP_DURATION_BAND
AIR_MANUAL_LOG_CASES_LOG	REP_EVENT_TMP	TMP_DURATION_DELAY
AIR_PRE_REQ_LOG	REP_EVT_ASSESS_LOG	TMP_EVENT_CASES
AIR_REPORTS_TO_DELETE	REP_EVT_ASSESS_TMP	TMP_EVENT_DETAILS
AIR_REPORTS_TO_DELETE_LOG	REP_PROD_DOSE_LOG	TMP_EVENT_DETAILS_ORPHAN
AIR_REPORTS_TO_PROCESS	REP_PROD_DOSE_TMP	TMP_EVENT_UD_RC
AIR_REPORTS_TO_PROCESS_LOG	RPT_CASE	TMP_LATE_REPORTS
AIR_UNFREEZE_CASES_TO_DELETE	RPT_CASE_DELTA_MESSAGE	TMP_PRIMARY_PRODUCT
AIR_UPDATED_STUDY_CASES	RPT_CASE_EVENT_PROD	TMP_PRODUCT_CASES
CASE_AGENCY	RPT_CASE_EVENT_PRODUCT	TMP_PRODUCT_DATASHEET
CASE_DETAIL	RPT_CASE_EVENT_PRODUCT_ASS ESS	TMP_PRODUCT_DETAILS
CASE_STUDY_REFERENCE	RPT_CASE_SUMMARY	TMP_PRODUCT_REGIMENS
CMN_AUDIT_LOG	RPT_CASE_SUMMARY_PRODUCT	TMP_PROD_IND_CODE
DTL_CASE	RPT_CASE_SUMMARY_REPORTS	TMP_RPT_CASE
DTL_CA_EVALUATION	RPT_CLD_NOTES	TMP_RPT_DEATH_DETAILS
DTL_CMD_NARRATIVE_TEXT	RPT_CLINICAL_TRIAL_CAUSALIT Y	TMP_RPT_EVENT
ETL_CASE_UPDATE_LOG	RPT_CNL_ENGLISH	TMP_RPT_PRODUCT
ETL_PROCEDURES_LOG	RPT_EVENT_ASSESS_CAUSALITY	TMP_RPT_PROD_INDICATIONS
FACT_PROD_LICENSE	RPT_REPORT_SUBMISSION	TMP_RRR_SD2
FROZEN_CASE_DETAIL	RPT_WORKFLOW	USER_ACCESS
----	----	USER_CASE

Glossary

adverse experience

Any adverse event associated with the use of a drug or biological product in humans, whether or not considered product-related, including:

- An adverse event occurring in the course of the use of a drug product in professional practice
- An adverse event occurring from drug overdose whether accidental or intentional
- An adverse event occurring from drug abuse
- An adverse event occurring from drug withdrawal
- Any failure of expected pharmacological action

Reporting an adverse experience does not necessarily reflect a conclusion by the applicant or the FDA that the product caused or contributed to the adverse experience.

Adverse experience is synonymous with adverse drug experience, adverse biological experience, adverse product experience, and adverse event.

affiliate

Any individual or entity related by employment or organizational structure to the applicant, including all subsidiaries, whether domestic or foreign.

applicant

An individual or entity who holds the new drug application (NDA), the abbreviated new drug application (ANDA), or the biologics license application (BLA). For purposes of this glossary, this term includes any person whose name appears on the label of a marketed drug or licensed biological product as its manufacturer, packer, distributor, shared manufacturer, joint manufacturer, or any participant involved in divided manufacturing.

causality assessment

Determination of whether there is a reasonable possibility that the product is etiologically related to the adverse experience. For example, causality assessment includes assessment of temporal relationships, dechallenge/rechallenge information, association with (or lack of association with) underlying disease, presence (or absence) of a more likely cause, and physiologic plausibility.

challenge

Administration of a suspect product by any route.

chart

A picture defined in graphics primitives and graphics attributes.

column

A character position within a print line or on display. The positions are numbered consecutively from 1, starting at the leftmost character position and extending to the rightmost position. In relational database, a field defined for a given record.

comma-separated values (.CSV) file

See .CSV file.

command

A statement used to initiate an action or start a service. Administrators use commands to start database administration functions that access and maintain the database. Commands consists of the command name abbreviation, and its parameters and flags if applicable.

.CSV file

Comma-separated values file. In computers, a CSV file contains the values in a table as a series of ASCII text lines organized so that each column value is separated by a comma from the next column's value and each row starts a new line.

data mart

A subset of a data warehouse that contains data that is tailored and optimized for the specific reporting needs of a department or team. A data mart can be a subset of a warehouse for an entire organization, such as data that is contained in online analytical processing (OLAP) tools.

data mining

The process of collecting critical business information from a data warehouse, correlating the information, and uncovering associations, patterns, and trends.

data warehouse

A central repository for all or significant parts of the data that an organization's business systems collect. A subject-oriented nonvolatile collection of data used to support strategic decision making. The warehouse is the central point of data integration for business intelligence. It is the source of data for data marts within an enterprise and delivers a common view of enterprise data.

dechallenge

Withdrawal of a suspect product from the patients therapeutic regimen.

disability

A substantial disruption in one's ability to conduct normal life functions.

electronic document

A document that is stored on the computer, instead of printed on paper.

encode

To convert data by the use of a code in such a manner that reconversion to the original form is possible.

ETL

Extract, transform, and load (ETL) process. The ETL process extracts a subset of data from the central data warehouse, transforms it, and loads it into one or more star schemas. These schemas can be included in data marts to answer specific business questions.

event log

A log that contains information about events for a particular system or group, for a particular metric, or for all the events that are associated with a specific monitor.

expected adverse experience

Adverse experience listed in the current FDA-approved labeling for the drug or licensed biological product. This would include any section of the labeling that refers to adverse experience information.

extract, transform, and load (ETL)

See ETL.

field

In a record, a specified area used for a particular category of data. For example, a record about an employee might be subdivided into fields containing the employee's name, address, and salary.

field description

Information that describes the characteristics of data in a field.

field format

A format in which the output consists of structured field introducers and variable data rather than output in line format.

filter

A device or program that separates data, signals, or material in accordance with specified criteria.

form

In query management, an object that describes how to format the data for printing or displaying a report. A display screen, printed document, or file with defined spaces for information to be inserted.

home page

The top-level web page of a portal. Sometimes used as a synonym for default portal page.

initial reporter

The original source of information concerning an adverse experience (for example, consumer or healthcare professional).

life-threatening adverse experience

An adverse experience that in the view of the initial reporter places the patient at immediate risk of death from the adverse experience as it occurred. It does not include an adverse experience that, had it occurred in a more severe form, might have caused death.

negative dechallenge

Continued presence of an adverse experience after withdrawal of the suspect product.

negative rechallenge

Failure of the product, when reintroduced, to produce signs or symptoms similar to those observed when the suspect product was previously introduced.

positive dechallenge

Partial or complete disappearance of an adverse experience after withdrawal of the suspect product.

positive rechallenge

Reoccurrence of similar signs and symptoms upon reintroduction of the suspect product.

query

A request for information from the database based on specific conditions.

rechallenge

Reintroduction of a suspect product suspected of having caused an adverse experience following a positive dechallenge.

report

In query management, the formatted data that results from running a query and applying a form to it. Data that has been selected and extracted according to the reporting tool, type of report desired, and formatting criteria.

report type

A data source and how it is mapped.

role

A job function that identifies the tasks a user can perform, defines the access level the user has, and specifies the resources the user can access and modify at those levels. Users are limited in how they can access information if they do not have the proper role. A user can be assigned one or more roles.

serious adverse experience

An adverse experience occurring from any dose that results in any of the following outcomes: death, life-threatening adverse experience, initial inpatient hospitalization, prolongation of hospitalization, significant or persistent disability/incapacity, or congenital anomaly/birth defect (including that occurring in a fetus). Important medical events, based upon appropriate medical judgment, that may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above.

spontaneous report

A communication from an individual (for example, consumer or healthcare professional) to a company or regulatory authority that describes a suspected adverse experience. It does not include cases identified from information solicited by the applicant such as individual cases or findings derived from a study.

study

Any organized data collection system (for example, adverse experience information derived from a clinical trial or patient registry including pregnancy registries). Reports from company sponsored patient support programs and disease management programs should be handled as if they were study reports and not spontaneous reports.

suspect product

Drug or biological product associated with an adverse experience as determined by the initial reporter, regardless of the opinion of the applicant.

type-ahead feature

Functionality where you begin to type a value in a field and the system displays the like values in a drop-down list. You can then select a value from the list.

unexpected adverse experience

Adverse experience not included in any section of the current FDA-approved labeling for the drug or licensed biological product. Includes an adverse experience that may differ from a labeled adverse experience because of greater severity or specificity (for example, abnormal liver function versus hepatic necrosis).

In addition, adverse experiences listed as occurring with a class of drugs or biological products but not specifically mentioned with a particular drug or biological product are considered unexpected (for example, a rash with antibiotic X would be considered unexpected if the labeling states *rash may be associated with antibiotics* because the labeling does not specifically state *rash is associated with antibiotic X*). Reports of death from an adverse experience are considered unexpected unless the possibility of a fatal outcome from that adverse experience is stated in the labeling.

web-based application

An application that is downloaded from the web each time it is run. The advantage is the application can be run from any computer, and the software is routinely upgraded and maintained by the hosting organization rather than by each individual user.

web browser

A client program that initiates requests to a web server and displays the information that the server returns.

web page

Any document that can be accessed by a URL on the World Wide Web.

web server

A software program that is capable of servicing Hypertext Transfer Protocol (HTTP) requests.

website

A related collection of files available on the web that is managed by a single entity (an organization or an individual) and contains information for its users. A website often includes links to other websites.