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BusinessObjects User's Guide
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Oracle Argus Insight BusinessObjects User's Guide, Release 7.0.1

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Glossary

Preface

This *Oracle Argus Insight BusinessObjects User's Guide* describes how to create queries, execute queries to generate a case series, and generate reports on the case series.

This preface includes the following topics:

- [Audience](#)
- [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 users.

Documentation Accessibility

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

Access to Oracle Support

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

Finding Information and Patches on My Oracle Support

Your source for the latest information about 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 opens.
3. Follow the instructions on the registration page.

Signing In to My Oracle Support

To sign in to My Oracle Support:

1. Open a web browser to <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 displays the results of your search. 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 system immediately filters the product list by 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 opens and displays the Patch Search region. You have the following options:
 - 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 opens.
4. Click the patch ID number. The system displays details about the patch. In addition, you can view the Read Me file before downloading the patch.
5. Click **Download**. Follow the instructions on the screen to download, save, and install the patch files.

Finding 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](#)" on page xi.

- *Oracle Argus Insight Installation Guide* (Part E28479)
- *Oracle Argus Insight BusinessObjects Administrator's Guide* (Part E28483)
- *Oracle Argus Insight BusinessObjects User's Guide* (Part E28482)
- *Oracle Argus Insight Cognos Administrator's Guide* (Part E28480)
- *Oracle Argus Insight Cognos User's Guide* (Part E28481)
- *Oracle Argus Insight Minimum Security Configuration Guide* (Part E28490)

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* (Part E28489)
- *Oracle Argus Insight CMN Profile Global Table Guide* (Part E28488)
- *Oracle Argus Insight Database Administrator's Guide* (Part E28486)
- *Oracle Argus Insight Entity Relationship Diagram Reference* (Part E28485)
- *Oracle Argus Insight Report Mapping Reference* (Part E28487)

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. |
| 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 various *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 the data 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 one of the following reports on the case series to create and store these in the Reports library:
 - Built-in standard reports
 - Custom reports
- Create custom reports and analyze the data using the Report Writer.
- Use the Report Writer to directly query the data mart.

Note: You primarily use the Report Writer to directly query the data mart and create custom reports. However, you can apply the active case series *filter* on the reports to reduce the data set and improve report performance. The case series might become obsolete each time the data mart is refreshed by running an ETL. This is because new cases with similar attributes might get added to the data mart.

Argus Insight Components

Argus Insight includes the following components:

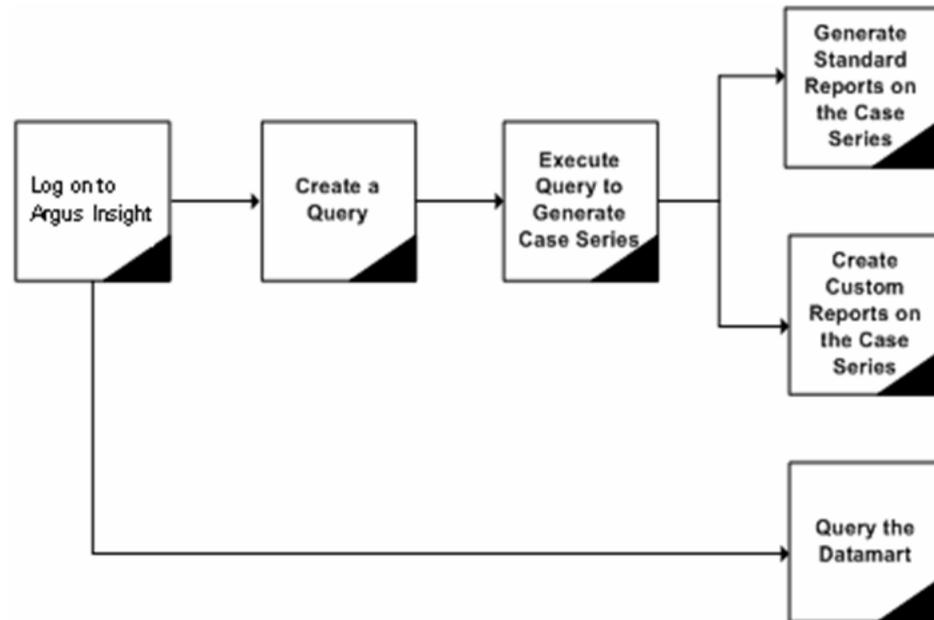
- **Query by Example (QBE)** — Lets you create simple queries by entering specific values in fields on a *form* that looks substantially like the Argus Safety case form.
- **Filters** — Lets you create queries by selecting a set of predefined fields and specifying multiple values in a *field*.
- **Advanced Conditions** — Lets you create complex queries by selecting any of the various different fields in the data 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.
- **Standard Reports** — Lets you run one or more reports on the case series. The standard reports are predefined reports built in to Argus Insight. Reports are grouped into categories such as Case Processing, Compliance, Configuration, General, Management, and Pharmacovigilance.
- **Report Writer** — Lets you directly query the data mart and create custom reports by selecting any data mart fields as report columns. In the report output, you can apply filters, create nested groupings, and perform operations such as sort, total, count, and drill.

The custom reports you create can be stored in the Report Writer library or added to the Argus Insight application; you can run the stored reports on a case series.

Argus Insight Process Flow

The flowchart in [Figure 1–1](#) depicts the steps that you typically follow 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 in to Argus Insight | Log in 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 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 and retrieve a list of cases (case series) that match the criteria you specified while creating the query. |
| Generate Standard Reports on the Case Series | Select and run a built-in standard report. You can limit this report to only run on the case series. |
| Generate Custom Reports on the Case Series | Select and run a custom report you created and stored in the Report Writer library. You can limit this report to only run on the case series. |
| Query the Data Mart | Use the Report Writer to directly query the data mart and generate the required report. |

Product Compatibility and Upgrade Options

This section describes the compatibility and upgrade options for Argus Insight 7.0.1.

Compatibility of Argus Insight with Argus Safety

Argus Insight 7.0.1 is compatible with Argus Safety 7.0.1.

Upgrade Paths to Argus Insight 7.0.1

There is no upgrade path from Argus Insight 6.0 to Argus Insight 7.0.1.

For information about installing Argus Insight 7.0.1, see the *Oracle Argus Insight Installation Guide*.

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](#)
- [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 automatically 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 right to various 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.
- The system administrator defines access to various 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 or Insight, you can start the application modules. The system does not ask you to enter a password again for the Power Reports or Argus 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 other modules.
- Logout is available only on the *parent* application dialog box. Logging out of the parent application dialog closes all child dialogs **without** saving information in the child applications.

Logging In to the Argus Insight Application

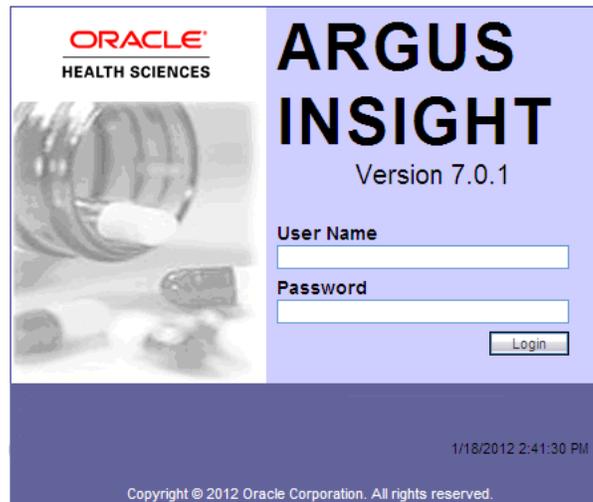
To start Argus Insight and log in to the application:

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 who is responsible for configuring the URL.

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

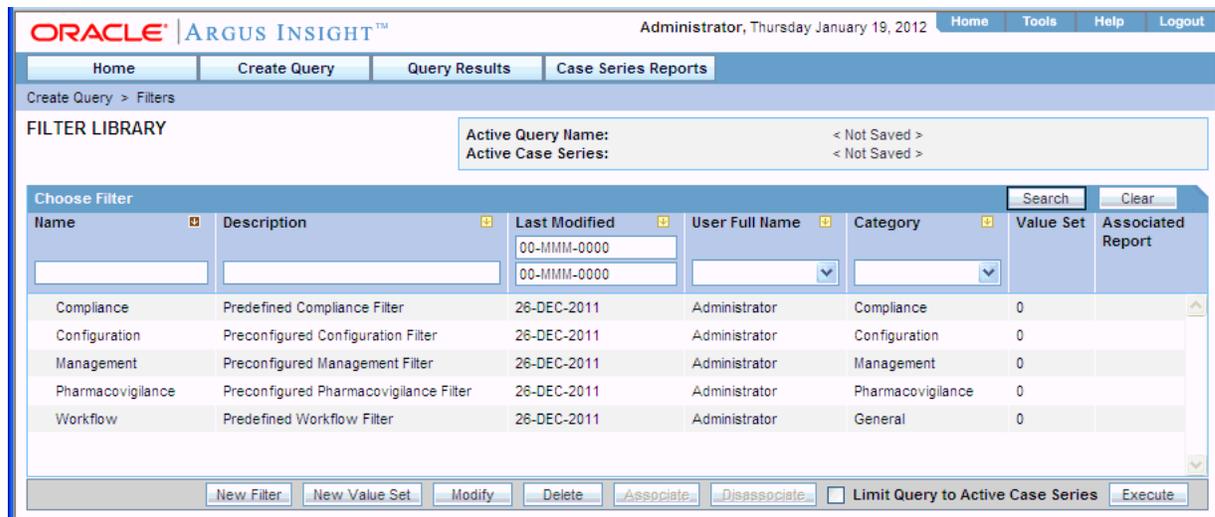
3. Press Enter. The system opens the Argus Insight login screen.



4. Type your user name and password in the respective fields.
5. Click **Login**. The system opens the default Argus Insight Home page, which is the FILTER LIBRARY page. See [Figure 2-1](#).

For information about making a different page your Home page, see "[Changing the Default Home Page](#)" on page 2-4.

Figure 2-1 Argus Insight Default Home Page

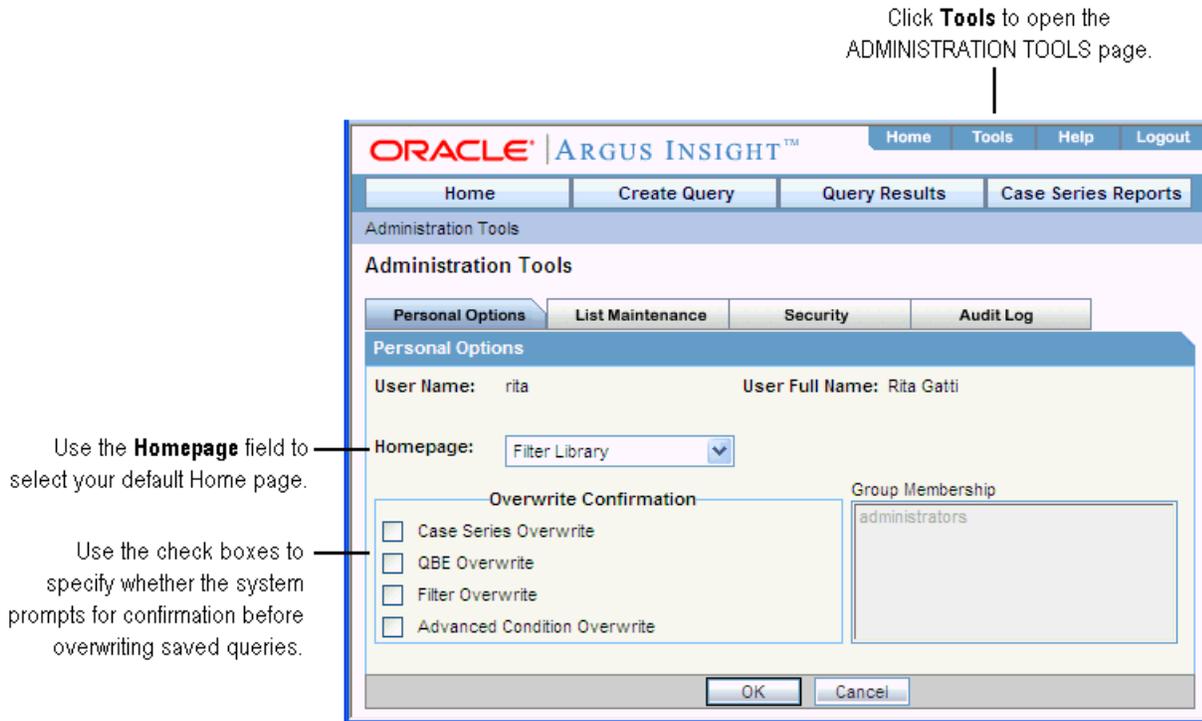


Setting Your Personal Options

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

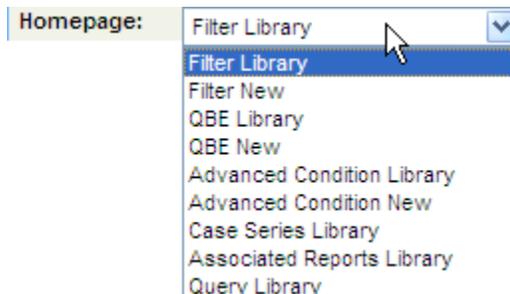


Changing the Default Home Page

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 system opens the ADMINISTRATION TOOLS page with the Personal Options tab in focus.
2. Click the **Homepage** field and select a page from the list.



3. Click **OK**. The system changes your default Home page to the selected page, and opens a dialog box confirming that your options have been updated.
4. Click **OK** to close the dialog box and 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.

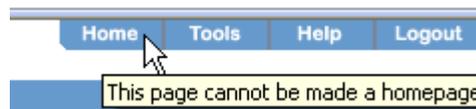


Alternative Method to Selecting a Home Page

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



Note that if you cannot make the current page your Home page, the system displays an informational message when you position the cursor over Home.



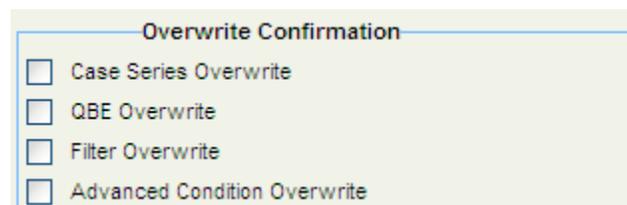
Changing Your Preferences for Overwrite Confirmation

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 system opens the ADMINISTRATION TOOLS page with the Personal Options tab in focus.
2. Select the check boxes in the Overwrite Confirmation section to define your preferences.



3. Click **OK**. The system confirms that your options have been updated.
4. Click **OK** to close the dialog box and 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.

To enter the month, you can enter a valid month number. In this case, the system automatically 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 a software interface with a tabbed menu at the top: General, Patient, Products, Events, and Analysis. The 'General' tab is selected, and the 'General Information' section is visible. It contains several data entry fields:

- Report Type**: A text input field.
- Country**: A dropdown menu.
- Initial Receipt Date**: A date field containing the partial date *??-??-0000*.
- Follow-up Received**: A date field containing the partial date *??-??-0000*.
- Safety Received**: A date 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 can enter any one of these sequences:

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

To enter a date that includes only the year (for example 2012), you can enter any one of these 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.

Logging Out

To log out:

1. Click **Logout** on the global toolbar. The system prompts for confirmation that you want to log out of Argus Insight.
2. Click **OK**. The system logs you out of the application and displays the Argus Insight login screen.

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 various 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](#)
- [Reviewing the Input Fields on Each QBE Tab](#)
- [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"](#))
- [Library](#) (see [Chapter 6, "Working with Libraries"](#))

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](#).

Figure 3-1 QUERY BY EXAMPLE Page

About the Tabs on the QUERY BY EXAMPLE Page

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** — Lets you enter querying criteria based on general, *study*, reporter, and literature information about the case.
- **Patient tab** — Lets you enter querying criteria based on information about the patient, lab data, other relevant history, and the patient's parent.
- **Products tab** — Lets you enter querying criteria based on product information and dosage regimens.
- **Events tab** — Lets you enter querying criteria based on information about the event and its seriousness criteria.

- **Analysis tab** — Lets you enter querying criteria based on information about case analysis and imputability.
- **Activities tab** — Lets you enter querying criteria based on case activity information, such as contact logs, action items, and case lock/archive dates.
- **Additional Info tab** — Lets you enter querying criteria based on additional information about the case such as reference type, ID, and notes.
- **Advanced Conditions tab** — Lets you integrate a QBE with an advanced condition stored in Argus Insight. In addition, you can convert a QBE into an advanced condition. For more information, see [Chapter 5, "Using Advanced Conditions to Create Queries."](#)

Example of a QBE

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

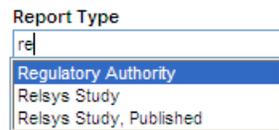
| Tab Name | Field Name | Value |
|----------|-------------------------------|---------------------|
| General | Country of Incidence | United States |
| Products | Product Name | Algoheal Injection |
| Events | Event Description to be Coded | Injection site rash |
| | Seriousness Criteria | Hospitalized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

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) |
| 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 **Create Query, Query by Example**, and then select **New**. The system displays the QUERY BY EXAMPLE page with the General tab in focus.

- Specify the criteria for your query. You can enter values into any of the fields on any of the QBE tabs, as appropriate.

Note: The fields 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:

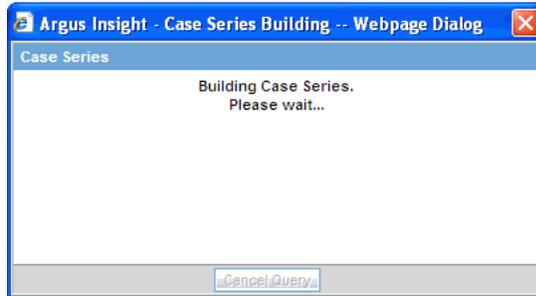
- [General Tab](#)
- [Patient Tab](#)
- [Products Tab](#)
- [Events Tab](#)
- [Analysis Tab](#)
- [Activities Tab](#)
- [Additional Info Tab](#)

Tip: When you are entering criteria for your query:

- If you want to clear all the values you entered on the current tab only, click **Clear Tab**.
- If you want 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"](#) 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 3-7.
- If the case series is appropriate, you may want to save your QBE. For more information, see ["Saving the QBE"](#) on page 3-8.
- 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 3-7.

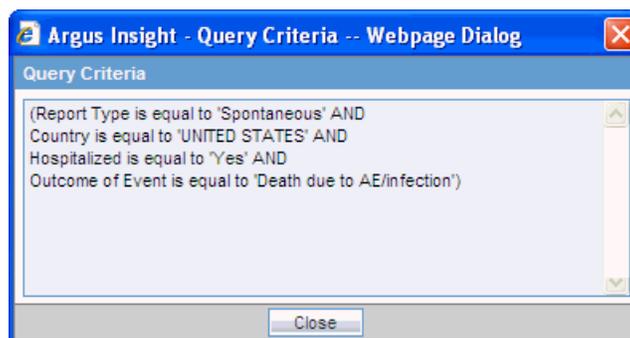
Figure 3–2 Example of Query Results on the ACTIVE CASE SERIES Page

Reviewing and Modifying the Criteria for an Executed QBE

As described earlier, 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 opens. 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 3-37 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.

Note: The QUERY BY EXAMPLE LIBRARY page lists all the QBEs saved to the system. See "[Working with Saved QBEs](#)" on page 3-38 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.

Reviewing the Input Fields on Each QBE Tab

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

The **General** tab (see [Figure 3-3](#)) differs from what you see in Argus Safety in the following ways:

- You can specify only one follow-up date.
- You can specify only one case classification.
- You can specify information only about one reporter.
- You need to scroll the page to view all the fields available.

Figure 3-3 General Tab on the QUERY BY EXAMPLE Page

The screenshot displays the Oracle Argus Insight interface for the 'QUERY BY EXAMPLE' page, specifically the 'General' tab. The page is organized into several sections:

- General Information:** Includes fields for Report Type, Country, Initial Receipt Date, Central Receipt Date, Case Status, Follow-up Received, Safety Received, and a checkbox for Significant.
- 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. There are also checkboxes for Report Sent to Regulatory Authority by Reporter?, Protect Confidentiality, Primary Reporter, and Correspondence Contact.
- Literature Information:** A section at the bottom of the form.

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

Table 3–2 describes the various fields in the **General** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Table 3–2 Fields in the General Tab on the QUERY BY EXAMPLE Page

| 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 3-12 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.) Fields in the General Tab on the QUERY BY EXAMPLE Page

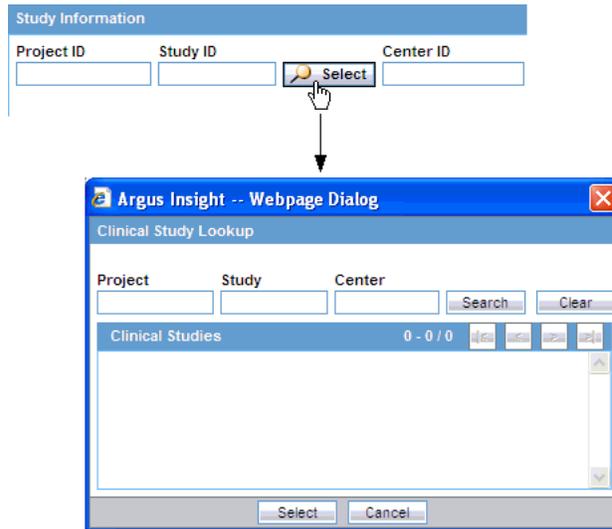
| Section | Field or Check Box | Description |
|-------------------------------|--|---|
| | Country | Enter the reporter's country ID that the query looks for in cases. |
| | Phone Number | Enter the reporter's phone number that the query looks for in cases. |
| | Alternate Phone | Enter the reporter's 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 automatically 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:

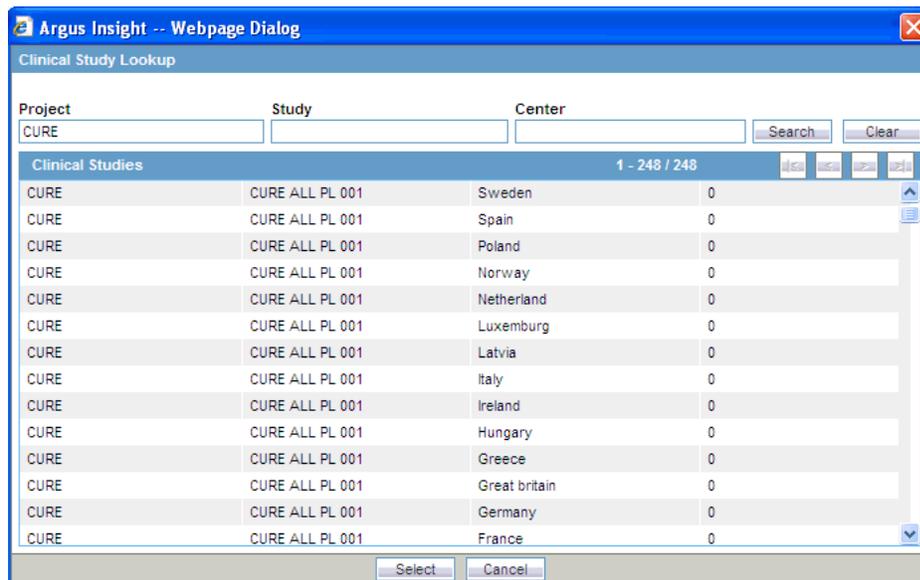
1. Click the **Select** button associated with the **Study ID** field. The system displays the Clinical Study Lookup dialog box.



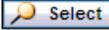
2. Enter the first few letters of the project name, study ID, or study center name in their respective text boxes.

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 system searches for the specified search strings. The Clinical Study Lookup dialog box displays the search results in a grid format.



4. Select a clinical study from the list.
5. Click **Select**. The system returns to the QUERY BY EXAMPLE page and automatically inserts your selected information 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

The **Patient** view (see [Figure 3-4](#)) differs from what you might see in Argus Safety in the following ways:

- You can specify information only about one lab data element
- You can specify details of only one relevant history
- You need to scroll the page to view all the fields available.

Figure 3-4 Patient View for the Patient Tab on the QUERY BY EXAMPLE Page

Table 3–3 describes the various 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 Fields in the Patient View of the Patient Tab on the QUERY BY EXAMPLE Page

| 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 Number | 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.) Fields in the Patient View of the Patient Tab on the QUERY BY EXAMPLE Page

| 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 3-17 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 3-18 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

This **Parent** view (see [Figure 3–5](#)) differs from what you might see in Argus Safety in the following ways:

- You can specify details of only one relevant history.
- You can specify details of only one medical history.

Figure 3–5 Parent View for the Patient Tab on the QUERY BY EXAMPLE Page

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

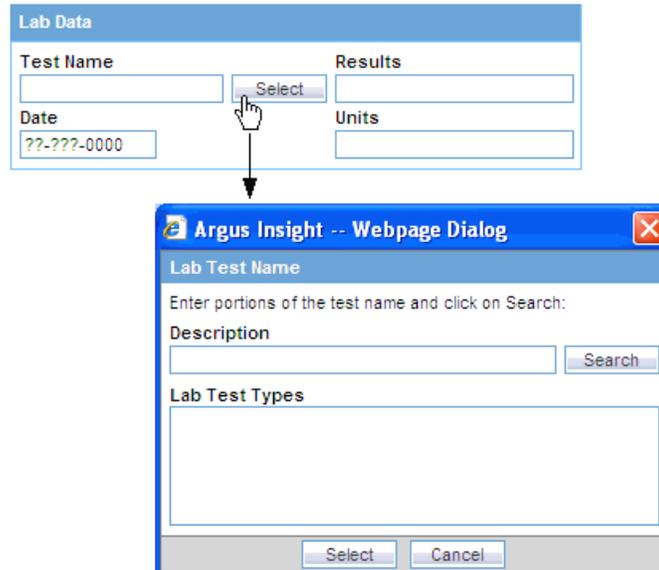
Table 3–4 Fields in the Parent View of the Patient Tab on the QUERY BY EXAMPLE Page

| 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. |
| Other Relevant History | Parent Breastfeeding | Select this check box to retrieve cases where parent is breast feeding. |
| | 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 3-18 for more information. |
| Ongoing | Select this check box to retrieve cases where the relevant history condition is continuing / ongoing. | |

Selecting a Lab Test

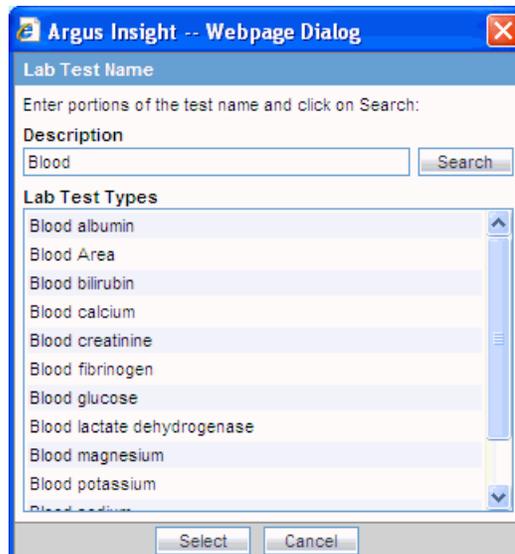
To select a lab test:

1. Navigate to the QUERY BY EXAMPLE page.
2. Click the **Patient** tab. Make sure the Patient view is displayed.
3. Click the **Select** button associated with the **Test Name** field in the Lab Data section. The system opens the Lab Test Name dialog box.



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 system displays the search results in the Lab Test Types section.

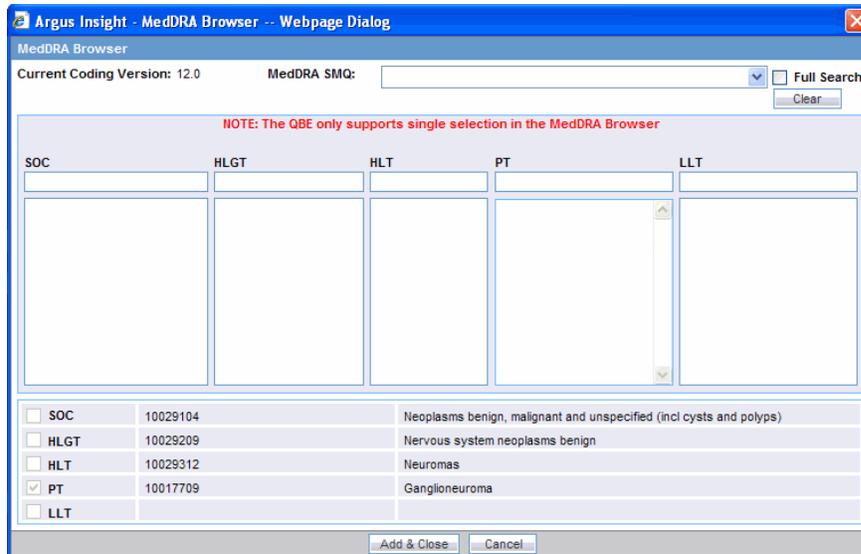


5. Select the required test name.
6. Click **Select**. The system inserts the selected test into the **Test Name** field.

Using the MedDRA Browser

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

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



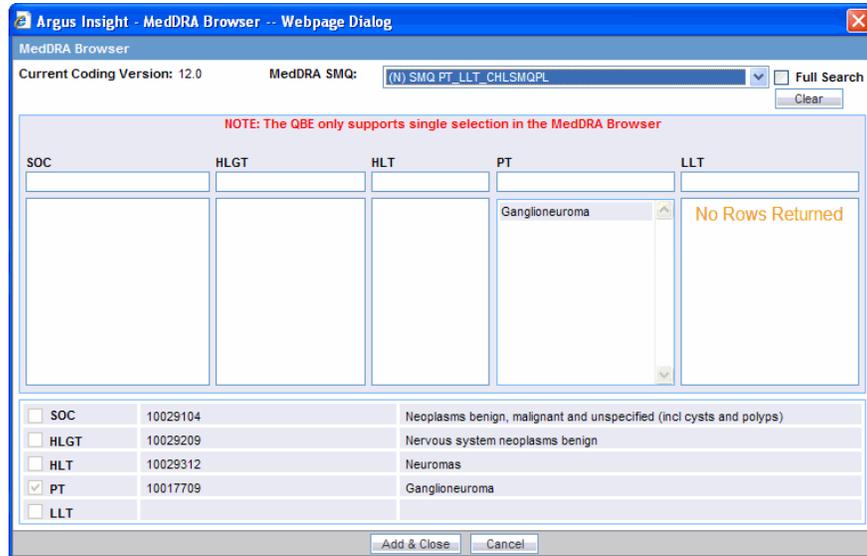
Note: The output returned by the MedDRA Browser for the **Patient**, **Product** and **Analysis** tabs of QBE is the **Preferred Term (PT)**. The **Events** tab of QBE provides output for multiple options. You can select and search the required term(s), based on the **Seriousness Criteria**.

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.

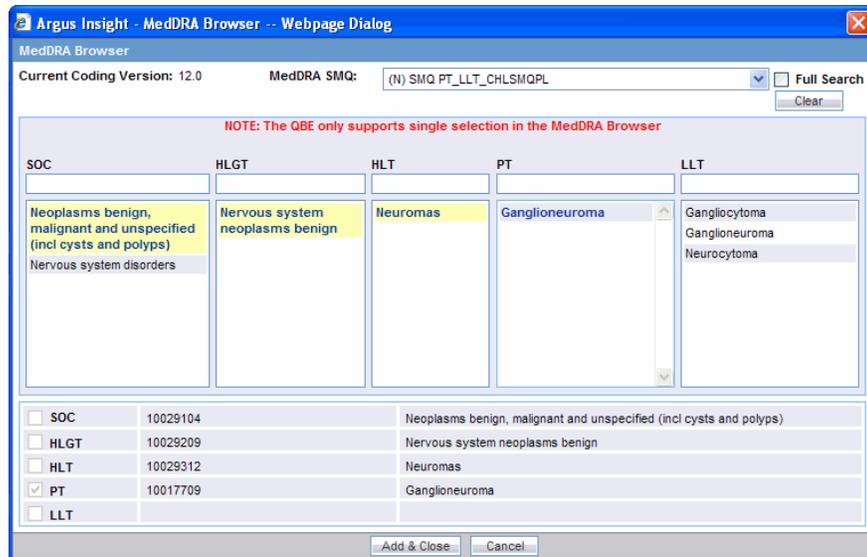
Note: The Special Category drop-down list displays all the SMQs that can be selected. The selected SMQ searches across PT and LLT levels of the MedDRA dictionary.

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 system searches for the specified word in the event terms. The MedDRA Browser displays the search results in a *column* below the text box in which you entered the text string.



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.



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 are displayed in the respective fields in the QBE form.

Products Tab

The **Products** tab (see [Figure 3–6](#)) differs from what you might see in Argus Safety in the following ways:

- You can enter information only about one product.
- You can specify details of only one dosage regimen.
- You need to scroll the page to view all the fields available.

Figure 3–6 Products Tab on the QUERY BY EXAMPLE Page

The screenshot displays the Oracle Argus Insight web application interface. At the top, there are navigation tabs: Home, Tools, Help, and Logout. Below this is a sub-navigation bar with Home, Create Query, Query Results, and Case Series Reports. The main header reads 'QUERY BY EXAMPLE' and shows the 'Active Query Name' as 'Pharmacovigilance' and 'Active Case Series' as 'SPT Injury M'. The 'Name' field is set to '< Not Saved >' and the 'Category' is 'General'. A tabbed interface is visible with 'Products' selected. The 'Product Information' section includes fields for Product Name, Generic Name, Product Indication PT, Company Product, Study Drug, Company Drug Code, Drug Code, Manufacturer, Formulation, WHO DRUG ATC CODE, WHO DRUG ATC DESCRIPTION, Concentration, Units, Interaction?, and Contraindicated?. The 'Dosage Regimens' section includes checkboxes for 'Ongoing' and 'Outside Therapeutic Range', and fields for Start Date/Time, Stop Date/Time, Duration of Regimen, Dose Number, Dose, Units, Dose Description, Daily Dosage, Regimen Daily Dosage Unit, Regimen Dosage, and Total Regimen Dosage Unit. At the bottom, there are buttons for Save, Save As, Convert to Advanced Condition, Clear Tab, Clear All, Permissions, and Execute.

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

Table 3–5 Fields in the Products Tab on the QUERY BY EXAMPLE Page

| 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 automatically 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 3-24 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 3-26 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 3-24 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 3-18 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 3-29 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 3-24 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 3-24 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 3-24 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 3-24 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.) Fields in the Products Tab on the QUERY BY EXAMPLE Page

| 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. | |

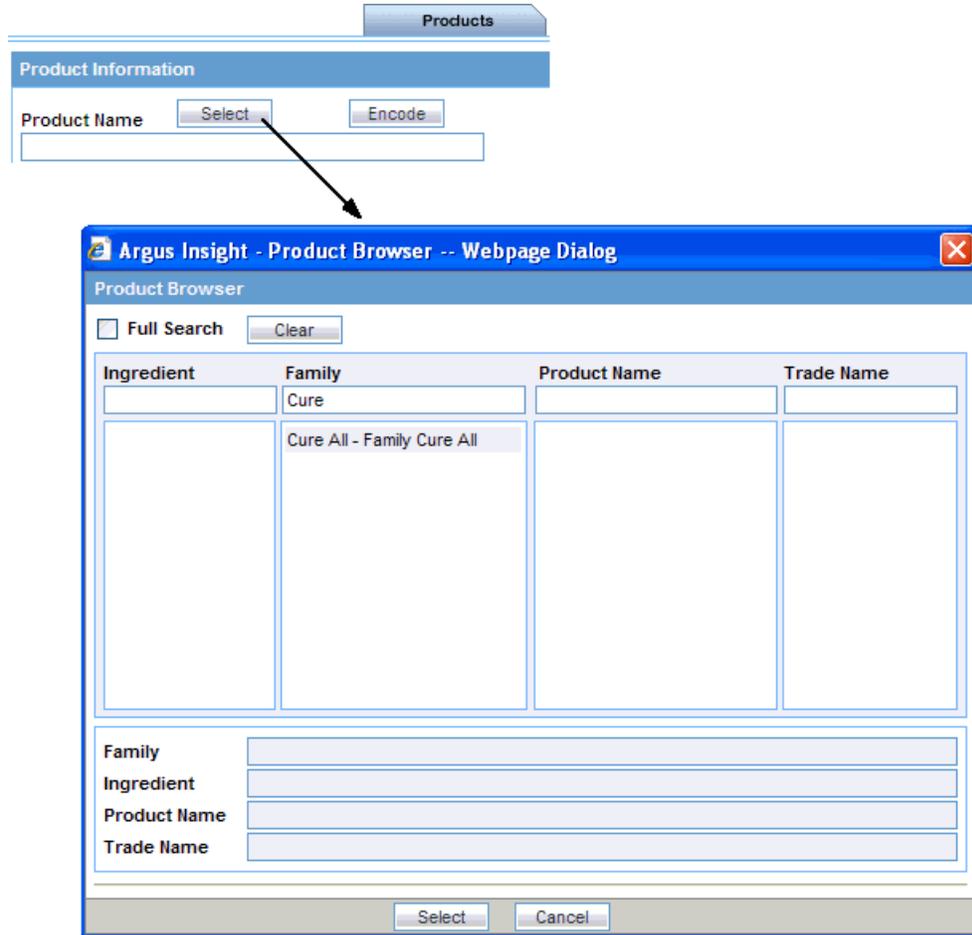
Table 3–5 (Cont.) Fields in the Products Tab on the QUERY BY EXAMPLE Page

| 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. |
| | Results Dechallenge | 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 | Select the Yes, No, Unknown, or Ignore option, as appropriate, to indicate whether the query looks for cases where drug was taken previously. |
| | Results <i>Rechallenge</i> | 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

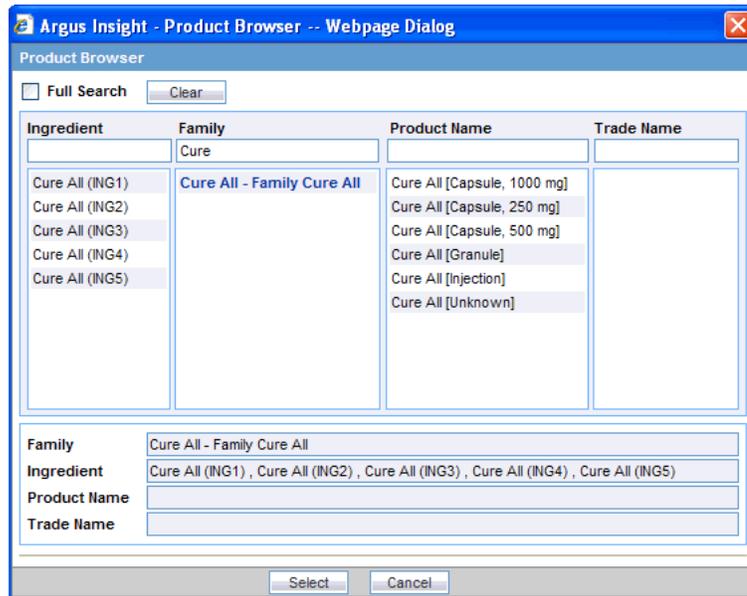
To select a product by using the Product Browser:

1. Select the **Products** tab on the QUERY BY EXAMPLE page.
2. Click the **Select** button associated with the **Product Name** field. The system opens the Product Browser dialog box.

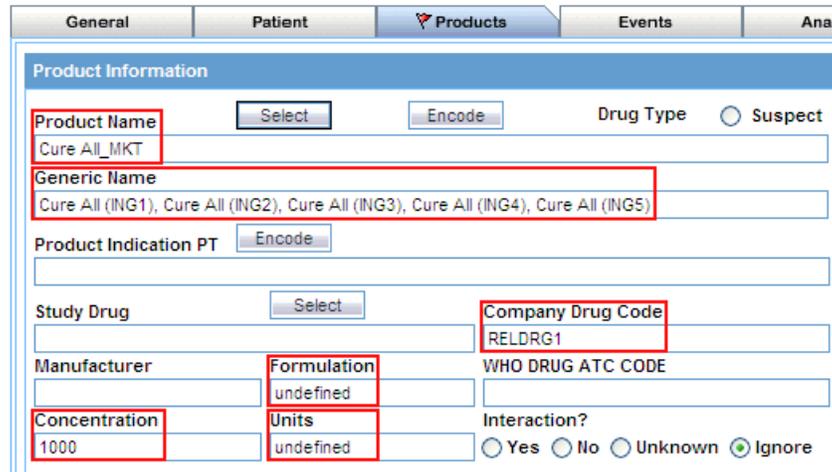


3. Enter the first few letters (text string) of the product ingredient, family name, product name, or trade name in the respective field.
 - If you want to search for the specified string in the entire product information, select the **Full Search** check box.
 - If you want to remove your search criteria and start over, click **Clear**.
4. Press Tab (or click another field in the dialog box) to begin the search. The system searches the database for the text string that you specified. The Product Browser displays the search results in the column below the field in which you entered the search string.

- Select an item from the search results list. The details for the selected item are displayed in all the Product Browser fields.



- Select the required product name or trade name, as appropriate.
- Click **Select**. The system returns to the Products tab and automatically populates the Product Name, Generic Name, Company Drug Code, Formulation, Concentration, and Units fields with the details of the product you selected.



Using the WHO Drug Browser

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

1. Select the **Products** tab on the QUERY BY EXAMPLE page.
2. Click the **Encode** button associated with the **Product Name** field. The system opens the WHO Drug Browser dialog box.

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.

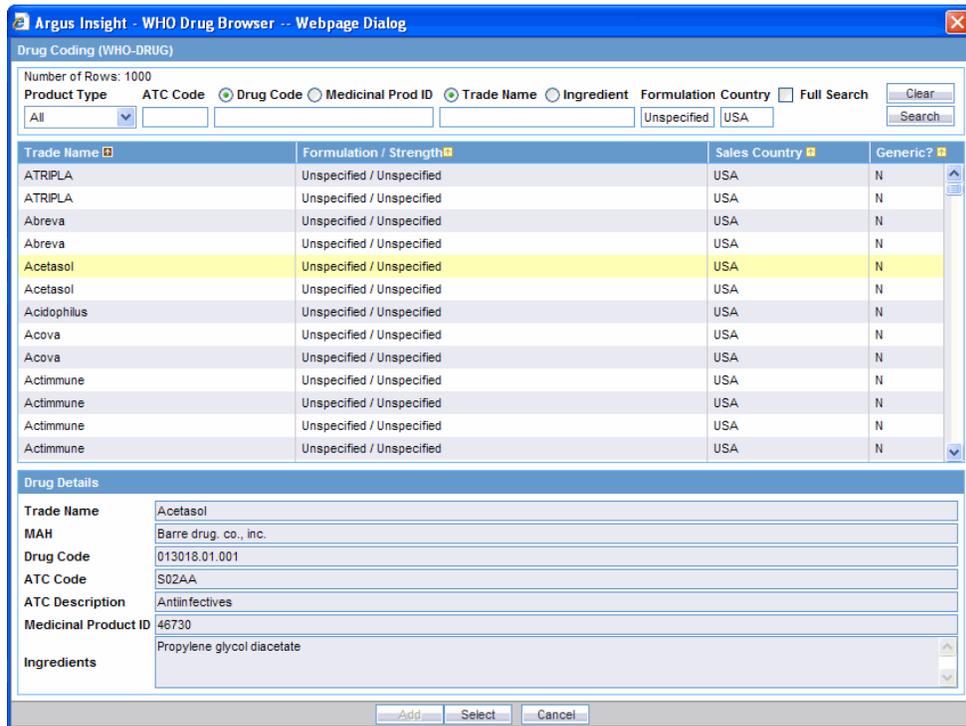
The primary difference between the two browsers is the availability of the following fields in WHO Drug Browser:

- **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 can enter values into one, several, or all fields.

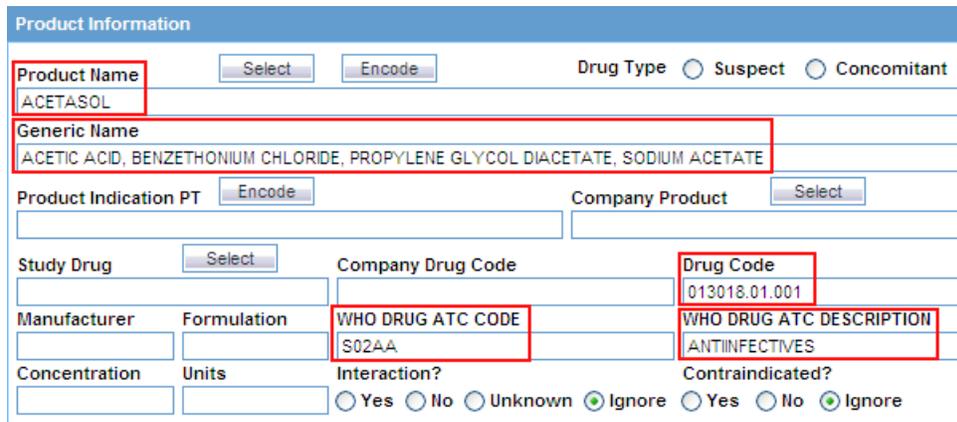
- a. In the **Product Type** field, select the kind of product to include in your search. You can include all products or a single product. The default value is **All**.
 - b. In the **ATC Code** field, type all or part of the Anatomical Therapeutic Chemical (ATC) classification code.
 - c. Select either 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 system searches the database for drug products that match your specified search criteria. The WHO Drug Browser displays the search results in a grid format.

- Select the required WHO drug. The WHO Drug Browser highlights the drug you selected and populates the fields in the Drug Details section.



- Click **Select**. The system returns to the **Products** tab and automatically populates the Product Name, Generic Name, Drug Code, WHO DRUG ATC CODE, and WHO DRUG ATC DESCRIPTION fields for the WHO drug you selected.

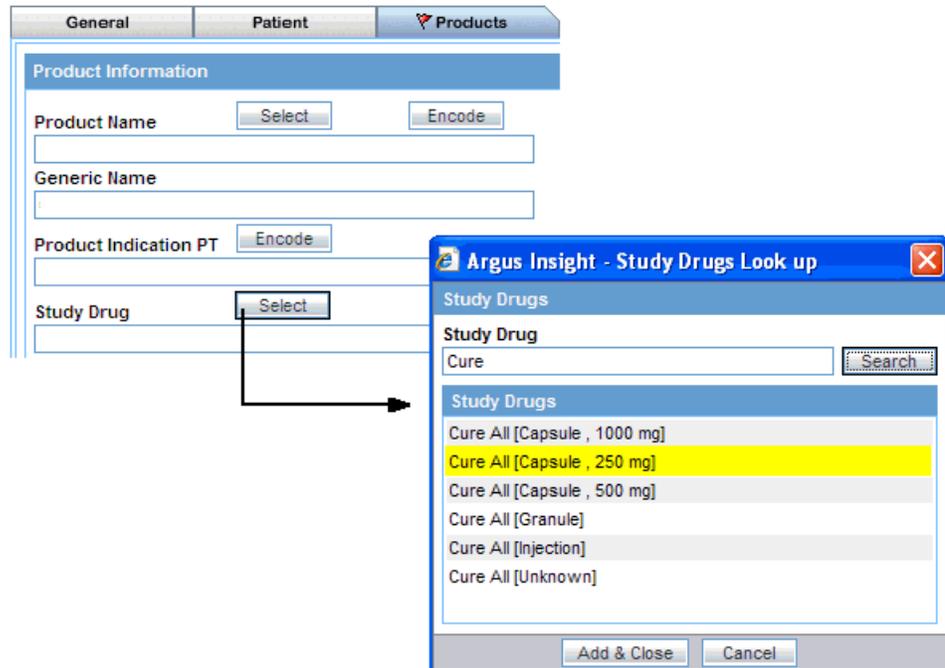
Note that the Generic Name field displays all the ingredients for the WHO drug you selected.



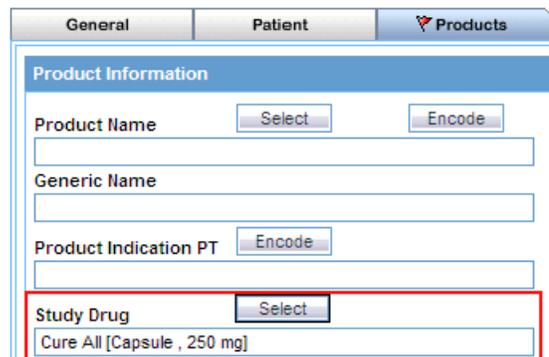
Using the Study Drug Lookup

To select a study drug:

1. Select the **Products** tab on the QUERY BY EXAMPLE page.
2. Click the **Select** button associated with the **Study Drug** field. The system opens the **Study Drugs Lookup** dialog box.
3. Enter the first few letters of the study drug name in the **Study Drug** field.
4. Click **Search**. The system searches the database for the specified search string and displays the search results.



5. Select the required study drug from the list.
6. Click **Add & Close**. The system returns to the **Products** tab and populates the **Study Drug** field with the drug you selected.



Events Tab

The **Events** tab (see [Figure 3-7](#)) differs from what you might be used to seeing in Argus in that details of only one event can be specified.

Figure 3-7 Events Tab on the QUERY BY EXAMPLE Page

[Table 3-6](#) describes the various fields in the **Events** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Table 3-6 Fields in the Events Tab on the QUERY BY EXAMPLE Page

| 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 3-18 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. | |
| | | | |
| | | | |
| | | | |

Table 3–6 (Cont.) Fields in the Events Tab on the QUERY BY EXAMPLE Page

| Section | Field or Check Box | Description |
|-----------------------------|--|---|
| | 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. |
| | 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 this check box to retrieve cases where Event Lack of Efficacy is selected. |
| | Related to <i>Study</i> Conduct? (As Reported) | Select the Yes , No , Unknown , or N/A option, as appropriate, 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 3-18 for details. |
| Seriousness Criteria | Seriousness Criteria check boxes | Select one or more associated check boxes to specify the seriousness criteria that the query looks for in cases. |

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 Analysis Tab on the **QUERY BY EXAMPLE** Page

[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 Fields in the **Case Analysis** View of the **Analysis** Tab on the **QUERY BY EXAMPLE** Page

| 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.) Fields in the Case Analysis View of the Analysis Tab on the QUERY BY EXAMPLE Page

| 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 3-18 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 Fields in the AFSSaPS View of the Analysis Tab on the QUERY BY EXAMPLE Page

| 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 3-18 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

The **Activities** tab (see [Figure 3–9](#)) differs from what you might see in Argus Safety in the following ways:

- You can specify information only about one contact log.
- You can specify information only about one action item.
- Routing search is not applicable.

Figure 3–9 Activities Tab on the QUERY BY EXAMPLE Page

[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 Fields in the Activities Tab on the QUERY BY EXAMPLE Page

| 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. |

Table 3–9 (Cont.) Fields in the Activities Tab on the QUERY BY EXAMPLE Page

| Section | Field | Description |
|-------------------|---------------------|---|
| 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

The **Additional Info** tab (see [Figure 3–10](#)) differs from what you might see in Argus Safety in the following ways:

- You can specify information only about one note.
- No attachments are permitted.
- You can specify information only about one reference.

Figure 3–10 Additional Info Tab on the QUERY BY EXAMPLE Page

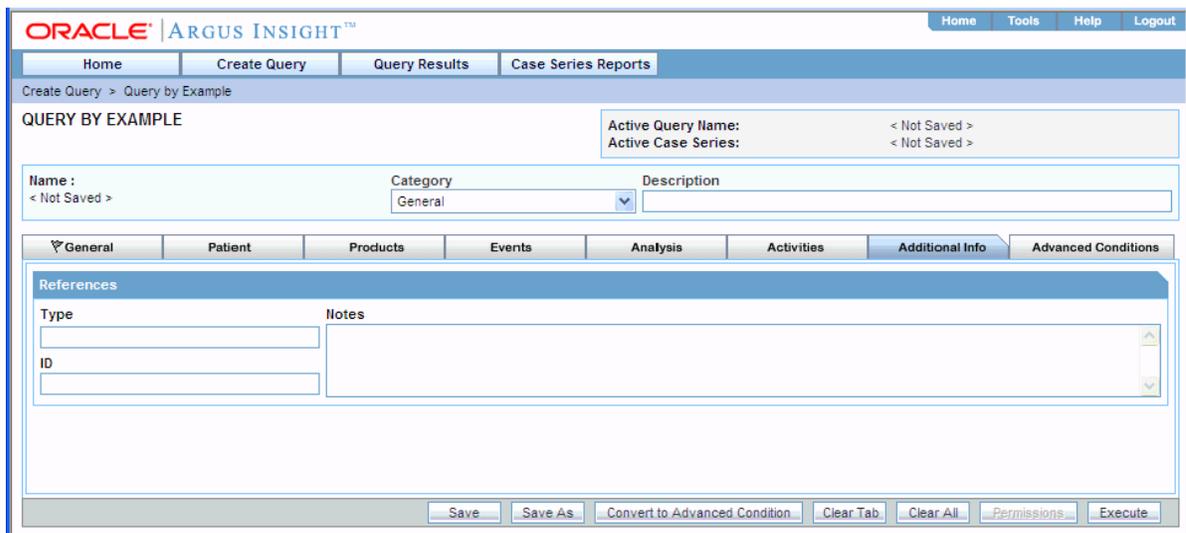


Table 3–10 describes all the fields in the **Additional Info** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

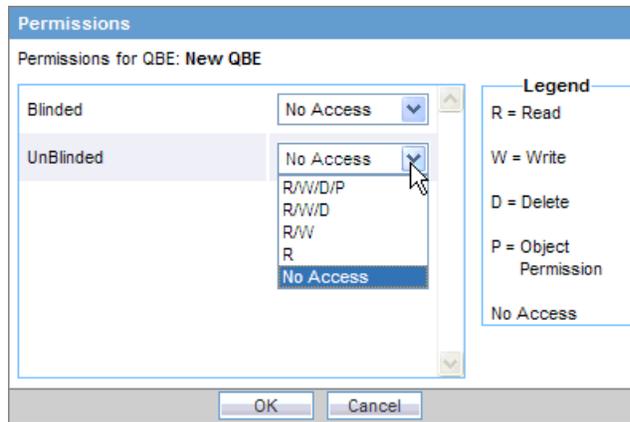
Table 3–10 Fields in the Additional Information Tab on the QUERY BY EXAMPLE Page

| 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 system opens the **Permissions** dialog box and displays 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. You can select from these options:

| 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 system saves the permission settings.

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, navigate to **Create Query, Query by Example**, and select **Active**. The ACTIVE QUERY BY EXAMPLE page displays 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 displays the name of the QBE. However, if the active QBE was not saved to the system before executing, the Active Query Name field displays the following text:

<Not Saved>

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 can 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, you can:

- Click **Clear Tab** to clear all the values for the current tab.
- Click **Clear All** to clear all the values specified in all the tabs for this active QBE.

Saving the Active QBE

You have two options for saving the active QBE:

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

The QUERY BY EXAMPLE LIBRARY page lists all the QBEs saved to the system. See "[Working with Saved QBEs](#)" on page 3-38 for more information.

Converting the Active QBE to an Advanced Condition

Click **Convert to Advanced Condition** to convert the QBE to an Advanced Condition. See "[Using QBEs with Advanced Conditions](#)" on page 3-42 for more information.

Assigning Permissions

Click **Permissions** to set the group-level access permissions on the QBE. The **Permissions** button is only available for saved active QBEs. See "[Assigning Group-Level Permissions to a Saved QBE](#)" on page 3-36 for more information.

Executing the Active QBE

Click **Execute** to generate a case series by using the active QBE.

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 **Create Query, Query by Example**, and select **Library**. The QUERY BY EXAMPLE LIBRARY page opens. See [Figure 3-11](#).

The QUERY BY EXAMPLE LIBRARY page displays the following information about each 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.
- An icon in the Associated Report column if the QBE has a report associated with it. See "[Associating a Report Group with a QBE](#)" on page 3-40 for more information.

Figure 3–11 QUERY BY EXAMPLE LIBRARY Page

The screenshot displays the Oracle Argus Insight interface for the 'QUERY BY EXAMPLE LIBRARY' page. At the top, there are navigation tabs: Home, Create Query, Query Results, and Case Series Reports. Below the tabs, the page title is 'QUERY BY EXAMPLE LIBRARY'. On the right side, there are two status fields: 'Active Query Name: < Not Saved >' and 'Active Case Series: < Not Saved >'. The main area is a search table with the following columns: Name, Description, Last Modified, User Full Name, Category, and Associated Report. The table contains one row with the following data: Name: COI - US, Description: COI - US, Last Modified: 27-DEC-11, User Full Name: insighttest, Category: General, and Associated Report: (empty). Below the table, there is a toolbar with buttons for New, Modify, Delete, Associate, Disassociate, Limit Query to Active Case Series (with a checkbox), and Execute. The page also includes a search bar and a clear button at the top right of the table area.

Searching for a Saved QBE

To search for a saved QBE:

- Specify the search criteria, as appropriate:
 - To search for a QBE by its name, type the QBE name in the **Name** text box.
 - To search for a QBE 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 QBE descriptions.
 - To search for a QBE by its date of modification, enter the modification date in the first **Last Modified** date field. You can 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.
- Click **Search**. Based on your search criteria, the system displays the search results in a list.
 - 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 **Create Query, Query By Example**, and then select **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. Select a QBE from the list of QBEs in the QUERY BY EXAMPLE LIBRARY page.
2. Click **Modify**. The QUERY BY EXAMPLE page displays the QBE form for the selected QBE.
3. Modify the field values in the QBE form.
4. Save your changes. Click **Save** to save the current query; click **Save As** to save the current query by another name.

Deleting a Saved QBE

To delete a saved QBE:

1. Select a QBE from the list of QBEs in the QUERY BY EXAMPLE LIBRARY page.
2. Click **Delete**. The system prompts for confirmation that you want to delete the QBE.
3. Click **OK**. The system deletes the selected QBE and returns to the QUERY BY EXAMPLE LIBRARY page.

Associating a Report Group with a QBE

Report packaging is the concept of grouping reports together. You can define multiple reports that are always or often executed at the same time into a group. A set of reports run on a weekly or periodic basis can be scheduled and run as a package.

In Argus Insight, you can associate a report group and the report scheduling to a power query (QBE, Filter Value Set, and Advanced Conditions) or to a case series.

Argus Insight lets you *associate* the report group, schedule a time to generate the reports, and automatically send the completed reports through email to one or more users that you specify.

Associating a report group with a QBE is helpful in situations when you need to generate the latest case series and run a report on it each time the data mart is refreshed. Instead of manually executing the QBE to generate the latest case series and then running the report, you can use the report association functionality of Argus Insight to accomplish the task automatically.

For detailed procedures and more information about associating report groups, see "[Scheduling and Associating Reports Against a Query or Case Series](#)" on page 8-10.

Note: To be able to schedule reports, you must have an enterprise login configured in the Business Intelligence tool (either BusinessObjects or Cognos) you are using with Argus Insight.

Executing a Saved QBE

To execute a saved QBE:

1. Navigate to **Create Query, Query by Example**, and select **Library**. The **QUERY BY EXAMPLE LIBRARY** page opens.
2. Select a QBE from the list.
3. Click **Execute**. The system executes the QBE, and then displays the **ACTIVE CASE SERIES** page.



After generating the case series, you can 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 3-41. This case series automatically 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 **Query Results, Case Series**, and select **Library**. When the **CASE SERIES LIBRARY** page opens, select the case series and click **Make Active**.
2. Navigate to **Create Query, Query by Example**, and select **Library**. The **QUERY BY EXAMPLE LIBRARY** page opens.
3. Select the query you want 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 QBE 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 QBEs with Advanced Conditions

Advanced conditions let you create complex queries that involve Boolean and set operations among various 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, 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 various tab pages in the QBE form.
3. Click **Convert to Advanced Condition**. The ACTIVE ADVANCED CONDITIONS EDITOR page opens.

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

The screenshot displays the 'ACTIVE ADVANCED CONDITIONS EDITOR' interface in Oracle Argus Insight. At the top, there are navigation tabs: Home, Create Query, Query Results, and Case Series Reports. Below the tabs, the 'ACTIVE ADVANCED CONDITIONS EDITOR' section is visible, showing the 'Active Query Name' and 'Active Case Series' both set to '< Not Saved >'. The main area contains a form with fields for 'Name', 'Category' (set to 'Pharmacovigilance'), and 'Description'. Below this is a table titled 'Advanced Condition' with the following structure:

| (| Attributes | Condition | Value |) | Operator |
|---|------------------|-----------|--------------------|---|----------|
| (| Report Type | equal to | Spontaneous |) | AND |
| (| Country | equal to | UNITED STATES |) | AND |
| (| Hospitalized | equal to | Yes |) | AND |
| (| Outcome of Event | equal to | Death due to AE/in |) | |

At the bottom right of the interface, there are 'Save' and 'Execute' buttons.

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 various attributes

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

Integrating a QBE with an Advanced Condition

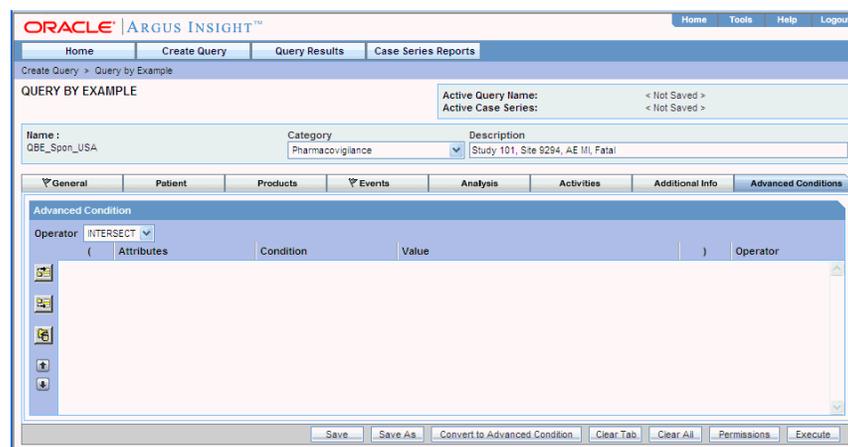
You can integrate a new, active, or saved QBE with an existing advanced condition through these set operators:

- INTERSECT
- MINUS
- UNION

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

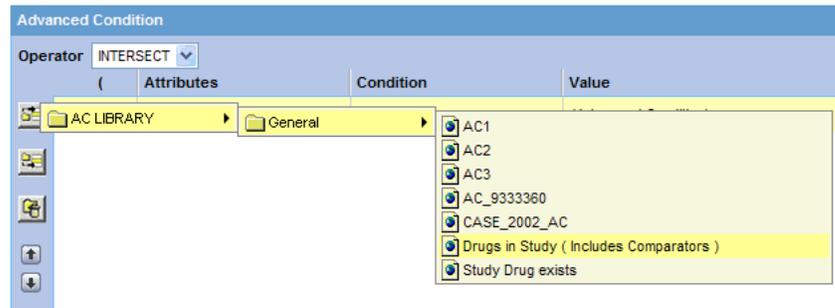
To integrate a QBE with existing advanced conditions:

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 various tab pages in the QBE form.
3. Click the **Advanced Conditions** tab.

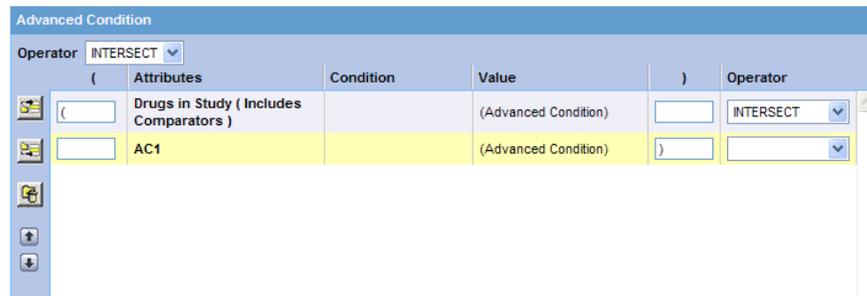


4. Use the **Operator** field to select the set operator you want to use to integrate the QBE and the advanced condition. You can select **INTERSECT**, **MINUS**, or **UNION**.
5. Select the advanced condition you want to integrate with the QBE as follows:
 - a. Click the **Add Advanced Condition Above** icon on the left bar to open the Advanced Conditions menu. This menu lists all the advanced conditions 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 system adds your selection 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 changing the order of the rows, select a row and then 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. Use the field in the **Operator** column to 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 opens and displays 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 3-42 for more information.

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

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 your querying criteria is based on multiple values or a range of values in fields.

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"](#))
- Library (see [Chapter 6, "Working with Libraries"](#))

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, select a predefined or custom filter and specify values (multiple or range) in the desired filter elements associated with the filter. You can then execute this query (value set) to generate a case series.

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 **Create Query, Filters**, and select **New Value Set**. The Select Filter for New Value Set dialog box opens:



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 one of the predefined filters (**Compliance, Configuration, Management, Pharmacovigilance, or Workflow**) depending on your reporting needs. If custom filters are saved to the system, you can select a custom filter instead.
3. Click **OK**. The **FILTER VALUE SET** page opens.



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:

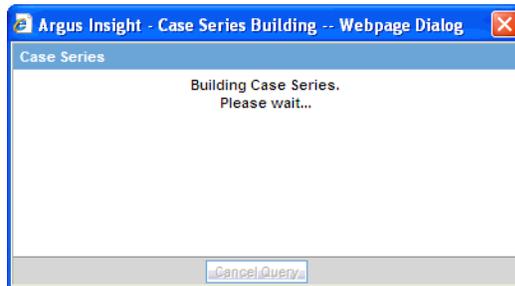
1. Specify values for the filter elements in the various sections. Depending on the filter you selected, the FILTER VALUE SET page may contain these sections:

| Sections in the New FILTER VALUE SET Page | Associated Elements (Fields) | |
|---|---|---|
| Case Information | Case Followup Receipt Date Case <i>Report</i> Type Family Name Product | Case Initial Receipt Date Event Listedness/Lic Country Owned by Site Project/Study |
| 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 **Create Query, Filters**, and select **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 is displayed:



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 ACTIVE CASE SERIES page displays the list of cases.

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.

The screenshot shows the Oracle Argus Insight interface for configuring a Filter Value Set. The page is titled 'FILTER VALUE SET' and includes a navigation bar with 'Home', 'Create Query', 'Query Results', and 'Case Series Reports'. The 'Active Query Name' is 'Study_429F' and the 'Active Case Series' is 'Study_429F'. The 'Name' field is currently empty and labeled '< Not Saved >'. The 'Description' field is also empty. The 'Case Information' section includes filters for Country (AFGHANISTAN, ALBANIA, ALGERIA), Report Type (Begin, Compassionate Use, EDD-Report Type), Owned by Site (Begin, EDD-Description, LAM site), and Case Serious (Serious, Life Threatening, Death). The 'Initial Receipt Date' and 'Follow-up Received' sections have date range pickers. The 'Product Information' section has a 'Company Product w/o Study' dropdown. The 'Report Information' section has a 'Reports Pending' dropdown. The 'Workflow Information' section includes filters for Case Delayed (All, Open), Case Status (All, Closed, Data Entry, Data Entry State), Workflow Group (Administrator Group, Central Administrator, Data Entry Group), and Has Followup (All, Initial only, Has Followup). The 'Advanced Conditions' section has an 'Operator' dropdown set to 'INTERSECT'. At the bottom, there are buttons for 'Save Values', 'Convert to Advanced Condition', 'Clear', and 'Execute'.

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. Type a description of the value set in the **Description** field. For example, you can describe the type of cases the value set retrieves.
9. Click **Save Values**. The Save Value Set dialog box opens.

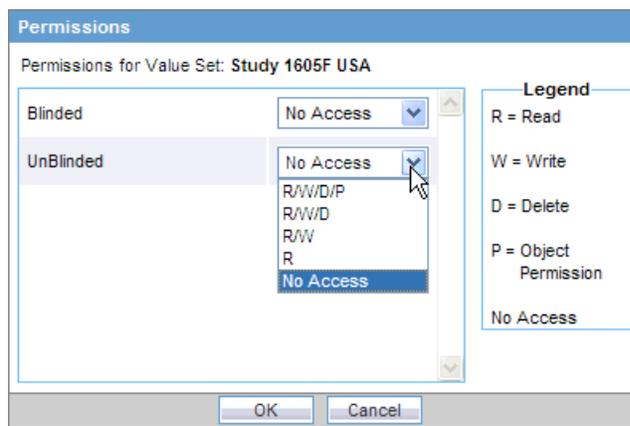
The screenshot shows a 'Save Value Set' dialog box. The title bar reads 'Argus Insight - Save Value Set -- Webpage Dialog'. The dialog has a blue header with the text 'Save Value Set'. Below the header is a text input field with a yellow arrow icon pointing to it, and the label 'For Filter - Pharmacovigilance Name:'. At the bottom of the dialog are 'OK' and 'Cancel' buttons.

10. Type the name of the value set in the **Name** field.
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. Click **Permissions** to assign group-level permissions on the saved value set. The system opens the **Permissions** dialog box and displays the names of all the groups (except the **Administrator** group) that the system administrator has created.



13. Use the drop-down list next to a group name to assign permissions to the group members on the value set you have created. You can select from these options:

| 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. |

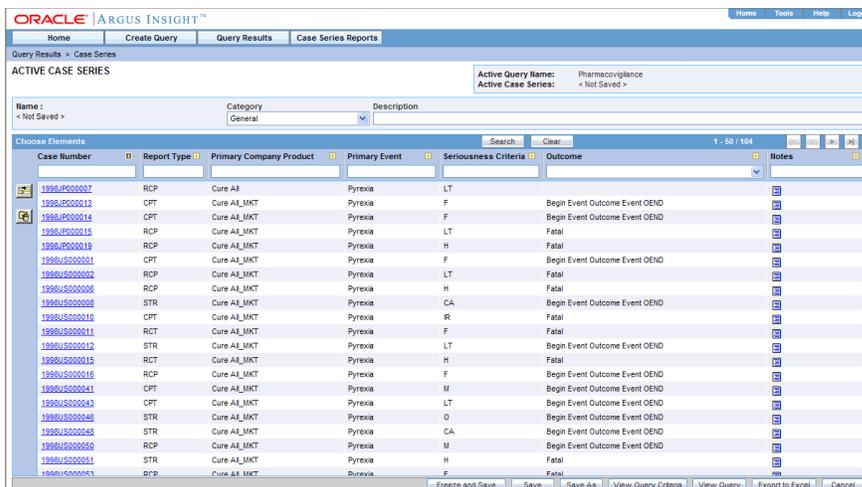
14. Click **OK**. The system saves the permission settings.

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, click **Execute**.

The system retrieves the cases that match the value set criteria and displays the list in the ACTIVE CASE SERIES page.



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

Creating Custom Filters

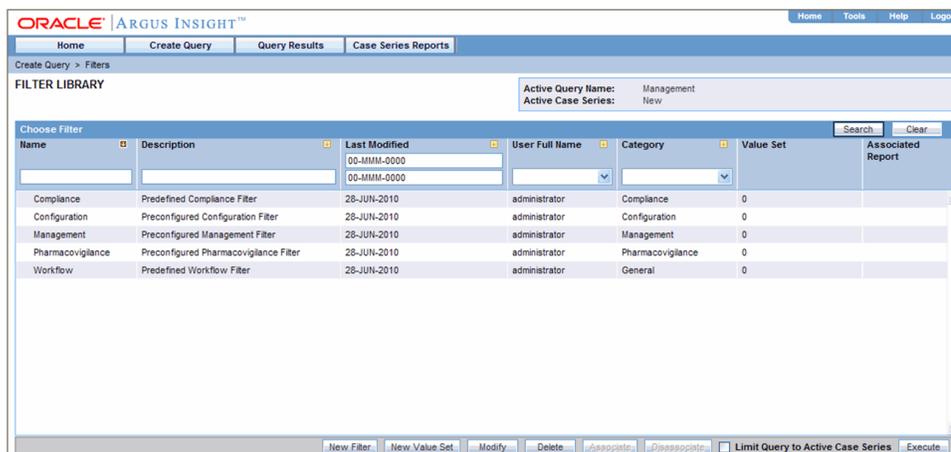
This section includes the following topics:

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

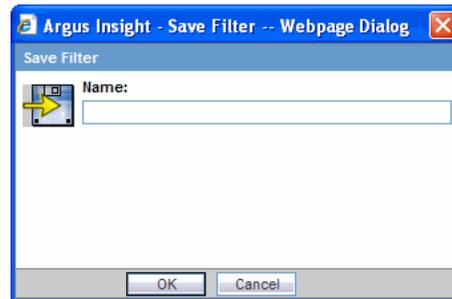
Creating a Custom Filter

To create a custom filter:

1. Navigate to **Create Query, Filters**, and select **Library**. The FILTER LIBRARY page opens. This page lists the predefined as well as custom filters and their value sets in a control tree format.



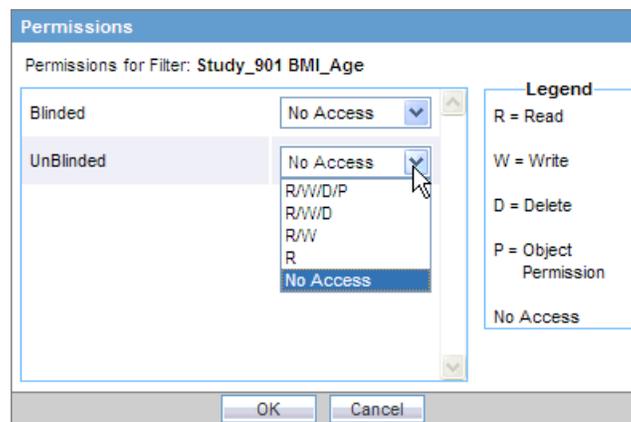
7. Type a description of the custom filter in the **Description** field.
8. Click **Save**. The Save Filter dialog box opens.



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. Click **Permissions** to assign group-level permissions on the filter. The system opens the **Permissions** dialog box and displays the names of all the groups (except the **Administrator** group) that the system administrator has created.



12. Use the drop-down list next to a group name to assign permissions to the group members on the filter you have created. You can select from these options:

| 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**. The system saves the permission settings.

Creating a Value Set for a Custom Filter

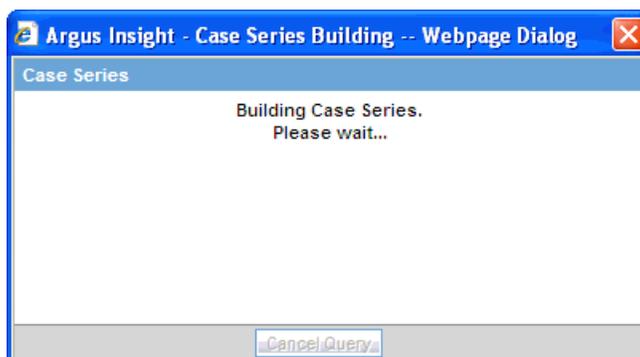
To create a value set for a custom filter:

1. Click **Continue** in the FILTER ELEMENTS page. The FILTER VALUE SET page opens.

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.

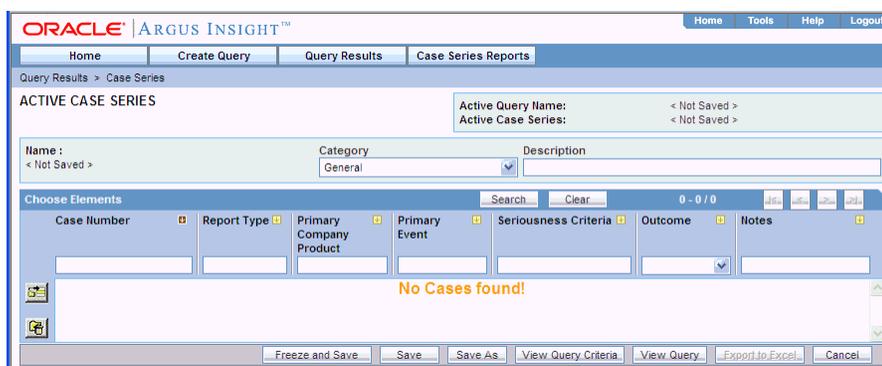
2. Specify values for the filter elements. See ["Using Predefined Filters"](#) on page 4-3 for details.
3. Examine the value set results.

- Click **Execute**. While the system searches for matching cases, the following dialog box is displayed.

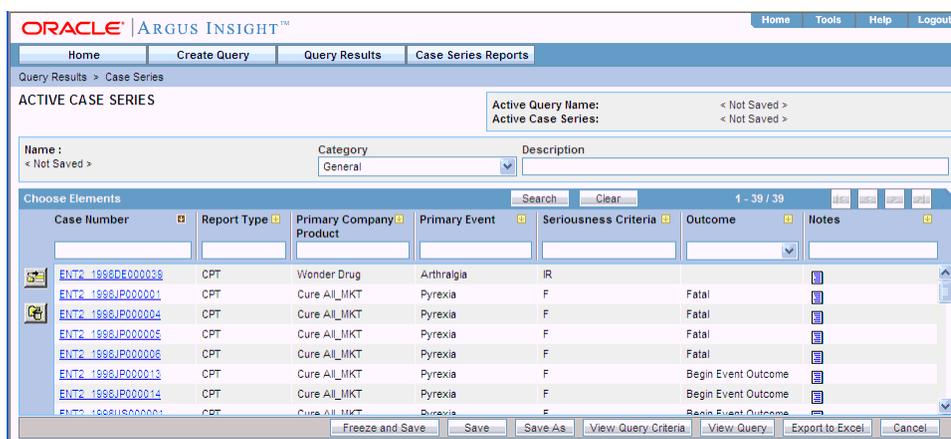


Note: To cancel the query execution at this point and return to the FILTER VALUE SET page, click **Cancel Query**.

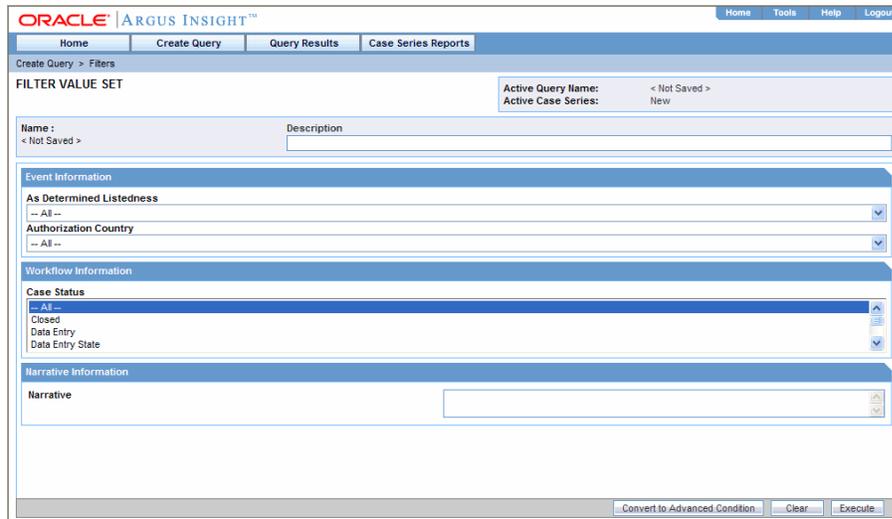
- If the system does not find any cases that match the querying criteria, the following dialog box is displayed. Click **OK** in this dialog box to return to the Value Set *form*, modify the criteria, and execute the value set again.



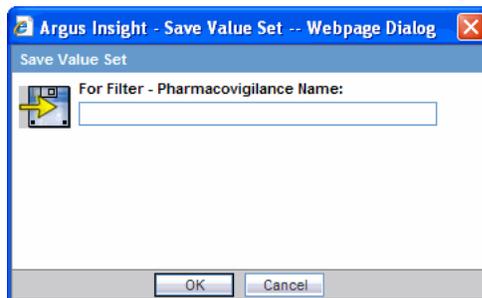
- If the system finds cases that match the query criteria, a list of such cases is displayed in the ACTIVE CASE SERIES page.



7. 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.
8. Click **View Query** in the ACTIVE CASE SERIES page to return to the FILTER VALUE SET page.



9. Modify the value set, if required, and examine the results again or proceed to save the value set.
10. Save the value set to the system.
11. Type a description of the value set in the **Description** field. For example, you can describe the type of cases the value set retrieves.
12. Click **Save Values**. The Save Value Set dialog box opens.

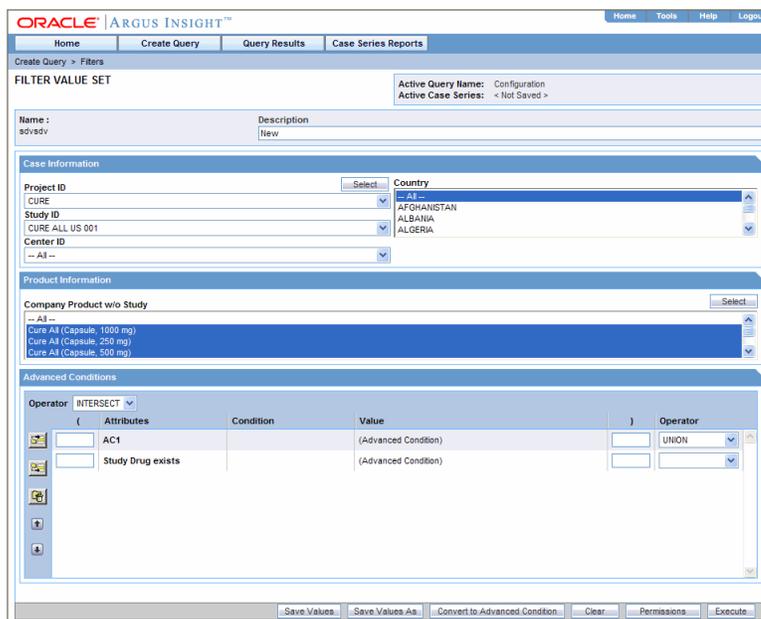


13. Enter a name for the value set.

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

14. Click **OK**. The FILTER VALUE SET page refreshes.

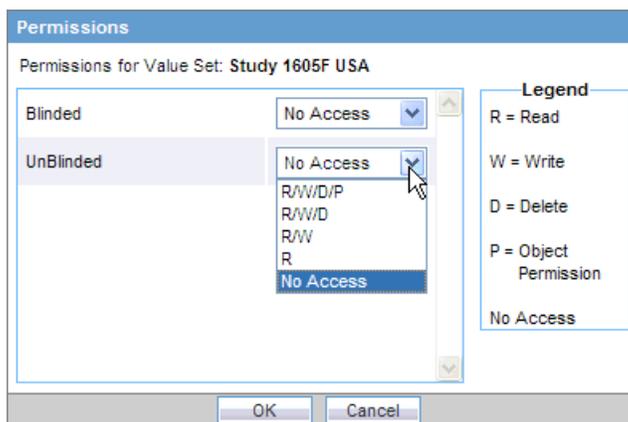
Note that the **Save Values As** button and the **Permissions** button are now enabled.



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. Click **Permissions** to assign group-level permissions on the saved value set. The system opens the **Permissions** dialog box and displays the names of all the groups (except the **Administrator** group) that the system administrator has created.



16. Use the drop-down list next to a group name to assign permissions to the group members on the value set you have created. You can select from these options:

| 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**. The system saves the permission settings.
18. Click **Execute**. The system retrieves the cases that match the value set criteria and displays the list in the ACTIVE CASE SERIES page. After generating the case series, you can 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 **Create Query, Filters**, and select **Active**. The FILTER VALUE SET page displays the value set you executed or modified last.

2. If the value set was saved to the system before executing, the name of the value set appears next to **Name** label. In addition, the name of the filter appears next to the **Active Query Name** label.
3. However, if the value set was not saved to the system before executing, the text <Not Saved> is displayed next to the **Name** label.
4. From the ACTIVE FILTER VALUE SET page, you can perform the following tasks:

| Task | Description |
|--|--|
| Modify the Active Value Set | <p>If required, you can modify the value set by changing the <i>field</i> values.</p> <p>While entering field values, if you want to remove all the values you entered, click Clear.</p> <p>Click Save Values to save the changed field values. This button is only available for a saved value set.</p> |
| Save the Active Value Set by another name | <p>Click Save Values As to save the active value set by a different name.</p> <p>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.</p> |
| Convert Active Value Set to Advanced Condition | <p>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.</p> |
| Assign Permissions on the Active Value Set | <p>Click Permissions to set the group-level access permissions.</p> <p>The Permissions button is only available for saved value sets.</p> |
| Change the Description of the Active Value Set | <p>You can change the description of the active value set by modifying the text displayed in the Description field.</p> <p>Click Save Values to store the changed description.</p> |
| Execute the Active Value Set | <p>Click Execute to generate a case series by using the active value set.</p> |

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 **Create Query, Filters**, and select **Library**.

The screenshot shows the Oracle Argus Insight interface. The top navigation bar includes 'Home', 'Tools', 'Help', and 'Logout'. Below that, there are tabs for 'Home', 'Create Query', 'Query Results', and 'Case Series Reports'. The main content area is titled 'FILTER LIBRARY' and displays a table of filters. The table has the following columns: Name, Description, Last Modified, User Full Name, Category, Value Set, and Associated Report. The table contains five rows of predefined filters. At the bottom of the page, there are several buttons: 'New Filter', 'New Value Set', 'Modify', 'Delete', 'Associate', 'Disassociate', 'Limit Query to Active Case Series', and 'Execute'.

| Name | Description | Last Modified | User Full Name | Category | Value Set | Associated Report |
|-------------------|--|---------------|----------------|-------------------|-----------|-------------------|
| Compliance | Predefined Compliance Filter | 28-JUN-2010 | administrator | Compliance | 0 | |
| Configuration | Preconfigured Configuration Filter | 28-JUN-2010 | administrator | Configuration | 0 | |
| Management | Preconfigured Management Filter | 28-JUN-2010 | administrator | Management | 0 | |
| Pharmacovigilance | Preconfigured Pharmacovigilance Filter | 28-JUN-2010 | administrator | Pharmacovigilance | 0 | |
| Workflow | Predefined Workflow Filter | 28-JUN-2010 | administrator | General | 0 | |

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. |
| Report | The report icon indicates that a report is associated with a value set. See " Associating a Report Group with a Value Set " on page 4-20 for more information. |

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.
2. Click **Search**. Based on your search criteria, the system displays the search results in a list.
3. To sort the search results list, click the sort icon next to the column headers in the list.

Creating a New Filter

Click **New Filter** in the FILTER LIBRARY page. See "[Creating a Custom Filter](#)" on page 4-9 for details.

Creating a New Value Set

To create a new value set, navigate to **Create Query, Filters**, and select **New Value Set**.

Alternatively, click **New Value Set** on the FILTER LIBRARY page to create a new value set. You can 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. Select the value set or the filter from the list in the FILTER LIBRARY page.
2. Click **Modify**.
 - If you selected a filter, the FILTER ELEMENTS page opens.
 - If you selected a value set, the FILTER VALUE SET page opens.
3. Make your modifications to the filter or value set, as appropriate.
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 can delete the value sets for predefined as well as custom filters. You can 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**. The system prompts for confirmation that you want to delete the filter or value set.
4. Click **OK**. The system deletes the selected filter/value set, and returns to the FILTER LIBRARY page.

Associating a Report Group with a Value Set

Report packaging is the concept of grouping reports together. You can define multiple reports that are always or often executed at the same time into a group. A set of reports run on a weekly or periodic basis can be scheduled and run as a package.

In Argus Insight, you can associate a report group and the report scheduling to a power query (QBE, Filter Value Set, and Advanced Conditions) or to a case series.

Argus Insight lets you *associate* the report group, schedule a time to generate the reports, and automatically send the completed reports through email to one or more users that you specify.

Associating a report group with a value set is helpful in situations when you need to generate the latest case series and run a report on it each time the data mart is refreshed. Instead of manually executing the value set to generate the latest case series and then running the report, you can use the report association functionality of Argus Insight to accomplish the task automatically.

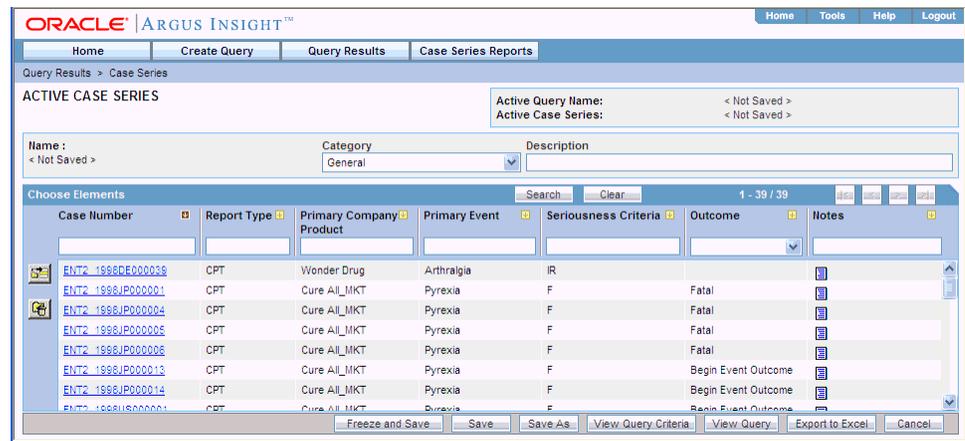
For detailed procedures and more information about associating report groups, see "[Scheduling and Associating Reports Against a Query or Case Series](#)" on page 8-10.

Note: To be able to schedule reports, you must have an enterprise login configured in the Business Intelligence tool (either BusinessObjects or Cognos) you are using with Argus Insight.

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 then opens the ACTIVE CASE SERIES page.



4. 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.
5. Enter the prompts value in the PRE FILTER page.
6. 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:

1. Generate the case series on which you want to run another value set:
 - You can generate the case series by using predefined filters or creating custom filters and executing a value set. This case series automatically 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 **Query Results, Case Series**, and select **Case Series Library**. When the CASE SERIES LIBRARY page opens, select the case series and click **Make Active**.
2. Navigate to **Create Query, Filters**, and select **Library**. The FILTER LIBRARY page opens.
3. Select the value set you want 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 various 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, open a saved value set from the FILTER LIBRARY page (see "[Working with Saved Filters and Value Sets](#)" on page 4-18).
2. Verify the *field* values you specified in the various fields in the value set.
3. Click **Convert to Advanced Condition**. The ACTIVE ADVANCED CONDITIONS EDITOR page opens.

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

The screenshot displays the 'ACTIVE ADVANCED CONDITIONS EDITOR' interface in Oracle Argus Insight. At the top, there are navigation tabs: Home, Create Query, Query Results, and Case Series Reports. Below the tabs, the 'ACTIVE ADVANCED CONDITIONS EDITOR' section is visible, showing 'Active Query Name: < Not Saved >' and 'Active Case Series: < Not Saved >'. The main area contains a form with 'Name: < Not Saved >', 'Category: Pharmacovigilance', and a 'Description' field. Below this is the 'Advanced Condition' table:

| (| Attributes | Condition | Value |) | Operator |
|---|------------------|-----------|--------------------|---|----------|
| (| Report Type | equal to | Spontaneous |) | AND |
| (| Country | equal to | UNITED STATES |) | AND |
| (| Hospitalized | equal to | Yes |) | AND |
| (| Outcome of Event | equal to | Death due to AE/in |) | |

At the bottom right of the interface, there are 'Save' and 'Execute' buttons.

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 various attributes

See [Chapter 5, "Using Advanced Conditions to Create Queries"](#) 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 your 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 existing advanced conditions:

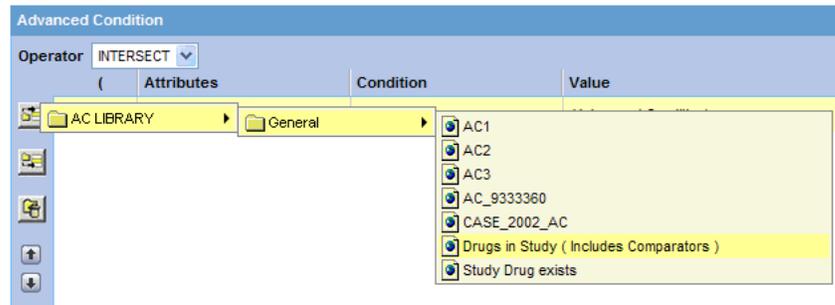
1. Create a new value set by either using predefined filters or creating custom filters. Alternatively, open a saved value set from the FILTER LIBRARY page (see ["Working with Saved Filters and Value Sets"](#) on page 4-18). If you create a custom value set, make sure you include the Advanced Condition element.
2. Verify the *field* values you specified for the value set.
3. Scroll to the **Advanced Condition** section on the FILTER VALUE SET page.

The screenshot displays the 'FILTER VALUE SET' configuration interface in Oracle Argus Insight. The 'Advanced Conditions' section is expanded, showing a table with the following data:

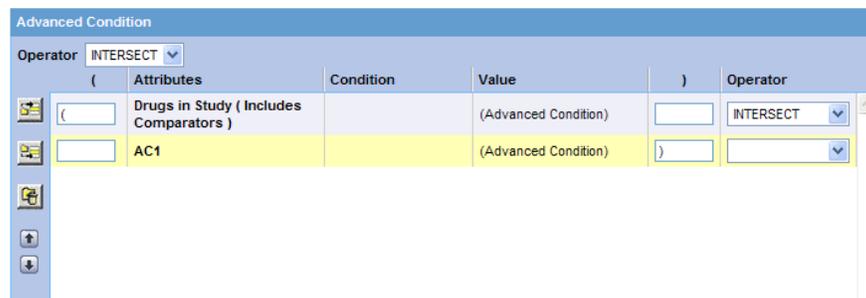
| Operator | Attributes | Condition | Value | Operator |
|----------|------------|-------------------|----------------------|----------|
| | AC3 | Study Drug exists | (Advanced Condition) | |
| UNION | | | | |

At the bottom of the Advanced Conditions section, there are buttons for 'Save Values', 'Convert to Advanced Condition', 'Clear', and 'Execute'.

4. Use the **Operator** field to enter the operator you want to use to integrate the value set and the advanced condition. You can select **INTERSECT**, **MINUS**, or **UNION**.
5. Select the advanced condition you want 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 the appropriate category and select the required advanced condition. The system adds your selection 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. Use the field in the **Operator** column to specify the set operation to perform between the selected advanced conditions.
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 opens and displays 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."](#)

Using Advanced Conditions to Create Queries

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).

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"](#))
- Library (see [Chapter 6, "Working with Libraries"](#))

Creating a New Advanced Condition

To start a new advanced condition:

1. Navigate to **Create Query, Advanced Conditions**, and select **New**. The **ADVANCED CONDITIONS EDITOR** page opens.

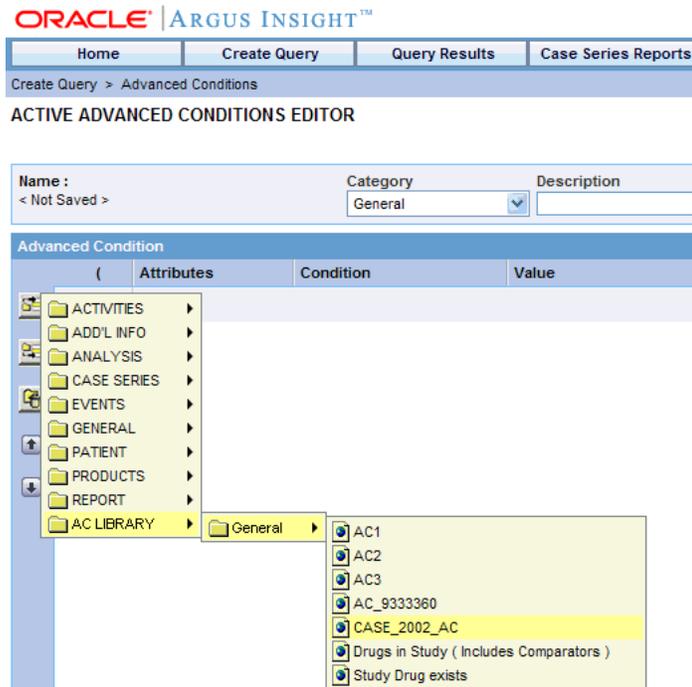
Note: You can also start an advanced condition by converting a QBE or a filter value set to an advanced condition. See ["Converting a QBE to an Advanced Condition"](#) on page 3-42 and ["Converting a Value Set to an Advanced Condition"](#) on page 4-22 for details.

2. Enter the attributes (fields and values) for the advanced condition.
3. Click the context menu icon. In the context menu, the first seven categories (**Activities, Additional Info, Analysis, Events, General, Patients, and Products**) represent the Argus case form tabs. In these categories, the various 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

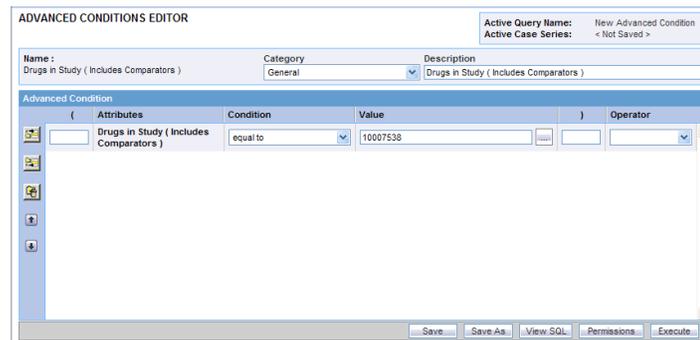
You can browse through the appropriate hierarchy and select the required *field* as an advanced condition attribute.

The eighth category **Reports** contains attributes that pertain to the reporting information of a case. You can browse through the **Reports** category and select the required advanced condition attribute.

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



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



Note: The user defined fields in Argus 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 attribute you selected, the system lets you populate the **Value** field by using 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 automatically 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 conditions available to you depends on the attribute you selected.

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 through which you want to join the attribute with another attribute.
8. 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, as appropriate.

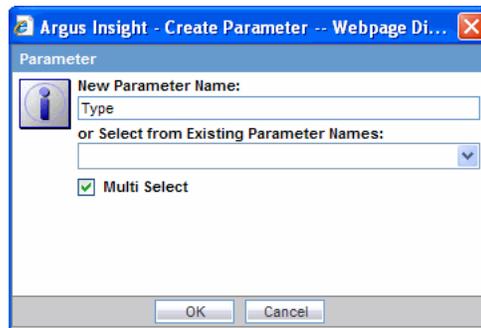
Note: Argus Insight lets you create advanced conditions which when executed, ask for user-specified values for certain attributes to generate the case series. For example, you may create an advanced condition in which the Case Number or the Product name may be specified only at the time of execution.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

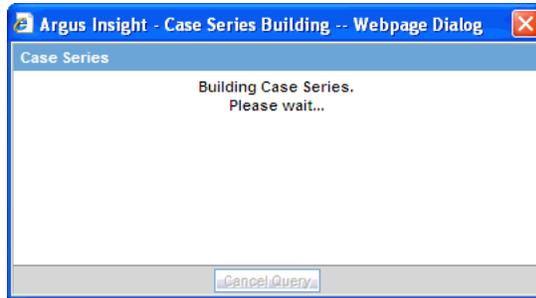
10. Identify the attribute row where you want to specify runtime parameters.
11. Click the ellipsis button next to the **Value** field, and then select **Parameters** from the menu.



12. Click **Parameter**. The Parameter dialog box opens.



13. Select the **Multi Select** check box if you want to pass multiple runtime values for a single attribute. For example, you might want to pass more than one case number or product name as runtime parameters.
14. Click **OK**. The field you configured as a runtime parameter is displayed in the **Value** text box enclosed within % symbol. For example, %Product Type% If you configured the field to accept multiple runtime parameters, the field name appears in the **Value** text box enclosed within %% symbol. For example, %%Product Type%%.
15. Type parentheses in the (and) columns to determine the order of execution for the selected advanced conditions, as appropriate.
16. Examine the advanced condition results.
17. Click **Execute**. While the system searches for matching cases, the following dialog box is displayed.



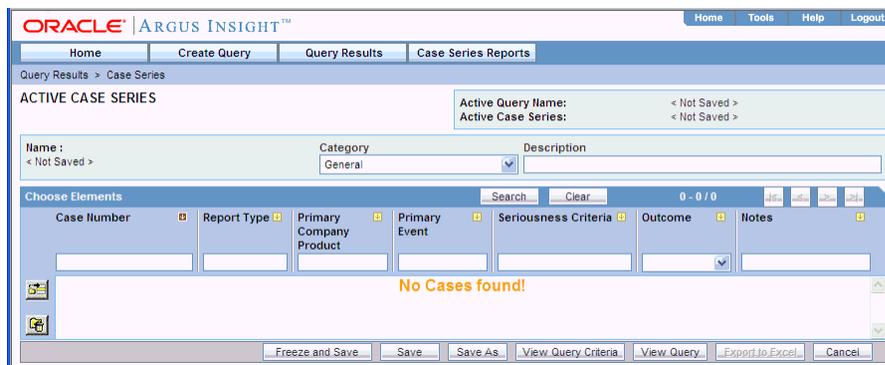
Tip: To cancel the query execution at this point and return to the Advanced Conditions Editor, click **Cancel Query**.

- If you configured any runtime parameters, the **Parameters** dialog box opens. Specify the parameter values by using the options in the dialog box. Next, click **Execute**; the system retrieves the matching cases from the data mart and displays them in the ACTIVE CASE SERIES page.

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.

- If the system does not find any cases that match the querying criteria, the following screen is displayed. Click **View Query** in this screen to return to the Advanced Conditions Editor, modify the criteria and execute again.



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

Returning to the Advanced Conditions Editor

To return to the Advanced Conditions Editor:

1. Click **View Query** in the ACTIVE CASE SERIES page. The ACTIVE ADVANCED CONDITIONS EDITOR page opens.

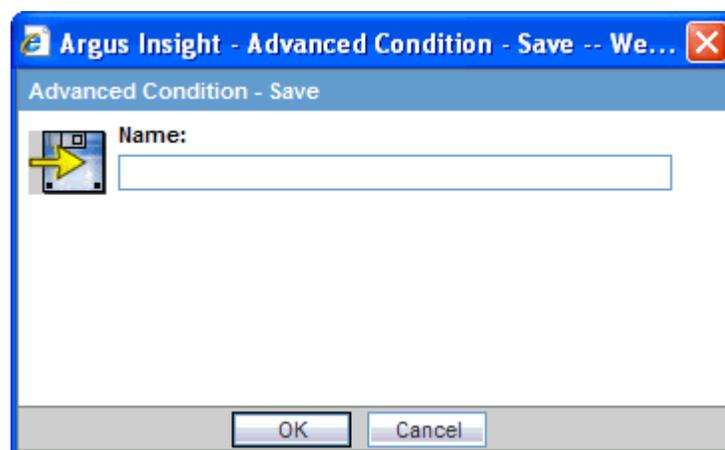
Note: When you save the modifications to an advanced condition or execute it, the system assigns the active status to the advanced condition. Therefore, when you return to the editor after executing the advanced condition, the page title changes to ACTIVE ADVANCED CONDITIONS EDITOR. The field values you specified in the editor before executing are retained. See "[Working with the Last Modified or Saved Advanced Condition](#)" on page 5-12 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

Use the **Category** drop-down list to assign a category to the advanced condition. A category indicates the reporting aspect to which your advanced condition pertains: **Case Processing, Compliance, Configuration, General, Management, or Pharmacovigilance**. Specifying the category also helps you in searching the relevant advanced conditions from a list of all the advanced conditions saved in the system.

1. Type a description of the advanced condition in the **Description** field. For example, you can describe the type of cases the advanced condition retrieves.
2. Click **Save** on the ACTIVE ADVANCED CONDITIONS EDITOR page. The Advanced Condition - Save dialog box opens.



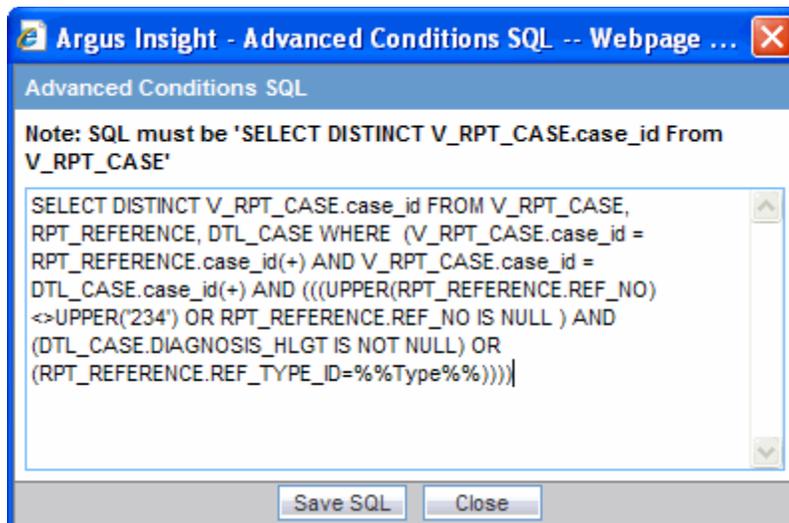
3. Type the name of the advanced condition in the **Name** field.

4. 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 5-13 for more information.

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

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

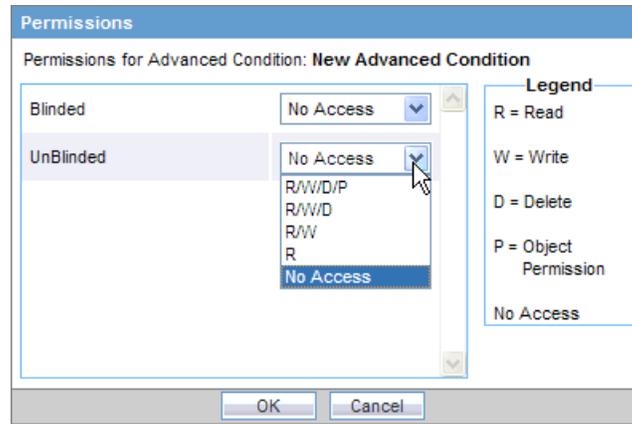


- a. Modify the SQL, if necessary.
- b. Click **Save SQL** after editing the query.

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

Tip: **Revert to Original** lets you to revert back to the original advanced condition.

- c. Click **Close**.
6. Click **Permissions** to assign group-level permissions on the saved advanced condition. The system opens the **Permissions** dialog box and displays the names of all the groups (except the **Administrator** group) that the system administrator has created.



7. Use the drop-down list next to a group name to assign permissions to the group members on the advanced condition you have created. You can select from these options:

| 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.

8. Click **OK**. The system saves the permission settings.
9. Click **Execute** to generate the case series.
 - The system retrieves the matching cases from the data mart and displays them on the ACTIVE CASE SERIES page.
 - If you configured any runtime parameters, the Parameters dialog box opens. Specify the parameter values by using the options in the dialog box. Next, click **Execute**; the system retrieves the matching cases from the data mart and displays them on the ACTIVE CASE SERIES page. See [Chapter 7, "Working with Case Series"](#) for more information.

Using and Ordering Advanced Condition Operators

Use the following order of precedence for the various 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 various queries (AC Library Attributes) |
| 4 | MINUS | Use between various queries (AC Library Attributes) |
| 5 | UNION | Use between various 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 Advanced Condition Example in Argus Insight

| (| 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) | | |

You do not need to include the parentheses if the PL/SQL syntax and 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 DISTINCTv_rpt_case.case_id
FROM v_rpt_case
WHERE v_rpt_case.case_id IN (

```

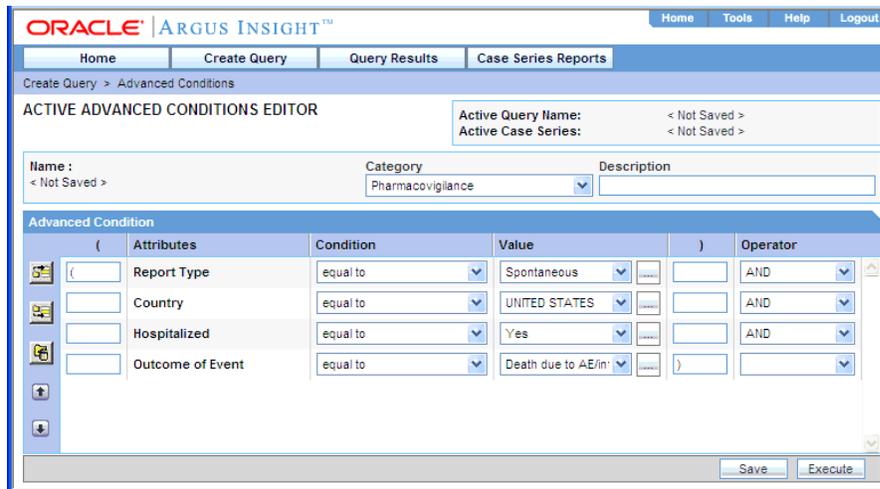
```
SELECT DISTINCT v_rpt_case.case_id
FROM v_rpt_case
WHERE (v_rpt_case.country_id = 13)
OR (v_rpt_case.country_id = 223))
```

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 view an active advanced condition:

1. Navigate to **Create Query, Advanced Condition**, and select **Active**. The ACTIVE ADVANCED CONDITIONS EDITOR page displays 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 **Name** label. 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.

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 5-2 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 5-13 for more information. |

| Task | Description |
|---|--|
| View the Advanced Condition in SQL | Click View SQL to view the underlying SQL query for the advanced condition. In this SQL, manually replace the V_RPT_CASE with RPT_CASE. This is required to execute the query in the Oracle database. |
| Assign Permissions | Click Permissions to set the group-level access permissions on the advanced condition. See " Creating a New Advanced Condition " on page 5-2 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

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

To access this page, navigate to **Create Query, Advanced Conditions**, and select **Library**. The ADVANCED CONDITIONS LIBRARY page opens. See [Figure 5-2](#).

The ADVANCED CONDITIONS LIBRARY page displays 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.
- Name of the fields for which runtime parameters need to be specified while executing the advanced condition.
- An icon in the Associated Report column if the advanced condition has a report associated with it. See "[Associating a Report Group with an Advanced Condition](#)" on page 5-16 for more information.

Figure 5–2 ADVANCED CONDITIONS LIBRARY Page

ORACLE ARGUS INSIGHT™ Home Tools Help Logout

Home Create Query Query Results Case Series Reports

Create Query > Advanced Conditions

ADVANCED CONDITIONS LIBRARY

Active Query Name: New Advanced Condition
Active Case Series: < Not Saved >

Choose Advanced Condition Search Clear

| Name | Description | Last Modified | User Full Name | Category | Parameters | Associated Report |
|---|---|----------------------------|----------------|----------|--|-------------------|
| | | 00-MMM-0000 00-MMM-0000 | | | | |
| Drugs in Study (Includes Comparators) | Drugs in Study (Includes Comparators) | 08-JUL-2010 | Blinded User 3 | General | Case Initial Receipt Date Range, Country, Gender, Preferred Term | |
| New Advanced Condition | | 11-JUL-2010 | johns | General | Type | |
| Study Drug exists | Study Drug exists | 08-JUL-2010 | Blinded User 3 | General | | |
| AC_9333360 | | 08-JUL-2010 | pangup | General | Company Product | |
| CASE_2002_AC | | 08-JUL-2010 | pangup | General | | |

New Modify Delete Associate Disassociate Limit Query to Active Case Series Execute

Searching Saved Advanced Conditions

To search for a saved advanced condition:

- Specify the search criteria, as appropriate:
 - 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.
- Click **Search**. Based on your search criteria, the system displays the search results in a list.
 - 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

To create a new advanced condition, click **New** in the ADVANCED CONDITIONS LIBRARY page.

See "[Creating a New Advanced Condition](#)" on page 5-2 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, as appropriate.
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 you want to modify.
3. Click **Modify**. The ACTIVE ADVANCED CONDITIONS EDITOR page opens.

4. Click **View SQL**. The Advanced Conditions SQL dialog opens.

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 system displays the results 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**. The system prompts for confirmation.
4. Click **OK** to delete selected advanced condition.

Associating a Report Group with an Advanced Condition

Report packaging is the concept of grouping reports together. You can define multiple reports that are always or often executed at the same time into a group. A set of reports run on a weekly or periodic basis can be scheduled and run as a package.

In Argus Insight, you can associate a report group and the report scheduling to a power query (QBE, Filter Value Set, and Advanced Conditions) or to a case series.

Argus Insight lets you *associate* the report group, schedule a time to generate the reports, and automatically send the completed reports through email to one or more users that you specify.

Associating a report group with an advanced condition is helpful in situations when you need to generate the latest case series and run a report on it each time the data mart is refreshed. Instead of manually executing the advanced condition to generate the latest case series and then running the report, you can use the report association functionality of Argus Insight to accomplish the task automatically.

For detailed procedures and more information about associating report groups, see "[Scheduling and Associating Reports Against a Query or Case Series](#)" on page 8-10.

Note: To be able to schedule reports, you must have an enterprise login configured in the Business Intelligence tool (either BusinessObjects or Cognos) you are using with Argus Insight.

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 system executes the advanced condition; the ACTIVE CASE SERIES page opens.

The screenshot displays the Oracle Argus Insight interface for the 'ACTIVE CASE SERIES' page. At the top, there are navigation tabs: Home, Create Query, Query Results, and Case Series Reports. Below the tabs, the 'ACTIVE CASE SERIES' section is visible, showing the active query name as 'Pharmacovigilance SPT Injury M'. A search bar and filters for Name (SPT Injury M), Category (General), and Description (SPT Injury M) are present. The main area contains a table with the following columns: Case Number, Report Type, Primary Company/Product, Primary Event, Seriousness Criteria, Outcome, and Notes. The table lists several case series, including '10001', 'CASE-SM-001', 'CASE_SUP_13', 'COMMON', 'ENTO_PRODUCT_1_CASE', 'ENTO_01-LEADING ZERO', 'ENTO_0807-003', 'ENTO_0807-004', 'ENTO_0807-006', 'ENTO_0808-007', 'ENTO_0808-008', and 'ENTO_0815-000'. At the bottom of the table, there are buttons for 'Freeze and Save', 'Save', 'Save As', 'Permissions', 'View Query Criteria', and 'Export to Excel'.

4. If a **report** is associated with the saved advanced condition, click **Execute**. The ACTIVE CASE SERIES page and PRE FILTER page of the associated report is displayed.
5. Enter the prompts value in the PRE FILTER page.
6. 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 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 on which you want to run another Value Set:
 - You can generate the case series by either using QBE, filters, or advanced conditions. This case series automatically 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 **Query Results, Case Series**, and select **Case Series Library**. When the CASE SERIES LIBRARY page opens, select the case series and click **Make Active**.
2. Navigate to **Create Query, Advanced Conditions**, and select **Library**. The ADVANCED CONDITIONS LIBRARY page opens.
3. Select the advanced condition you want 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 advanced condition 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.

Working with Libraries

Argus Insight provides a library that serves as a repository for all queries. This library, called the *Query library*, contains all the saved queries performed using QBEs, filters, and advanced conditions.

In addition, from the *Associated Reports* library, you can search for queries or case series that have a report associated with them.

This chapter includes the following topics:

- [Viewing Save Queries in the Query Library](#)
- [Viewing All Reports Associated with a Query or Case Series](#)

Viewing Save Queries in the Query Library

To view a list of all the saved queries, navigate to **Create Query, Library**, and select **Query Library**. The QUERY LIBRARY page opens. See [Figure 6-1](#)

The QUERY LIBRARY page displays the following information about each query:

- Name of the query.
- Brief description of the query.
- Date when the query was last modified.
- Type of query (Advanced Condition, Filter Value Set, or Query By Example)
- Full name of the user who created the query.
- Category where the query is saved. The default categories are Case Processing, Compliance, Configuration, General, Management, and Pharmacovigilance.
- Number of reports, if any, associated with the query.

Figure 6-1 QUERY LIBRARY Page

The screenshot shows the Oracle Argus Insight interface. The top navigation bar contains 'Home', 'Create Query', 'Query Results', and 'Case Series Reports'. A dropdown menu under 'Create Query' is open, showing 'Query by Example', 'Filters', 'Advanced Conditions', and 'Library'. The 'Library' option is highlighted, and an arrow points to the 'QUERY LIBRARY' page. The 'QUERY LIBRARY' page has a header with 'ORACLE ARGUS INSIGHT' and 'Home Tools Help Logout'. Below the header, there are tabs for 'Home', 'Create Query', 'Query Results', and 'Case Series Reports'. The main content area is titled 'QUERY LIBRARY' and includes a search bar and a table of queries. The table has columns for Name, Description, Last Modified, Query Type, User Full Name, Category, and Associated Report. The table lists various queries such as AC1, AC2, AC3, AC4, AC_9333360, CASE_2002_AC, Drugs in Study (Includes Comparators), New Advanced Condition, New QBE, Outside 2, sdvsdv, Study Drug exists, Union - Case Series 1- Non Protected, and Union - Case Series 2- Non Protected. At the bottom of the page, there are buttons for 'Delete', 'Associate...', 'Disassociate...', 'Limit Query to Active Case Series', and 'Execute'.

Associating a Query in the Query Library

To associate a report to a query in the query library:

1. Navigate to the QUERY LIBRARY page.
2. Select a query from the list.
3. Click **Associate** to open the Scheduled Reports Group dialog box.

| Associate | Name | Description | Last Run Time | Next Run Time | Created By | Created Date | Modified By | Modified Date | Number of Reports |
|--------------------------|----------------------|-----------------|---------------|---------------|------------|--------------|-------------|---------------|-------------------|
| <input type="checkbox"/> | Test Group | Test Group Desc | N/A | 30-JAN-2012 | Robert | 30-JAN-2012 | Robert | 30-JAN-2012 | 2 |
| <input type="checkbox"/> | Test Group_RunNow | Test Group Desc | N/A | 30-JAN-2012 | Robert | 30-JAN-2012 | Robert | 30-JAN-2012 | 2 |
| <input type="checkbox"/> | Test Schedule | Test Schedule | N/A | 24-JAN-2012 | NAVUSER1 | 24-JAN-2012 | NAVUSER1 | 24-JAN-2012 | 2 |
| <input type="checkbox"/> | Test Schedule_RunNow | Test Schedule | N/A | 24-JAN-2012 | NAVUSER1 | 24-JAN-2012 | NAVUSER1 | 24-JAN-2012 | 2 |
| <input type="checkbox"/> | tc21ovm | tc21ovm | N/A | 11-JAN-2012 | NAVUSER1 | 11-JAN-2012 | NAVUSER1 | 11-JAN-2012 | 5 |

4. Select a report group and click **Modify**.
5. Make the necessary modifications and click **OK**.
6. Click **Execute** to execute a report.

Note that the Execute button is available only if the group has just one report in it.

Deleting a Query from the Query Library

To delete a query from the query library:

1. Navigate to the QUERY LIBRARY page.
2. Select a query from the list.
3. Click **Delete**. The system prompts for confirmation that you want to delete the query.
4. Click **OK**.

Disassociating a Report in the Query Library

To disassociate a report from the query library:

1. Navigate to the QUERY LIBRARY page.
2. Select a query from the list.
3. Click **Disassociate**. The system prompts for confirmation that you want to remove the report association.
4. Click **OK**.

Viewing All Reports Associated with a Query or Case Series

To view a list of all the reports associated with a query or a case series, navigate to **Case Series Report** and select **Associated Reports Library**. The ASSOCIATED REPORTS LIBRARY page opens. See [Figure 6-2](#).

The ASSOCIATED REPORTS LIBRARY page displays the following information:

- Name of either the query or the case series associated with the report.
- Brief description of the query or case series associated with the report.
- Name of the report associated with the query or case series.
- Type of query (Advanced Condition, Filter Value Set, or Query By Example) if the report is associated with a query or the words **Case Series** if the report is associated with a case series.
- Full name of the user who created the query or case series.
- Status.

The **Limit Query to Active Case Series** check box is enabled *only if* the report is associated against a query. The check box is disabled for all reports associated against a case series.

Figure 6-2 ASSOCIATED REPORTS LIBRARY Page

The screenshot shows the Oracle Argus Insight interface. At the top, there is a navigation bar with 'Home', 'Create Query', 'Query Results', and 'Case Series Reports'. The 'Case Series Reports' menu is open, showing 'Standard Reports', 'Report Writer', and 'Associated Reports Library' (highlighted). Below this, the 'ASSOCIATED REPORTS LIBRARY' page is displayed. It includes a search bar, a table of reports, and a 'Limit Query to Active Case Series' checkbox.

| Query/Case Series Name | Group Name | Report Name | Query Type | User Full Name | Status |
|------------------------|------------|---------------------------------|--------------------|----------------|--------|
| All Cases | tc21ovm | US FDA MedWatch 3500A | Advanced Condition | NAVUSER1 | |
| All Cases | tc21ovm | CIOMS Report | Advanced Condition | NAVUSER1 | |
| All Cases | tc21ovm | Mortality Report | Advanced Condition | NAVUSER1 | |
| All Cases | tc21ovm | Case Narrative Listing - Enroll | Advanced | | |

Active Query Name: COI - US
Active Case Series: < Not Saved >

Buttons: Associate To All Cases, Modify, Disassociate, Limit Query to Active Case Series, Execute

Modifying a Query or Case Series in the Associated Reports Library

To modify a query or case series in the associated library:

1. Navigate to the ASSOCIATED REPORTS LIBRARY page.
2. Select the query or case series that you want to modify.
3. Click **Modify**. The Scheduled Reports Group dialog box opens.

| Associate | Name | Description | Last Run Time | Next Run Time | Created By | Created Date | Modified By | Modified Date | Number of Reports |
|--------------------------|----------------------|-----------------|---------------|---------------|------------|--------------|-------------|---------------|-------------------|
| <input type="checkbox"/> | Test Group | Test Group Desc | N/A | 30-JAN-2012 | Robert | 30-JAN-2012 | Robert | 30-JAN-2012 | 2 |
| <input type="checkbox"/> | Test Group_RunNow | Test Group Desc | N/A | 30-JAN-2012 | Robert | 30-JAN-2012 | Robert | 30-JAN-2012 | 2 |
| <input type="checkbox"/> | Test Schedule | Test Schedule | N/A | 24-JAN-2012 | NAVUSER1 | 24-JAN-2012 | NAVUSER1 | 24-JAN-2012 | 2 |
| <input type="checkbox"/> | Test Schedule_RunNow | Test Schedule | N/A | 24-JAN-2012 | NAVUSER1 | 24-JAN-2012 | NAVUSER1 | 24-JAN-2012 | 2 |
| <input type="checkbox"/> | tc21ovm | tc21ovm | 11-JAN-2012 | N/A | NAVUSER1 | 11-JAN-2012 | NAVUSER1 | 11-JAN-2012 | 5 |

4. Select any report group and click **Modify**.
5. Make the necessary modifications and click **OK**.
6. Click **Execute** to execute a report. The **Execute** button is available only if a group has just one report in it.

Disassociating a Report in the Associated Reports Library

To disassociate a report from the associated report library:

1. Navigate to the ASSOCIATED REPORTS LIBRARY page.
2. Select a report from the list.
3. Click **Disassociate**.
4. Click **OK**.

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. All the predefined reports you generate in Argus Insight are run on the case series. This means that the *report* output contains information from only those cases that are part of the case series.

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](#)

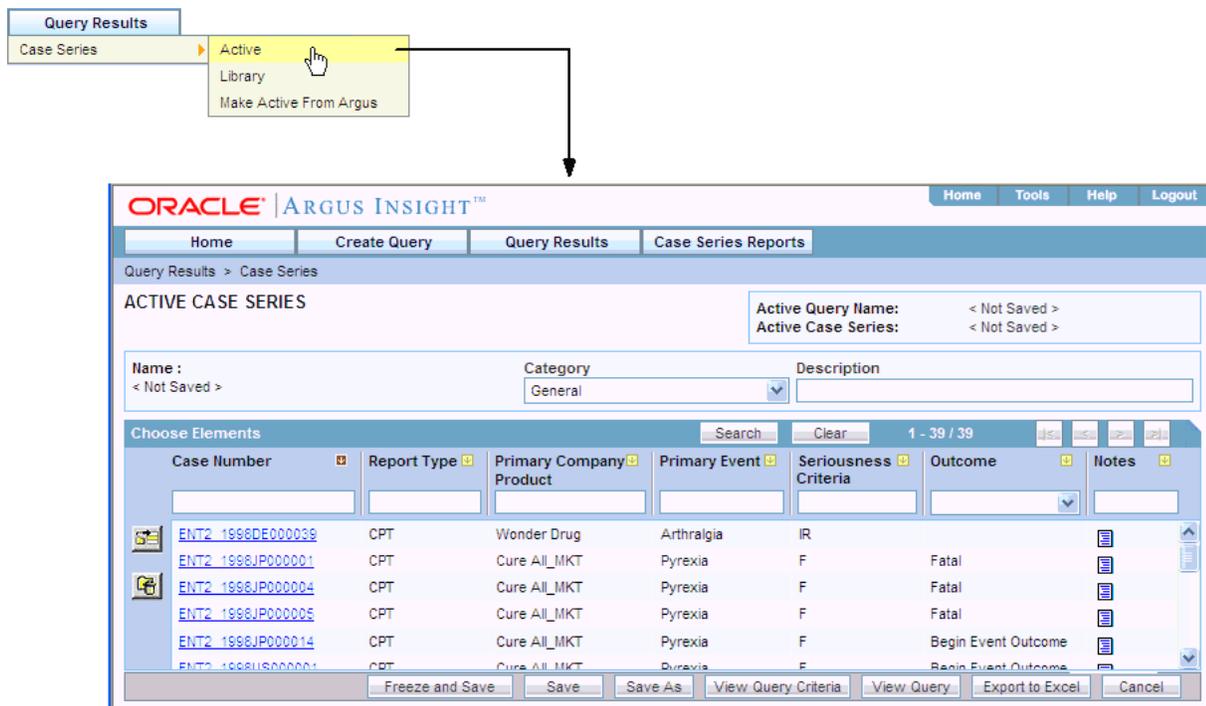
Viewing the Active Case Series

The system assigns the *active* status to the case series that you last generated by executing a *query*. Only one case series can be active at a time. The last case series you 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 7-11 for details.

To view the active case series, navigate to **Query Results, Case Series**, and select **Active**. The ACTIVE CASE SERIES page opens and displays the last case series that you executed, modified, or manually made active. See [Figure 7-1](#).

Figure 7-1 Viewing the Active Cases Series



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>.
- The **Active Case Series** label displays the text <Not Saved> until you save the case series by a name. Similarly, the **Name** label displays the text <Not Saved> until you save the case series by a name.

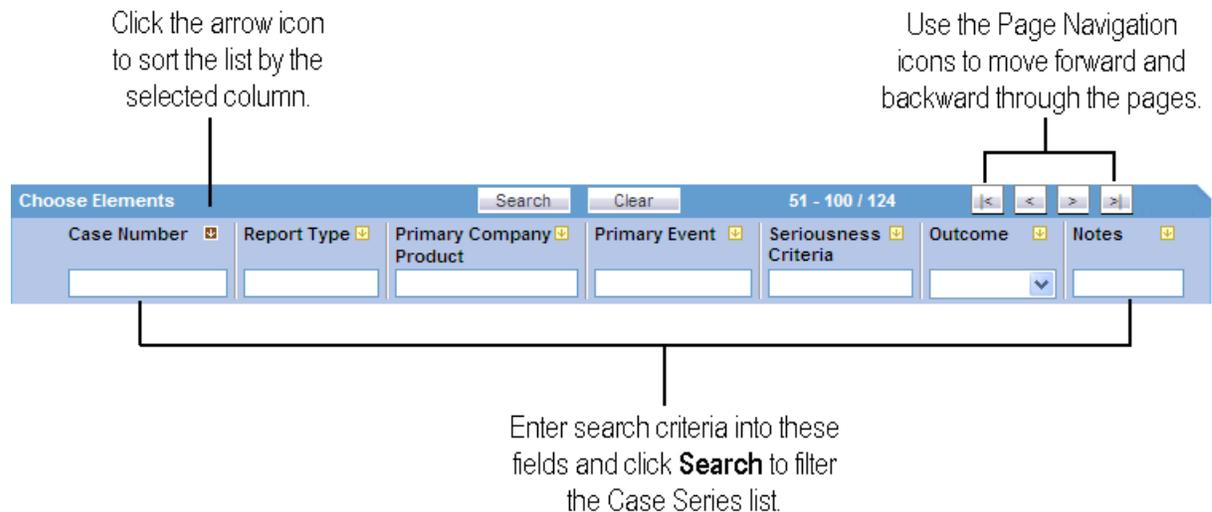
Sorting, Searching, and Navigating

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**.
- 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 7-15 for more information.

Figure 7-2 *Sorting, Searching, and Navigating the List of Cases*



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 **SaveAs** 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.

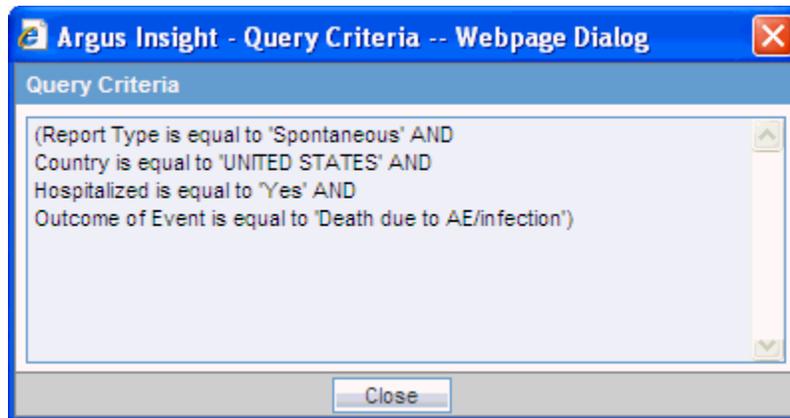
Viewing the Criteria that Generated the Active Case Series

Use one of the following options to view the query criteria that generated the active case series:

- To return to the appropriate *Create Query* 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.

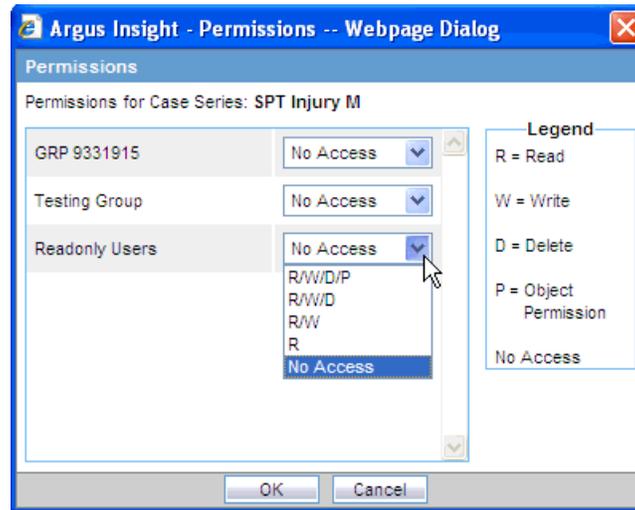
Note: You can set permissions only on case series you saved to the system.

To set case series permissions:

1. Navigate to **Query Results, Case Series**, and select **Active**. The ACTIVE CASE SERIES page opens.

- Click **Permissions** to assign group-level permissions on the saved case series.

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



- Use the drop-down list next to a group name to assign permissions to the group members on the case series you have created. You can select from these options:

| 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.

- 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.

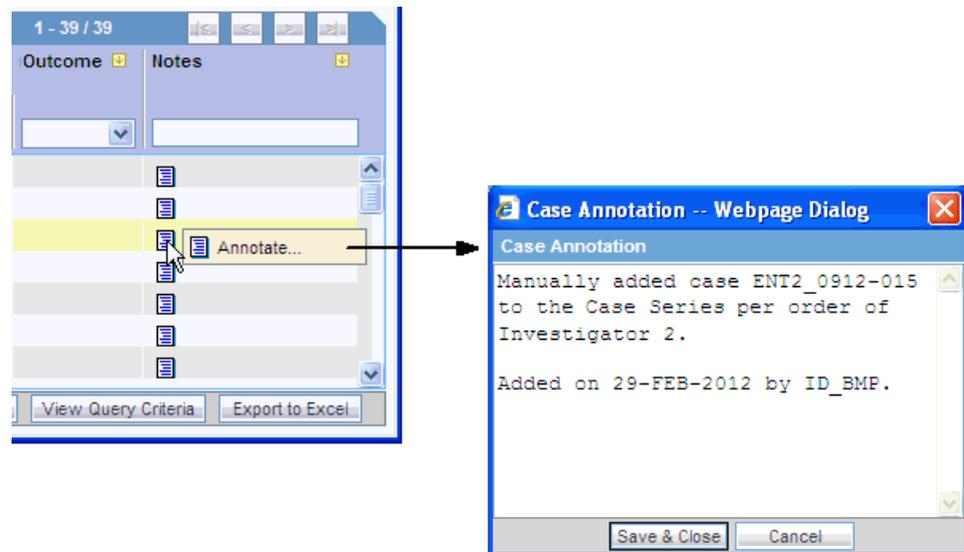
Annotations in the Active Case Series

For any case in the active case series, you can 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. Click the **Annotate** icon in the Notes column.

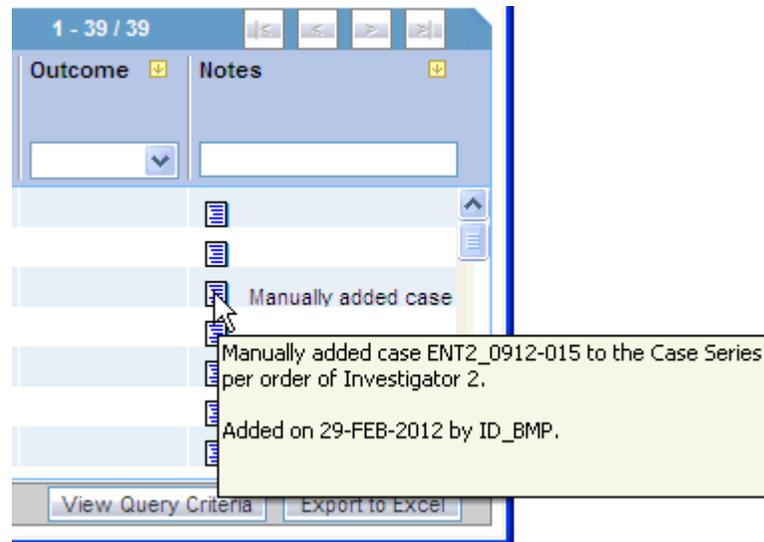
4. Select **Annotate** from the menu to open the Case Annotation dialog box.



5. Type your notes, comments, or remarks about the case.
6. Click **Save & Close**.

The system updates the selected case with your 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.

Annotations in Report Writer

To use case annotations in Report Writer:

1. Navigate to **Case Series Reports, Report Writer**, and select **New**.
2. Navigate to **Report Writer, Case Series**, and select **Case Annotation**.
3. Click **Insert**.

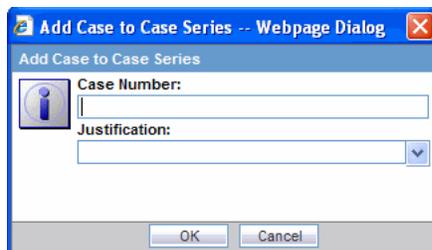
Adding a Case to a Case Series

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 opens.

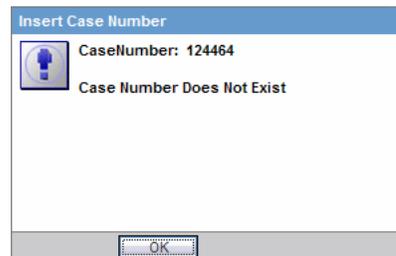


3. Enter the case number that you want to add to the case series manually.
4. Click the **Justification** field to select the reason you are modifying the case series.

Alternatively, you can type your own justification text to explain why you are modifying the case series.

In addition, you can 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:



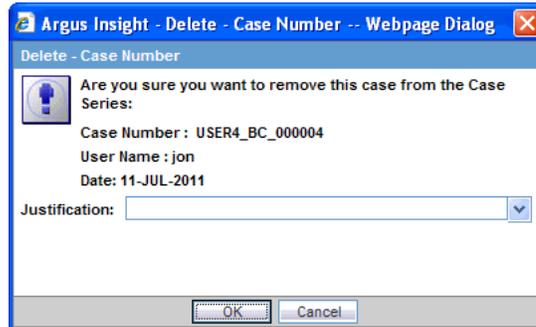
6. Click **OK** to close the message dialog box.

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 opens.



4. Click the **Justification** field to select the reason you are deleting the case.

Alternatively, you can type your own justification text to explain why you are deleting the case.

In addition, you can 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](#)
- [Associating a Report Group with a 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 **Query Results, Case Series**, and select **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.
 - **External** indicates the case series was imported into Argus Insight from another source, such as a TXT or CSV file. See ["Importing a Case Series from an External Source"](#) on page 7-13 for more information.
- Number of cases in the case series. In addition, the Cases column displays 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.
- Report icon if reports are associated with the case series. Positioning the cursor over the icon displays the number of reports associated with the case series.

Figure 7-3 CASE SERIES LIBRARY Page

The screenshot shows the Oracle Argus Insight interface for the CASE SERIES LIBRARY. The top navigation bar includes 'Home', 'Tools', 'Help', and 'Logout'. Below this is a sub-navigation bar with 'Home', 'Create Query', 'Query Results', and 'Case Series Reports'. The main content area is titled 'CASE SERIES LIBRARY' and shows the 'Active Query Name' as 'Pharmacovigilance' and 'Active Case Series' as 'SPT Injury M'. A 'Choose Filter' section is present above the table. The table has the following data:

| Name | Description | Last Modified | User Full Name | Category | Source | Cases | Associate Report |
|------------------------------------|------------------------------------|---------------|----------------|----------|---------------|-------|------------------|
| AE HospMID | AE Hosp/MVD | 07-FEB-2012 | Rita Gitti | General | Argus Insight | 121 | |
| Blank page report test case series | Blank page report test case series | 29-NOV-2011 | Dheerajd | General | Argus Insight | 1 | |
| Blinded Test | Blinded Test | 15-JAN-2012 | Shubh | General | Argus Insight | 1 | |
| Compassionate Use | Compassionate Use | 04-FEB-2012 | Rita Gitti | General | Argus Insight | 39 | |

At the bottom of the page, there is a row of action buttons: 'Un-freeze Case Series', 'Freeze Case Series', 'Make Active', 'Modify', 'Merge', 'Import', 'Delete', 'Query Criteria', 'Associate', and 'Disassociate'.

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.

| Name | Description | Last Modified | User Full Name | Category | Source | Cases | Associate Report |
|------|-------------|---------------|----------------|----------|--------|-------|------------------|
| | | 00-0000-0000 | | | | | |
| | | 00-0000-0000 | | | | | |

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.
3. Click **Search**. Based on your specified criteria, the system refreshes the page and displays the search results.
 - 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. Select the case series you want to make active.
3. 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** to display the selected case series. See "[Working with the Active Case Series](#)" on page 7-2 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 opens.

The screenshot displays the 'CASE SERIES MERGE' interface in Oracle Argus Insight. At the top, there are navigation tabs: Home, Create Query, Query Results, and Case Series Reports. Below this, the 'CASE SERIES MERGE' page is active, showing the 'Active Query Name' as 'Drugs in Study (Includes Comparators)' and 'Active Case Series' as '< Not Saved >'. The main area is titled 'Choose Case Series' and is divided into two columns: 'Case Series #1 (Notes from this series will be preserved in the merged case series)' and 'Case Series #2'. Each column contains a list of case series names, such as 'Union - Case Series 1- Non Protected UNION Union', 'All 56 Cases', and 'Drugs in Study (Includes Comparators) missing'. A central 'Action' menu is visible, with 'Union' selected. Below the lists are 'Description' and 'Author' input fields for each selected case series. At the bottom, there are 'Merge' and 'Cancel' buttons.

3. Select the two case series you want to merge:
 - a. Select the first case series from the **Case Series # 1** list.
 - b. Select the second case series from the **Case Series # 2** list.

Note that the system automatically populates the Description and Author fields for each case you selected. You can modify the information if necessary.

4. Select the **Action** (set operator) that you want to use to merge the two case series you selected. 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.
5. Click **Merge** to merge the two selected case series and display the resultant case series on the ACTIVE CASE SERIES page.

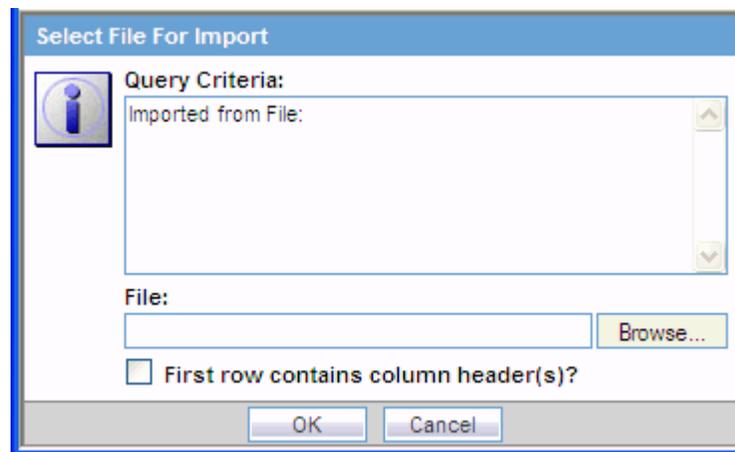
Importing a Case Series from an External Source

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** to open the **Select File For Import** dialog box.



3. Click **Browse** to locate and select the external case series source file. Alternatively, type the file name with its complete system path in the **File** field.
4. 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.
5. Click **OK**. The Import Case Series dialog box displays the status of the import operation.

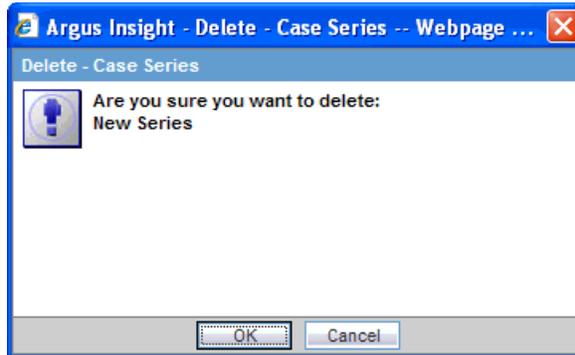
Note: To view the import operation log, click **View Log**.

6. 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 the case series you want to delete.
3. Click **Delete**. The system prompts for confirmation that you want to delete the case series.

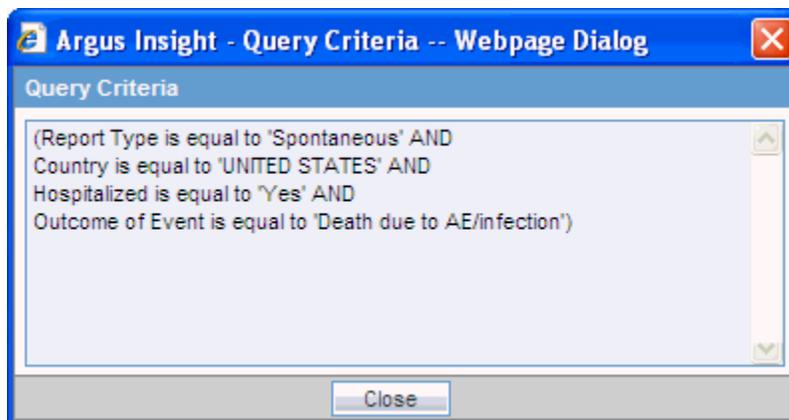


4. Click **OK** to delete the selected case series and return to the CASE SERIES LIBRARY page.

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.

Associating a Report Group with a Case Series

Report packaging is the concept of grouping reports together. You can define multiple reports that are always or often executed at the same time into a group. A set of reports run on a weekly or periodic basis can be scheduled and run as a package.

In Argus Insight, you can associate a report group and the report scheduling to a case series or to a power query (QBE, Filter Value Set, and Advanced Conditions).

Argus Insight lets you *associate* the report group, schedule a time to generate the reports, and automatically send the completed reports through email to one or more users that you specify.

For detailed procedures and more information about associating report groups, see "[Scheduling and Associating Reports Against a Query or Case Series](#)" on page 8-10.

Note: To be able to schedule reports, you must have an enterprise login configured in the Business Intelligence tool (either BusinessObjects or Cognos) you are using with Argus Insight.

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.

To share cases between Argus Insight and Argus Safety Web:

1. Log in to Argus Insight with your user name and password.
2. Navigate to **Query Results, Case Series**, and select **Make Active From Argus**.

The system displays the active case series from Argus Safety Web. The active case series present in Argus are now the active case series in Argus Insight.

Note: The system displays an error message if there are no cases present in the active series of Argus.

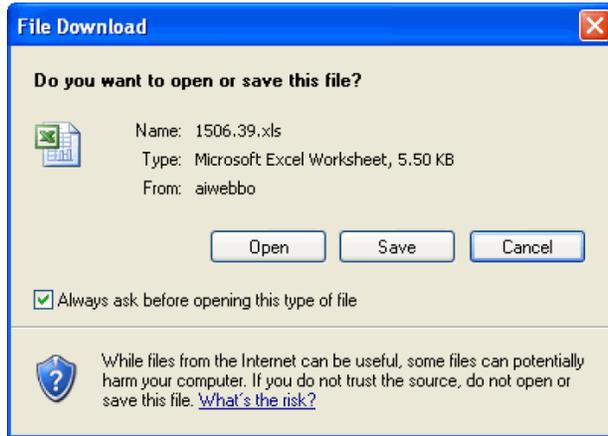
3. Click **Save** or **Save As** to save the case series.

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.

- 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

| Case Number | Report Type | Primary Company Product | Primary Event | Seriousness Criteria | Outcome | Notes |
|-------------------|-------------|-------------------------|----------------------|----------------------|--------------------------|-------|
| ENT0_1998DE000008 | RAT | Wonder Drug | Arthralgia | IR | Unknown | |
| ENT0_2001US000000 | RAT | Algoheal | Dyspnoea NOS | Non-Serious | Congenital Anomaly | |
| ENT0_2001US000004 | RAT | Flunomore | Paraesthesia | Non-Serious | Unknown | |
| ENT0_2001US000008 | RAT | Cure All | Pyrexia | Non-Serious | Recovered | |
| ENT0_2001US000009 | RAT | Painocide Unknown | Renal failure acute | H | Recovered | |
| ENT0_2001US000011 | RAT | Wonder Drug | Hepatic failure | H | Recovered | |
| ENT0_2002US000002 | RAT | Cure All | Alanine increased | LT | Recovered with Treatment | |
| ENT0_2002US000008 | RAT | Wonder Drug | Headache | Non-Serious | Improved | |
| ENT0_2002US000011 | RAT | Algoheal | Abdominal pain upper | Non-Serious | Recovering/Resolving | |
| ENT0_2002US000013 | RAT | Algoheal | Dyspnoea NOS | Non-Serious | Congenital Anomaly | |
| ENT0_2002US000021 | RAT | Flunomore | Paraesthesia | Non-Serious | Unknown | |
| ENT0_2002US000024 | RAT | Cure All | Hepatic failure | H | Recovered | |
| ENT0_2002US000026 | RAT | Painocide Unknown | Renal failure acute | H | Recovered | |
| ENT0_2002US000029 | RAT | Wonder Drug | Headache | Non-Serious | Resolved | |
| ENT0_2003US000000 | RAT | Cure All | Alanine increased | LT | Recovered with Treatment | |

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](#)

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 proper 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
 - Report scheduling
 - Derivation rules

Reports and a Frozen Case Series

- By default, the Report Writer displays all the versions (both frozen and current) for a case.
 - If the report needs to contain only the current case version, use the **Display Latest Data** filter.
 - If you select the **Active Case Series** filter, then the report contains only the frozen case data if the active case series is frozen. Otherwise, the report contains the current case version if the active case series is a normal case series.
- The frozen case series data is available after reinitializing the ETL.

- Reports run on frozen case series data show the following text next to the Case Series name:
 The data in this report was frozen as of *date_and_time*.
 The time is the database system time with the Greenwich Mean Time (GMT) offset.
- Reports run on normal case series data show the following text next to the Case Series name:
 The case series was last modified on *date_and_time*.

List Maintenance Items and Derivation Rules in a Frozen Case Series

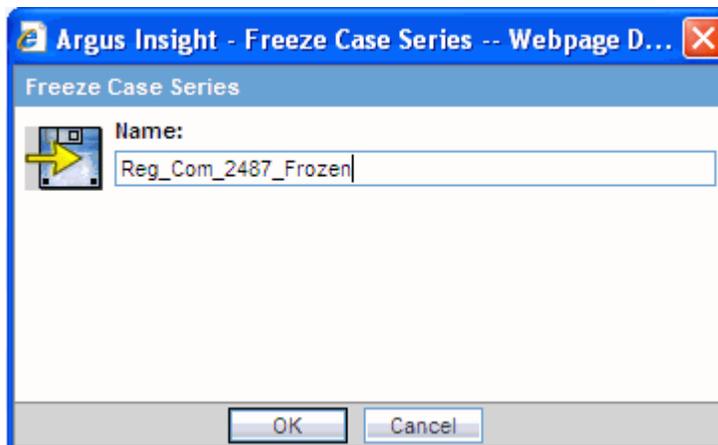
- List Maintenance items are not frozen. Therefore, some reports will have a mismatch of List Maintenance items and the frozen case series data.
- The derivation rules operate against current case data if the List Maintenance rules are modified. The frozen case series are shown if there is a change in 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:

- Navigate to the CASE SERIES LIBRARY page.
- Select a case series.
- Click **Freeze Case Series**. The Freeze Case Series dialog box opens and prompts you to provide a new name for the frozen case series.



- Enter a name for this frozen case series.
- Click **OK**.

The system freezes and saves the case series with the name you specified.

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 | Associated Report |
|----------|---------------|-------|-------------------|
| General | Argus Insight | 177 | |
| General | Argus Insight | 177 | |

Frozen on 2/14/2012 10:58:28 AM

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.

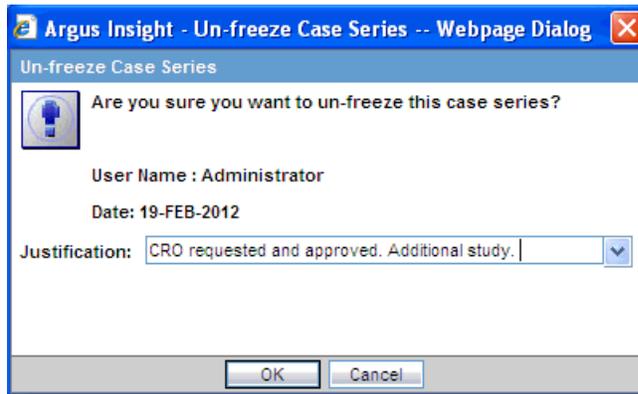
If you have access rights to the List Maintenance tab on the ADMINISTRATION TOOLS page, use the **Case Series Un-Freezing Justification** option to configure one or more justifications that can be selected when you unfreeze a case series. You can add new justifications, modify existing justifications, 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 that you want 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 opens and prompts for confirmation and justification.



4. Click the **Justification** field to select the reason you are unfreezing the Case Series. Alternatively, you can type your own justification text to explain why you are unfreezing the case series.

In addition, you can 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**.

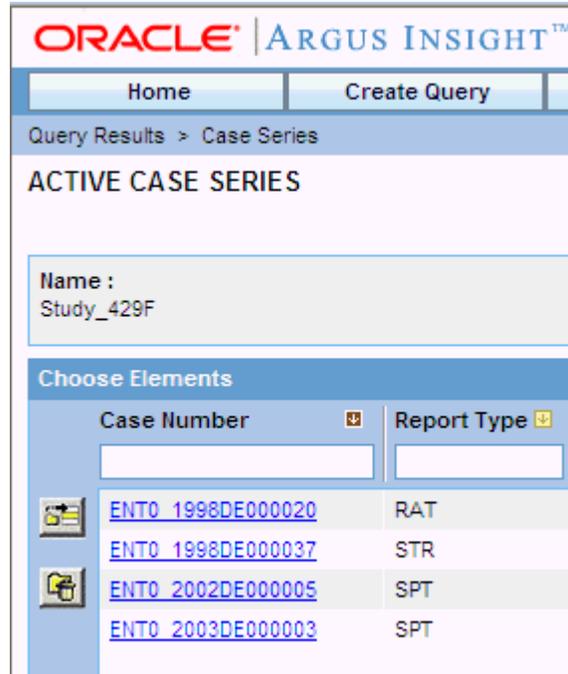
The system retrieves the latest information for all the cases in the series, refreshes the CASE SERIES LIBRARY page, and displays the updated case series in the list.

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.



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

Argus Insight provides built-in *standard 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 Standard Reports](#)
- [Working in the STANDARD REPORTS Page](#)
- [Generating Standard Reports](#)
- [Producing an Event-Level Report](#)
- [Scheduling and Associating Reports Against a Query or Case Series](#)
- [Creating and Scheduling a New Report Group](#)
- [Scheduling a Report without a Query](#)
- [Listing of the Standard Reports](#)

In addition to the preformatted and predefined standard reports, Argus Insight provides the Report Writer tool that you can use to create custom reports. For more information, see [Chapter 9, "Creating Custom Reports."](#)

About Standard Reports

Although standard reports are predefined reports, you can define pre-filters before generating a 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 standard report.

Alternatively, you can directly associate a *query* (QBE, filter, or advanced condition) to a standard report to avoid manual generation of the case series. For more information, see these topics:

- ["Associating a Report Group with a QBE"](#) on page 3-40
- ["Associating a Report Group with a Value Set"](#) on page 4-20
- ["Associating a Report Group with an Advanced Condition"](#) on page 5-16

Browser Configuration

Before using Argus Insight to generate standard 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 image shows a sample report cover page for 'Compliance'. The page is divided into three sections: Page header, Page contents, and Page footer.

Page header: The top right corner displays 'Compliance' in a large blue font. Below it, the date and time '20-JUL-2010 17:04 GMT+5:30' are shown.

Page contents: The main body of the page features a title 'Destination Report Submission Listing' in blue. Below the title is a 'Sub Title' field. The content is organized into several sections, each with a grey header bar:

- Report Filter:** Regulatory Authorities in (ALL), Countries in (ALL), Late vs. On-Time: ALL, Submission Date Range between: 01-JUN-1900 and 30-JUN-2010
- MedDRA Version:** 13.0
- Start Time of Last ETL Run:** 13-JUL-2010 14:21:48 GMT-8
- Case Series Count:** Total No. of Cases in Hitlist: 40
- Case Series Name:** US 2000 Dose > 1 (The case series was last modified on : 13-JUL-2010 11:43 GMT-07:00)
- Case Series Criteria:** Dose is greater than '1' AND Case Number contains 'US' AND Case Number does not contain '1999'

Page footer: The bottom of the page contains the name 'Amit Aggarwal', the word 'Confidential', and 'Page 1 of 34'.

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. For example, Destination Report Submission Listing or AE Count Tabulation.
- 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.
- MedDRA version used 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 STANDARD REPORTS Page

The STANDARD REPORTS page, shown in [Figure 8–2](#), lists all the standard reports built in to Argus Insight.

To display the STANDARD REPORTS page, navigate to **Case Series Reports, Standard Reports**, and select an option.

The STANDARD REPORTS page displays the following information for each report:

- Name of the report.
- Brief description of the report.
- Date when the report was last modified.
- Author of the report. For standard reports, the author is Oracle Corporation.
- Category to which the report belongs. For example, Compliance, Management, or Pharmacovigilance.

In addition, the STANDARD REPORTS page provides several standard tools to help you find a specific report or group of reports. You can:

- Scroll up and down to browse through the list.
- Click a column heading to sort the list.
- Enter keywords in one or more column fields and then click **Search** to find reports that satisfy your specified criteria

Figure 8–2 Sample Listing on the STANDARD REPORTS Page

ORACLE | ARGUS INSIGHT™

Home Tools Help Logout

Home Create Query Query Results Case Series Reports

Case Series Reports

Standard Reports

Active Query Name: QBE_Spon_USA
Active Case Series: SPT Cure-All Fatal

Choose Elements Search Clear

| Name | Description | Last Modified | Author | Category |
|---|---|---------------|--------------------|------------|
| | | 00-MMM-0000 | | |
| | | 00-MMM-0000 | | |
| Case Narrative Listing - English | Narrative Overview lists all cases per drug per report type with international and local narratives | 24-NOV-2011 | Oracle Corporation | General |
| Case Routing History | Detailed listing of all states a case has been routed to. | 24-NOV-2011 | Oracle Corporation | Management |
| Case Versions Processed | Obtain a summary tabulation of follow-ups processed. | 24-NOV-2011 | Oracle Corporation | Management |
| Case Volume History - Product - All Company Suspect Products | To obtain an overview of case volume by specified time period and broken down by key indicators (Product - All Company Products) | 24-NOV-2011 | Oracle Corporation | Management |
| Case Volume History - Product - Primary Suspect Products Only | To obtain an overview of case volume by specified time period and broken down by key indicators (Product - Primary Suspect Only). | 24-NOV-2011 | Oracle Corporation | Management |
| Case-Load | Obtain a graphical representation of cases in each workflow state. | 24-NOV-2011 | Oracle Corporation | Management |
| Case-Load Listing | Obtain a listing of the number of cases received and processed per workflow state for a given time period. | 24-NOV-2011 | Oracle Corporation | Management |
| CIOMS II Line Listing | Prints the standard CIOMS II Listing report for all cases of the case series. | 24-NOV-2011 | Oracle Corporation | General |

Modify Limit Report to Active Case Series Execute

Generating Standard Reports

To generate a standard report:

1. Navigate to **Case Series Reports** and select **Standard Reports**.



2. Select the report category, such as Compliance, to view a list of standard reports for that category, or select **All** to view a list of all the standard reports.

The STANDARD REPORTS page opens and lists the standard reports for the category you selected.



3. Select the report that you want to generate.

You can scroll through the list to find a report, click a column heading to sort the list, or search for report based on the criteria you specify in the column fields.

4. Select the **Limit Report to Active Case Series** check box to generate the report on the active case series only.

Note: Select the **Limit Report to Active Case Series** check box before generating the report. This prevents the report from querying the entire data mart and slowing down the report output generation.

To view the currently active case series, navigate to **Query Results, Case Series**, and select **Active**. To make a different case series active, navigate to **Query Results, Case Series**, and select **Library**. When the CASE SERIES LIBRARY page opens, select the case series you want to make active and click **Make Active**.

- Click **Execute**. The system opens a new browser window that displays the REPORT FILTER/FORMAT OPTIONS page.

- Enter a subtitle for your report in the **Sub Title** field. The subtitle prints below the title on the report cover page. Subtitles are useful in further defining the contents of the report. Subtitles are not part of the filtering criteria.
- Specify your report filtering criteria, as appropriate.

The REPORT FILTER/FORMAT OPTIONS page displays a variety of *prompts* (in the form of selection lists, check boxes, and fields) that you use to specify filtering criteria for your selected report. The filtering criteria options that are available depends on the type of information in the report. The filtering criteria can include one or more of the following options:

- Single selection lists — You can filter the report output by selecting a single value from the list; for example, the country of incidence, a regulatory authority, or a predefined date range. Some lists may contain options for grouping the report output; for example, grouping by age group or product name.
- Multiple selection lists — You can filter the report output by selecting one or more values from the list; for example, license countries or report types.

Note: If you select **All** along with other entities for a category, the All selection takes precedence. The system will search all items in the category.

- Fields — You can filter the report output by specifying a numerical value for timelines or dates for date ranges.

Some of the prompts (that is, fields) on the REPORT FILTER/FORMAT OPTIONS page display a list of values from which you can select one or more values. By default, the prompts display values from the List Maintenance tables.

- You can select the **Limit Prompt Values to Active Case Series** check box to generate pre-filter prompts and view values limited to the cases in the case series. This impacts only those prompts that are populated from case tables and the corresponding List Maintenance tables exist for that prompt.

- Custom prompts that you create for ad-hoc reporting do not have the option of displaying values in prompts from List Maintenance tables. Custom prompts always display data as per the conditions (SQL) that were defined during the creation of the prompts.
- 8. Select the **PDF** or **Excel** option to specify the report output format.
- 9. Click **Execute**. The system generates the report and displays the output in the selected format. You can print this report or save it to the system drive, if required.
- 10. Close the new browser window to return to the STANDARD REPORTS page.

Producing an Event-Level Report

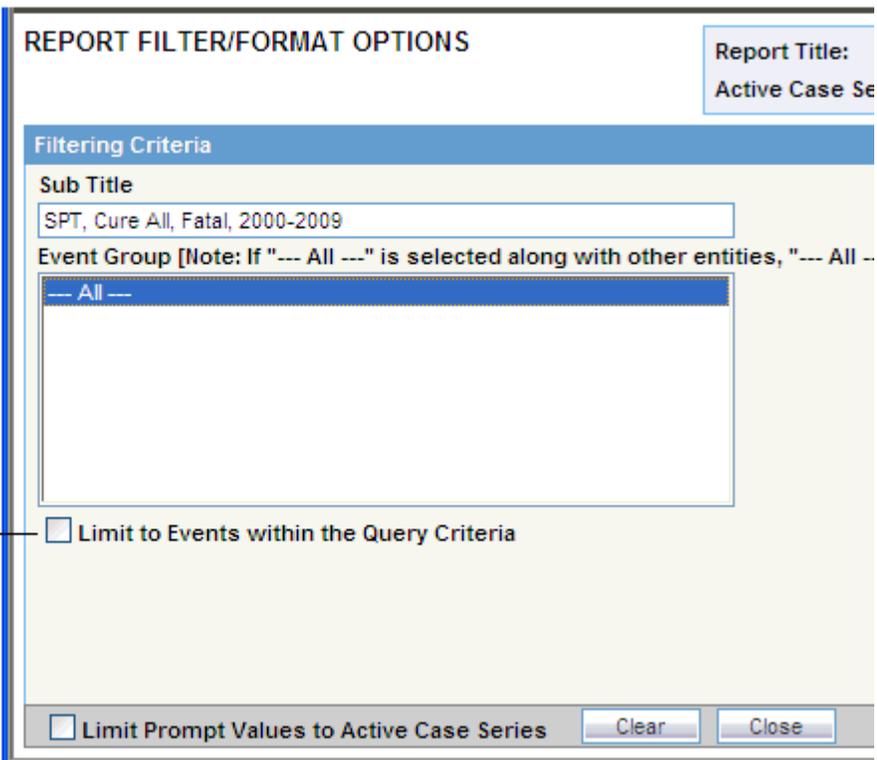
The reports in Argus Insight focus on cases. This permits event-level reporting in the Argus Insight report output.

Event-level reporting is available for the following Pharmacovigilance standard reports only:

- AE Count Tabulation (case causality)
- Event Term Frequency Listing by HLGT
- Event Term Frequency Listing by HLT
- Event Term Frequency Listing by PT
- Event Term Frequency Listing by SOC

When you execute one of the standard Pharmacovigilance reports in the previous list, the REPORT FILTER/FORMAT OPTIONS page displays filtering criteria that lets you create an event-level report. See [Figure 8-3](#).

Figure 8-3 Options for Producing an Event-Level Report



REPORT FILTER/FORMAT OPTIONS

Report Title: Active Case Se

Filtering Criteria

Sub Title
SPT, Cure All, Fatal, 2000-2009

Event Group [Note: If "--- All ---" is selected along with other entities, "--- All ---

--- All ---

Limit to Events within the Query Criteria

Limit Prompt Values to Active Case Series

Clear Close

Select this check box to produce an event-level report.

Event Group Selection List

- The system populates the event group information from the Event Groups.
- You can select multiple Event Groups.
- If you select Event Groups, the system limits the report output to only those events selected in the Event Group definition.

Limit to Events within Query Criteria Check Box

If you select the **Limit to Events within Query Criteria** check box, the system limits the report output to the events chosen in the report output query criteria.

- This feature applies to all queries executed from Query By Example, Filters, or Advanced Conditions.
- This feature applies for Event Terms for the entire hierarchy (that is, SOC, HLGT, HLT, PT, and LLT for the MedDRA coded events only).
- You cannot use this feature with hard-coded SQL queries.
- You cannot use this feature with a case series from Argus Safety.
- You cannot use this feature with an imported case series.

Power Queries

If you use a power query to generate a case series, the following terms are respected as the event query in the reports:

- From Query by Example, Events tab, Event Coding section
 - System Organ Class (SOC)
 - High Level Group Term (HLGT)
 - High Level Term (HLT)
 - Preferred Term (PT)
 - Lower Level Term (LLT)
- From Filters, Event Information section
 - Event Term (SOC, HLGT, HLT, PT, LLT)
 - Preferred Term
- From Advanced Conditions
 - EVENTS, Event Information, Event Body System Code
 - EVENTS, Event Information, Event High Level Group Term Code
 - EVENTS, Event Information, Event High Level Term Code
 - EVENTS, Event Information, Event Included Term Code
 - EVENTS, Event Information, Event Low Level Term
 - EVENTS, Event Information, Event SMQ (Broad)
 - EVENTS, Event Information, Event SMQ (Narrow)
 - EVENTS, Event Information, High Level Group Term
 - EVENTS, Event Information, High Level Term
 - EVENTS, Event Information, Lower Level Term

- EVENTS, Event Information, Preferred Term
- EVENTS, Event Information, Preferred Term Code
- EVENTS, Event Information, System Organ Class (SOC)
- EVENTS, Primary Event, Event SMQ (Broad)
- EVENTS, Primary Event, Event SMQ (Narrow)

Scheduling and Associating Reports Against a Query or Case Series

Report packaging is the concept of grouping reports together. You can define multiple reports that are always or often executed at the same time into a group. A set of reports run on a weekly or periodic basis can be scheduled and run as a package.

In Argus Insight, you can associate a report group and the report scheduling to a power query (QBE, Filter Value Set, and Advanced Conditions) or to a case series.

Argus Insight lets you *associate* the report group, schedule a time to generate the reports, and automatically send the completed reports through email to one or more users that you specify.

Note: To be able to schedule reports, you must have an enterprise login configured in the Business Intelligence tool (either BusinessObjects or Cognos) you are using with Argus Insight.

To associate reports with a query or case series:

- You can select any query from any library (Query By Example library, Filter library, Advanced Conditions library, or Query library) and click **Associate**.
- You can select any case series from the CASE SERIES LIBRARY page and click **Associate**.
- You can use the Query library and the Associated Reports library to schedule an association.

Because you can associate multiple reports with a single query, clicking **Execute** does not open the REPORT FILTER/FORMAT OPTIONS page after generating the case series.

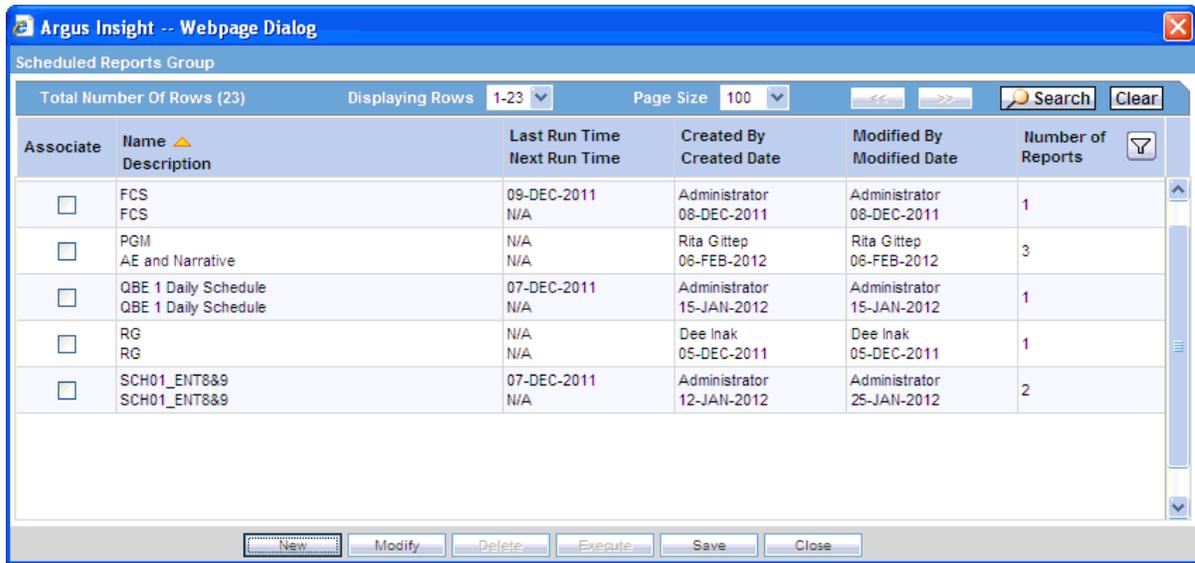
Working in the Scheduled Reports Group Dialog Box

When you select either a query or a case series and then click **Associate**, the system opens the Scheduled Reports Group dialog box. See [Figure 8-4](#).

The Scheduled Reports Group dialog box displays information about all the report groups created by all the users in the same user group. In a CRO setup or hosting installation, the system displays the report groups specific to the enterprise.

Each group can contain one or more reports. A *report group* means that all the reports are scheduled for the same time for a power query or a case series.

Figure 8–4 Scheduled Reports Group Dialog Box



Viewing the Reports in a Group

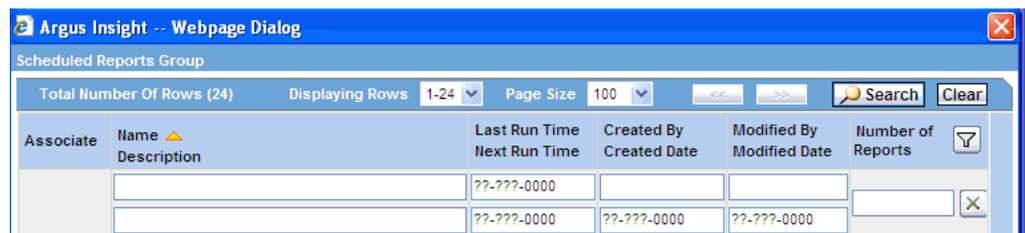
To view a list of the reports in a group, position the cursor over the group name in the Scheduled Reports Group dialog box. For example:



Viewing, Sorting, and Searching the Report Groups

The Scheduled Reports Group dialog box provides the several tools for viewing, sorting, and searching the report groups. You can:

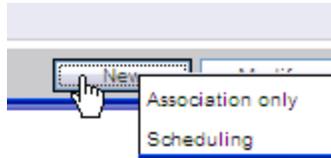
- Use the scroll bar and pagination icons to browse through the list of report groups.
- Click a column heading to sort the report groups according to the selected column.
- Use the **Filter** icon to enter search criteria into fields and click **Search** to find the report groups that match your search criteria. You can click **Clear** to remove all search criteria. You can click the **Close** icon to hide the search fields. The search fields are hidden when you open the dialog box.



Using the Command Buttons

The Scheduled Reports Group dialog box has the following commands buttons:

- Click **New** to create a new report group. You can select **Association only** or **Scheduling** from the context menu. Once you make your selection, the system opens the Reports Scheduling dialog box.



- Click **Modify** to change the settings for an existing scheduled report group.
- Click **Delete** to remove the selected report group. You can delete a report group *only if* the report group is not associated with a query or case series.
- Click **Execute** to close the Scheduled Reports Group dialog box, and then execute the query/case series in the parent window and open the pre-filter for the selected report. The **Execute** button is enabled *only if* the scheduled report group has a single report.
- Click **Save** to save your changes after you associate (or disassociate) a report group by selecting (or clearing) a check box in the Associate column.
- Click **Close** to close the Scheduled Reports Group dialog box.

Associating a Report Group

To associate an existing report group to a selected query or case series:

- Navigate to the QUERY LIBRARY page or CASE SERIES LIBRARY page.
- Select the query or case series for which you want to associate a report group.
- Click **Associate**. The Scheduled Reports Group dialog box opens.
- Select the check box in the Associate column for the report group that you want to schedule for your selected query or case series. You can associate one or more report groups for your selected query or case series.

| Scheduled Reports Group | |
|-------------------------------------|--|
| Total Number Of Rows (25) | |
| Associate | Name ▲ Description |
| <input checked="" type="checkbox"/> | Monthly Event Reports January-December 2012 |
| <input type="checkbox"/> | PGM AE and Narrative |
| <input checked="" type="checkbox"/> | QBE 1 Daily Schedule QBE 1 Daily Schedule |

- Click **Save**. The report groups are now scheduled for the selected query or case series.

To remove the scheduling of a report group for a selected query or case series, clear the check box in the Associate column and click **Save**.

Creating and Scheduling a New Report Group

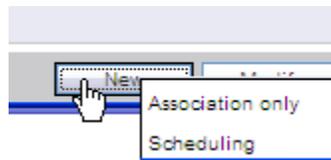
To create and schedule a new report group for a query or a case series:

1. Navigate to the QUERY LIBRARY page or the CASE SERIES LIBRARY page.
2. Select the query or case series for which you want to create, schedule, and associate a report group.
3. Click **Associate**. The Scheduled Report Groups dialog box opens.



| Associate | Name Description | Last Run Time Next Run Time | Created By Created Date | Modified By Modified Date | Number of Reports |
|--------------------------|--|--------------------------------|------------------------------|------------------------------|----------------------|
| <input type="checkbox"/> | FCS FCS | 09-DEC-2011 N/A | Administrator 08-DEC-2011 | Administrator 08-DEC-2011 | 1 |
| <input type="checkbox"/> | PGM AE and Narrative | N/A N/A | Rita Gittep 06-FEB-2012 | Rita Gittep 06-FEB-2012 | 3 |
| <input type="checkbox"/> | QBE 1 Daily Schedule QBE 1 Daily Schedule | 07-DEC-2011 N/A | Administrator 15-JAN-2012 | Administrator 15-JAN-2012 | 1 |
| <input type="checkbox"/> | RG RG | N/A N/A | Dee Inak 05-DEC-2011 | Dee Inak 05-DEC-2011 | 1 |

4. Click **New**. The system opens a menu with options for associating a report only or for scheduling and associating a report.



5. Click **Scheduling** to open the Reports Scheduling dialog box. See [Figure 8-5](#).
6. See the following sections for information about completing the Reports Scheduling dialog box, including:
 - [Working in the Scheduled Reports Group Dialog Box](#)
 - [Entering the Report Name and Description](#)
 - [Setting Up the Schedule](#)
 - [Setting Up to Run the Reports Now](#)
 - [Defining E-Mail Information](#)
 - [Browsing and Sorting the List of Available Reports](#)
 - [Selecting and Adding Reports to the Group](#)
 - [Entering Required Pre-filters and Selecting a Report Format](#)
 - [Saving the Schedule](#)

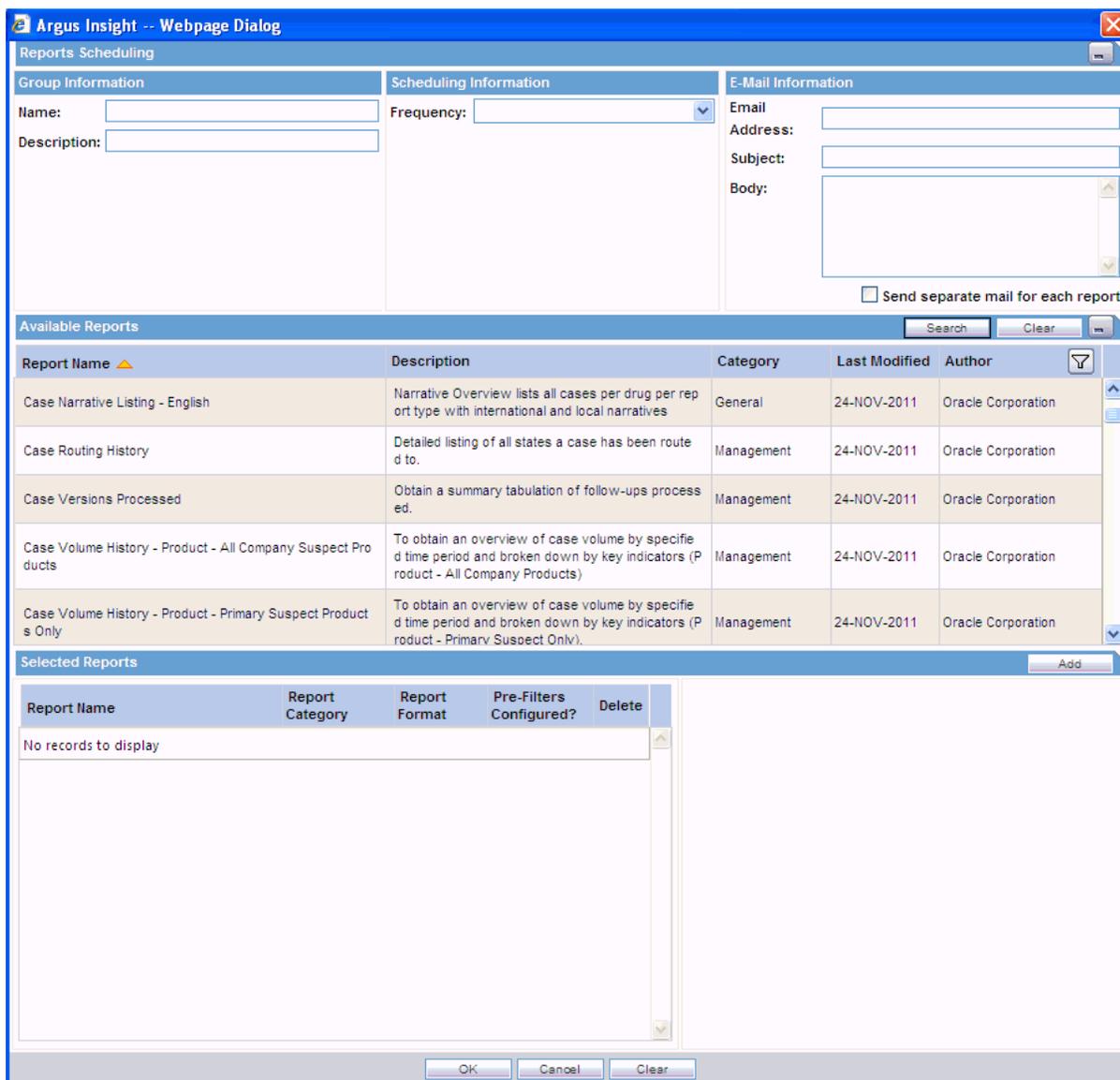
Working in the Reports Scheduling Dialog Box

The Reports Scheduling dialog box is the main scheduling page in Argus Insight. See [Figure 8-5](#). From this dialog box, you can select any number of reports for scheduling.

The Reports Scheduling dialog box has the following sections:

- Group Information
- Scheduling Information
- E-Mail Information
- Available Reports
- Selected Reports

Figure 8-5 Reports Scheduling Dialog Box



Entering the Report Name and Description

In the Group Information section, use the **Name** and **Description** fields to enter a title for the report and a brief summary of the report.

Setting Up the Schedule

In the Scheduling Information section, click the **Frequency** field to specify how often you want the system to run the selected QBE and generate the selected reports. The options available are **Once**, **Daily**, **Weekly**, **Monthly**, **Quarterly**, and **Yearly**.

Based on the frequency option you select, the Scheduling Information section displays additional parameters that you must specify. For example, if you choose to run the report weekly, the system prompts you to enter the day, the time, the start date, and the end date.

The image shows two views of the 'Scheduling Information' dialog box. The top view shows the 'Frequency' dropdown menu open with options: Once, Daily, Weekly (highlighted), Monthly, Quarterly, and Yearly. An arrow points from the 'Weekly' option to a second view of the dialog box. In this second view, the 'Frequency' is set to 'Weekly', and additional fields are shown: 'Day of Week' (Monday), 'Time' (empty), 'Start Date' (??-??-0000), and 'End Date' (??-??-0000).

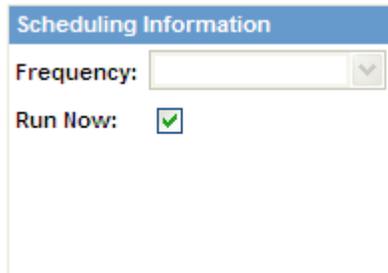
Based on the frequency option you select, enter the additional scheduling information:

- **Once** — Enter the date and time when the system will generate the report.
- **Daily** — Enter the time when the system will generate the report. The system generates the report every day at the specified time. In addition, enter the start date and the end date for this schedule.
- **Weekly** — Select the day of the week when the system will generate the report. In addition, enter the time, the start date, and the end date for this schedule.
- **Monthly** — Select the day (1-31) of the month when the system will generate the report. In addition, enter the time, the start date, and the end date for this schedule.
- **Quarterly** — For reports generated quarterly, the system automatically generates the report on the first day of the quarter. You enter the time of day when the system generates the report, as well as the starting and ending dates.
- **Yearly** — Enter the date and time when the system will generate the yearly report. In addition, enter the start date and the end date for this schedule.

Note: In the **Time** field, you must enter the time value in the HH:MM AM/PM format. Hours must be between 1 and 12.

Setting Up to Run the Reports Now

If you are scheduling a report group for a case series, you have the option to run the reports immediately. For case series, the Scheduling Information section includes a **Run Now** check box.

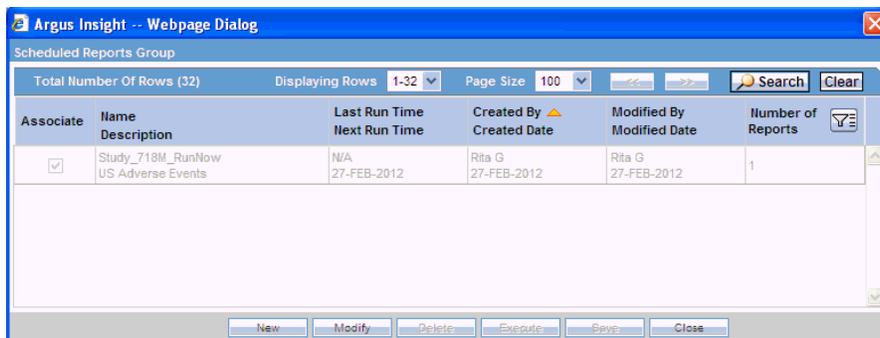


When you select the **Run Now** check box and save the scheduling information, Argus Insight saves the schedule to execute immediately.

Note that:

- The Run Now option is available only when you schedule a report group for a case series.
- When you select the Run Now option, all other settings in the Scheduling Information section are disabled. In addition, changes you make in the E-Mail Information section or the Selected Reports section when using the Run Now option do not affect the existing report group information.
- The ASSOCIATED REPORTS LIBRARY page does not list the report groups scheduled using the Run Now option.
- The Associated Reports Count tooltip on the CASE SERIES REPORTS LIBRARY page does not include Run Now schedules in its count.

The Scheduled Reports Group dialog box displays a new row for each report group schedule that you create using the Run Now option. For example:



Note that the system:

- Appends the **_RunNow** text to the report group name to indicate that it was scheduled using the Run Now option.
- Displays the row in read-only mode (grayed out). You cannot select this row; you cannot perform any operation available in the dialog box on this row.
- Displays the row only until all the related scheduling activities are completed.
- Makes the row visible only to the user who created the Run Now schedule.

Defining E-Mail Information

In the E-Mail Information section, enter the email address of each report recipient. If there are multiple recipients, use a semicolon (;) to separate each address.

The screenshot shows a form titled "E-Mail Information". It contains the following fields:

- Email Address:** A text input field.
- Subject:** A text input field.
- Body:** A large text area with a vertical scrollbar on the right side.
- Send separate mail for each report:** A checkbox located at the bottom of the form.

Enter the subject and body text for your email. For example, you may want to include general information about the reports generated, the scope of the report, the time frame of the report, and who to contact for additional information.

You can schedule multiple reports for a single QBE. Be sure to select the **Send separate mail for each report** check box if you want the system to send an email notification for each report generated.

Browsing and Sorting the List of Available Reports

The Available Reports section lists all the reports that you can include in the schedule and associate with the QBE.

To help you locate specific reports, you can:

- Click a column heading to sort the list of reports by the selected column.
- Click the **Filter** icon to display search fields below the column headings, enter one or more values, and then click **Search** to find the reports that match your criteria.
- Scroll up and down to browse through the list.

Click a column heading to sort the reports by that column.

Click the **Filter** icon to display the search fields, enter values, and then click **Search** to find specific reports.

| Report Name ▲ | Description | Category | Last Modified | Author |
|------------------------------|---|------------|---------------|--------------------|
| | | | ??-??-0000 | |
| Case Activity History | Graph to show the count of incoming and closed cases and aggregate total of cases in process. | Management | 24-NOV-2011 | Oracle Corporation |
| Case Narrative Listing - Eng | Narrative Overview lists all cases per drug per report type with international and local narratives | General | 24-NOV-2011 | Oracle Corporation |
| Case Routing History | Detailed listing of all states a case has been routed to. | Management | 24-NOV-2011 | Oracle Corporation |
| Case Versions Processed | Obtain a summary tabulation of follow-ups processed. | Management | 24-NOV-2011 | Oracle Corporation |

Selecting and Adding Reports to the Group

In the Available Reports section, select a report that you want to include in this scheduling and then click **Add**. The system displays the report in the Selected Reports section. Continue to select and add each report that you want to include in this scheduling.

If you want to remove a report from this scheduling, click the **Delete** icon. The system prompts for confirmation before deleting the report.

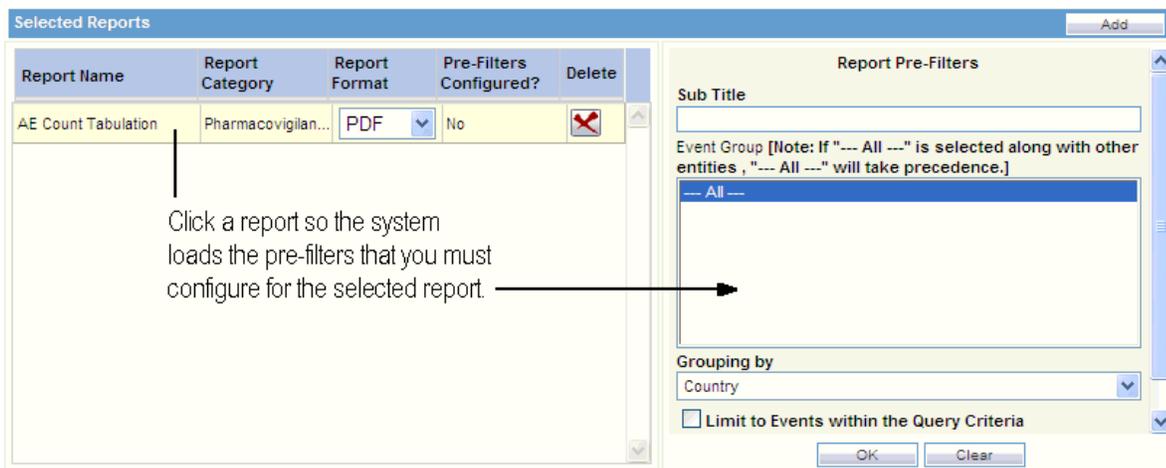
Entering Required Pre-filters and Selecting a Report Format

For each report that you select to include in this scheduling, the system displays the report name and category in the Selected Reports section.

You cannot save a schedule without entering the pre-filter information for each report. The system uses the value in the Pre-Filters Configured? column to detect whether you entered the pre-filter information.

To configure the required pre-filters for a report:

1. Click the report name in the Selected Reports section. The system loads the pre-filter fields into the pane to the right. The pre-filters are specific to the selected report; pre-filters will vary from report to report.



2. Enter the required information into each field.
3. Click **OK** to save your changes to the pre-filter information for the selected report. Note that the system updates the value in the Pre-Filters Configured? column to **Yes** to indicate you defined the pre-filters for this report.

To reset the pre-filter fields and reenter values, click **Clear**.

4. Repeat the procedure to configure the pre-filters for each report included in this scheduling.

In the Report Format column, select the output format for each report. You can select either **PDF** or **Excel**.

If you want to remove a report from this scheduling, click the **Delete** icon. The system prompts for confirmation before deleting the report.

Saving the Schedule

Click **OK** in the Reports Scheduling dialog box to save your report scheduling.

The system associates the report group with the selected query or case series, saves the scheduling information, and returns to the Scheduled Reports Groups dialog box.

Note that the system automatically selects the Associate check box in the Scheduled Reports Groups dialog box to indicate that reports are associated with the query or case series. Position the cursor over the report name to list the associated reports.

| Scheduled Reports Group | |
|-------------------------------------|---|
| Total Number Of Rows (30) | |
| Associate | Name  Description |
| <input checked="" type="checkbox"/> | Monthly Event Reports January-December 2011 |
| <input type="checkbox"/> | |

Event vs. Age Group
 Event vs. Daily Dose
 Event vs. Gender

Close the Scheduled Reports Groups dialog box to return to the starting library page. Note that the Associated Report column now displays an icon to indicate that reports are associated with this query or case series. Position the cursor over the icon to display the number of reports associated.



Scheduling a Report without a Query

Navigate to **Case Series Reports** and select **Associated Reports Library** to display the ASSOCIATED REPORTS LIBRARY page, which is the main status page for all scheduled reports.

You can see all reports in different/same groups at the same time. For example, if you have two (2) report groups with three (3) reports in each group, the library has six (6) rows, one for each report association. The Status column displays the current status of the reports association.

From the ASSOCIATED REPORTS LIBRARY page, you can click **Associate To All Cases** to schedule reports without a query. The system opens the Scheduled Report Groups dialog box so you can select any number of reports for scheduling. See ["Working in the Reports Scheduling Dialog Box"](#) on page 8-14 for more information.

By default, the button is labeled **Associate To All Cases**. However, if you have access privileges to the List Maintenance tab on the ADMINISTRATION TOOLS page, you can customize the text on the button.

The button label uses the following format:

Associate To *configured_text*

where *configured_text* is the part of the button label you can customize. The default value is **All Cases**.

To customize the *configured_text* on this button:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Profile Switches** from the List Maintenance Items section. The system updates the Attributes section with the profile switches that you can configure.
4. Select **ALL CASES QUERY NAME** in the Attributes section.
5. Click **Modify**. The Modify Attribute dialog box opens.
6. Enter the text that the system appends to the **Associate To** text. For example, if you enter All System Cases, the new label for the button is **Associate To All System Cases**.
7. Click **OK** to save your changes.

Listing of the Standard Reports

This section lists the Argus Insight standard reports. The reports are grouped by category; a title and brief description are listed for each report.

Case Processing Reports

[Table 8–1](#) describes the standard Case Processing reports.

Table 8–1 Standard Case Processing Reports

| Report Title | Description |
|-------------------------------|--|
| Adverse Events Line Listing | A tabular report that contains the data of selected fields from study cases. |
| DCA-TME Notification Report | A listing of the cases in which an event of special interest is associated with a specific product. |
| Serious Adverse Events Report | A case-wise compilation of selected data, including the narrative, from study cases of special interest. |

Compliance Reports

Table 8–2 describes the standard Compliance reports.

Table 8–2 Standard Compliance Reports

| Report Title | Description |
|--|--|
| Data Entry Performance Over Time Report | List of the serious and non-serious cases in which data entry is not performed within the required timelines. |
| Destination Report Submission Listing | Submission details based on an on-line country. |
| Manufacturing Monthly Report | List of the cases that have specific products (drugs and medical devices) of special interest for manufacturing. |
| Process Performance Report - Notification | Provides formal volume and performance metrics for forwarding of adverse event reports from Company to Licensing Parties within timeframes established in the Pharmacovigilance Agreements (PVAs). |
| Process Performance Report - Workflow | Provides volume and performance metrics for forwarding of safety reports within Company or agents thereof to the point to Case Lock, which precedes the Distribution step within the Argus Safety workflow. |
| Regulatory Submission and Distribution Compliance Report | Measures the volume and timeliness of single case paper and electronic safety reports sent directly to regulatory agencies or licensed parties. |
| Reporting Compliance by Grouped Destination (Count) | Graphical overview of compliance grouped by reporting destination. |
| Reporting Compliance by Grouped Destination (Percentage) | Graphical overview of compliance grouped by reporting destination expressed in percentages. |
| Reporting Compliance Listing - Detail | Detailed listing of submitted as well as outstanding reports for the selected cases and reporting destinations. The listing is grouped by destination; subtotals and compliance percentages are provided for each destination along with an overall total and total compliance percentages. |
| Reporting Compliance Listing - Summary | Summary listing of submitted as well as outstanding reports for the selected cases and reporting destinations. The listing is grouped by destination; subtotals are provided for each destination along with compliance percentage. |
| Reports Out of Compliance Listing - Detail | Detailed listing of all reports that were past the due date for the selected cases and reporting destinations. The listing is grouped by reporting destination; subtotals are provided for each destination apart from the overall total. |
| Reports Out of Compliance Listing - Summary | Summary listing of all reports that were past the due date for the selected cases and reporting destinations. The listing is grouped by reporting destination; subtotals are provided for each destination apart from the overall total. |
| Supplier Performance Report | Provides formal volume and performance metrics for individual supplying organizations in forwarding each instance of adverse event information within specific timeframes established in the Corporate Standard Operating Procedure (SOP) or Pharmacovigilance Agreements (PVAs) which defines processes for reporting adverse events. |

Configuration Reports

Table 8–3 describes the standard Configuration reports.

Table 8–3 Standard Configuration Reports

| Report Title | Description |
|---|--|
| ETL Log Argus to Staging Incremental | ETL log for the latest Argus to Staging ETL incremental process. |
| ETL Log Staging to Mart Incremental | ETL log for the latest Staging to Data Mart ETL incremental process. |
| ETL Log Summary | ETL summary for all the ETL processes. |
| Listing of Licenses by Family and Product | Overview of defined licenses grouped by families. |
| Listing of Product by Family and Licenses | Overview of defined products grouped by families. |
| Reporting Rules Configuration | List of configured reporting rules. |
| Study Configuration | List of configured studies. |

General Reports

Table 8–4 describes the standard General reports.

Table 8–4 Standard General Reports

| Report Title | Description |
|----------------------------------|--|
| Case Narrative Listing - English | Narrative overview list of all cases per drug per report type with international and local narratives. |
| CIOMS II Line Listing | Standard CIOMS II listing report for all cases of the case series. |
| CIOMS Report | Standard CIOMS I report for all cases of the case series. |
| Lot Number Listing - Detail | Correlation of events for a certain lot number (detailed listing). |
| Lot Number Listing - Summary | Correlation of events for a certain lot number (summary). |
| Study Reconciliation Report | Data-set that lets you reconcile between Argus and the company clinical database. |
| US FDA MedWatch 3500A | Standard US FDA MedWatch 3500A report for all cases of the case series. |

Management Reports

Table 8–5 describes the standard Management reports.

Table 8–5 Standard Management Reports

| Report Title | Description |
|---|--|
| Case Activity History | Graph to show the count of incoming and closed cases and an aggregate total of cases in process. |
| Case Routing History | Detailed listing of all states to which a case has been routed. |
| Case Versions Processed | Summary tabulation of follow-ups processed. |
| Case Volume History - Product - All Company Suspect Products | Overview of case volume by specified time period and broken down by key indicators (Product - All Company Products). |
| Case Volume History - Product - Primary Suspect Products Only | Overview of case volume by specified time period and broken down by key indicators (Product - Primary Suspect Only). |
| Case-Load | Graphical representation of cases in each workflow state. |
| Case-Load Listing | List of the number of cases received and processed per workflow state for a given time period. |
| Event Comparison of Two Periods | List of events (diagnoses) over two time periods and comparison of these different time periods in one document including labeledness. |
| Follow-up Status Listing | List of cases requiring follow-up and the status of those cases. |
| Open Action Items Listing | List of cases with open action items by responsible group. |
| Receipt Latency of Cases by Site - Initial and All Follow-ups | List of latency from initial receipt date to central received date for initial and follow-up reports. |
| Receipt Latency of Cases by Site - Initial and Significant Follow-ups | List of latency from initial receipt date to central received date for initial and follow-up reports. |
| Receipt Latency of Cases by Site and Country of Origin | List of latency from initial receipt date to central received date for initial and follow-ups, broken down by country of origin. |
| Received AE Reports by Protocol | List of all cases received grouped by protocol number (Study ID). |
| Total Case WorkLoad by Site | List of total number of cases in the system. |
| Total Case Workload by Site and COI - Init. and Sig. Follow-ups | List of total number of cases in the system grouped by site and country of origin. |
| Total Case Workload by Site and COI - Initial and All Follow-ups | List of total number of cases in the system grouped by site and country of origin. |
| Total Case Workload by Site Graphical Summary | Graphical overview of the total number of cases in the system broken down by seriousness. |
| Workflow Monitoring Report | List of case workflow milestones and lead times for workflow as well as minimal case information. |
| Workflow Report - 3 months | Counts based on groups over three-month periods, based on a selected date range. |
| Workflow Report - 4 quarters | Counts based on groups over four quarters, based on a selected date range. |

Pharmacovigilance Reports

Table 8–6 describes the standard Pharmacovigilance reports.

Table 8–6 Standard Pharmacovigilance Reports

| Report Title | Description |
|---|--|
| AE Count Tabulation | Summary tabulation that displays a count of events and breaks them down by causality. |
| Clinical Trial Causality Tabulation | Tabulates the causality assessments for each occurring PT. |
| Count of Serious Related Cases by Product | Overview of serious related cases over a given time period. |
| Event (PT) vs. Age Group | Analysis of the relationships between two or more attributes. |
| Event (PT) vs. Gender | Analysis of the relationships between two or more attributes. |
| Event (PT) vs. Report Type | Analysis of the relationships between two or more attributes. |
| Event Term Frequency Listing by HLGT | Identifies the frequency of events in descending order, grouped by SOC, HLGT, HLT, or PT. |
| Event Term Frequency Listing by HLT | Identifies the frequency of events in descending order, grouped by SOC, HLGT, HLT, or PT. |
| Event Term Frequency Listing by PT | Identifies the frequency of events in descending order, grouped by SOC, HLGT, HLT, or PT. |
| Event Term Frequency Listing by SOC | Identifies the frequency of events in descending order, grouped by SOC, HLGT, HLT, or PT. |
| Event vs. Age Group | Analysis of the relationships between two or more attributes. |
| Event vs. Daily Dose | Analysis of the relationships between two or more attributes. |
| Event vs. Gender | Analysis of the relationships between two or more attributes. |
| Product Interaction Tabulation | Summary tabulation that displays a count of the incidence of other products involved in cases. |
| Quick Signal | List of the event-reporting rates that might suggest a possible change in the safety profile of a product. |
| SOC/PT Tabulation (Event Count) | Comparison of events based on report type. |

Creating Custom Reports

In addition to the preformatted standard reports, Argus Insight provides the Report Writer tool that you can use to create custom reports for ad hoc/special reporting requirements.

Report Writer is used to create a custom report by directly selecting data mart fields and applying filters on them. The report output can be displayed in various layouts and can be saved in file formats, such as PDF, XLS, or CSV.

This chapter, which explains how to use the custom report tools, includes the following topics:

- [General Report Writer Information](#)
- [Creating a New Report](#)
- [Editing Reports](#)
- [Turning the Report Layout into a Table or Chart](#)
- [Saving and Accessing Reports](#)
- [Using SMQs in Report Writer](#)
- [Creating AdHoc Reports](#)

General Report Writer Information

In this version of Argus Insight, Report Writer uses the features of BusinessObjects XI to let you create custom reports by directly selecting data mart fields and viewing the customized results (report output). The Report Writer interface provides a list of database fields organized in a tree structure. To create a report, expand the trees corresponding to the required database fields and select the fields to be displayed as columns in your report.

Once you have created your report, you can edit the report, change the report layout, run the report in specific formats, and save the report.

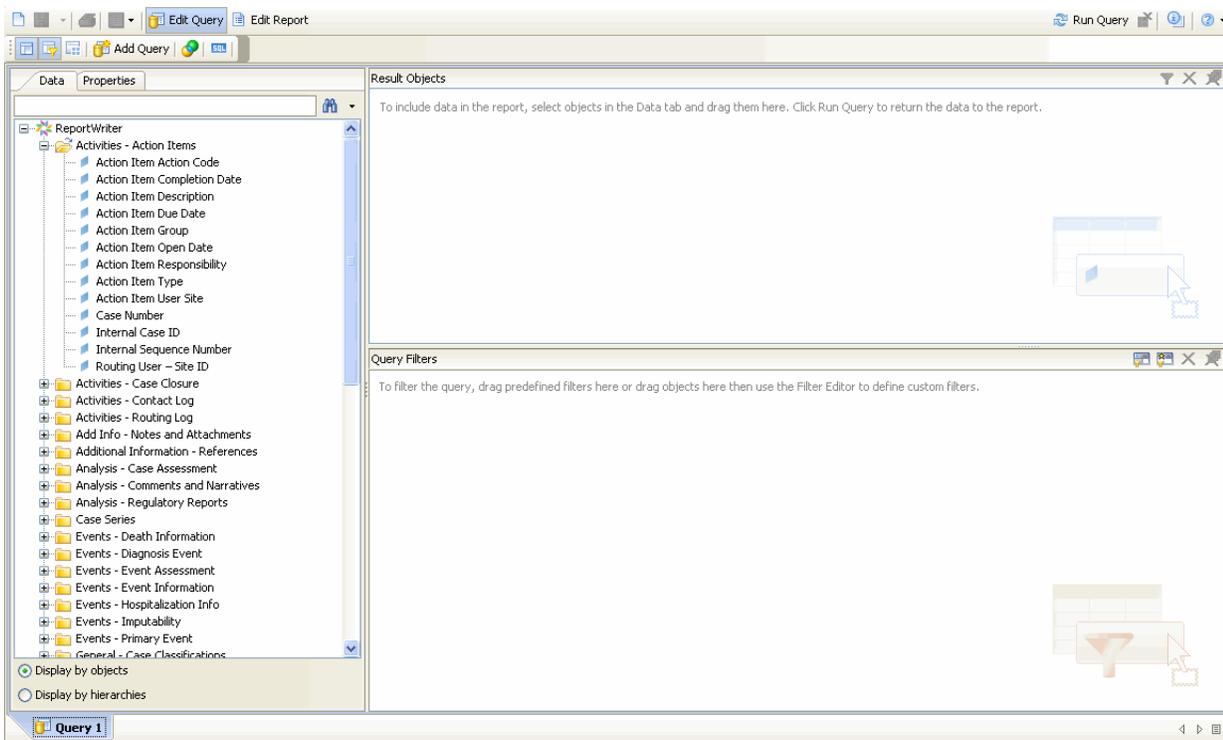
Note: When you finish using the Report Writer to create, edit, and save custom reports, you **must log out** of the BusinessObjects application. If you do not log out of BusinessObjects but you do log out of Argus Insight, another user logging in to Argus Insight has access to BusinessObjects with your user credentials. The system does not prompt the new user to log on to BusinessObjects.

Creating a New Report

To start Report Writer and create a new report:

1. Navigate to **Case Series Reports, Report Writer**, and select **New**. The BusinessObjects InfoView logon window opens.
2. Enter your user name and password, and click **Log On**. The home page for BusinessObjects InfoView opens.
3. Click **Document List**.
4. Open the **New** menu and select **Web Intelligence Document**.
5. Scroll through the list of universes and select **Report Writer**.

The BusinessObjects XI report panel opens. In the left frame, the Data tab lists all the fields that you can use as the filtering criterion for data analysis. The fields that you select here are displayed as columns in your report output.



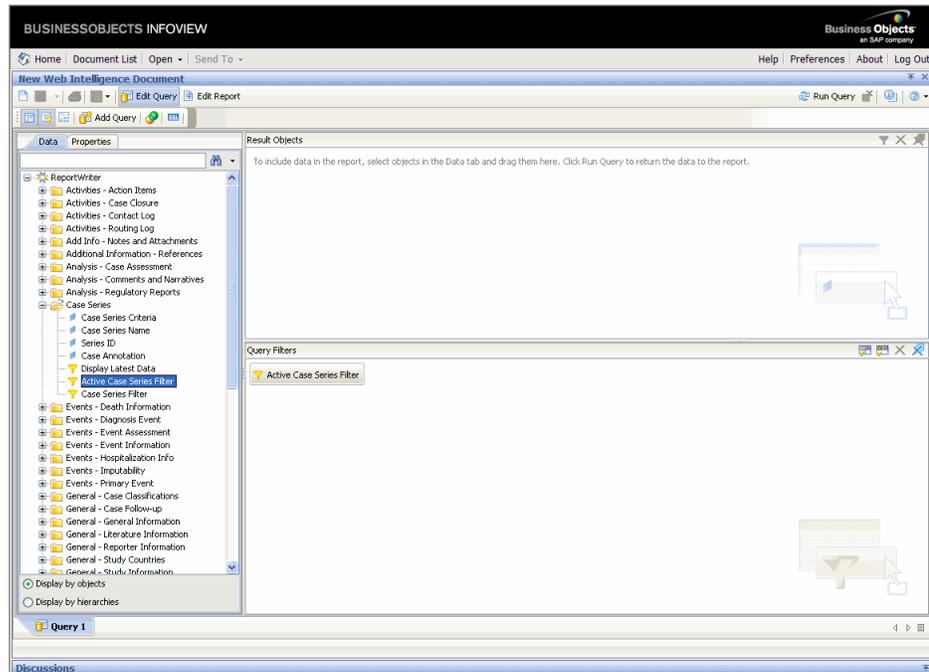
6. Expand **Report Writer** and then expand the **Case Series** folder.

Note: Select the active case series filter before selecting data mart fields for your report. This prevents Report Writer from querying the entire data mart and slowing down the report output generation.

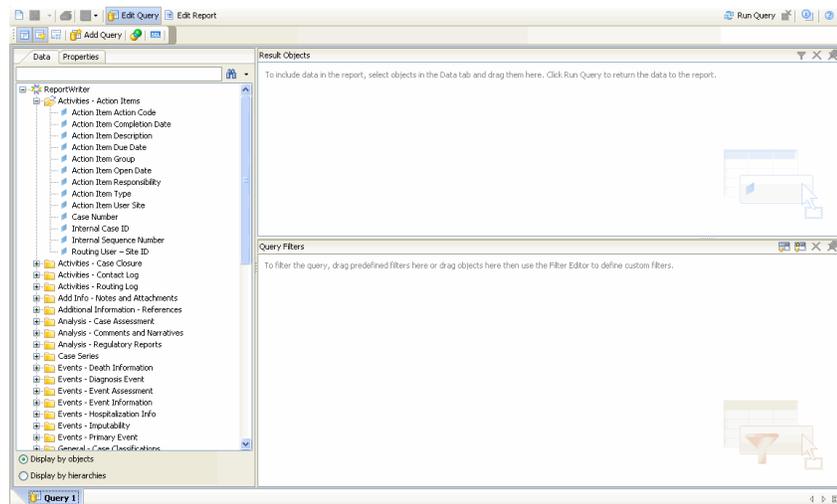
To view the active case series, navigate to **Query Results, Case Series**, and select **Active** in Argus Insight.

To make a different case series active, navigate to **Query Results, Case Series**, and select **Library** in Argus Insight. When the CASE SERIES LIBRARY page opens, select the case series you want to make active and click **Make Active**.

7. Drag and drop the **Active Case Series Filter** into the Query Filters panel. The selected filter appears in the right frame.



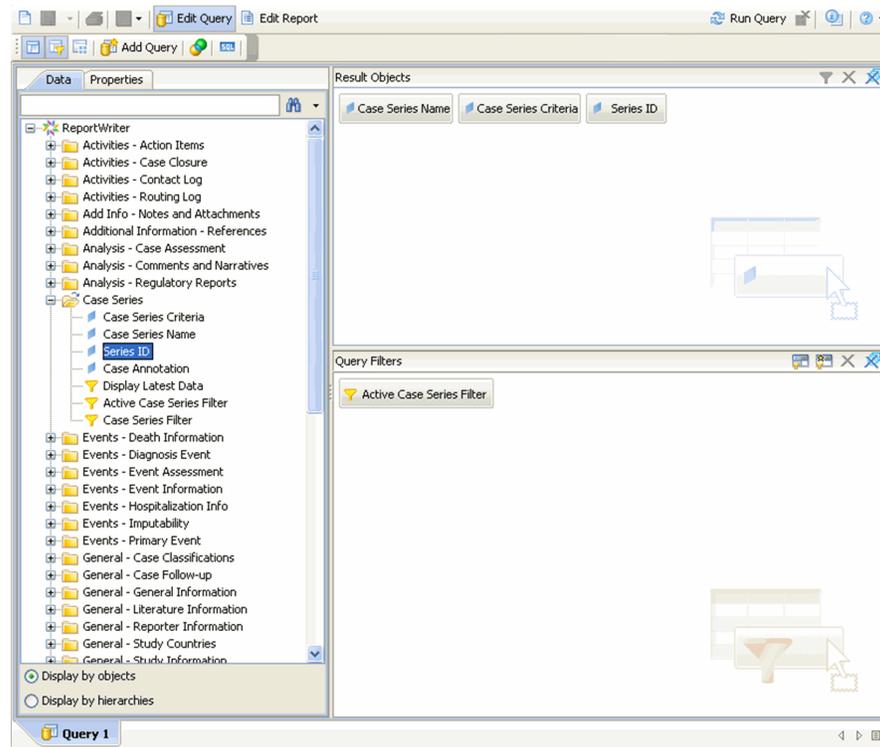
8. Select the data mart fields to include in your report as follows:
 - a. Expand **Report Writer**.



- b. Select the fields, as appropriate.

WARNING: If your report consists of fields from the **Event** and **Product** tables, it will only display data for those cases where event assessment has been done. This is because event assessment is the only way of defining relationship between an event and a product.

- c. Drag and drop fields from the **Report Writer** panel into the **Result Objects** panel.



Tip: To select multiple fields, hold down the **CTRL** key and select the fields. Then drag the field entities to the report output area (in the right panel).

To delete a column from the report output, right-click the column and then click **Remove** from the menu.

To revert an action you perform, click **Undo** on the toolbar.

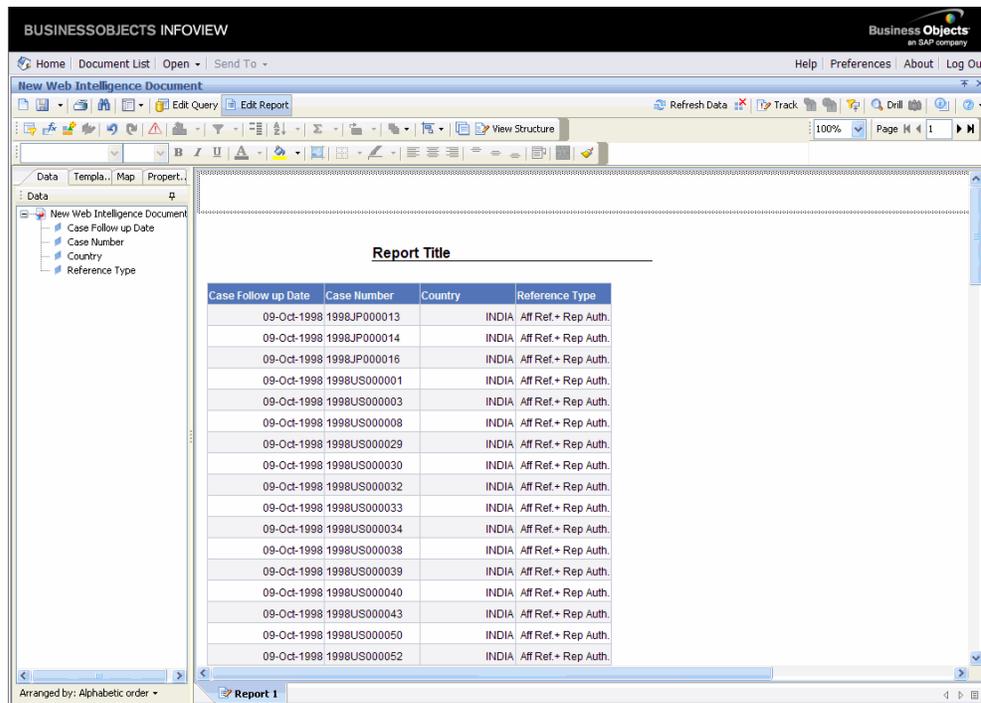
9. Click **Run Query** in the toolbar to execute the query.

The Report Writer queries the data mart, automatically executes the query for every *field* you selected, and displays the data for the selected fields. The fields you selected are displayed as columns in the report output.

For example, [Figure 9–1](#) shows a sample custom report.

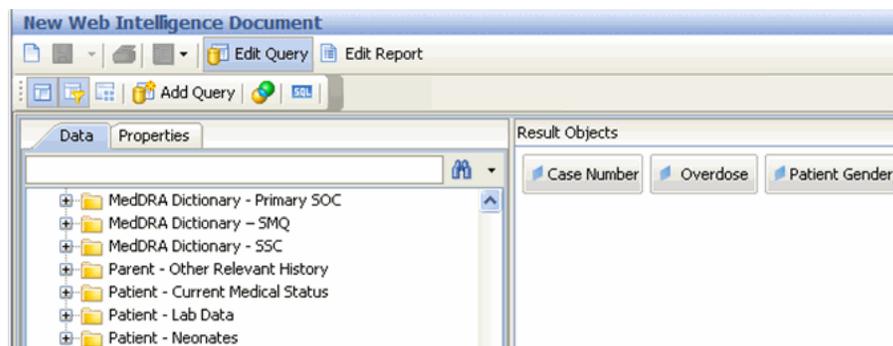
Note: When you finish using the Report Writer to create, edit, and save custom reports, you **must log out** of the BusinessObjects application. If you do not log out of BusinessObjects but you do log out of Argus Insight, another user logging in to Argus Insight has access to BusinessObjects with your user credentials. The system does not prompt the new user to log on to BusinessObjects.

Figure 9–1 Sample Custom Report



Editing Reports

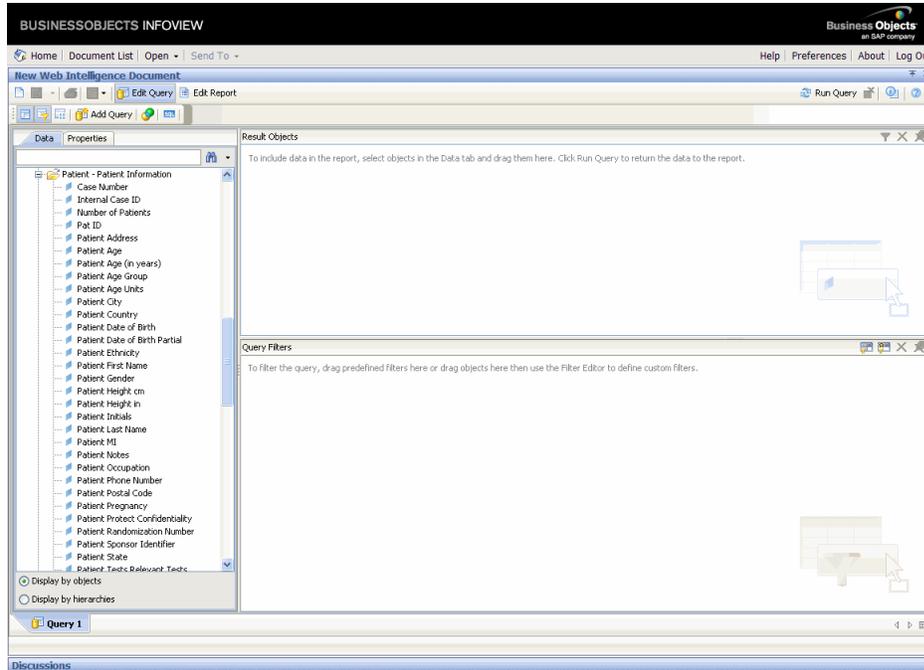
To access the *report* editing options provided by BusinessObjects, select **Edit Query**. The report editing options let you control what data appears in your report as well as how it is formatted, calculated, and sorted. None of the edit operations you perform are stored in the database.



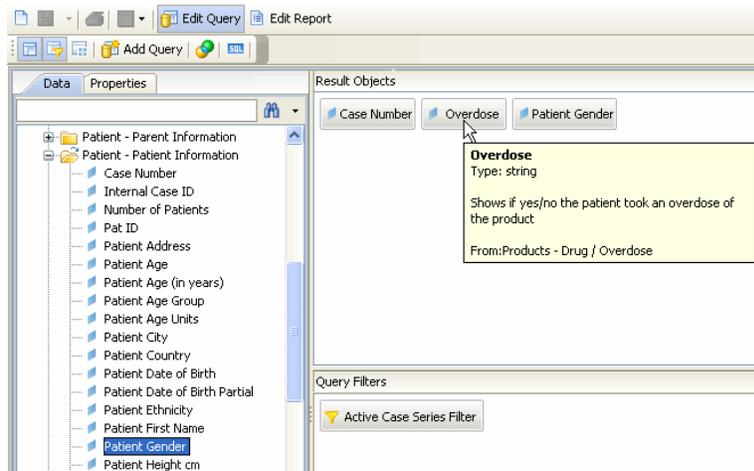
Filtering Data

To use the filtering option to reduce data in your report:

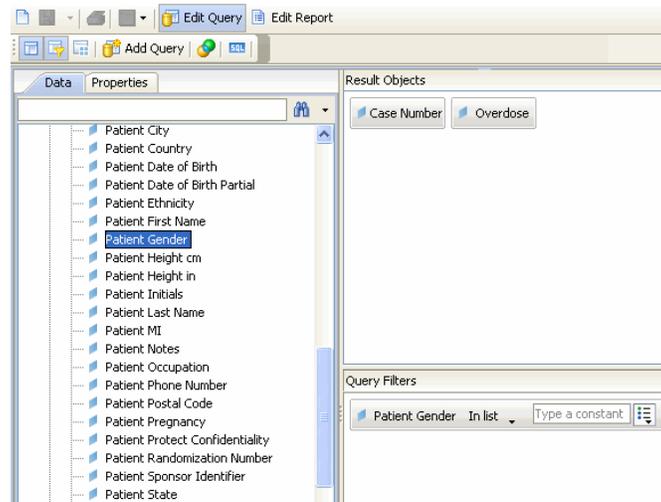
1. Click **Edit Query** to view the Data tab (objects) and the Result Objects panel.
2. Expand **Report Writer** in the Data tab.



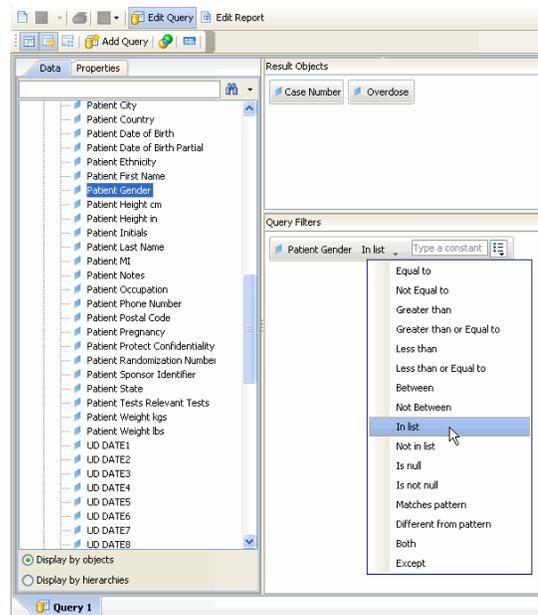
3. Drag and drop the data fields from the Data tab into the **Result Objects** panel.



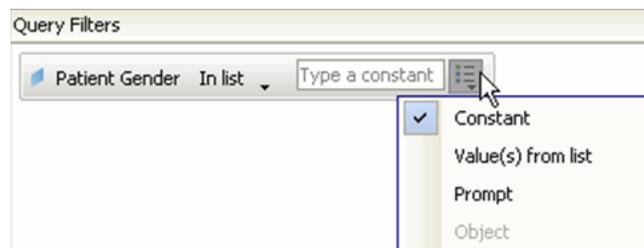
4. Drag and drop the filter criterion from the Data tab into the Query Filters panel.



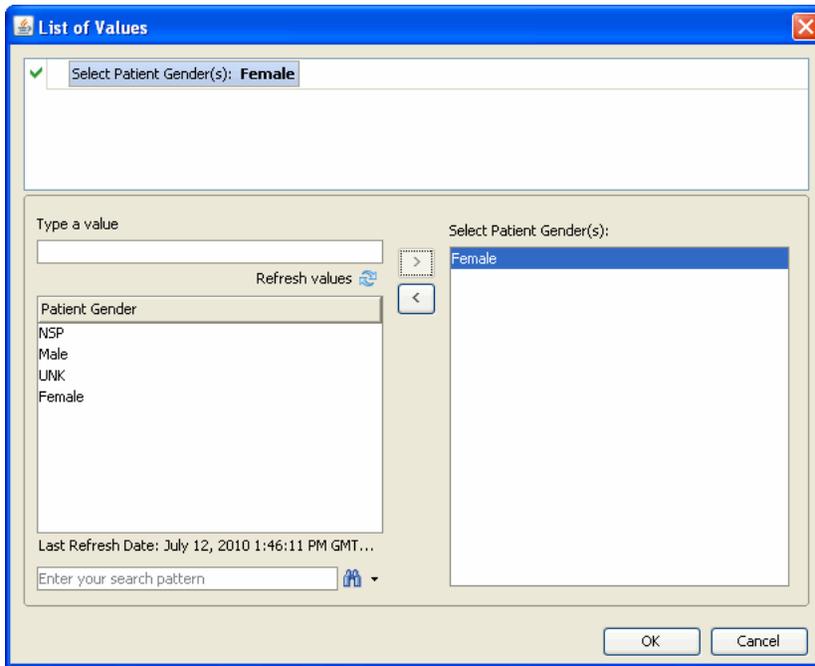
5. Select the **operator type** from the drop-down list. For example, if you select **In list** as the operator, the filter is limited to any one or all of the values defined in the list.



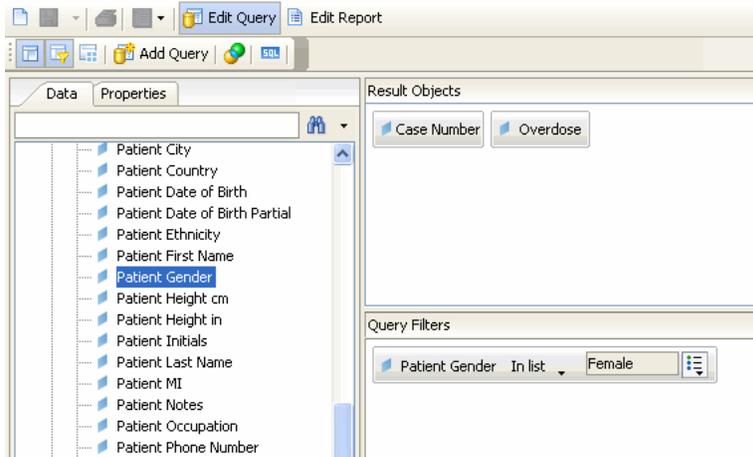
6. Click the icon next to the text field to select the values associated with the selected operator.



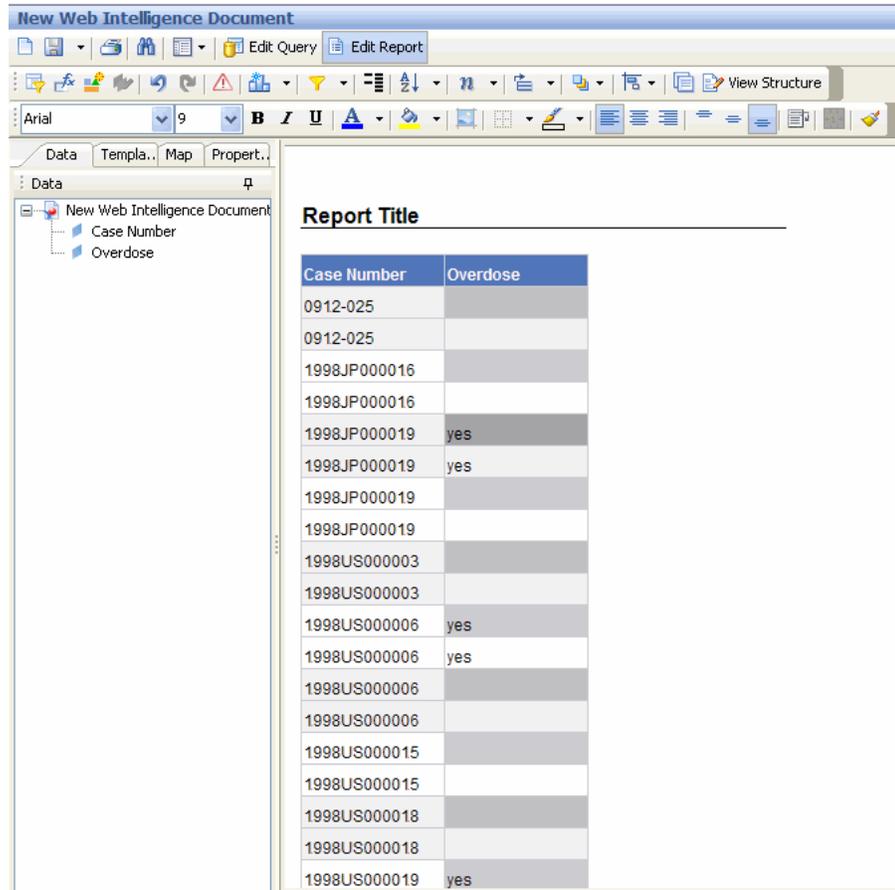
- Define the value by selecting the term/word to be used as a filtering criterion.



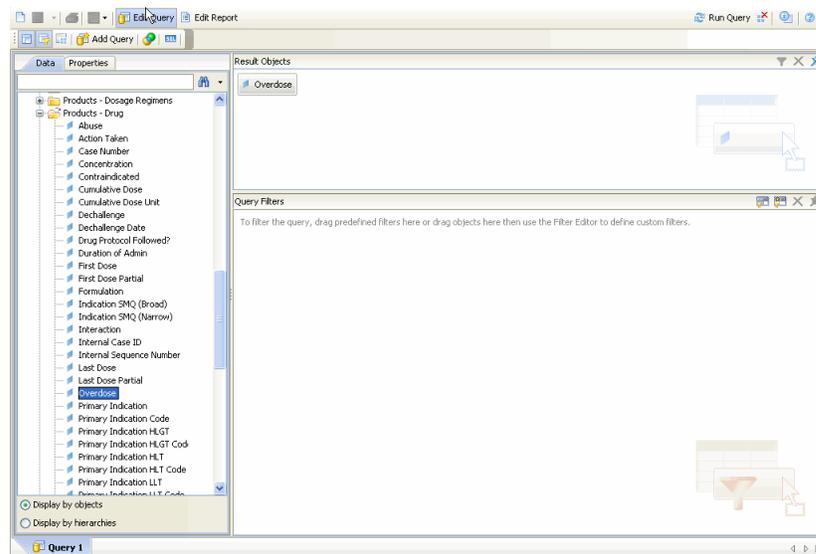
- Click **OK** to confirm the action. The **Query Filters** panel refreshes automatically to display the complete filtering criterion.



- Click **Run Query** to execute the query. The example in the following illustration shows those cases that have been filtered and limited to female patients. For each female patient, the report includes the case number and whether the patient overdosed.



To modify or remove a filter, click the **Edit Query** tab. Drag and drop the data fields (as the filtering criterion) from the **Result Objects** panel into the **Data** tab.

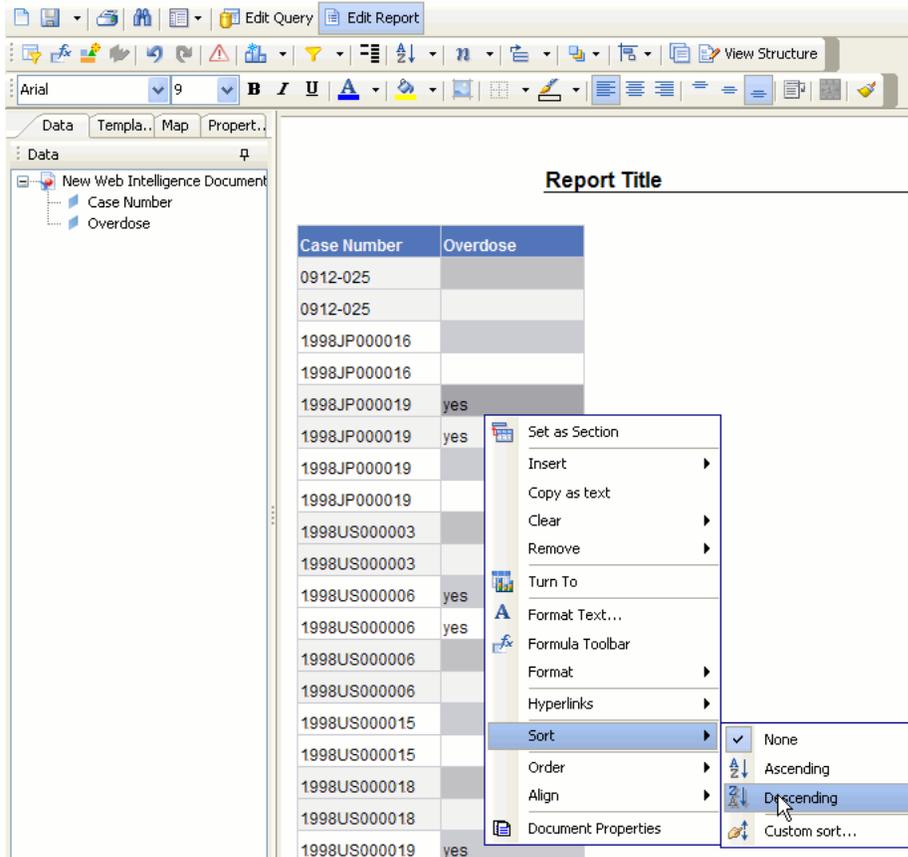


Repeat the procedure to add new data fields and filtering criterion, and then execute the query.

Sorting Data

To change the sort order in your report:

1. View your report.
2. Select the column values that you want to sort for the report output. The selected column is highlighted.
3. Right-click in a data cell of the selected column.



4. Click **Sort** and then select the required sorting option. For example, you can select an ascending or descending sort order. The system refreshes the report and displays the sorted output.

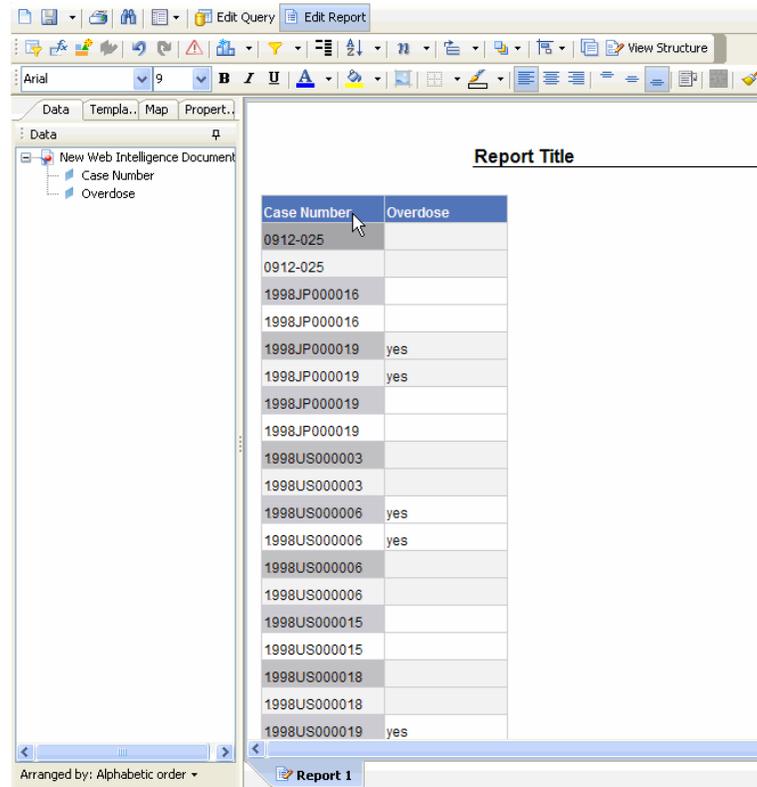
Summarizing Data

Use the predefined summary options to calculate the total, count, maximum, minimum, average, and percentage of the values in columns of your reports.

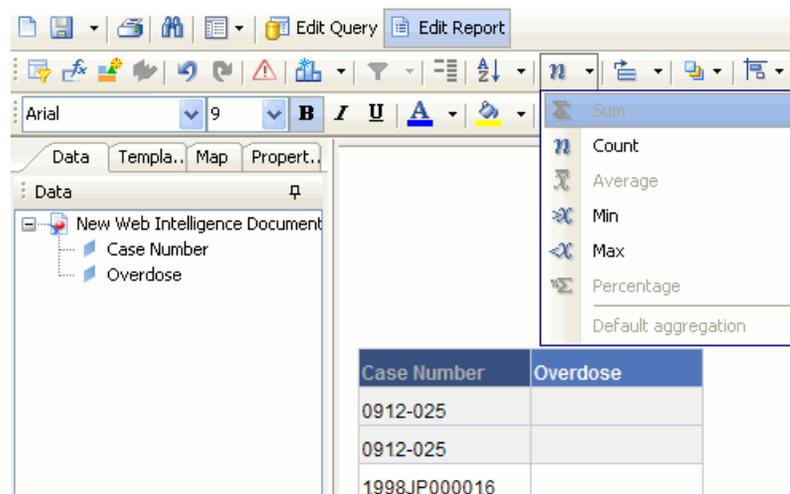
The summary options available to you depend on the type of data in the column you want to summarize. For example, you can only use the Count option if your column contains text data whereas you can use total, maximum, minimum, or average options if the column contains numeric data.

To summarize data:

1. In the **Report Title** section, click the column that you want to summarize. The selected column is highlighted.



2. Click the **Insert Sum** icon in the toolbar, and select the required summary option from the list. For example, count, average, min, max, or percentage. The options available depend on the type of values in the column you selected.



The report output displays the column summary at the bottom of the report.

To remove summary information, right-click the cell that has the summary information, select **Remove**, and then select the appropriate option from the menu.

Formatting Data in Reports

You can use predefined formats to change the appearance of text, numbers, currency, dates, and times in your report. Formatting does not change the underlying data.

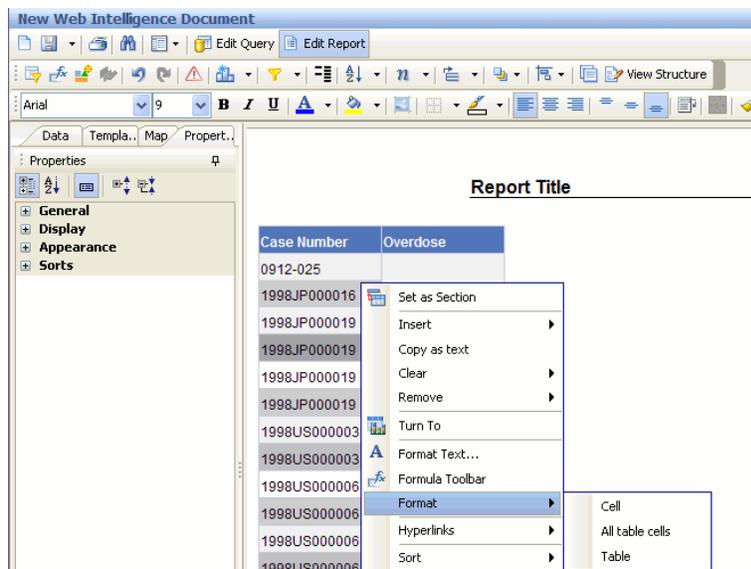
Table 9-1 describes the available formatting options.

Table 9-1 Formatting Options for Data in Reports

| Format | Description |
|---------------|---|
| Default | The default format is the format of the report item before any formatting is applied. Use default to remove formatting. |
| Number | Use the number format to change the number of decimal places, to specify whether to use a thousands separator, to choose different symbols to represent negative numbers, and to scale large numbers. |
| Currency | You can choose from many world currencies. Use either the currency symbol or the international code. For example, the currency symbol for the euro is € and the international code is EUR. In addition, you can change the number of decimal places, specify whether to use a thousands separator, choose different symbols to represent negative numbers, and to scale large numbers. |
| Date and Time | You can choose from a list of date and time formats, including the 12 or 24 hour clock. |
| Boolean | You can choose from the true/false values. |

To change the format of the data in a report:

1. Display the report output.
2. Click within the header of the column that you want to format. The selected column is highlighted.
3. Right-click the highlighted column, select **Format** from the menu, and then select the appropriate option from the list.



4. Set the data format properties from the **Properties** tab, as appropriate.
5. Click **OK**. The report output is refreshed and displays the formatted data.

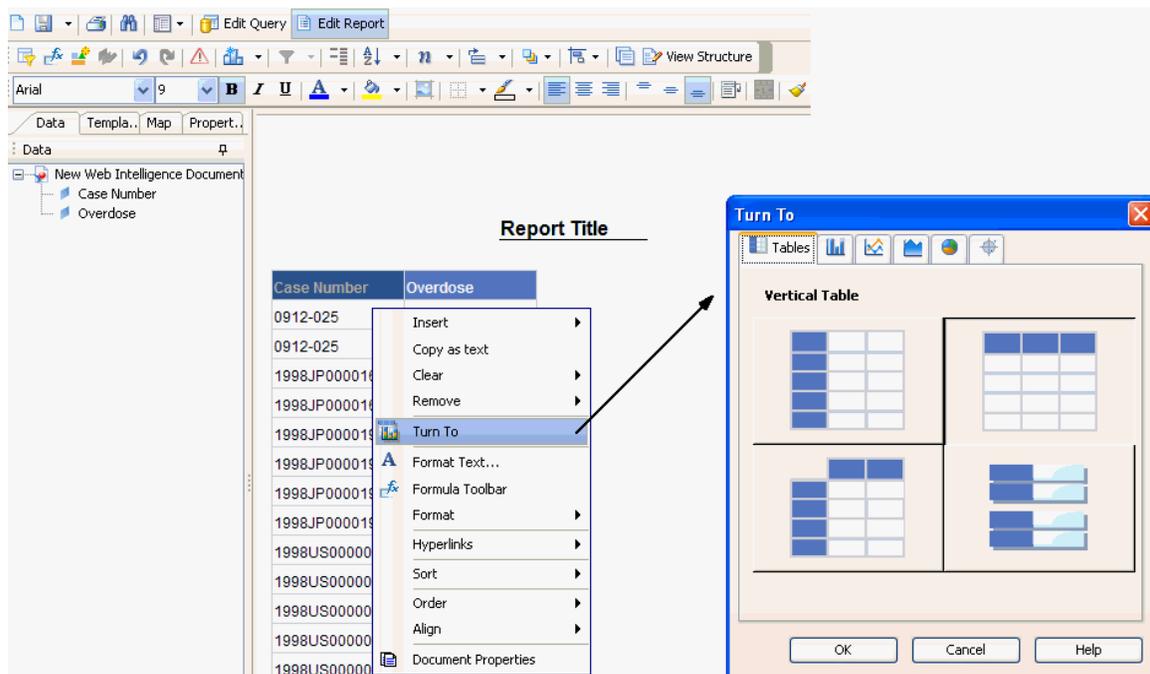
Turning the Report Layout into a Table or Chart

To access the *report* layout options for BusinessObjects, use the **Turn To** context menu option. The layout options let you change the appearance of your reports without changing the underlying data. For example, you can convert your report into a *chart* or group the report into crosstab *column* headers.

This section describe the basic layout operations. For detailed information, see the documentation supplied with the your BusinessObjects products.

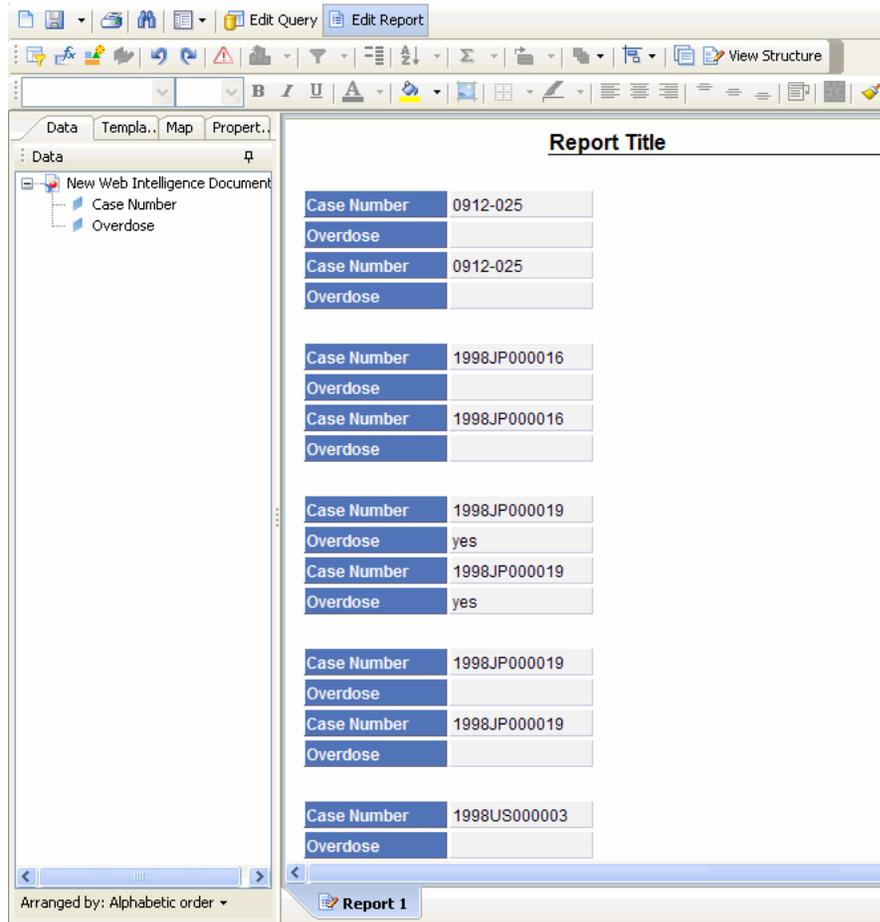
To turn the report layout into a table or chart:

1. Display the report output.
2. Right-click the report and select **Turn To** from the context menu. The Turn To dialog box opens.



3. Select the appropriate tab and the appropriate option depending on the type of report format you want. You can select an option from one of the following tabs:
 - Tables
 - Bar Chart
 - Line Chart
 - Area Chart
 - Pie Chart
 - Radar Chart

4. Click **OK**. The report output refreshes and displays in the selected layout. For example:



Saving and Accessing Reports

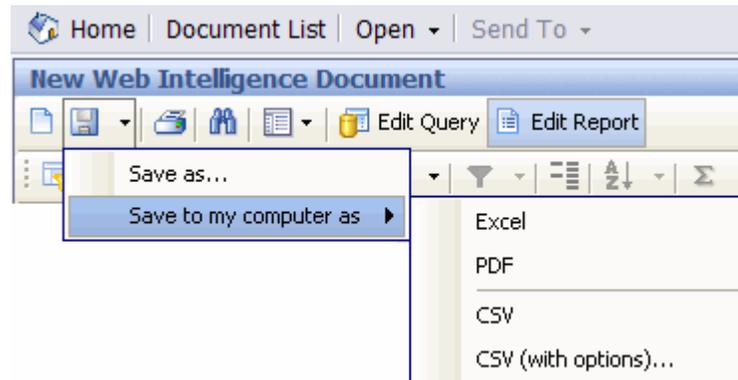
Use the **Save** menu option to save the reports you create by using Report Writer. You can save your reports in either Personal or Public folders.

The reports you save are not a snapshot of the data displayed in the report output. Instead, the system stores the specific set of instructions (data mart fields you select) for extracting data from the data mart when you run the report. For example, if you run a report that you saved a week ago, the data in the report reflects any changes in the data mart as a result of the ETL process.

Saving Reports

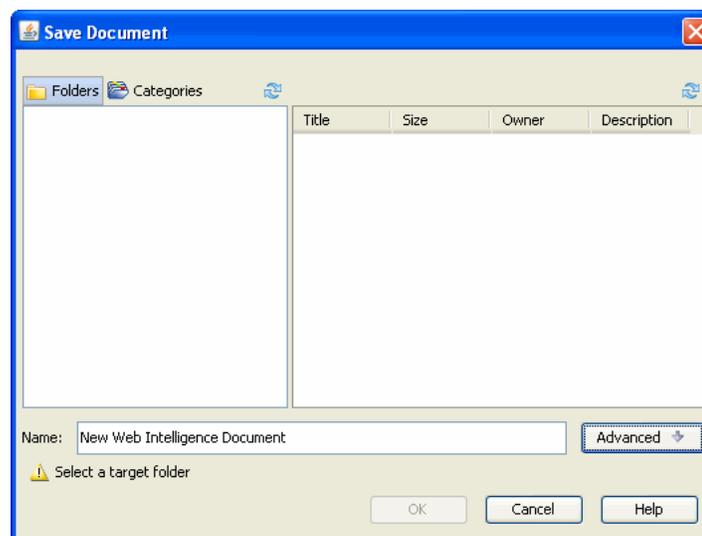
To save a report:

1. Click the **Save** icon in the toolbar. The options for saving the report appear.



Tip: You can save the report in Microsoft Excel, Adobe PDF, CSV, and CSV (with options) formats.

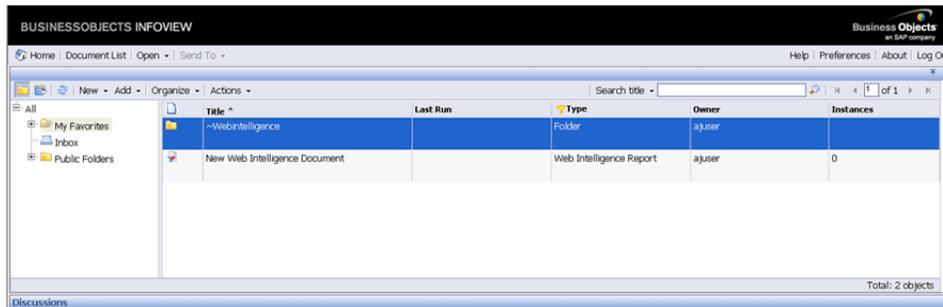
2. Click **Save as** to save the report on your system. The Save Document dialog box opens.



3. Enter a name for the report in the **Name** field.
4. Select a to specify the location where the report needs to be saved:
 - Select the **Public Folders, Report Writer** folder if you want all users to be able access the report.
 - Select the **My Folders, Favorites** folder if you want to save the report as a personal document.
5. Click **OK** to save the report in the location you specified.

Accessing the Report Writer Library

To access the reports you save in the My Favorites folder, navigate to **Case Series Reports, Report Writer, New**, BusinessObjects InfoView home page, and then select **My Favorites**. You can access the saved reports from the following page:



Note: The **Case Series Reports, Report Writer, Library** menu is no longer available in Argus Insight.

Right-click a report and select **Modify** to edit a saved report. The report opens in the BusinessObjects XI web intelligence interface. After you edit the report, you can save it by another name by using the **Save as** option in the **Save** menu.

Using SMQs in Report Writer

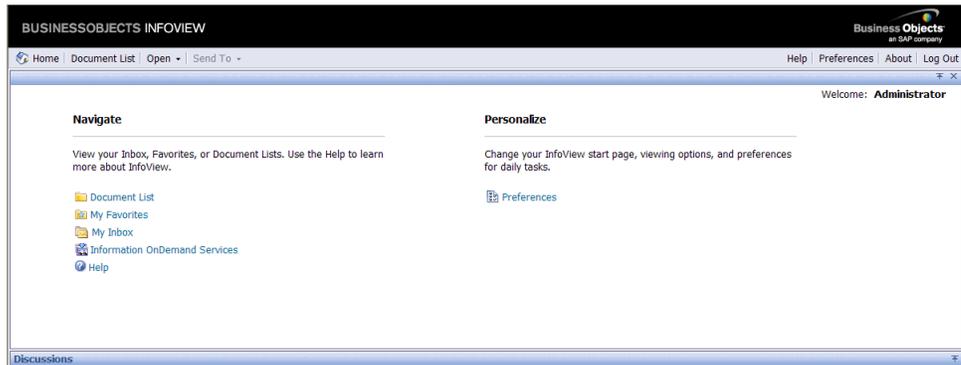
If you select a SMQ, the system displays all the cases based on that SMQ.

To use SMQs in Report Writer:

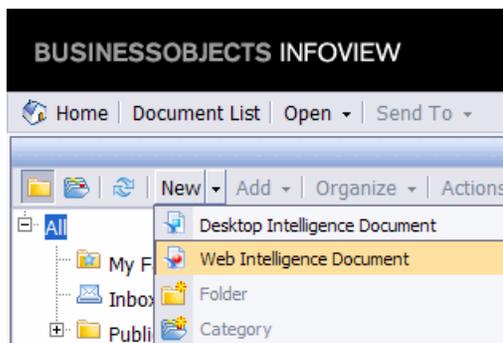
1. Navigate to **Case Series Reports, Report Writer**, and select **New**. The BusinessObjects InfoView logon window opens.

The screenshot shows the BusinessObjects InfoView logon window. The window title is 'Log On to InfoView'. Below the title, there is a prompt: 'Enter your user information and click Log On. (If you are unsure of your account information, contact your system administrator.)'. There are two input fields: 'User Name:' with the value 'administrator' and 'Password:'. A 'Log On' button is located below the input fields.

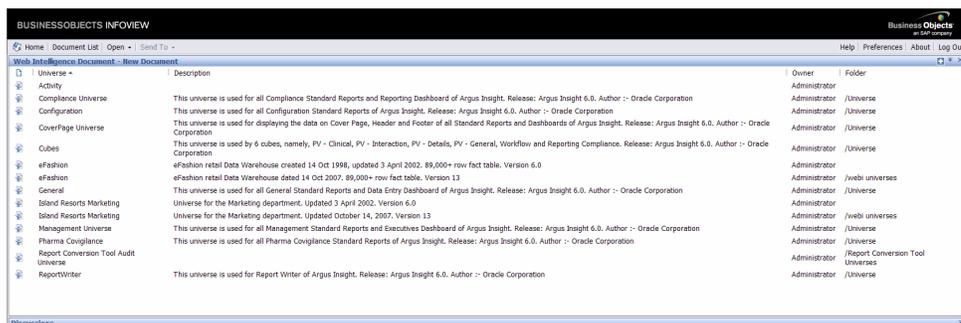
2. Enter your user name and password, and click **Log On**. The home page for BusinessObjects InfoView opens.



3. Click **Document List**.
4. Open the **New** menu and select **Web Intelligence Document**.

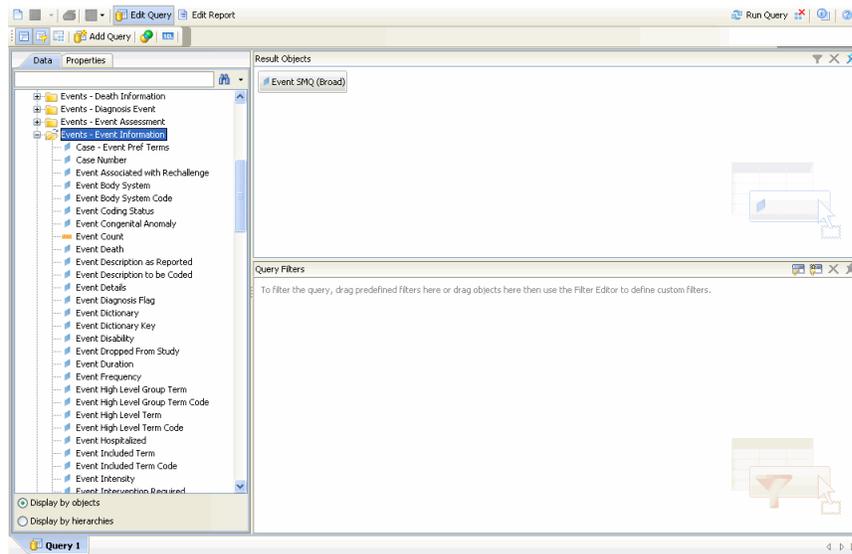


The following page opens:



5. Click **Report Writer**.
6. Click the **Data** tab.

7. Navigate to **Events - Event Information**, and drag and drop **Event SMQ (Broad)** into the Result Objects panel.



8. Click **Run Query**.
9. Click **Edit Query**.
10. Navigate to **Events - Event Information**, and drag and drop **Event SMQ (Narrow)** into the Result Objects panel.
11. Click **Run Query**.
12. Navigate to **Events - Event Information**, and drag and drop **Case Number** into the Result Objects panel.
13. Click **Run Query** to display all the case numbers that correspond to the selected SMQ.

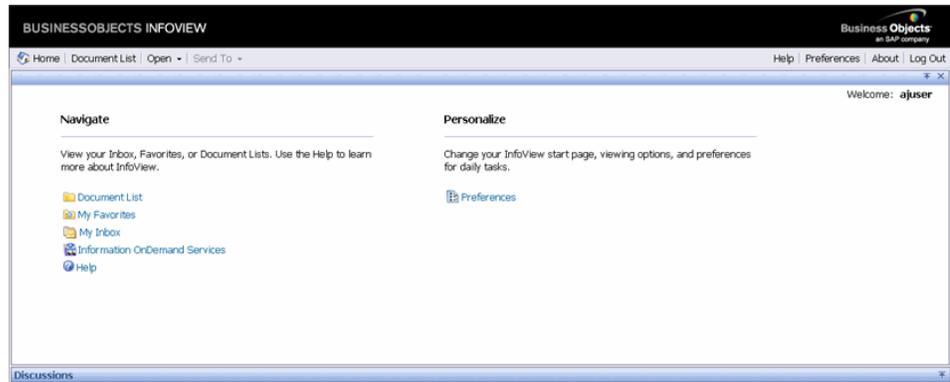
Creating AdHoc Reports

This section describes how to use BusinessObjects InfoView to save the customized reports under the AdHoc Reports menu. *AdHoc Reports* is a repository where all the customized reports are saved. Reports can be shared among different users.

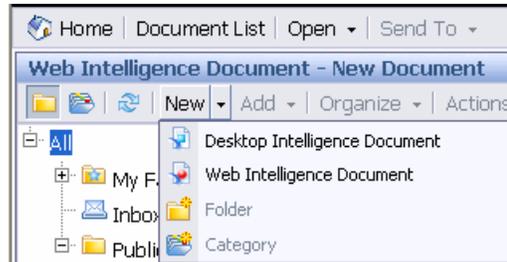
To save adhoc reports:

1. Log in to Argus Insight.
2. Navigate to **Case Series Reports, Report Writer**, and select **New**.

3. Log on to the home page for BusinessObjects InfoView.



4. Click **Document List**.
5. Open the **New** menu and select the type of document you want to create.



6. Copy or save the selected item to the folder structure corresponding to the Argus Insight menu.

You must use BusinessObjects InfoView to access your saved ad hoc reports that you create using BusinessObjects InfoView. You cannot access these reports from Argus Insight.

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](#)
- [Reports](#)

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)** — If you want 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.
- **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.

The following items are recommended to ensure that the values being copied from the source enterprise are appropriate for the newly created enterprise:

- Power Queries used within any configuration item
- Reports scheduling data

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 10–1 describes the modules in Argus Insight as per their data segregation status in Clinical Research Organization mode (CRO mode) and hosting installations.

Table 10–1 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. |
| Standard Reports | Yes | Makes all standard reports available to all enterprises. An enterprise can grant access to reports by navigating to Tools, Security , and selecting the Access Rights tab in Groups Administration. An executed report retrieves cases from the logged-in enterprise only. |
| Custom Reports | Yes | Displays all the custom reports that are set up and created by a specific enterprise. |
| Report Writer | Yes | Displays only those reports that are created by the logged-in user (irrespective of the enterprise). An executed report retrieves cases from 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. |

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 various 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 automatically 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.



The screenshot shows a portlet titled "Application Access". It contains two dropdown menus: "Enterprise" and "Application". The "Application" dropdown is currently set to "Argus Insight". To the right of the dropdowns is a button labeled "Open".

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 10-1](#), 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 10-1 Global Enterprise Management Portlet

The screenshot shows the Global Enterprise Management Portlet interface. On the left, a tree view under 'Enterprises' shows 'PF1', 'Amgen', and 'Novartis'. The main area is divided into two panes. The top pane, titled 'PF1', shows the 'Enterprise Name' as 'Pfizer' and 'Enterprise Short Name' as 'PF1'. It includes a 'Contact Information' section with fields for Title (Dr), First Name (B), Middle Name, Last Name (Williams), Address, City, State/Province, Postal Code, Country, Department (228-987-0213), Phone, FAX, Email Address, and Notes. Below this is the 'Associate Users' section, which includes a 'Select Users From' dropdown set to 'Baseline'. It features two lists: 'Available Users to Copy' (atsushi, balraj, balrajv, bkannusa, charlie, charlej) and 'Users associated to this Enterprise' (de reporting 1, de reporting 2, fuji, fukao, hiroki). Navigation buttons include 'Add >', '< Remove', 'Add All >>', and '<< 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.

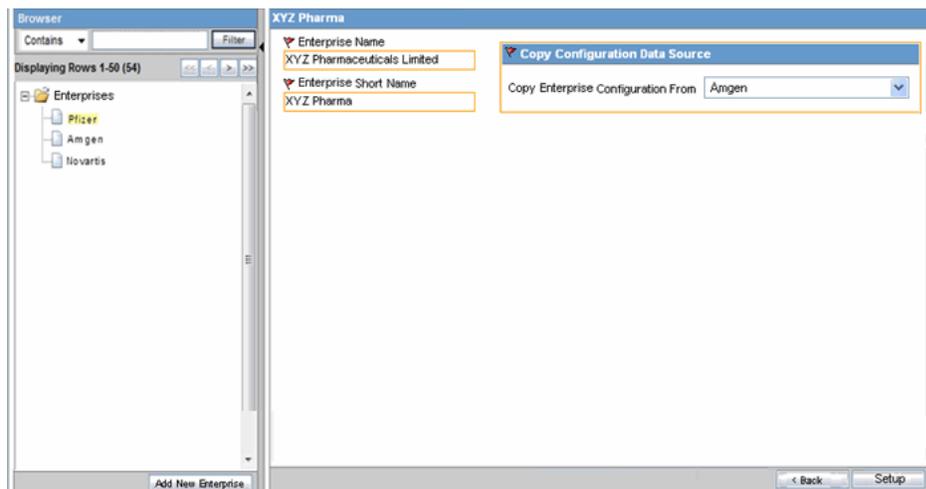
Copying an Enterprise

To copy an enterprise to Argus Insight:

1. Open the Global Enterprise Management portlet.
2. Click **Copy Enterprise to Insight**.

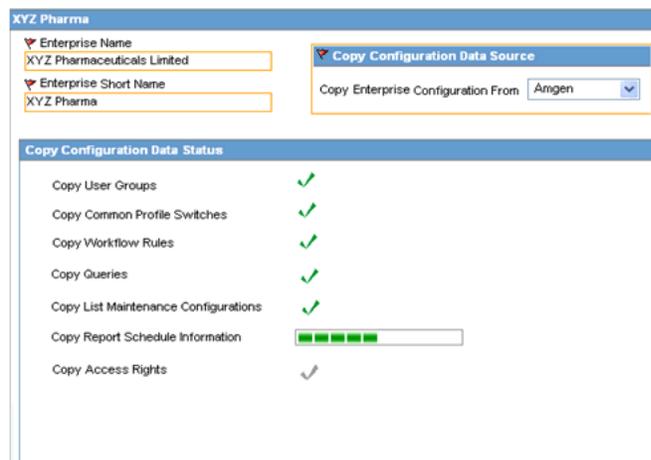
Note: The **Copy Enterprise to Insight** button is disabled for the default enterprise.

The system updates the right pane and displays information about the enterprise you want to copy. The details in the Enterprise Name and Enterprise Short Name fields are read-only.



3. Use the **Copy Enterprise Configuration From** field to select the enterprise that you want to copy.
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 *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 *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 opens.
2. Click the **List Maintenance** tab.

3. Select **Profile Switches** from the List Maintenance Items section. The system updates the Attributes section 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.

Reports

The section describes how the following reports function in a multi-tenant installation:

- [Standard Reports](#)
- [Custom Reports](#)
- [Report Writer Reports](#)
- [Reports in the BusinessObjects Environment](#)

Standard Reports

The Standard Reports library displays all the reports configured in Argus Insight.

Argus Insight administrators can assign enterprise-specific access rights to standard reports. To enable or disable report access, administrators use the options on the Access Rights tab when creating or modifying user groups.

Optionally, reports can include the Enterprise Short Name, along with the User ID, in the page footer of the report output for both PDF and Excel formats.

To include the Enterprise Short Name in the report page footer, you must select the **Display Enterprise Short Name in Application Header** check box in Global Enterprise Management for the logged-in enterprise.

Note, however, that regardless of the check box setting, the Enterprise Short Name does not print in the page footer for the following reports:

- CIOMS Report
- CIOMS II Line Listing
- US FDA MedWatch 3500A

Custom Reports

You can make a custom report available across all enterprises or available only to a specific enterprise.

- To make a custom report available across all enterprises, add the report in the *Argus_Insight* folder in BusinessObjects. BusinessObject has category-specific folders, such as Compliance and Management, under the enterprise folder where you save custom reports. Any user can add custom reports into the *Argus_Insight/Category* folder.
- To make a custom report available only to a particular enterprise, add the report in the enterprise/category-specific folder at the root level in BusinessObject. With this setup, you cannot view the report if you log in with a different enterprise.

You can view the enterprise/category-specific custom reports created through BusinessObject InfoView along with the other available standard reports in their respective report category in the report library, based on the logged-in enterprise.

When you run a custom report, the report includes only the data that pertains to the logged-in enterprise.

Report Writer Reports

The enterprise is not available as an object when you create new reports in Report Writer.

The reports created through Report Writer can be saved in the user specific folder.

The reports include only the data that pertains to the logged-in enterprise.

Reports in the BusinessObjects Environment

You can log in to the BusinessObjects environment after specifying an enterprise and entering your user credentials. If you do not enter an enterprise when logging in, the system assigns you the default enterprise.

A set of standard reports is available in the *Argus_Insight* folder, which is common across all enterprises. You have write-access to this folder.

When you run a standard report, the report includes only the data that pertains to the logged-in enterprise.

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 automatically 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.

