Oracle® Argus Insight

Administrator's Guide

Release 7.0.2

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Oracle Argus Insight Administrator's Guide, Release 7.0.2

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Preface

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

This preface includes the following topics:

Audience

This document is intended for all Argus Insight administrators.

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.

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

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

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

- *Oracle Argus Insight CMN Profile Enterprise Table Guide* (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.
italic	Italic type indicates book titles, emphasis, or placeholder variables for which you supply particular values.
`monospace`	Monospace type indicates commands within a paragraph, URLs, code in examples, text that appears on the screen, or text that you enter.

1 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

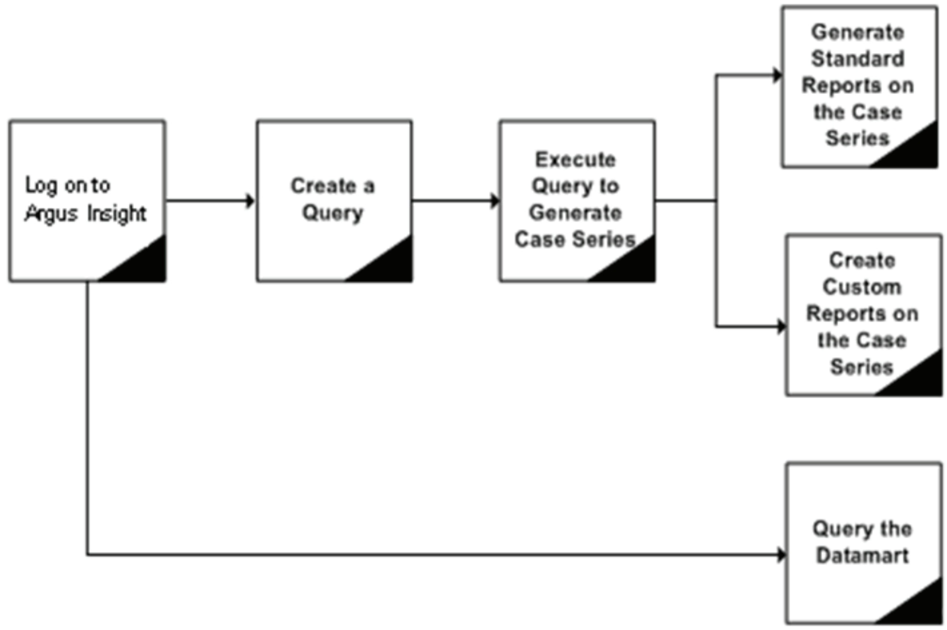


Table 1–1 describes the tasks shown in the flowchart.

Table 1–1 Tasks in the Process Flow

Task	Description
Log in to Argus Insight	Log in to the Argus Insight application.
Create a *Query*	Depending on the complexity of the query, use these Argus Insight components to create a query: ▪ Query by Example (QBE) — To create simple queries based on the fields in the Argus case *form* ▪ 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 7.0.2.

Compatibility of Argus Insight with Argus Safety

Argus Insight 7.0.2 is compatible with Argus Safety 7.0.2.

Upgrade Paths to Argus Insight 7.0.2

You can upgrade directly to Argus Insight 7.0.2 from the following versions of Argus Insight:

- Argus Insight 7.0.1 (single-tenant to single-tenant installation)
- Argus Insight 7.0.1(multi-tenant to multi-tenant installation)

The general steps for upgrading to Argus Insight 7.0.2 are as follows:

- Upgrade your current Argus Safety application to the Argus Safety 7.0.2 environment.
- Install the Argus Insight 7.0.2 application.
- Create the enterprise in Argus Insight.
- Run the Copy Configuration utility for that enterprise.
- Run the Initial ETL.

For information about upgrading your database and your Cognos Server to Argus Insight 7.0.2, see the *Oracle Argus Insight Installation Guide*.

Copy Configuration Utility

Use the Copy Configuration utility to import all the configuration data from the following Argus Insight versions and then export the data to Argus Insight 7.0.2:

- Argus Insight 7.0.1 (single-tenant to single-tenant installation).
- Argus Insight 7.0.1 (multi-tenant to multi-tenant installation). In this case, the utility copies all the enterprise data from one multi-tenant enterprise to another multi-tenant enterprise in Argus Insight, including the enterprises that are marked as *Inactive.*

The Copy Configuration utility:

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

2 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. Cognos uses the Power Reports namespace.
- 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.

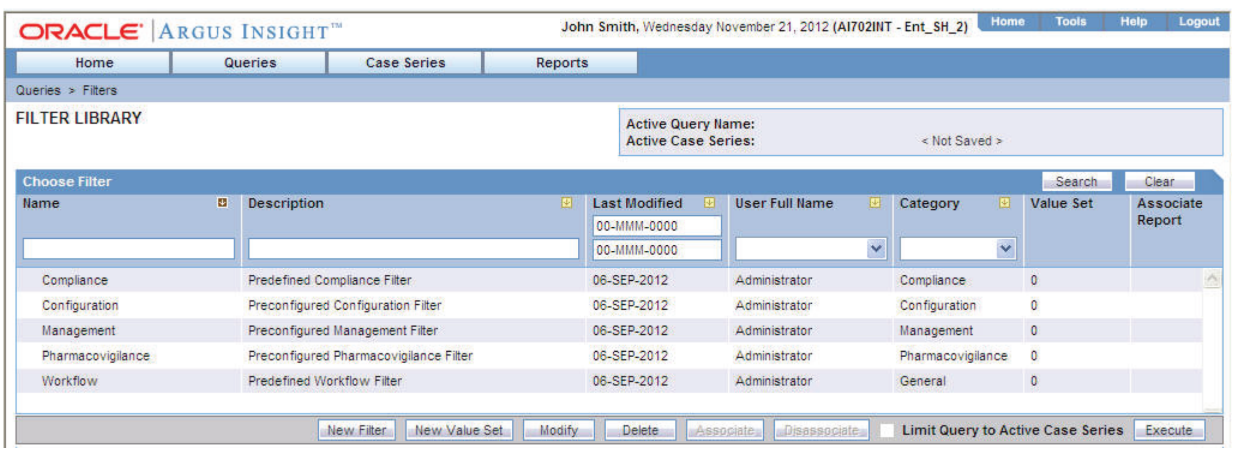
   If you do not know the URL, contact your system administrator who is responsible for configuring the URL.

   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



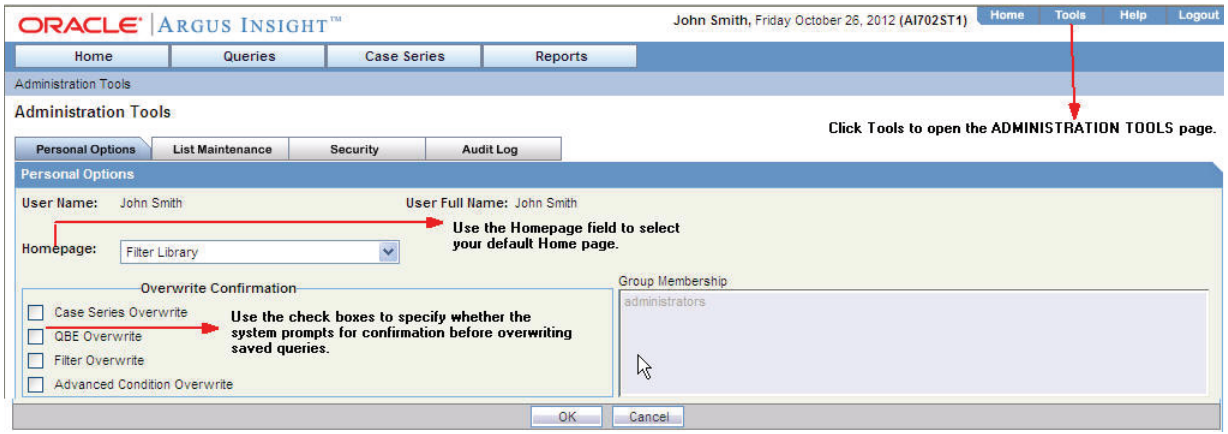
Setting Your Personal Options

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

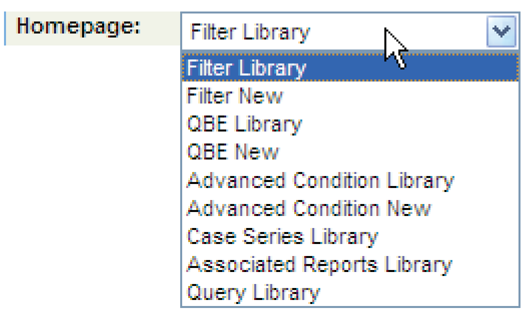


Changing the Default Home Page

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.



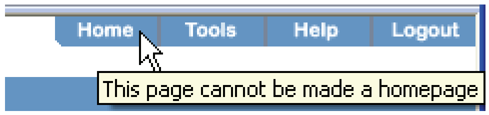
3. Click **OK.** The system changes your default Home page to the selected page, and opens a dialog box confirming that your options have been updated.
4. Click **OK** to close the dialog box and return to the Personal Options tab.

   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.



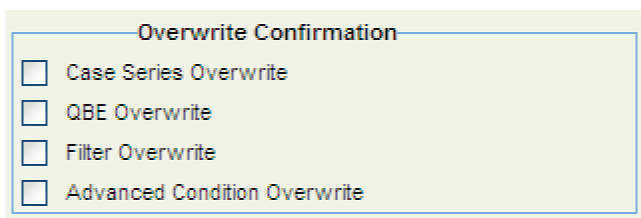
Changing Your Preferences for Overwrite Confirmation

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.

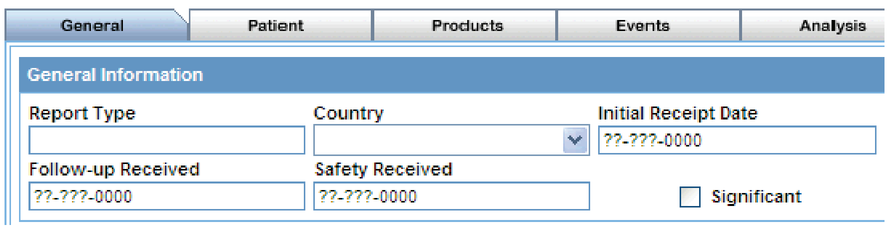
Entering Today's Date

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



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.

3

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

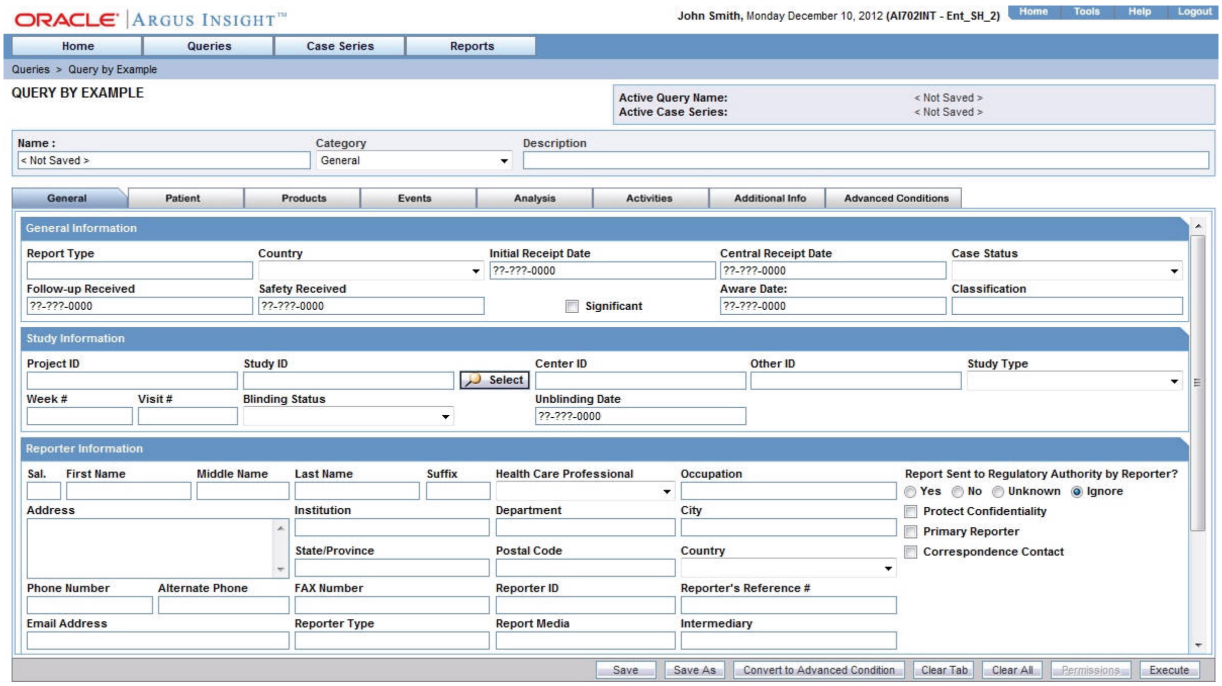
In addition to the QBE tool, Argus Insight provides the following query tools:

- 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:

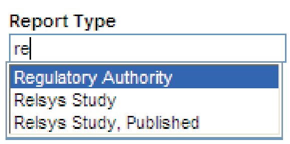
Tab Name	Field Name	Value
General	Country of Incidence	United States
Products	Product Name	Algoheal Injection
Events	Event Description to be Coded	Injection site rash
	Seriousness Criteria	Hospitalized

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:

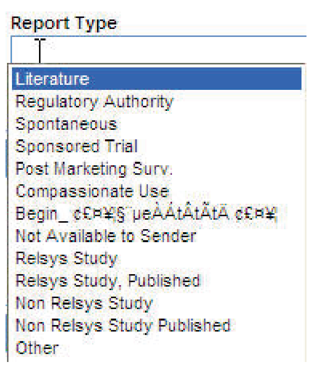


Table 3–1 lists the input fields in the QUERY BY EXAMPLE page that support the type-ahead feature.

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

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

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

Starting a New QBE

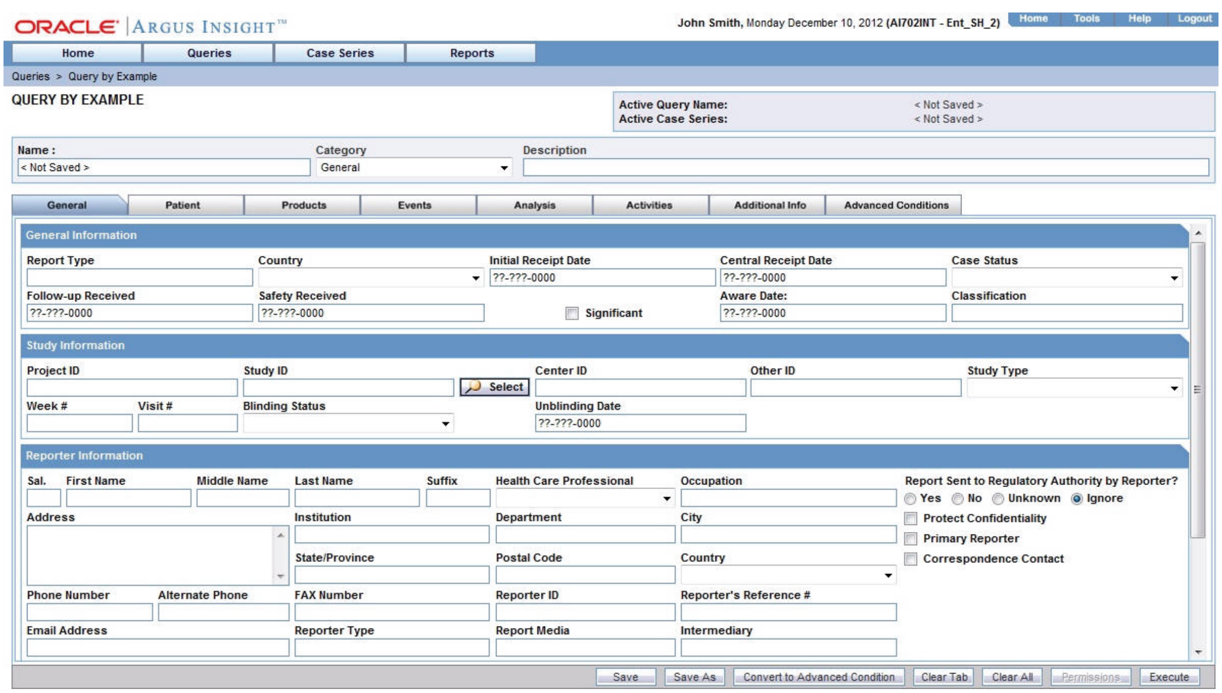
This section describes the tasks for creating a new QBE:

- Entering Your Search Criteria and Executing the QBE
- Reviewing the Results of Your QBE
- Reviewing and Modifying the Criteria for an Executed QBE
- Saving the QBE

Entering Your Search Criteria and Executing the QBE

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

1. Navigate to **Queries, Query by Example,** and select **New.** The system displays the QUERY BY EXAMPLE page with the **General** tab in focus.



2. 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 field labels are displayed as per the field labels configured in Argus Safety.

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

- General Tab
- Patient Tab
- Products Tab
- Events Tab
- Analysis Tab
- Activities Tab
- Additional Info Tab

Tip: When you are entering criteria for your query:

- 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 3-6.

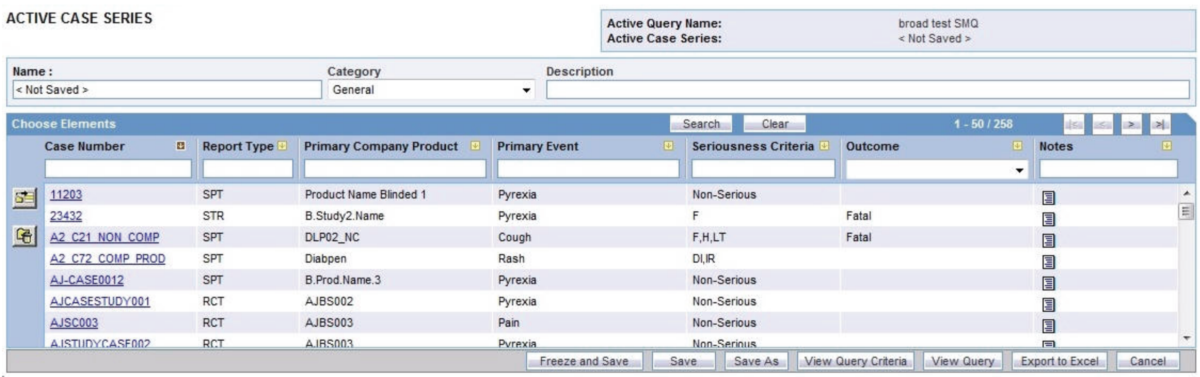
– If the case series is appropriate, you may want to save your QBE. For more information, see "Saving the QBE" on page 3-7.

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

  `No Cases found!`

  You probably want to modify your query and then execute the QBE again. For more information, see "Reviewing and Modifying the Criteria for an Executed QBE" on page 3-6.

Figure 3–2 ACTIVE CASE SERIES Page

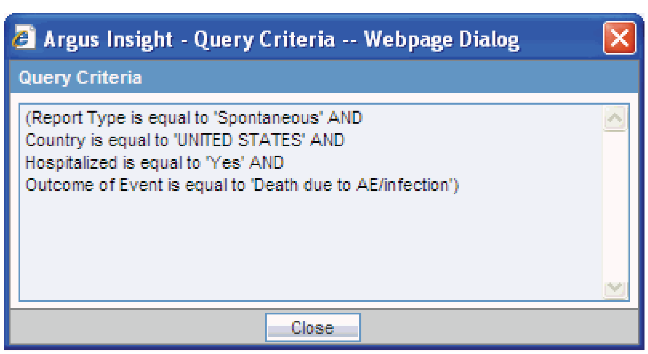


Reviewing and Modifying the Criteria for an Executed QBE

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 3-34 for details on active QBEs.

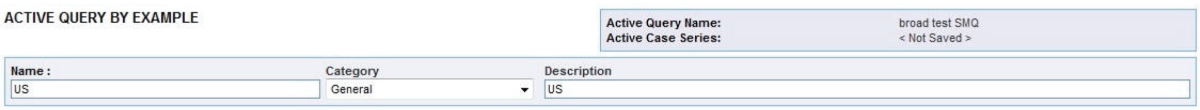
- To cancel the current QBE and return to the QUERY BY EXAMPLE page, click **Cancel.**

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

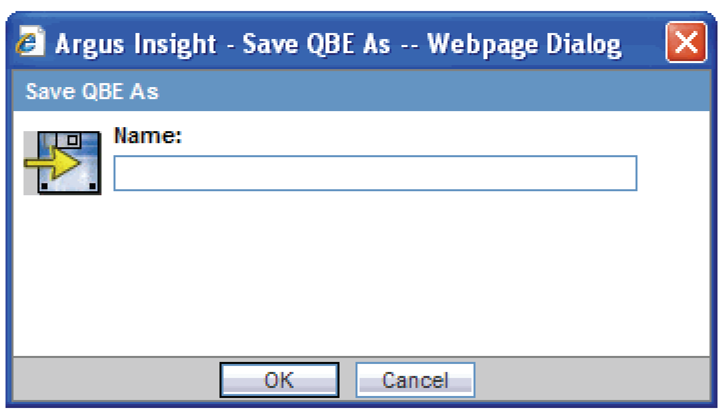
Saving the QBE

To save a QBE:

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



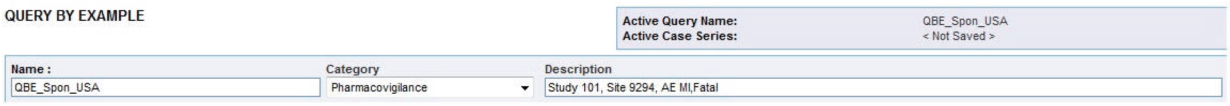
2. Use the **Category** field to assign a category to the QBE you want to save. The category indicates the reporting aspect to which your QBE pertains. For example, Case Processing, Compliance, Configuration, General, Management, or Pharmacovigilance. Specifying the category helps you when searching for relevant QBEs from a list of all the QBEs saved in the system.
3. Use the **Description** field to enter summary information about the QBE. For example, you can describe the type of cases the QBE retrieves.
4. Click **Save As.** The system opens the **Save QBE As** dialog box.



5. Type the name of the QBE.

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

6. Click **OK** to close the Save dialog box and refresh the page. Note that:
   - The page title changes to QUERY BY EXAMPLE.
   - The Active Query Name field in the upper-right corner of the page now displays the name you specified when saving the QBE.
   - The Category and Description fields display the information you entered before you saved the QBE.



Note: The QUERY BY EXAMPLE LIBRARY page lists all the QBEs saved to the system. See "Working with Saved QBEs" on page 3-36 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

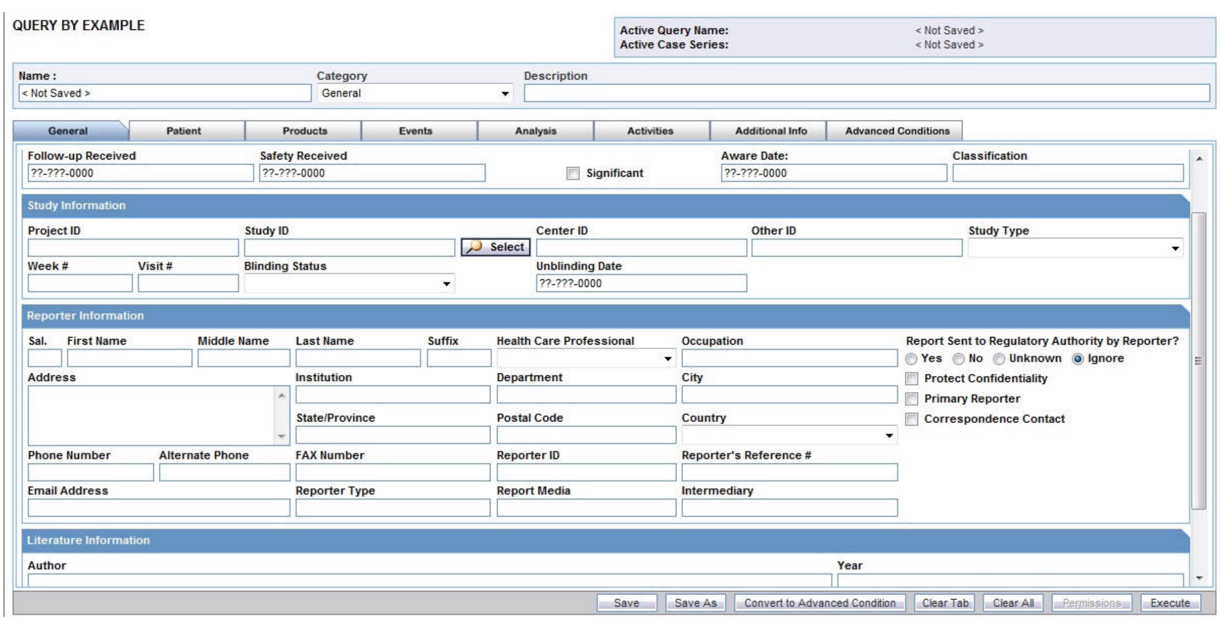


Table 3–2 describes the various fields in the **General** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

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 3-10 for details.
	Other ID	Enter any other ID that can be relevant to the study.
	Study Type	Select the study type to include in the query.
	Week #	Enter the week number of the study during which the adverse event occurred. The query will only look for such cases.
	Visit #	Enter the visit number of the study during which the adverse event occurred. The query will only look for such cases.
	Blinding Status	Select the study blinding status that the query looks for in cases.
	Unblinding Date	Enter the date on which the study was broken. The query will only look for cases with matching study broken date.
Reporter Information	Sal.	Enter the reporter's salutation that the query looks for in cases.
	First Name	Enter the reporter's first name to look for in cases.
	Middle Name	Enter the reporter's middle name to look for in cases.
	Last Name	Enter the reporter's last name to look for in cases.
	Suffix	Enter the reporter's suffix to look for in cases.
	Health Care Professional	Select an option from the list to include a query criterion based on whether the reporter is a health care professional.
	Occupation	Select the reporter's occupation that the query looks for in cases.
	Address	Enter the report address that the query looks for in cases.
	Institution	Enter the reporter's institution that the query looks for in cases.
	Department	Enter the reporter's department that the query looks for in cases.
	City	Enter the reporter's city that the query looks for in cases.
	State/Province	Enter the reporter's state that the query looks for in cases.
	Postal Code	Enter the reporter's postal code that the query looks for in cases.

Table 3–2 (Cont.) Fields in the General Tab on the QUERY BY EXAMPLE Page

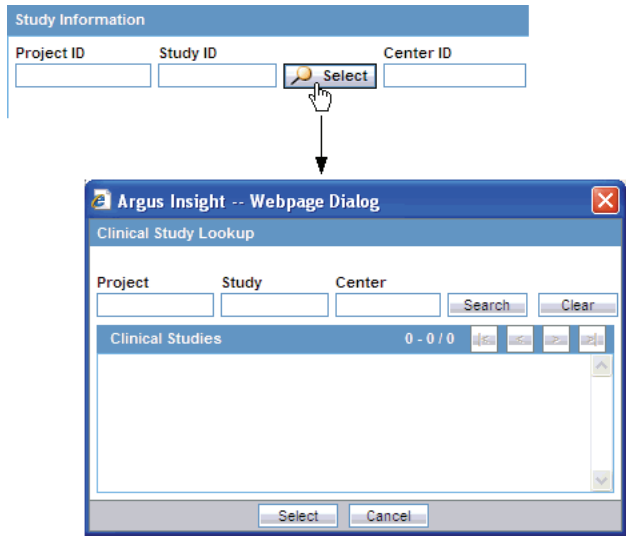
Section	Field or Check Box	Description
	Country	Enter the reporter's country ID that the query looks for in cases.
	Phone Number	Enter the reporter's phone number that the query looks for in cases.
	Alternate Phone	Enter the reporter's alternate phone number that the query looks for in cases.
	FAX Number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

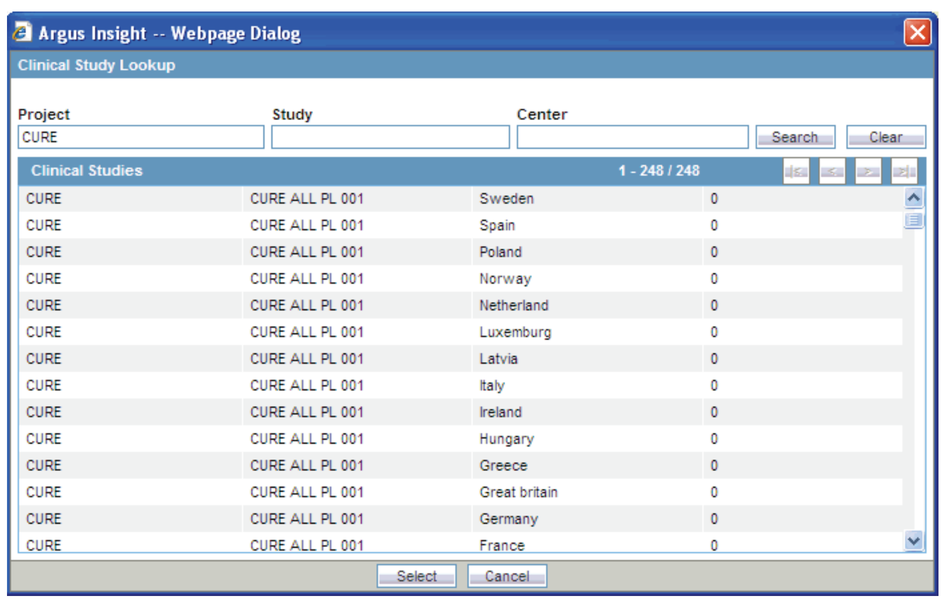
1. Click the **Select** button associated with the **Study ID** field. The system displays the Clinical Study Lookup dialog box.



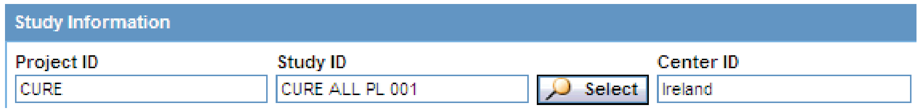
2. Enter the first few letters of the project name, study ID, or study center name in their respective text boxes.

   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.



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

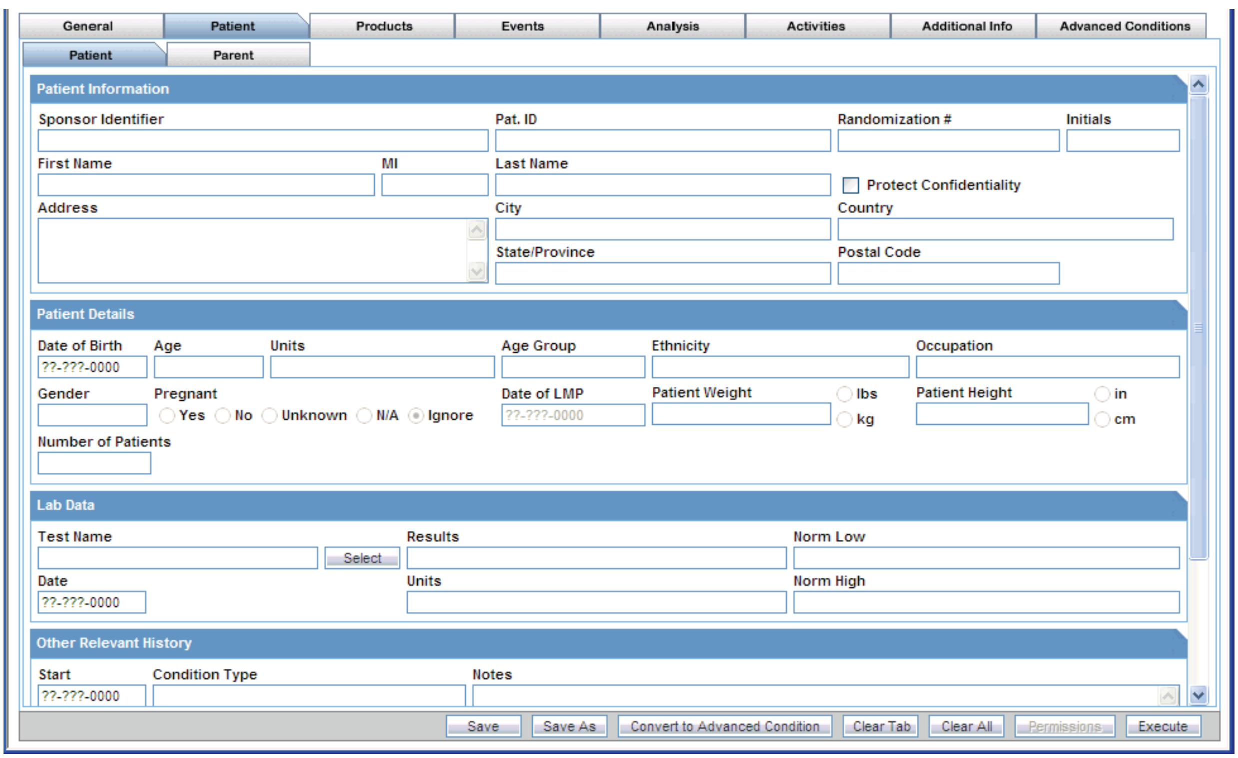


Table 3–3 describes the various fields in the **Patient** view of the **Patient** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

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 *study* 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 3-15 for more information.
	Results	Enter the lab data results that the query looks for in cases.
	Norm Low	Enter the lab data normal low value that the query looks for in cases.
	Date	Enter the lab test date that the query looks for in cases.
	Units	Enter the unit for the value you specified in the **Results** field in the Lab Data section.
	Norm High	Enter the lab data normal high value that the query looks for in cases.
Other Relevant History	Start	Enter the relevant history start date that the query looks for in cases.
	Condition Type	Select the relevant history condition type that the query looks for in cases.
	Notes	Enter the relevant history notes that the query looks for in cases.
	Stop Date	Enter the relevant history stop date that the query looks for in cases.
	Coded PT	Click the associated **Encode** button to select the relevant history condition by using the MedDRA Browser. The query will look for the encoded term. See "Using the MedDRA Browser" on page 3-17 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

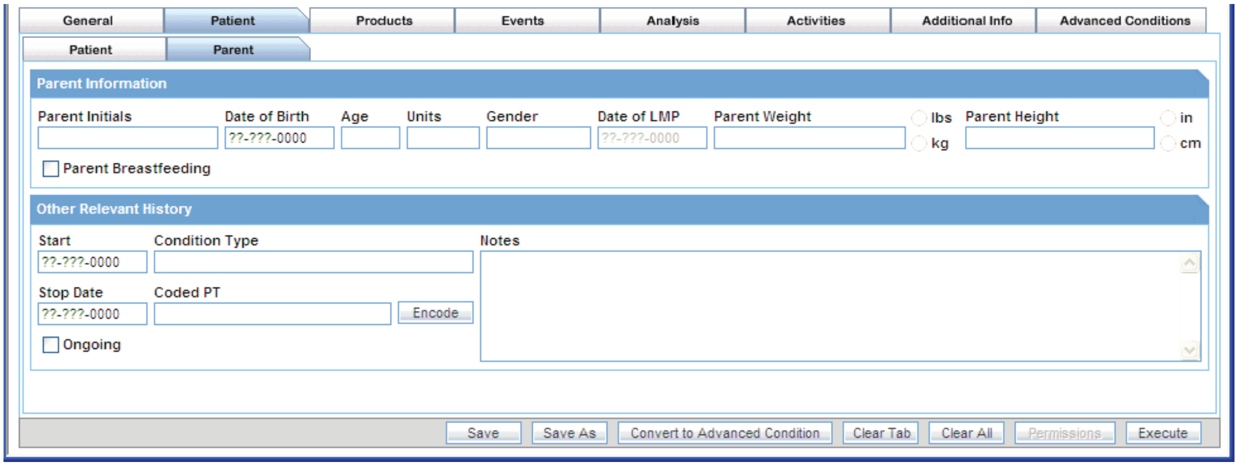


Table 3–4 describes the various fields in the **Parent** view of the **Patient** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

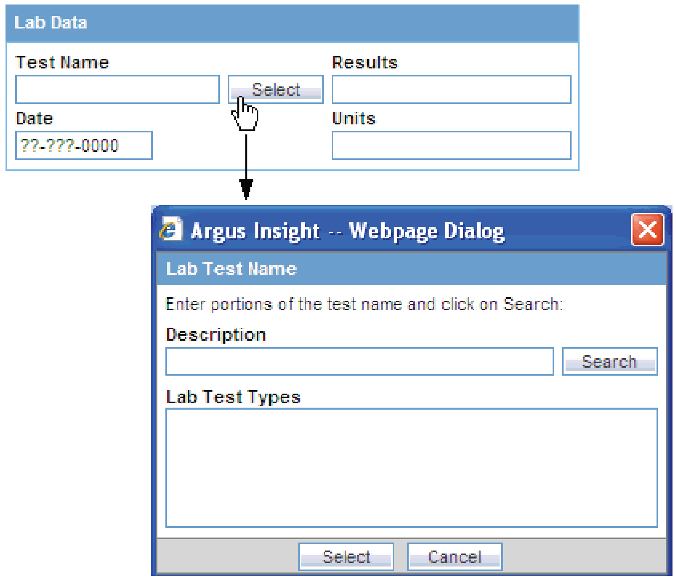
Table 3–4 Fields in the Parent View of the Patient Tab on the QUERY BY EXAMPLE Page

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.
	Parent Breastfeeding	Select this check box to retrieve cases where parent is breast feeding.
Other Relevant History	Start	Enter the relevant history start date that the query looks for in cases.
	Condition Type	Select the relevant history condition type that the query looks for in cases.
	Notes	Enter the relevant history notes that the query looks for in cases.
	Stop Date	Enter the relevant history stop date that the query looks for in cases.
	Coded PT	Click the associated **Encode** button to select the relevant history condition by using the MedDRA Browser. The query will look for the encoded term. See "Using the MedDRA Browser" on page 3-17 for more information.
	Ongoing	Select this check box to retrieve cases where the relevant history condition is continuing / ongoing.

Selecting a Lab Test

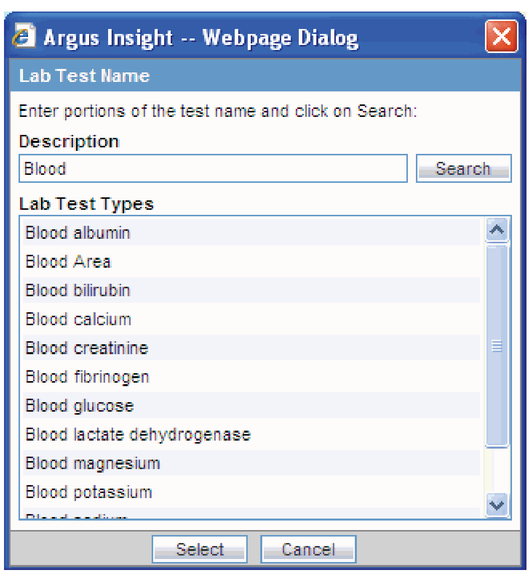
To select a lab test:

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.

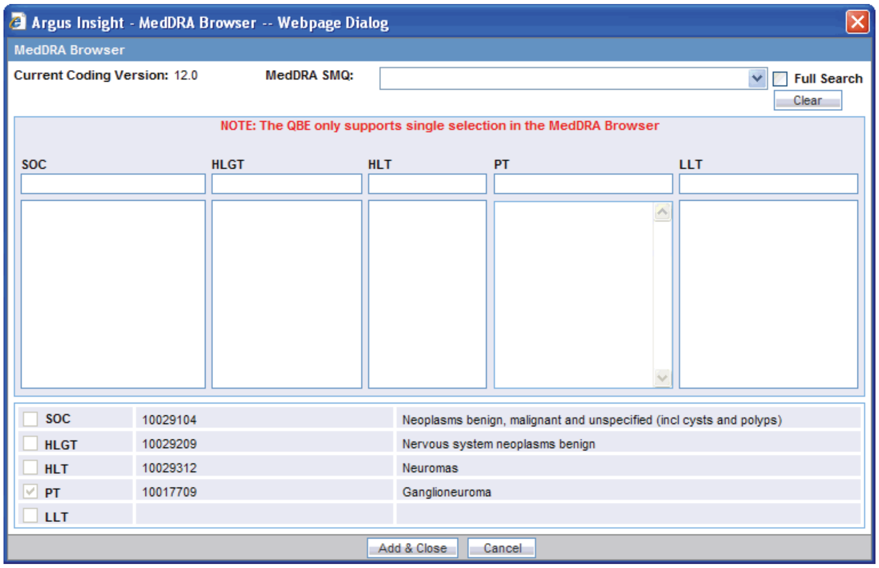


5. Select the required test name.
6. Click **Select.** The system inserts the selected test into the **Test Name** field.

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.

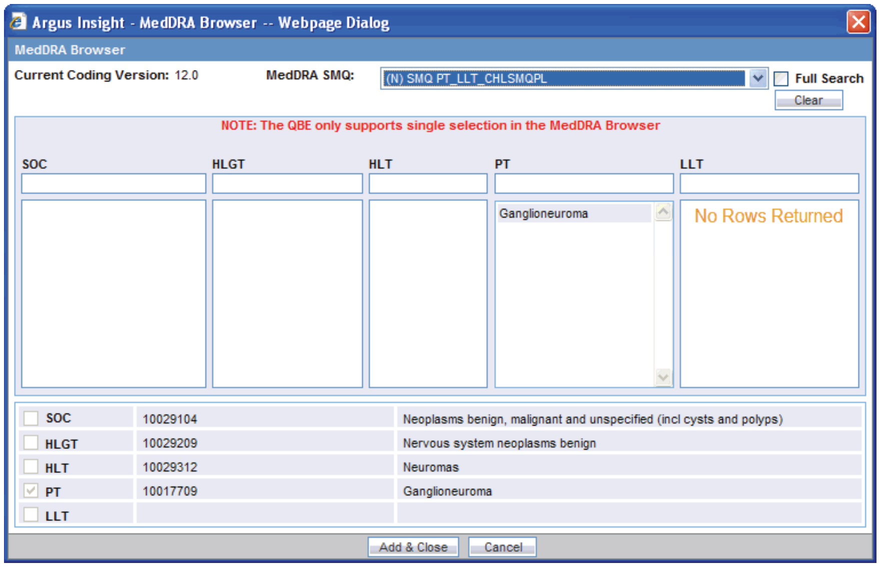


> **Note:** The output returned by the MedDRA Browser for the **Patient**, **Product** and **Analysis** tabs of QBE is the **Preferred Term (PT).** The **Events** tab of QBE provides output for multiple options. You can select and search the required term(s), based on the **Seriousness Criteria.**

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.

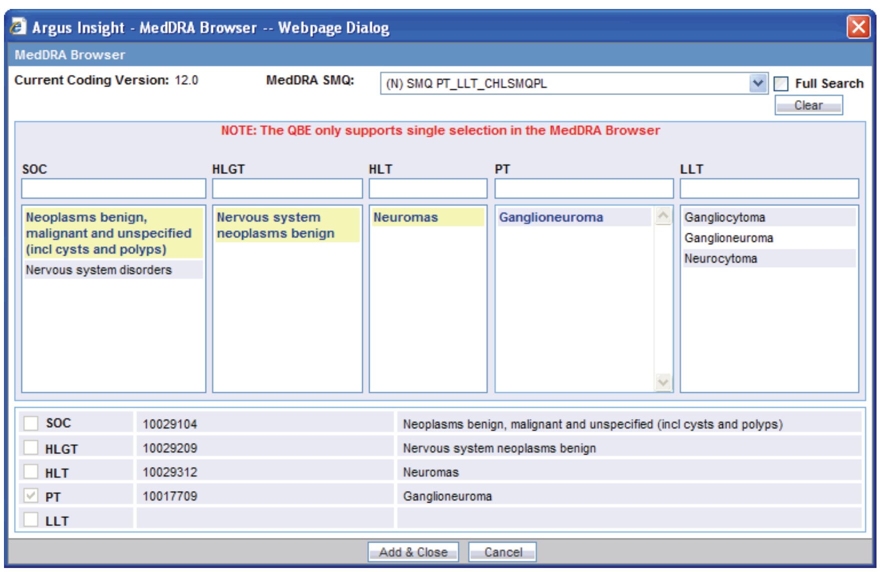
> **Note:** The Special Category drop-down list displays all the SMQs that can be selected. The selected SMQ searches across PT and LLT levels of the MedDRA dictionary.
>
> The Special Category drop-down list is hidden in MedDRA 10. The MedDRA SMQs drop-down list is hidden in versions lesser than MedDRA 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

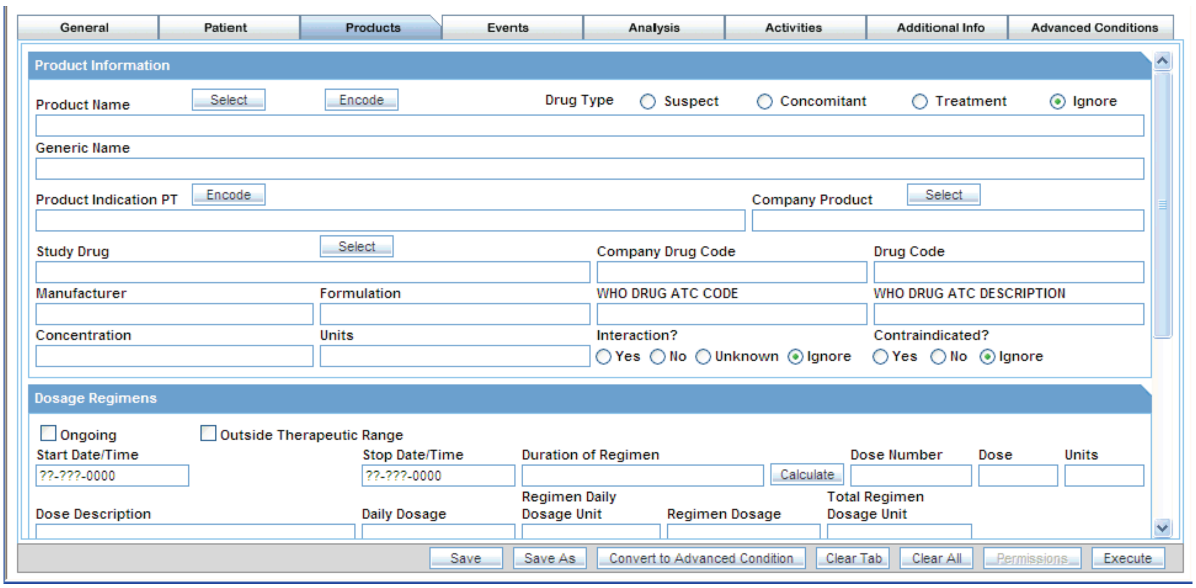


Table 3–5 describes the various fields in the **Products** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

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 3-22 for details. Alternatively, click the associated **Encode** button to use the Drug Coding Browser to specify the WHO drug name as the query criteria. See "Using the WHO Drug Browser" on page 3-24 for details.
	Drug Type	Select the **Suspect**, **Concomitant**, **Treatment**, or **Ignore** option, as appropriate, to indicate whether the query looks for cases where drug type is specified.
	Generic Name	Click the **Select** button associated with the Product Name field to select a generic name that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	Product Indication PT	Click the associated **Encode** button to use the MedDRA Browser to specify the drug primary indication event term as the query criteria. See "Using the MedDRA Browser" on page 3-17 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 3-27 for details.
	Company Drug Code	Click the **Select** button associated with the Product Name field to select the company drug code that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	Drug Code	Enter the drug code that the query looks for in cases.
	Manufacturer	Enter the product manufacturer that the query looks for in cases.
	Formulation	Click the **Select** button associated with the Product Name field to select a drug formulation that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	WHO DRUG ATC CODE	Enter the Anatomical, Therapeutic, Chemical (ATC) classification code that the query looks for in cases.
	WHO DRUG ATC DESCRIPTION	Enter the Anatomical, Therapeutic, Chemical (ATC) classification description that the query looks for in cases.
	Concentration	Click the **Select** button associated with the Product Name field to select a drug concentration that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	Units	Click the **Select** button associated with the Product Name field to select the units that the query looks for in cases. See "Using the Product Browser" on page 3-22 for details.
	Interaction?	Select the **Yes, No, Unknown,** or **Ignore** option, as appropriate, to indicate whether the query looks for cases where drug interaction status is specified.
	Contraindicated?	Select the **Yes, No,** or **Ignore** option, as appropriate, to indicate whether the query looks for cases where drug contraindication status is specified.

Table 3–5 (Cont.) 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.

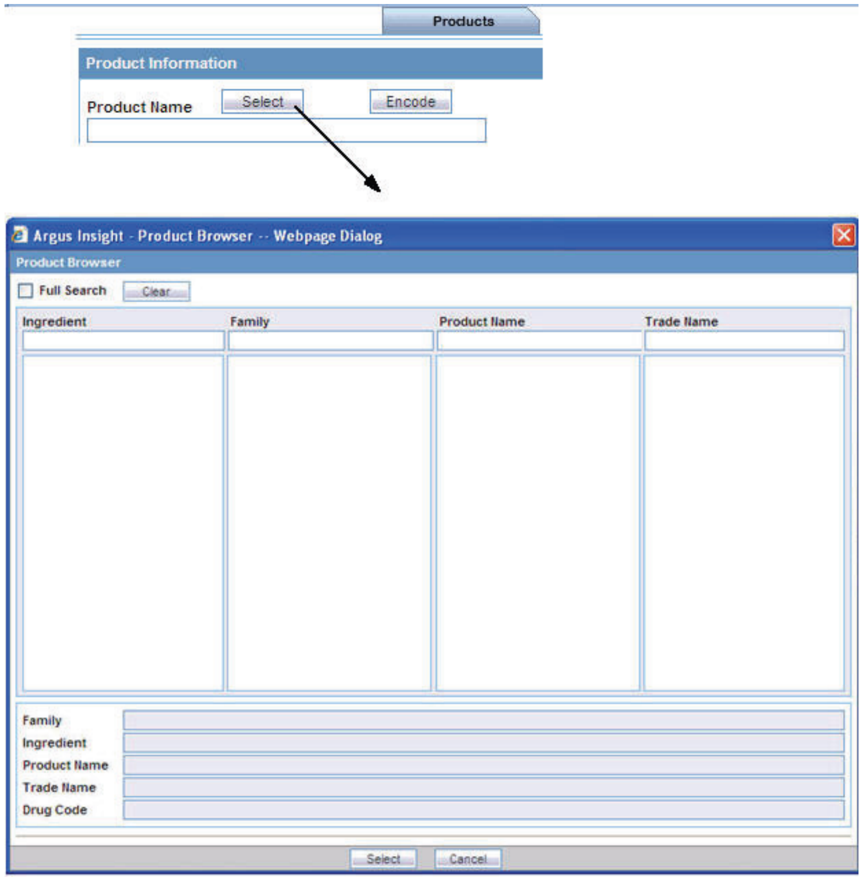
Table 3–5 (Cont.) Fields in the Products Tab on the QUERY BY EXAMPLE Page

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 *Rechallenge*	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.

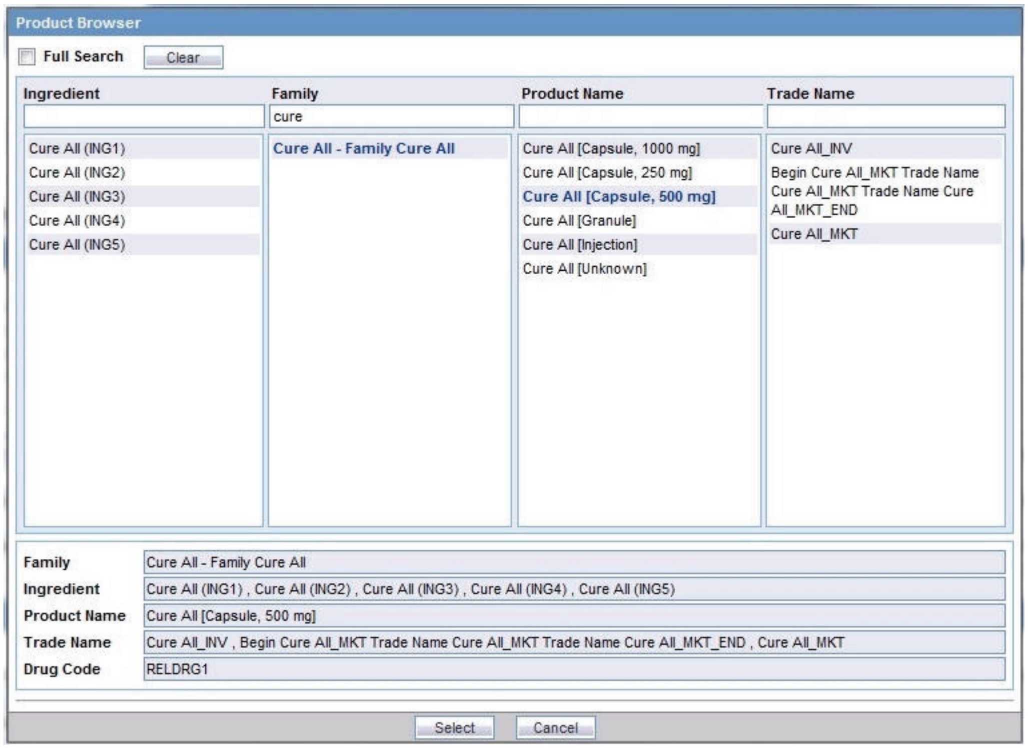


3. Enter the first few letters (text string) of the product ingredient, family name, product name, or trade name in the respective field.

   - 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.**

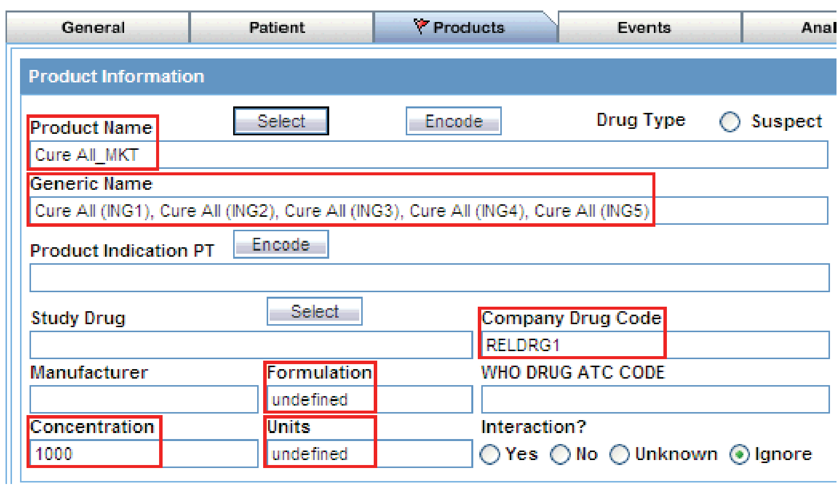
4. Press Tab (or click another field in the dialog box) to begin the search. The system searches the database for the text string that you specified. The Product Browser displays the search results in the column below the field in which you entered the search string.

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



6. Select the required product name or trade name, as appropriate.

7. 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.

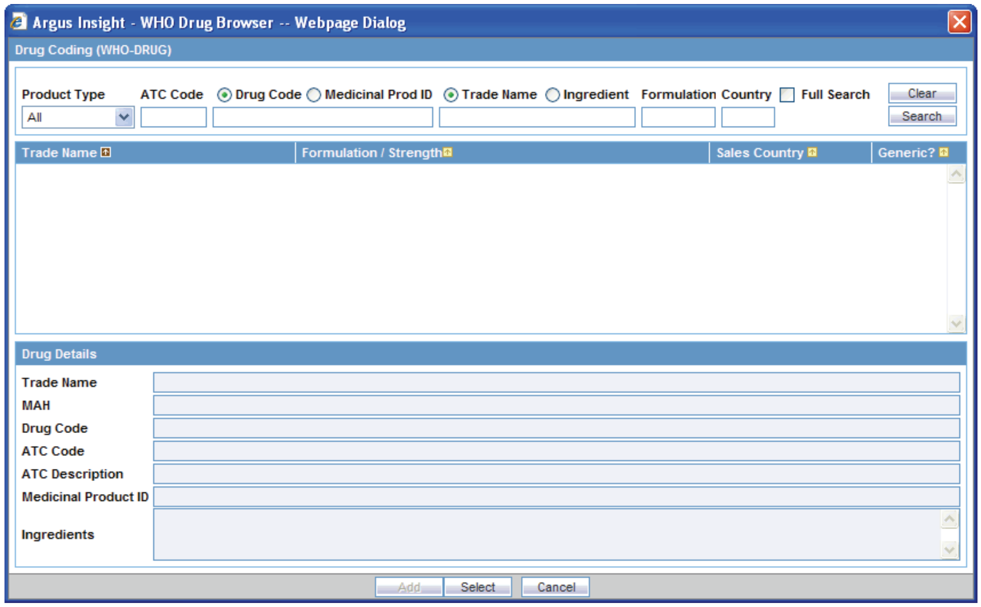


Using the WHO Drug Browser

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)

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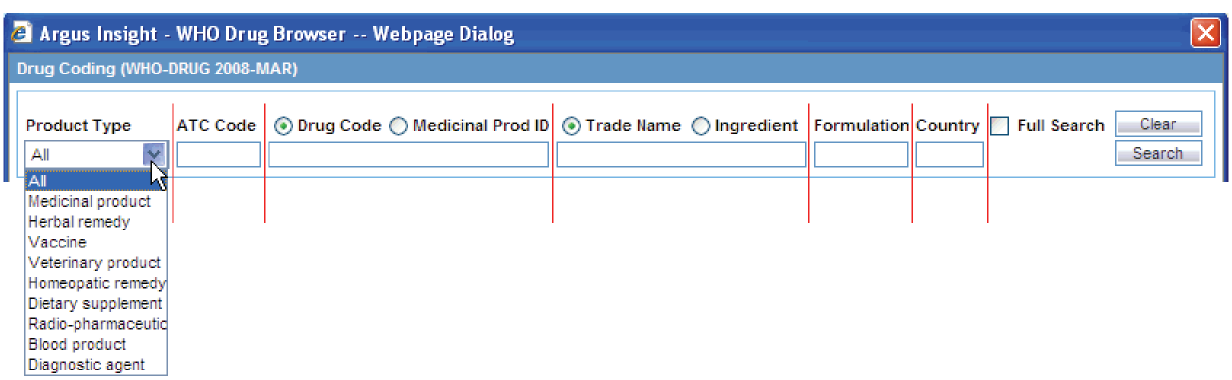
3. Use the fields at the top of the WHO Browser dialog box to define your search criteria. You can enter values into one, several, or all fields.



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.**

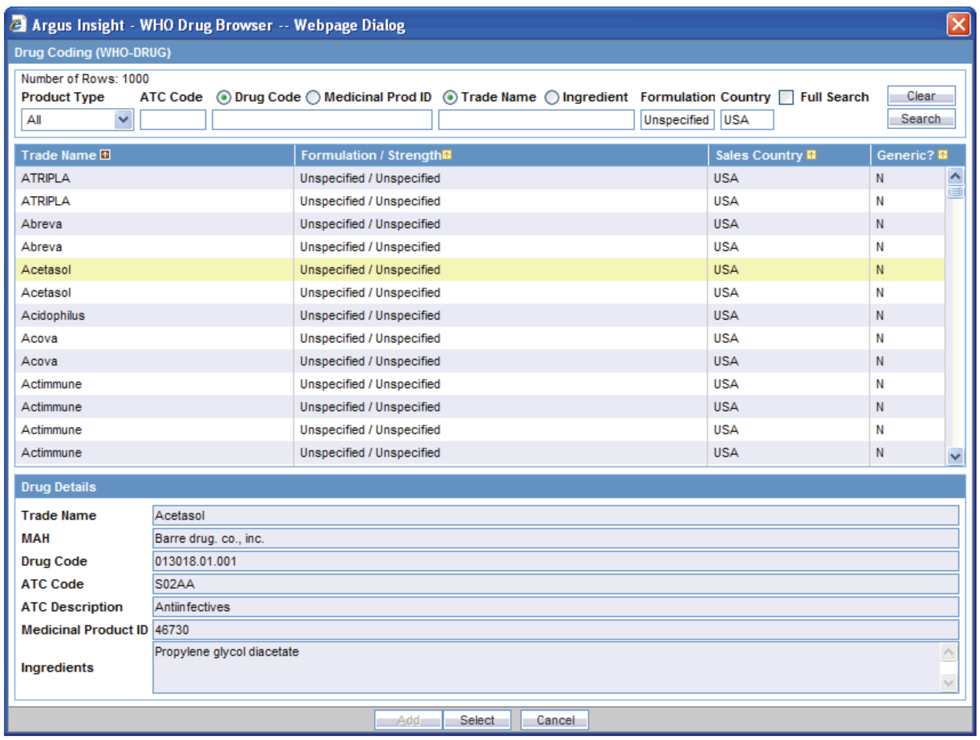
d. Select either the **Trade Name** or **Ingredient** option as one of the search criterion, and then enter the appropriate search string in the text box below the options. The default selection is **Trade Name.**

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.

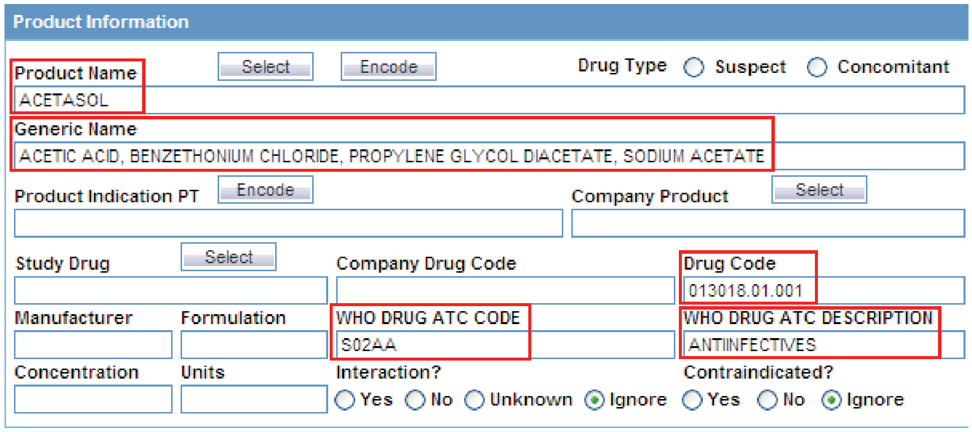
4. Click **Search.** The system searches the database for drug products that match your specified search criteria. The WHO Drug Browser displays the search results in a grid format.

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



6. 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.

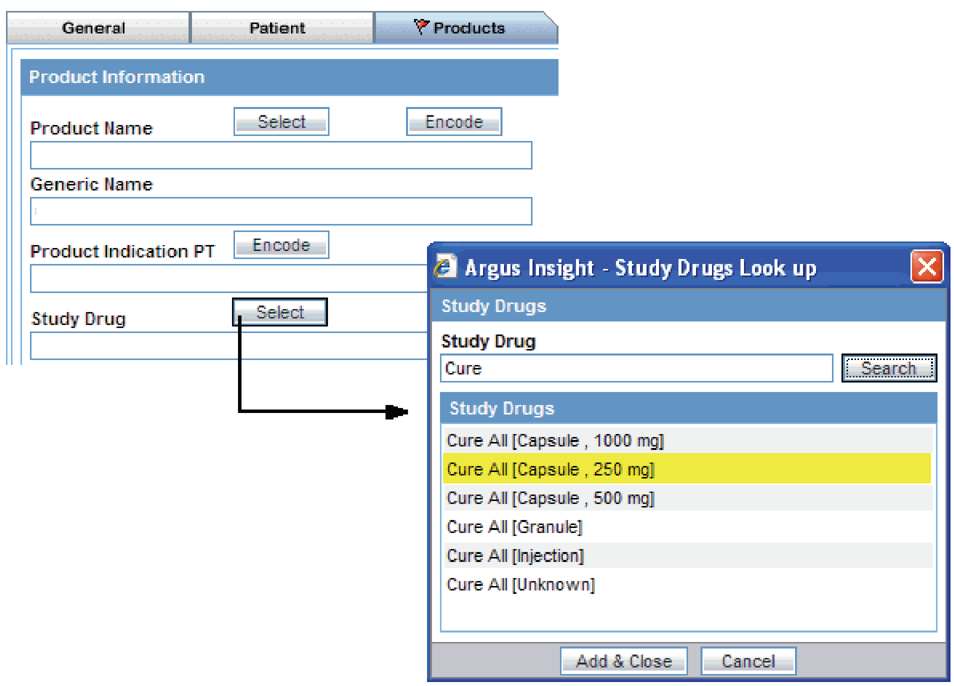
   Note that the Generic Name field displays all the ingredients for the WHO drug you selected.



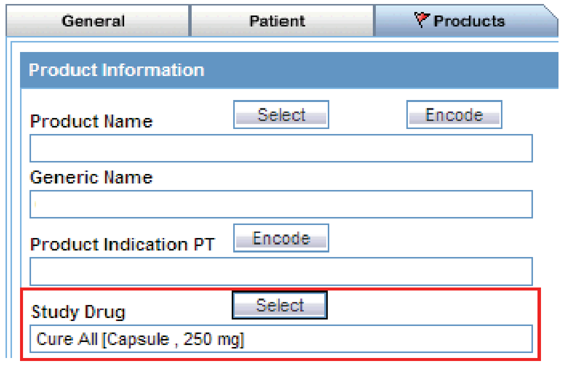
Using the Study Drug Lookup

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

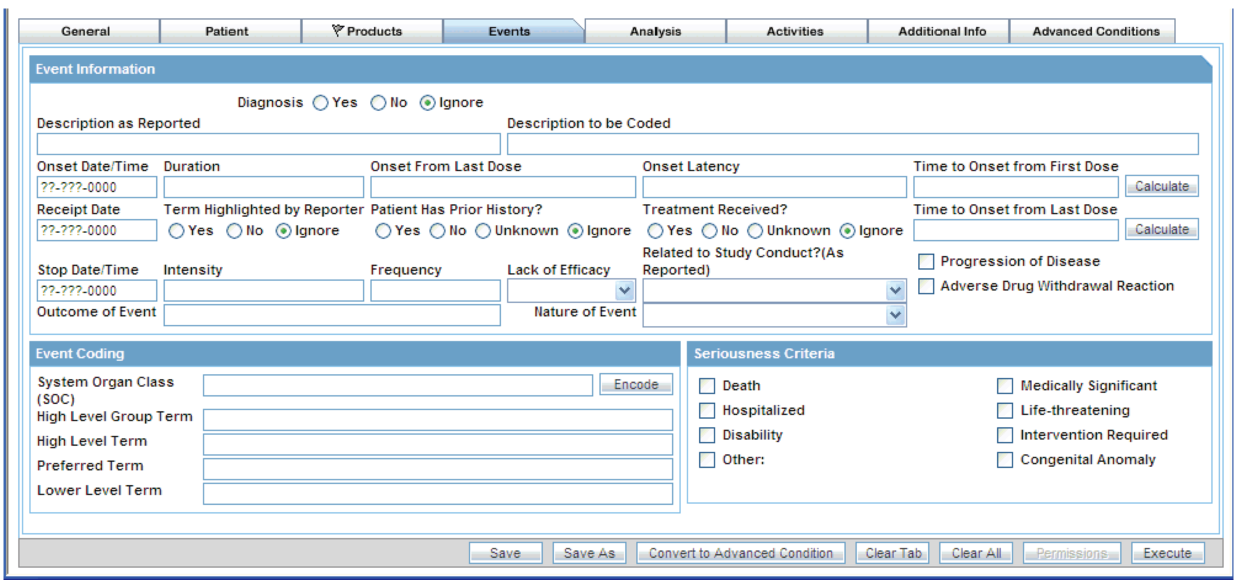


Table 3–6 describes the various fields in the **Events** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

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 3-17 for more information. The MedDRA event terms for the selected term are displayed in the **Seriousness Criteria** section. The query is restricted to the terms displayed.
	Onset Date/Time	Enter the event onset date that the query looks for in cases.
	Duration	Enter the event duration that the query looks for in cases.
	Onset From Last Dose	Enter the event onset duration from last dose as the query criteria.
	Onset Latency	Enter the event onset latency duration that the query looks for in cases.
	Time to Onset from First Dose	Enter the duration from first dose to the event onset as the query criteria. Alternatively, click the associated **Calculate** button to view the Duration Calculator dialog box and make your selection.
	Receipt Date	Enter the event receipt date that the query looks for in cases.
	Term Highlighted by Reporter	Select the **Yes**, **No**, or **Ignore** option, as appropriate, to indicate whether the query looks for cases where case seriousness status is specified.
	Patient Has Prior History?	Select the **Yes**, **No**, **Unknown**, or **Ignore** option, as appropriate, to indicate whether the query looks for cases where event past history is specified.
	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 *Study* 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.

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

Section	Field or Check Box	Description
	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 3-17 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

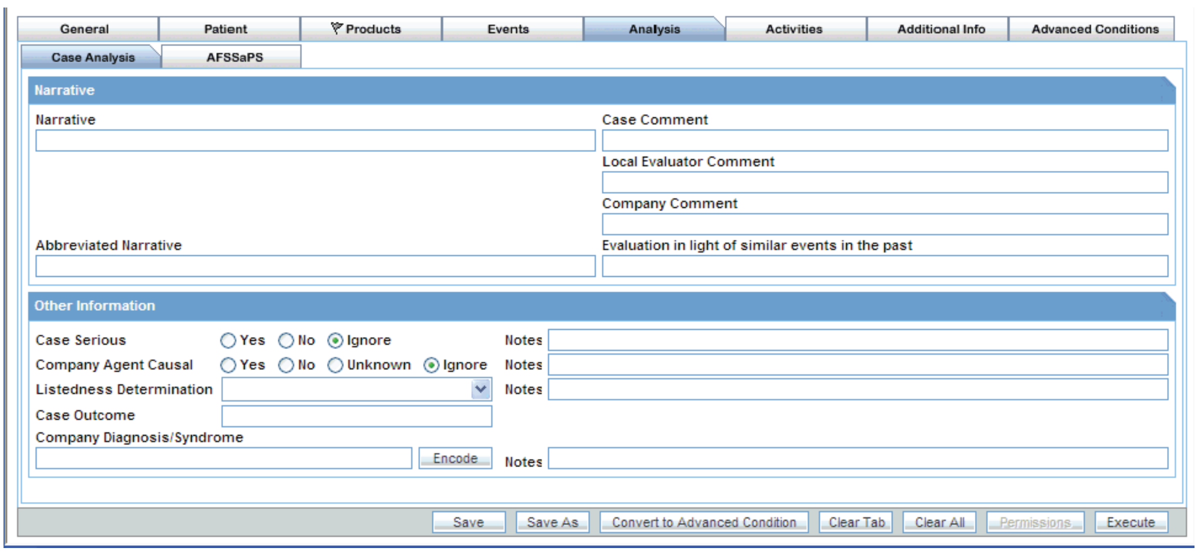


Table 3–7 describes all the fields in the **Case Analysis** view. The field values you specify are used as the *query* criteria to retrieve matching cases.

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.
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 3-17 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 3-17 for more information.
	Agent	Click the associated **Select** button to choose the *suspect product* 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

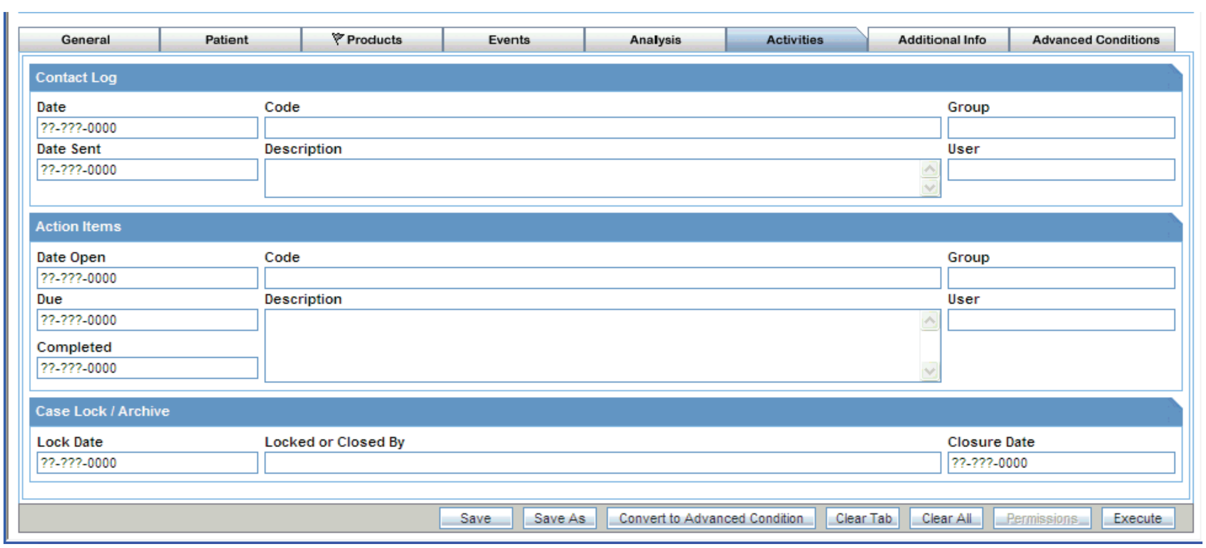


Table 3–9 describes all the fields in the **Activities** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

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.
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

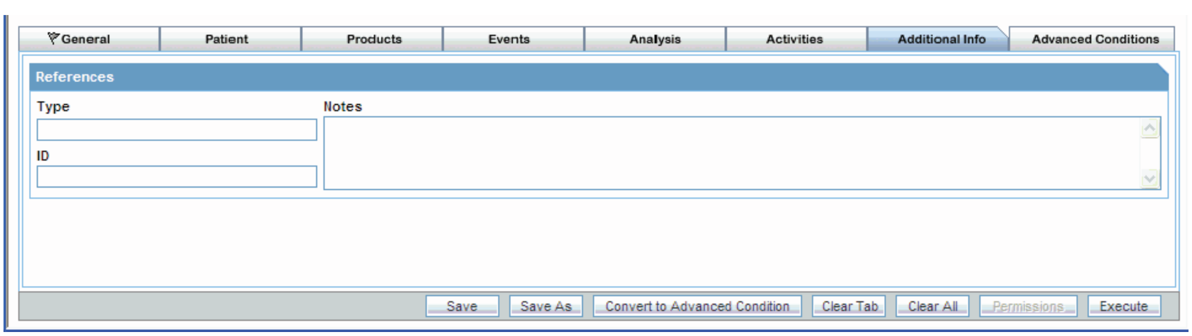


Table 3–10 describes all the fields in the **Additional Info** tab. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

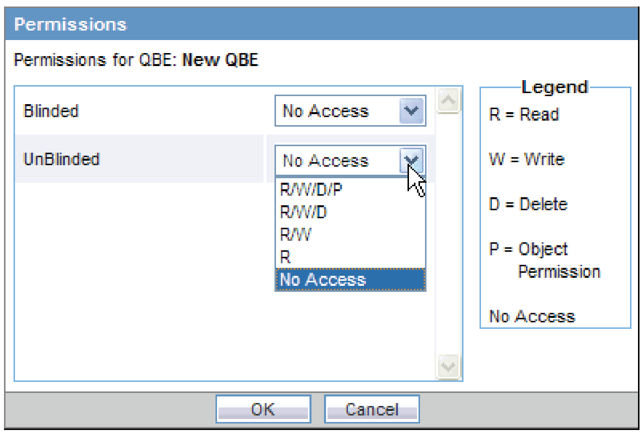
Table 3–10 Fields in the Additional Information Tab on the QUERY BY EXAMPLE Page

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.

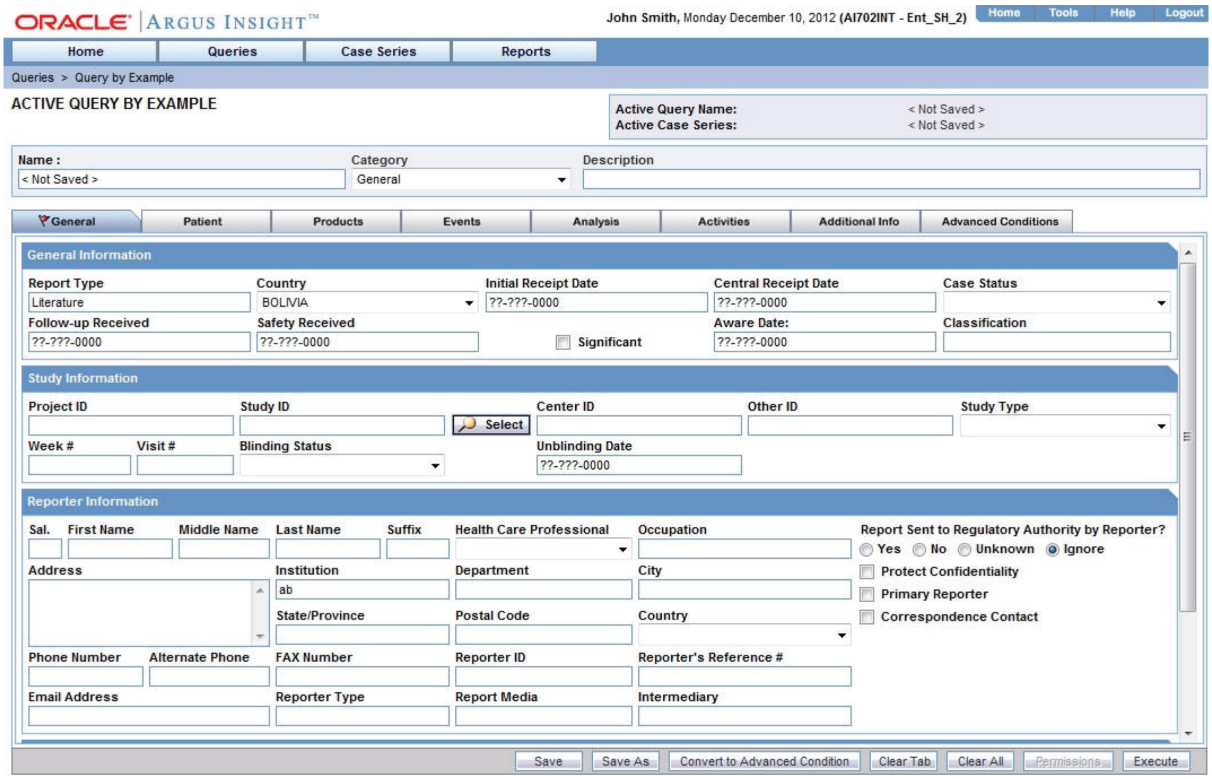
3. Click **OK.** The system saves the permission settings.

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 **Queries, 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 display 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>
```

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

You can also rename an already saved QBE, by entering the new name in the **Name** field and clicking **Save**.

Modifying the Description and Values for the Active QBE

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

In addition, you 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 3-36 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 3-40 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 3-34 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

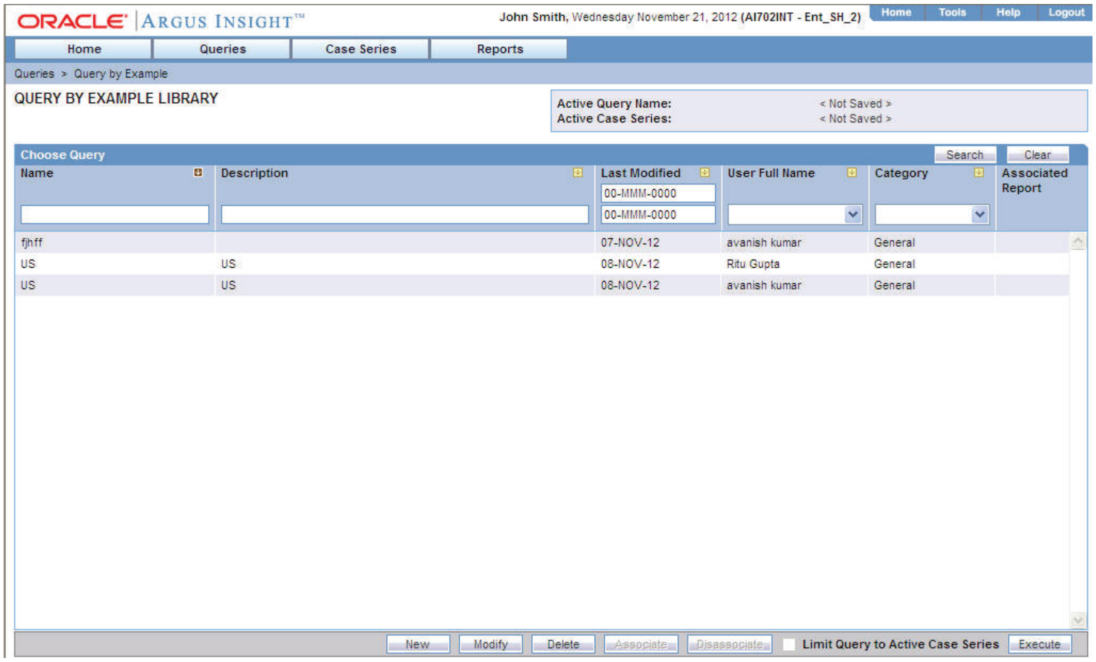
The QUERY BY EXAMPLE LIBRARY page lists all the QBEs saved to the system.

To view the list of saved QBEs, navigate to **Queries, 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 3-38 for more information.

Figure 3–11 QUERY BY EXAMPLE LIBRARY Page



Searching for a Saved QBE

To search for a saved QBE:

1. 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.

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

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2. 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 **Queries, 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.

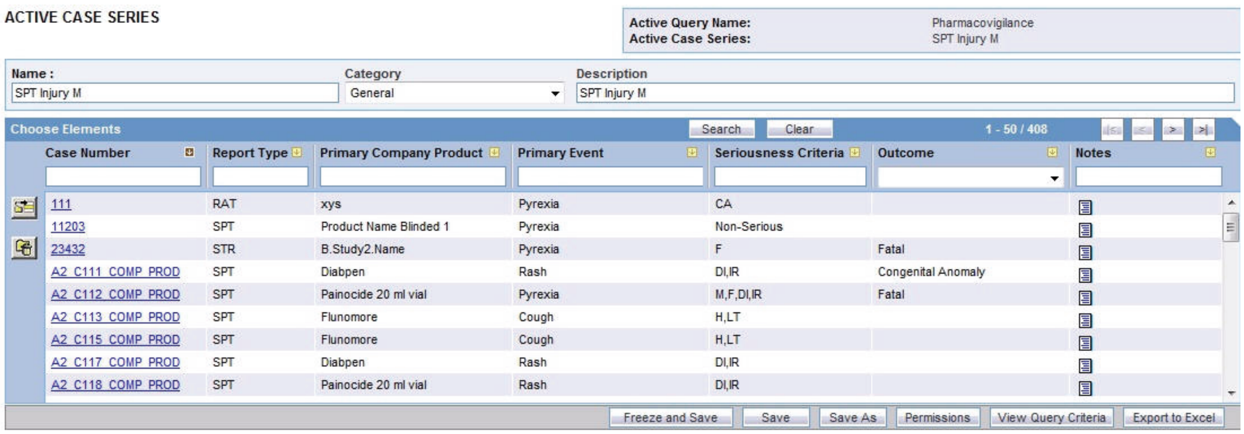
For detailed procedures and more information about associating report groups, see "Scheduling and Associating Reports Against a Query or Case Series" on page 8-9.

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

Executing a Saved QBE

To execute a saved QBE:

1. Navigate to **Queries, 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 3-39. 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 **Case Series, Open Case Series,** and select **Library**. When the CASE SERIES LIBRARY page opens, select the case series and click **Make Active.**
2. Navigate to **Queries, 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

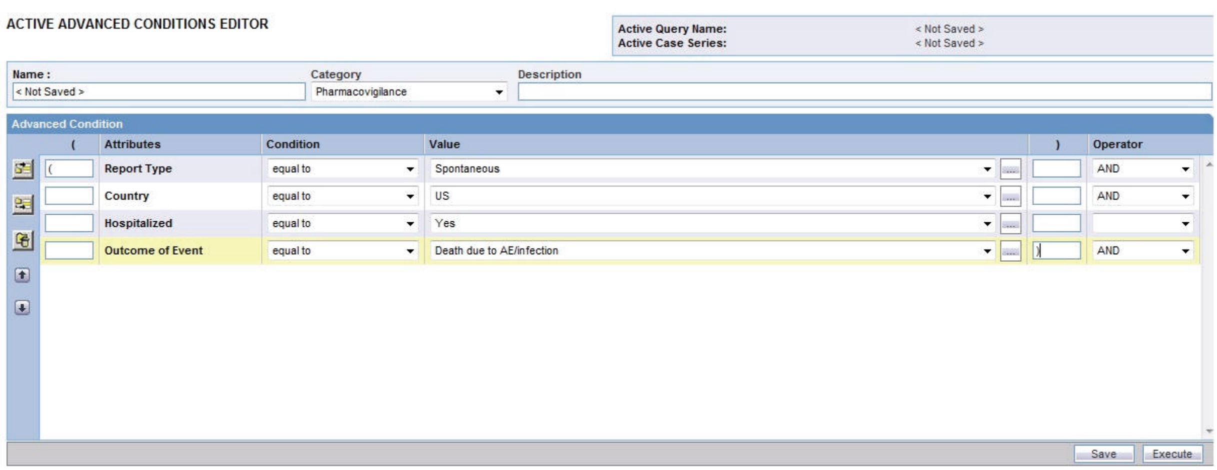
Converting a QBE to an Advanced Condition

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.



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

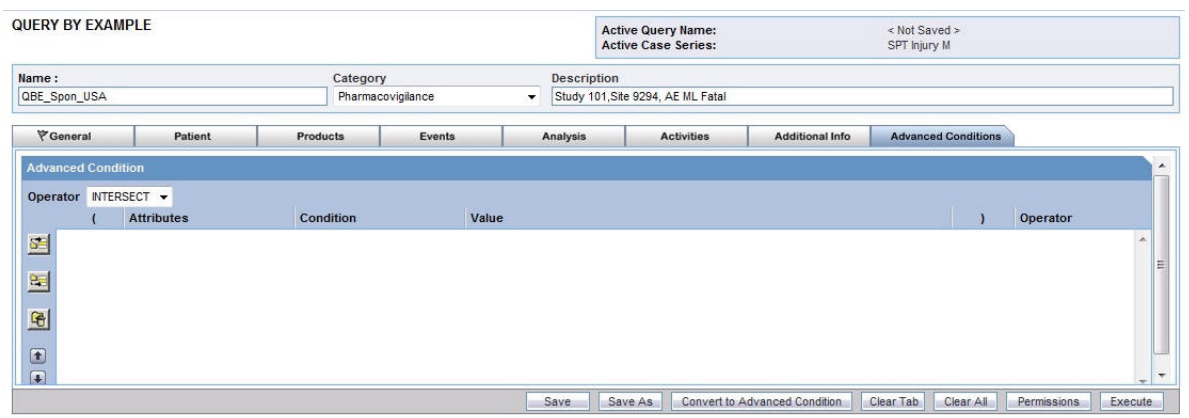
You can integrate a new, active, or saved QBE with an existing advanced condition through these set operators:

- INTERSECT
- MINUS
- UNION

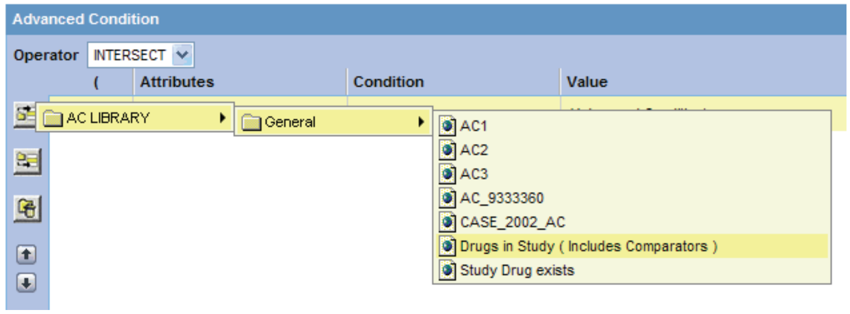
If required, you can integrate your QBE with multiple advanced conditions that can have Boolean or set operations between them.

To integrate a QBE with existing advanced conditions:

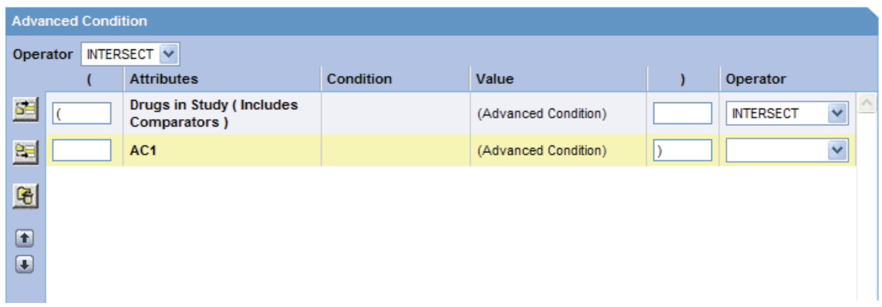
1. Open a QBE form by either starting a new QBE, opening the active QBE, or opening a saved QBE.
2. Verify the *field* values you specified in the various tab pages in the QBE form.
3. Click the **Advanced Conditions** tab.



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 3-40 for more information.

For detailed information about using the Advanced Conditions Editor, see Chapter 5, "Using Advanced Conditions to Create Queries."

4

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

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

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

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

Using Predefined Filters

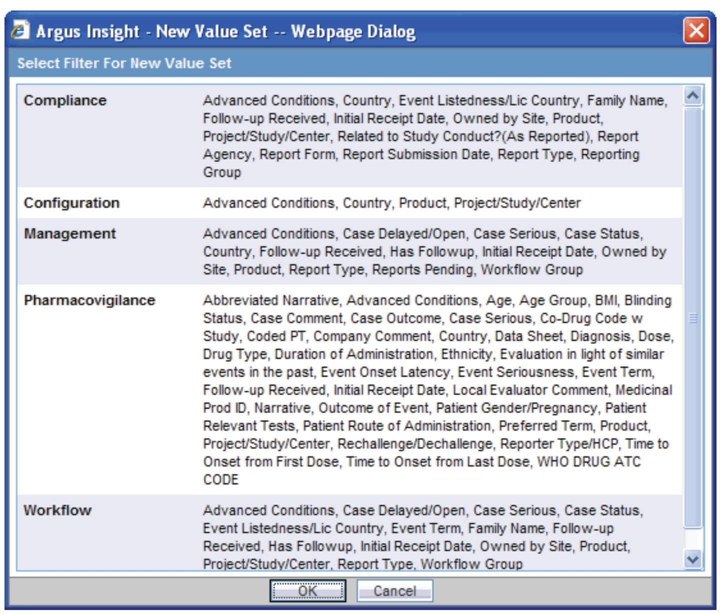
This section describes the following tasks:

- Selecting a Predefined Filter
- Creating a Value Set for the Predefined Filter
- Executing a Value Set

Selecting a Predefined Filter

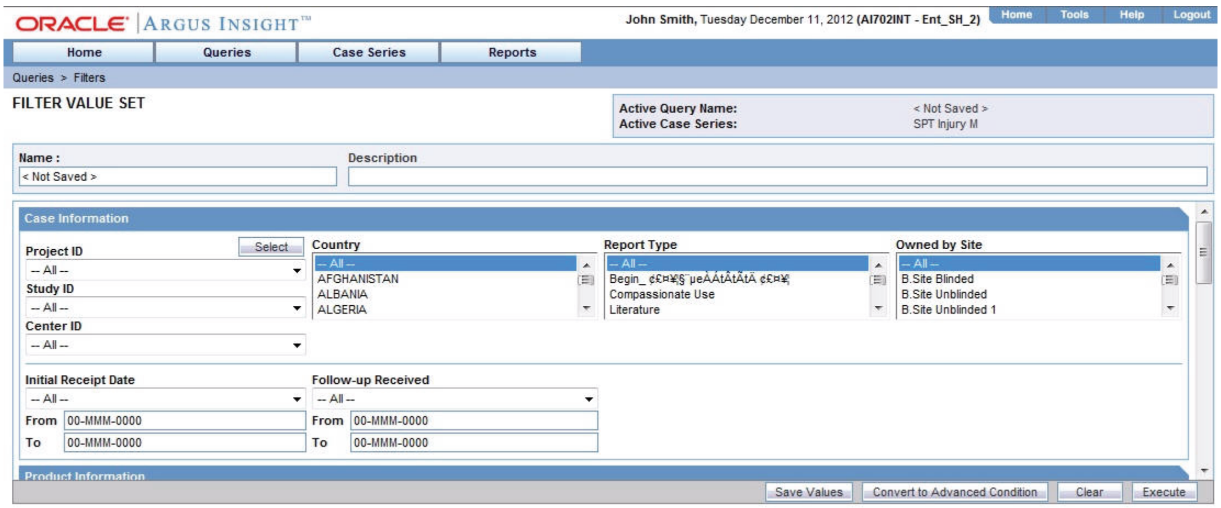
To select a predefined filter:

1. Navigate to **Queries, Filters,** 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 4-21 for details. To convert the entire value set to an advanced condition, see "Converting a Value Set to an Advanced Condition" on page 4-20 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 *Report* 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

Sections in the New FILTER VALUE SET Page	Associated Elements (Fields)	
Product Information	ATC Code Product Regimen Daily Dose Total Regimen Dosage	Drug Primary Indication Code *Rechallenge/Dechallenge* 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 *Form* Reports Pending

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Note: To access the MedDRA Browser from the Pharmacovigilance or Workflow filters, navigate to **Queries, 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.

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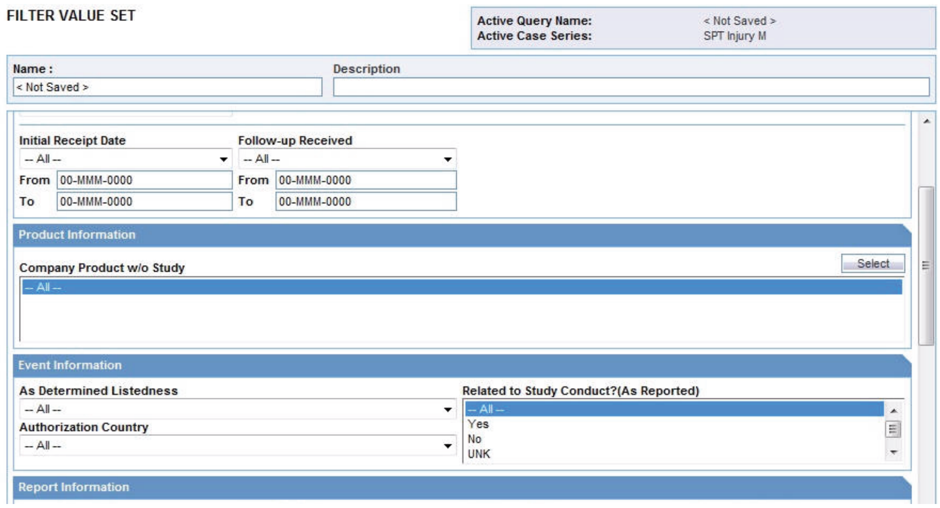
2. Examine the value set results.
3. Click **Execute.** While the system searches for matching cases, the following dialog box is displayed:

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.



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.

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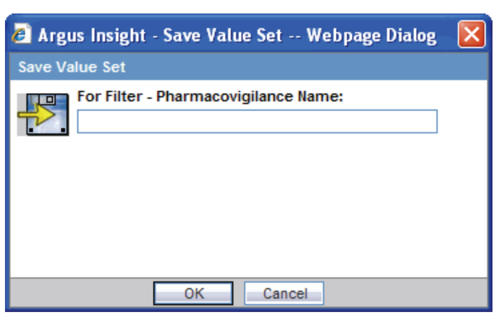
6. If required, modify the value set and examine the results again or proceed to save the value set.
7. Save the value set to the system.
8. Type a description of the value set in the **Description** field. For example, you can describe the type of cases the value set retrieves.
9. Click **Save Values.**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

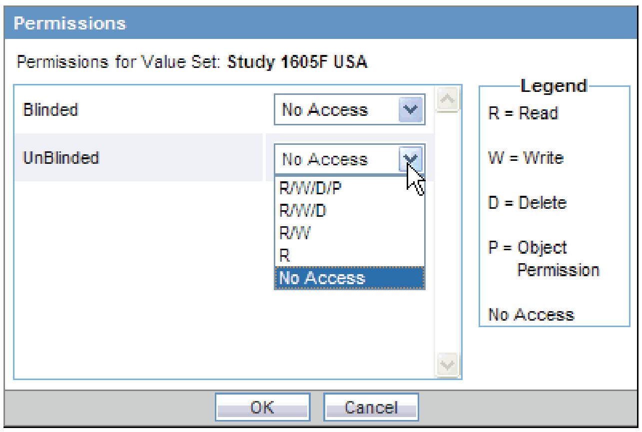


10. Type the name of the value set in the **Name** field.
11. Click **OK** to close the dialog box and refresh the FILTER VALUE SET page. Note that:
    - The Name label displays the name of the value set you specified.
    - The **Save Values As** button and the **Permissions** button are now enabled.

Note: The FILTER LIBRARY page displays all the value sets saved to the system. See "Working with Saved Filters and Value Sets" on page 4-16 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.

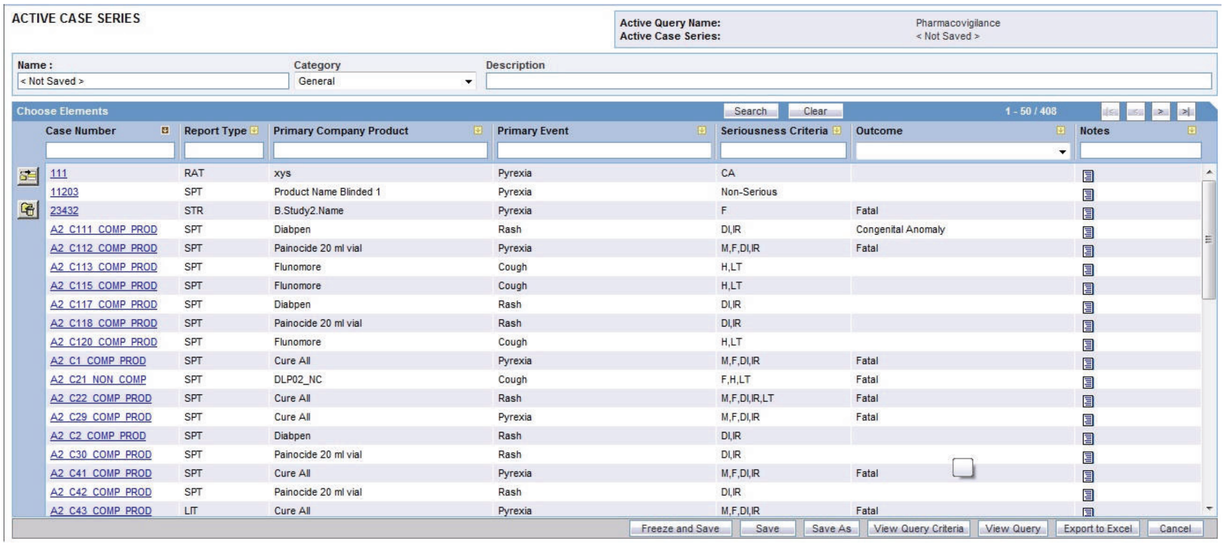
14. Click **OK.** The system saves the permission settings.

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

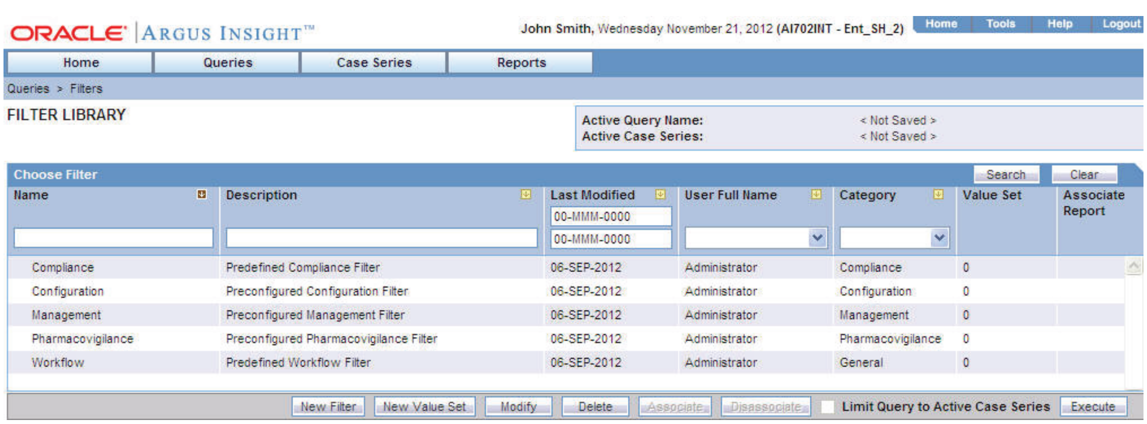
This section includes the following topics:

- Creating a Custom Filter
- Creating a Value Set for a Custom Filter

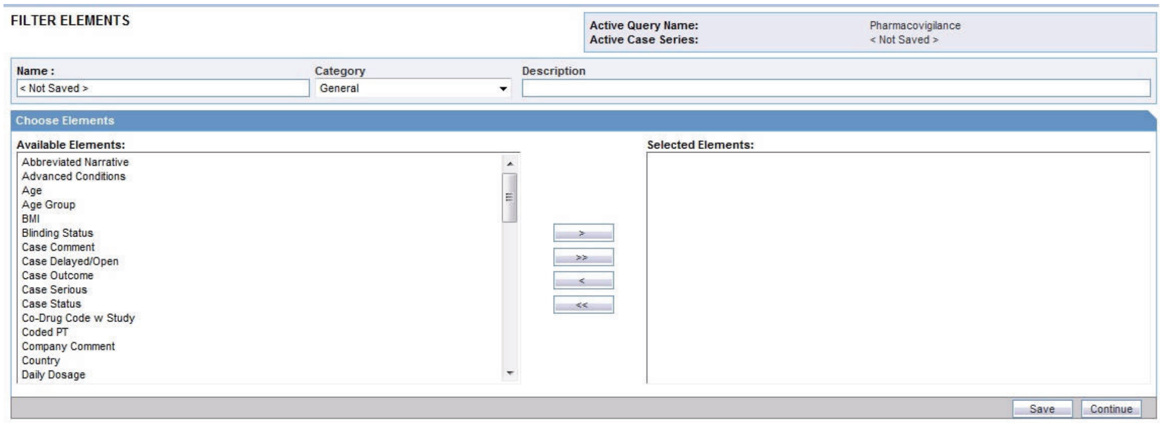
Creating a Custom Filter

To create a custom filter:

1. Navigate to **Queries, 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.

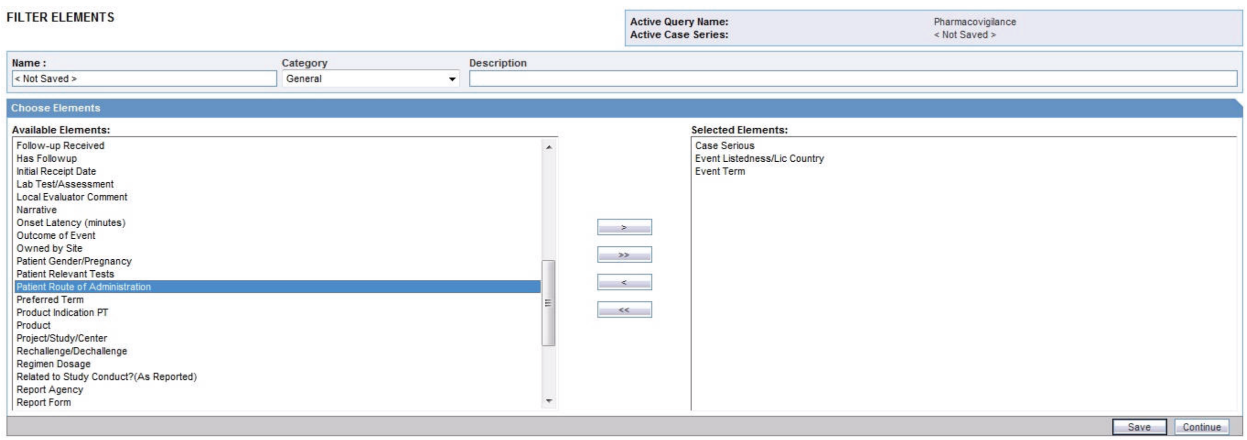


2. Click **New Filter.** The FILTER ELEMENTS page opens.



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

4. Click the right arrow (>) button to associate the selected element with the custom filter. The selected element appears in the **Selected Elements** list.



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

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

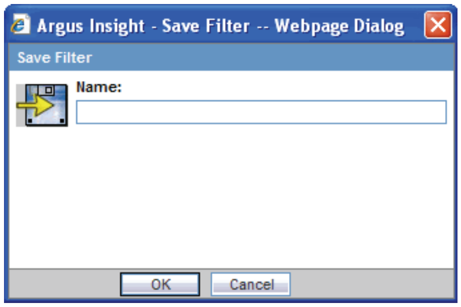
To remove all the elements from the **Selected Elements** list, click >> the button.

5. Save the filter.

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

7. Type a description of the custom filter in the **Description** field.

8. Click **Save.** The Save Filter dialog box opens.

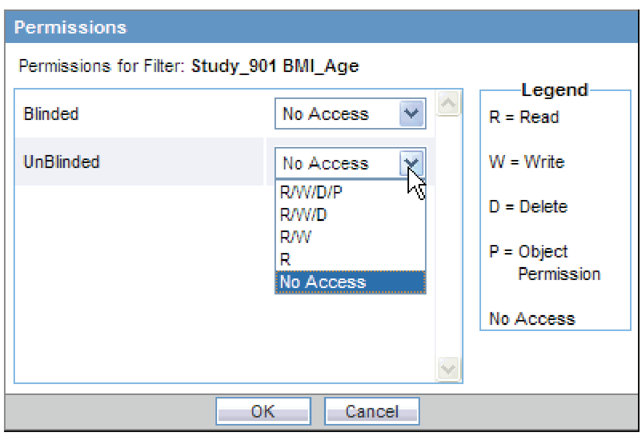


9. Enter a name for the custom filter.
10. Click **OK** to save the custom filter and refresh the FILTER ELEMENTS page. Note that:
    - The **Name** label displays the name of the saved filter.
    - The **Active Query Name** label in the upper-right corner of the page now displays the name of the filter 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.

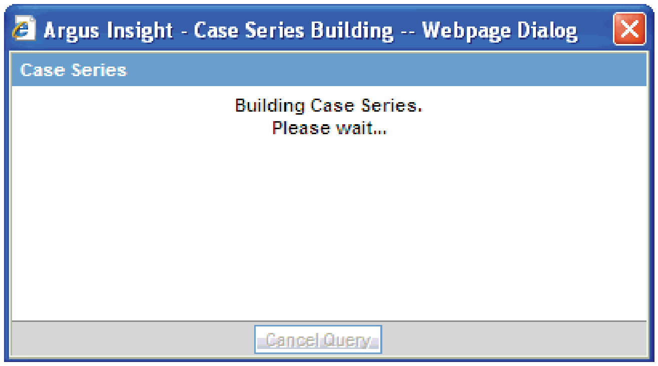
Creating a Value Set for a Custom Filter

To create a value set for a custom filter:

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

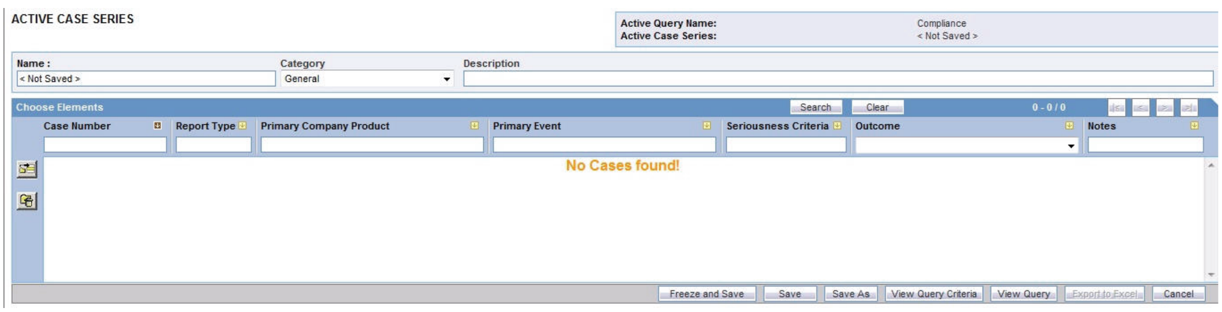
   Note: In the FILTER VALUE SET page, all the elements associated with the filter are organized in sections. You need to scroll the page to view all the sections. If you included the advanced condition element while creating your filter in Step 2, the FILTER VALUE SET page displays an additional Advanced 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 4-21 for details. To convert the entire value set to an advanced condition, see "Converting a Value Set to an Advanced Condition" on page 4-20 for details.

2. Specify values for the filter elements. See "Using Predefined Filters" on page 4-3 for details.
3. Examine the value set results.
4. Click **Execute.** While the system searches for matching cases, the following dialog box is displayed.

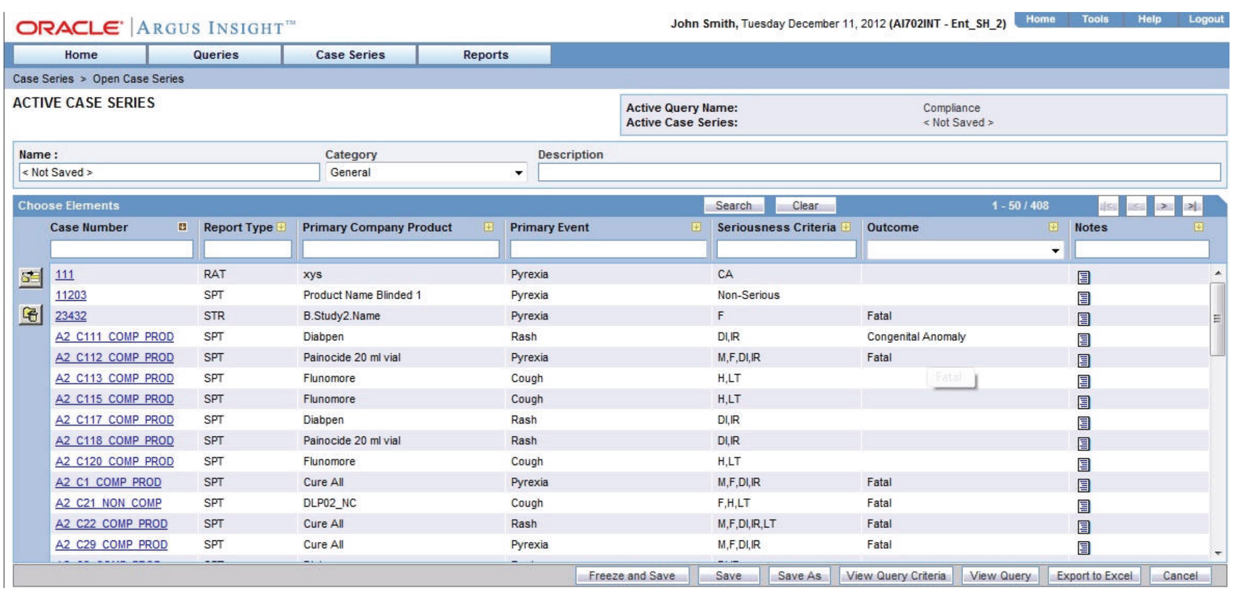


> **Note:** To cancel the query execution at this point and return to the FILTER VALUE SET page, click **Cancel Query.**

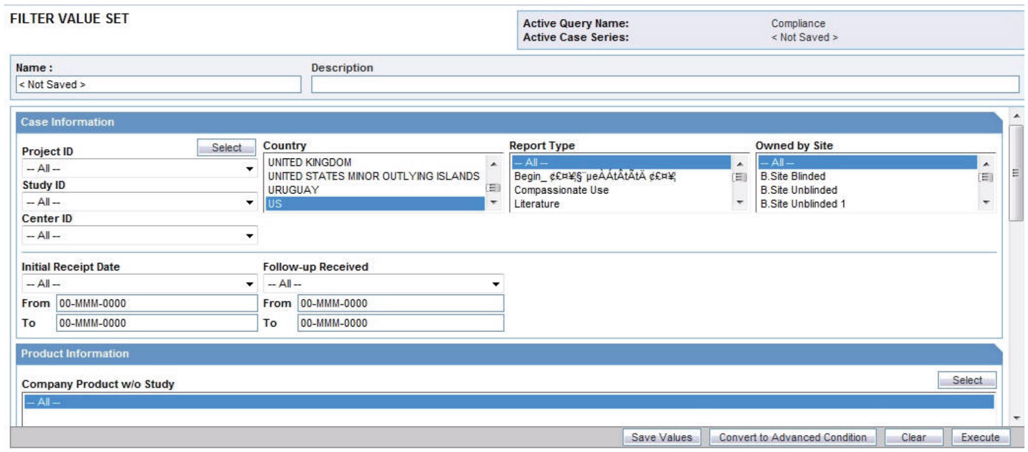
5. If the system does not find any cases that match the querying criteria, the following dialog box is displayed. Click **OK** in this dialog box to return to the Value Set *form*, modify the criteria, and execute the value set again.



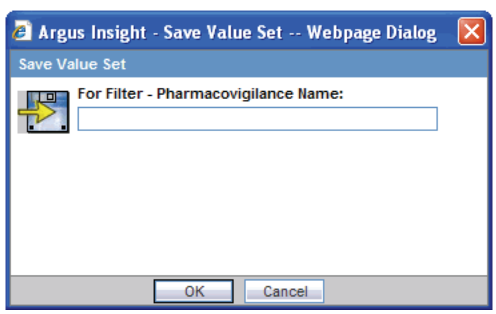
6. If the system finds cases that match the query criteria, a list of such cases is displayed in the ACTIVE CASE SERIES page.



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.

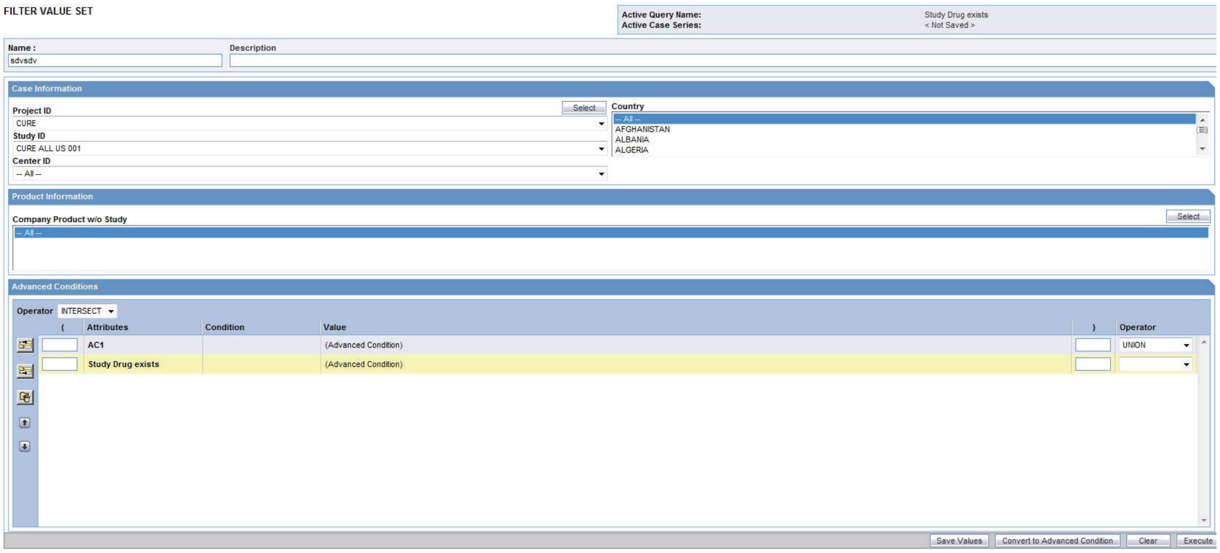


13. Enter a name for the value set.

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

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

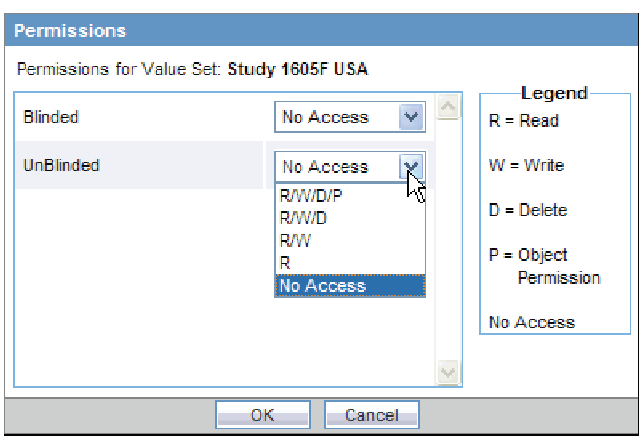
    Note that the **Save Values As** button and the **Permissions** button are now enabled.



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 4-16 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.

---

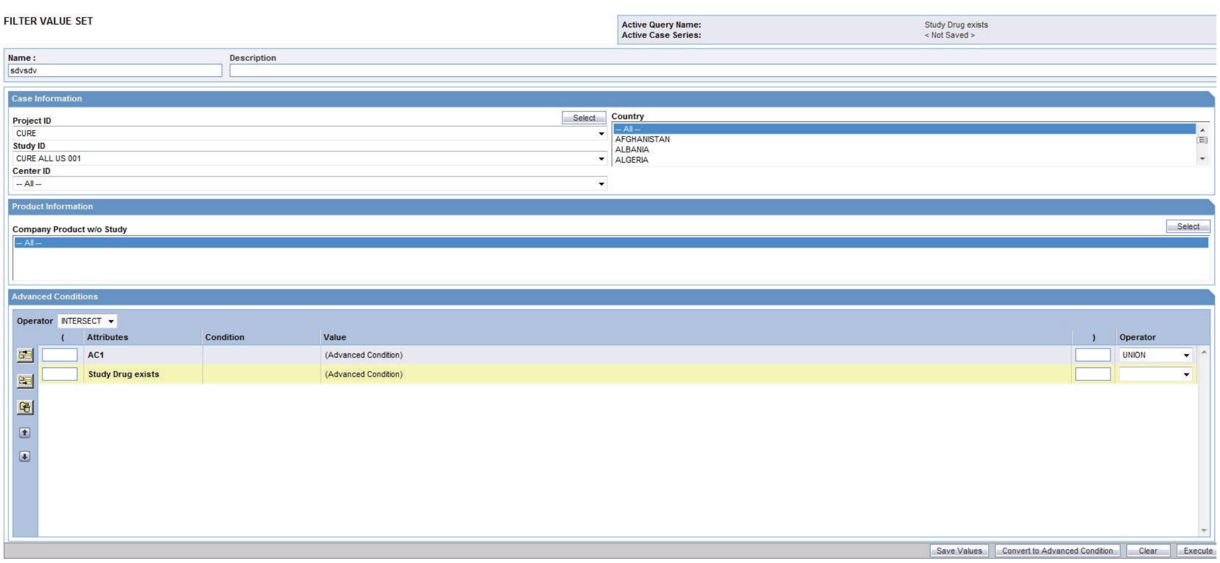
17. Click **OK.** The system saves the permission settings.
18. Click **Execute.** The system retrieves the cases that match the value set criteria and displays the list in the ACTIVE CASE SERIES page. After generating the case series, you can manually modify or save the series. See Chapter 7, "Working 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 **Queries, 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 in the **Name** field. In addition, the name of the filter appears next to the **Active Query Name** label.

   You can rename an already saved value set, by entering the new name in the **Name** field and clicking **Save Values**.

3. However, if the value set was not saved to the system before executing, the text `<Not Saved>` is displayed in the **Name** field.

   You can enter the name of the value set in the **Name** field and click **Save**.

4. From the ACTIVE FILTER VALUE SET page, you can perform the following tasks:

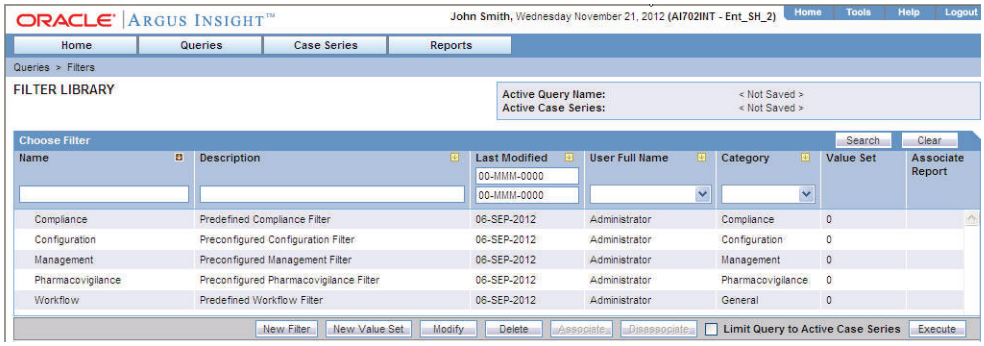
Task	Description
Modify the Active Value Set	If required, you can modify the value set by changing the *field* values. While entering field values, if you want to remove all the values you entered, click **Clear.** Click **Save Values** to save the changed field values. This button is only available for a saved value set.
Save the Active Value Set by another name	Click **Save Values As** to save the active value set by a different name. The FILTER LIBRARY page displays all the value sets you saved to the system. See "Working with Saved Filters and Value Sets" on page 4-16 for more information.
Convert Active Value Set to Advanced Condition	Click **Convert to Advanced Condition** to convert the active value set to an advanced condition. See "Converting a Value Set to an Advanced Condition" on page 4-20 for more information.
Assign Permissions on the Active Value Set	Click **Permissions** to set the group-level access permissions. The **Permissions** button is only available for saved value sets.
Change the Description of the Active Value Set	You can change the description of the active value set by modifying the text displayed in the **Description** field. Click **Save Values** to store the changed description.
Execute the Active Value Set	Click **Execute** to generate a case series by using the active value set.

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

Working with Saved Filters and Value Sets

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

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



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

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

Column	Description
Name	Displays the name of the filters and value sets.
Description	Displays the description of the filters and value sets.
Last Modified	Displays the date when the filters/value set was last modified.
User Full Name	Displays the name of the user who created the filter/value set.
Category	Displays the filter category.
Value Set	Displays the number of value sets created for a filter.
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 4-19 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.

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

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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 4-8 for details.

Creating a New Value Set

To create a new value set, navigate to **Queries, 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.

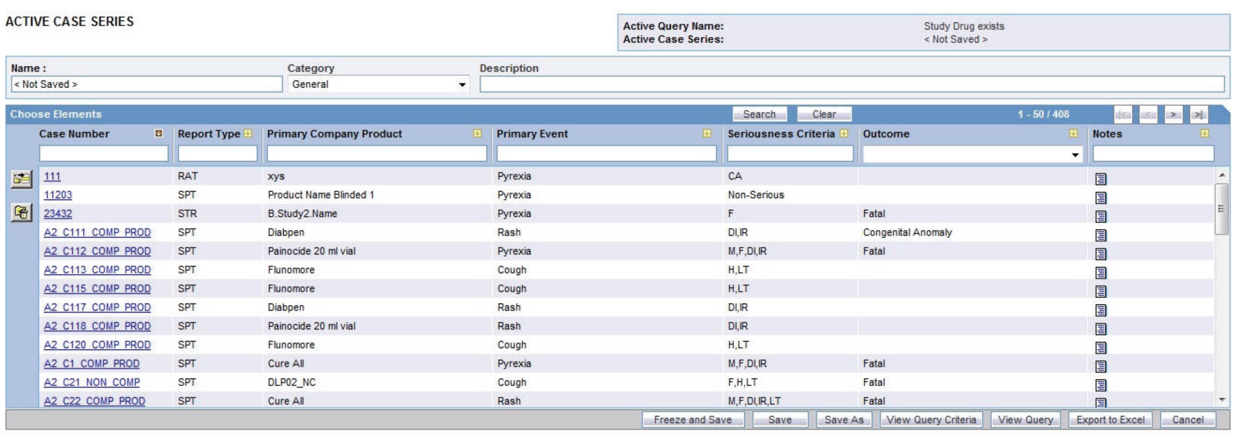
For detailed procedures and more information about associating report groups, see "Scheduling and Associating Reports Against a Query or Case Series" on page 8-9.

Note: To be able to schedule reports, you must have an enterprise login configured in the Business Intelligence tool 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 **Case Series, Open Case Series,** and select **Library.** When the CASE SERIES LIBRARY page opens, select the case series and click **Make Active.**
2. Navigate to **Queries, 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

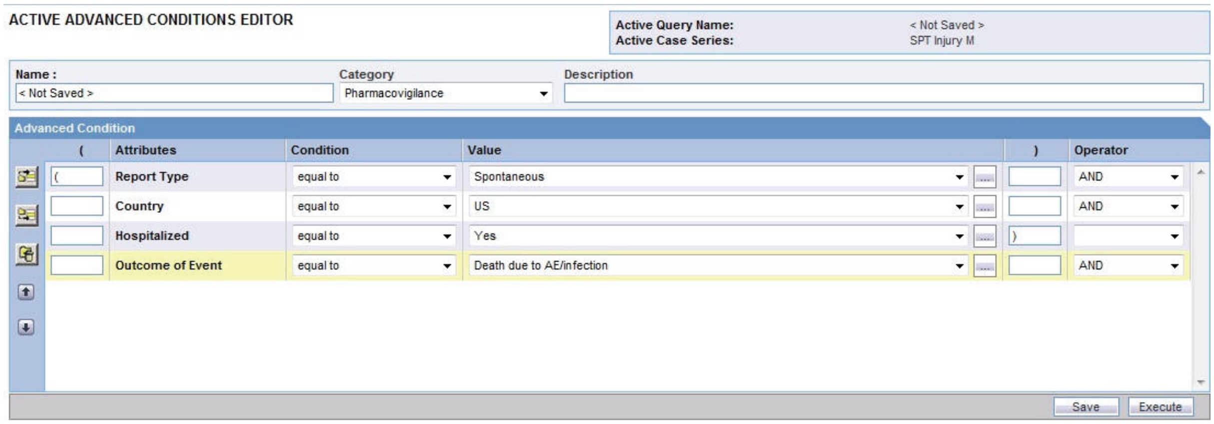
You can use an existing *filter value set* to start to build an advanced condition that uses Boolean or set operations between elements that have multiple values. When you convert a value set to an advanced condition, all the fields in which you entered values are listed on the ACTIVE ADVANCED CONDITIONS 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 4-16).
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.



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:

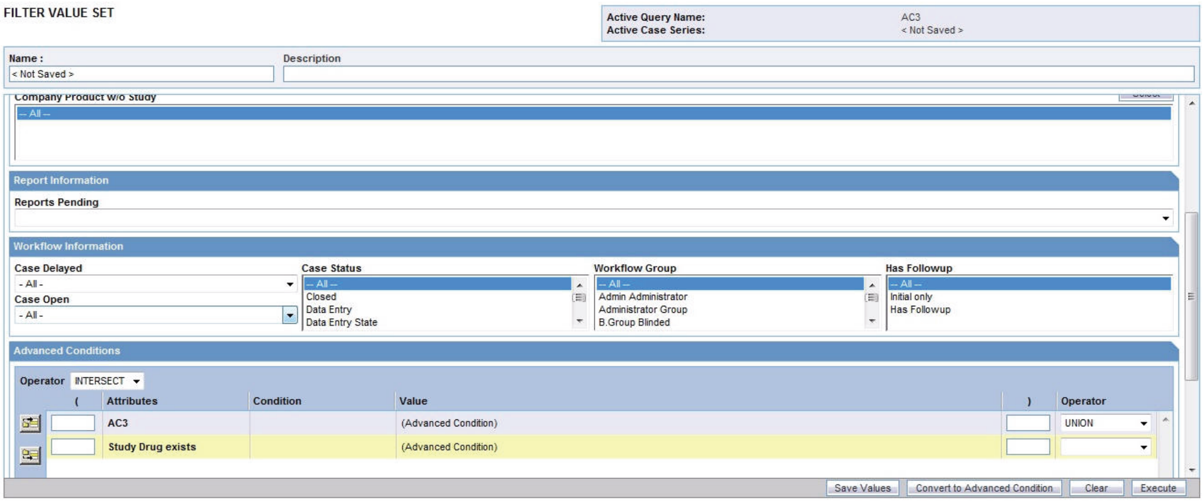
- INTERSECT
- MINUS
- UNION

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

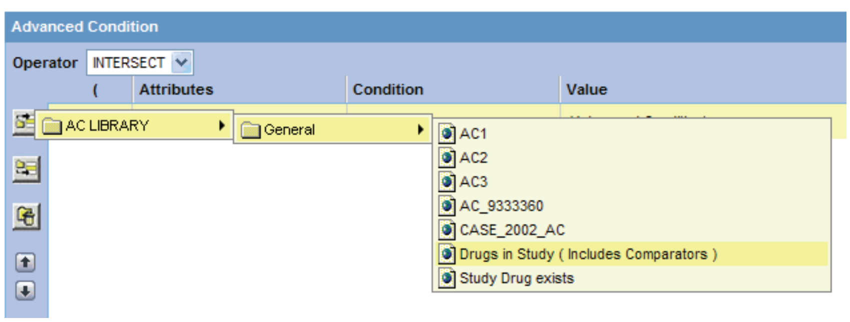
Note: Only those value sets that have the **Advanced Condition** element can be integrated with advanced conditions. All value sets that you create for predefined filters contain the **Advanced Condition** element. If you want to convert a *custom filter value set* to an advanced condition, make sure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

To integrate a value set with existing advanced conditions:

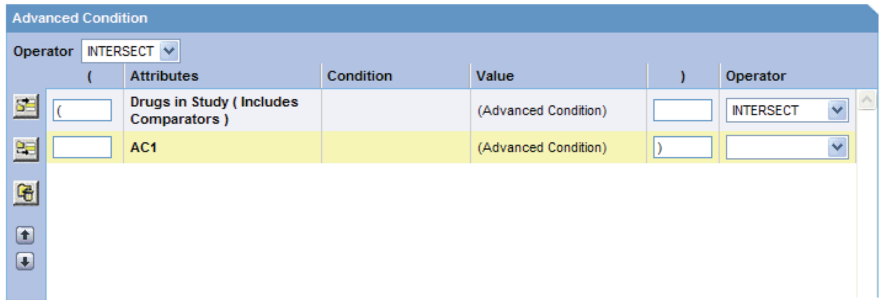
1. Create a new value set by either using predefined filters or creating custom filters. Alternatively, open a saved value set from the FILTER LIBRARY page (see "Working with Saved Filters and Value Sets" on page 4-16). If you create a custom value set, make sure you include the Advanced Condition element.
2. Verify the *field* values you specified for the value set.
3. Scroll to the **Advanced Condition** section on the FILTER VALUE SET page.



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 4-20 for more information.

For detailed information about using the Advanced Conditions Editor, see Chapter 5, "Using Advanced Conditions to Create Queries."

5

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

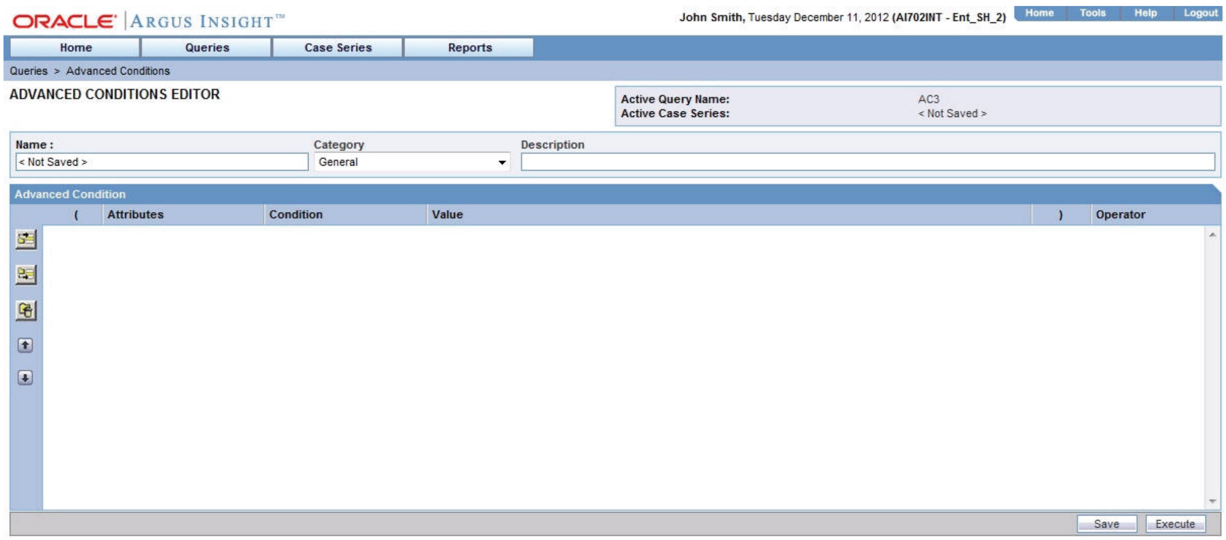
In addition to advanced conditions, Argus Insight provides the following query tools:

- 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 **Queries, 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 3-40 and "Converting a Value Set to an Advanced Condition" on page 4-20 for details.

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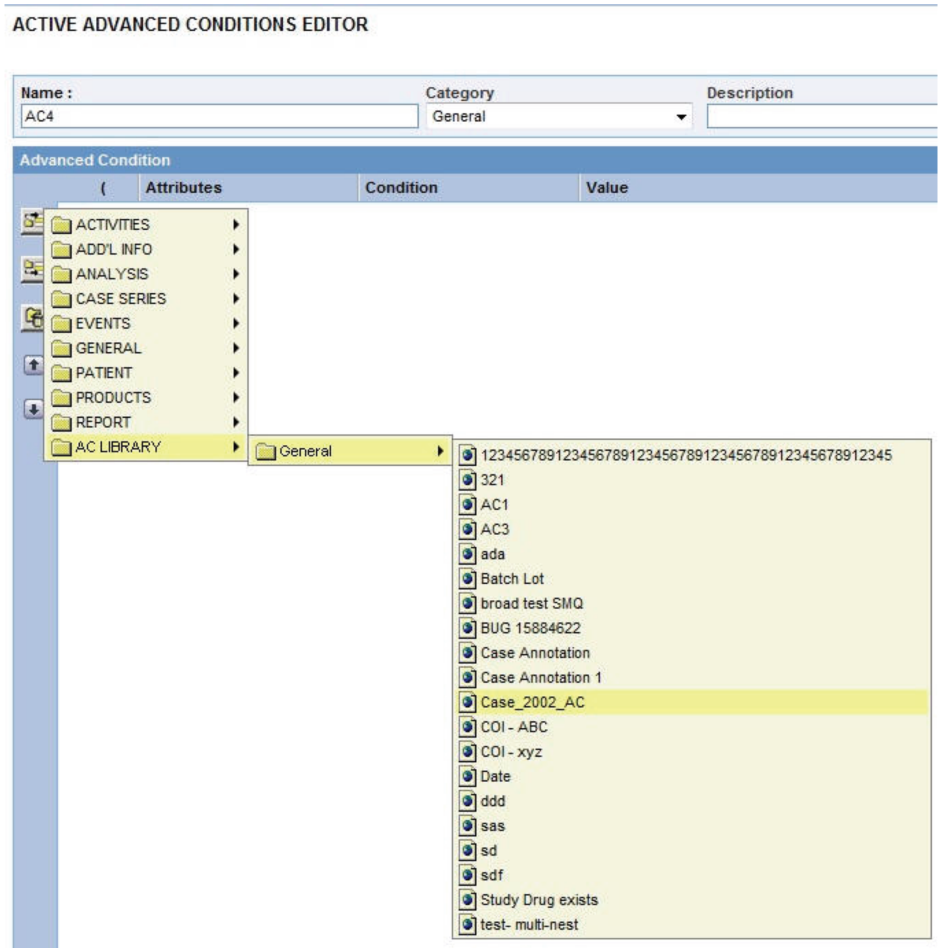
2. Enter the attributes (fields and values) for the advanced condition.
3. Click the context menu icon. In the context menu, the first seven categories (**Activities**, **Additional Info**, **Analysis**, **Events**, **General**, **Patients**, and **Products**) represent the Argus case form tabs. In these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

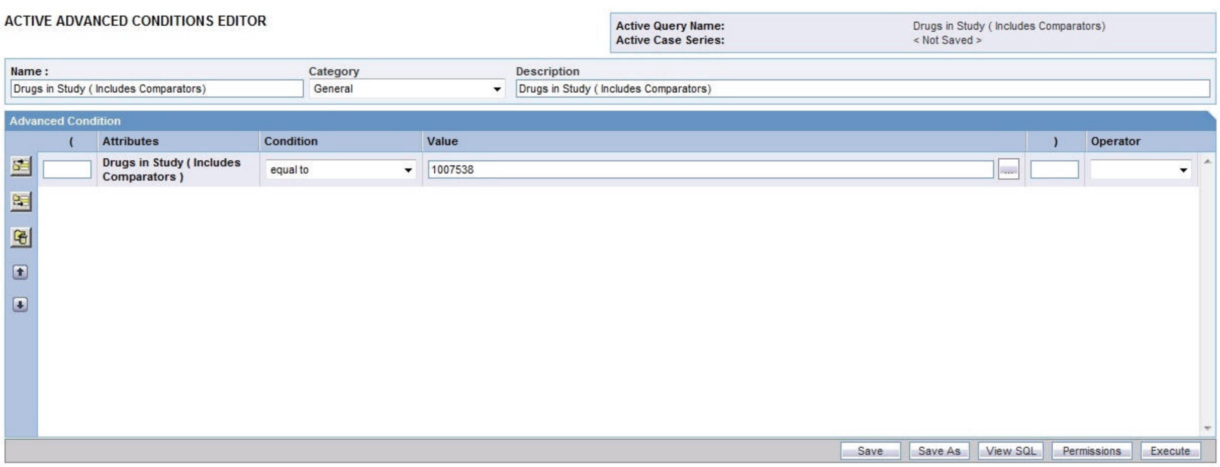
   You can browse through the appropriate hierarchy and select the required *field* as an advanced condition attribute.

   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.

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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.

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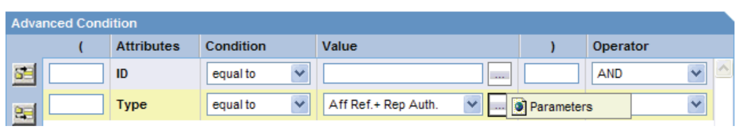
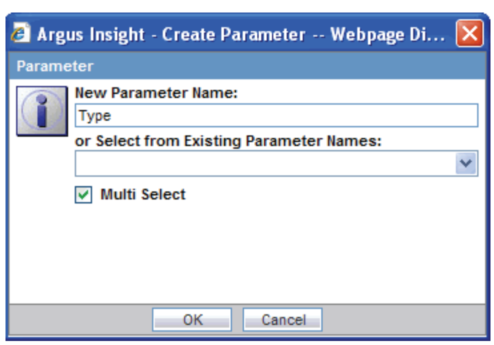
10. Identify the attribute row where you want to specify runtime parameters.
11. Click the ellipsis button next to the **Value** field, and then select **Parameters** from the menu.



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

If 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.

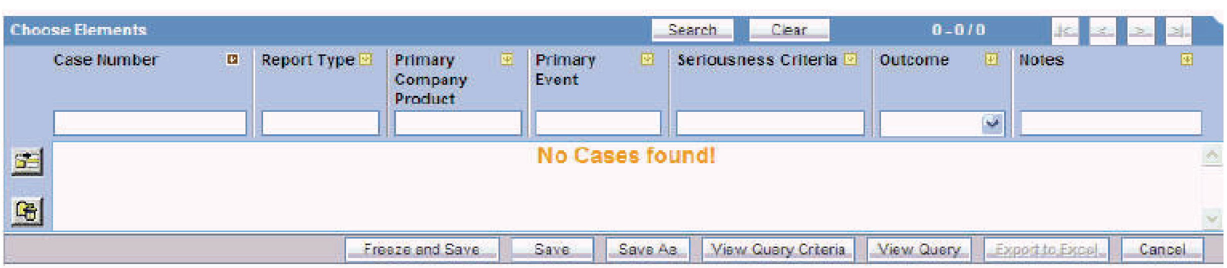
Tip: To cancel the query execution at this point and return to the Advanced Conditions Editor, click **Cancel Query.**

- 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.

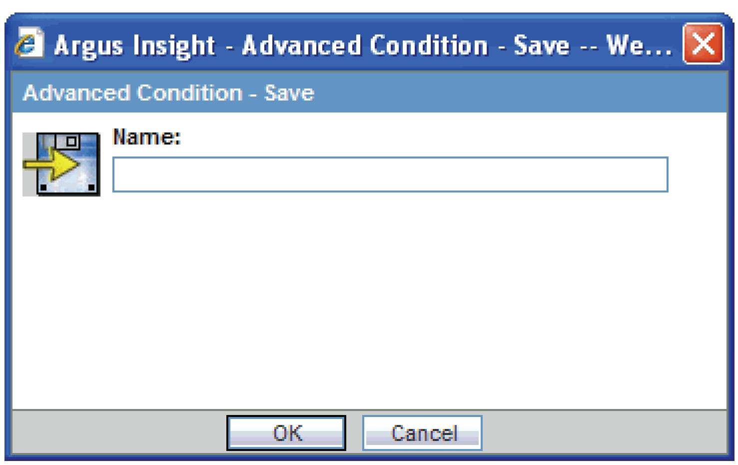
> **Note:** When you save the modifications to an advanced condition or execute it, the system assigns the active status to the advanced condition. Therefore, when you return to the editor after executing the advanced condition, the page title changes to ACTIVE ADVANCED CONDITIONS EDITOR. The field values 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.



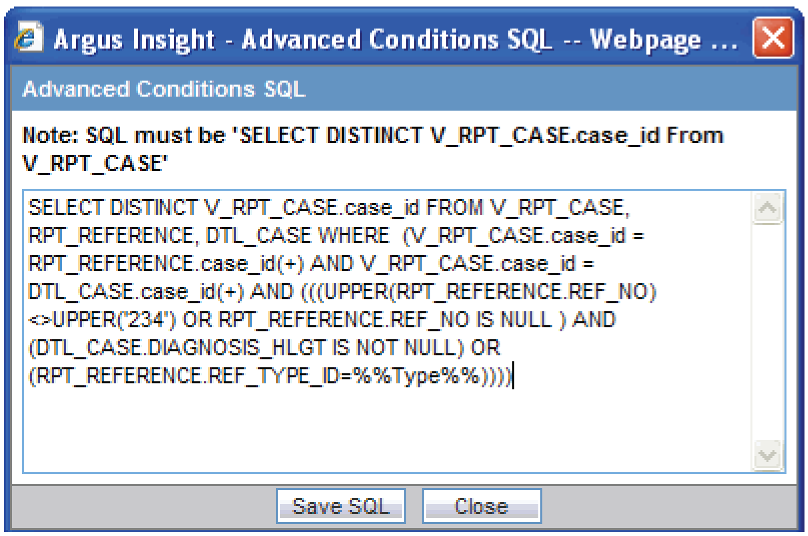
3. Type the name of the advanced condition in the **Name** field.
4. Click **OK** to save the advanced condition and refresh the ACTIVE ADVANCED CONDITIONS EDITOR page. Note that:

- 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.



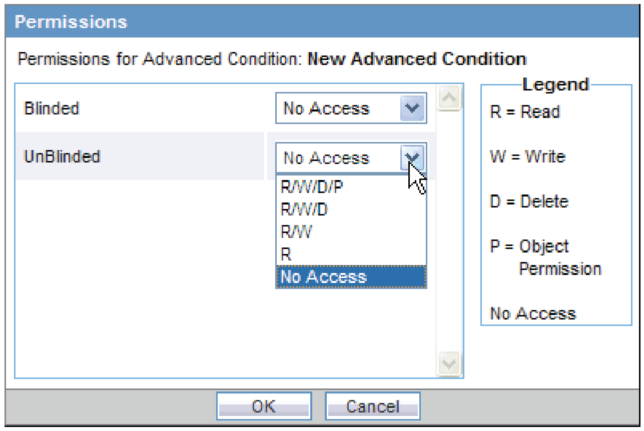
   a. Modify the SQL, if necessary.
   b. Click **Save SQL** after editing the query.

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:

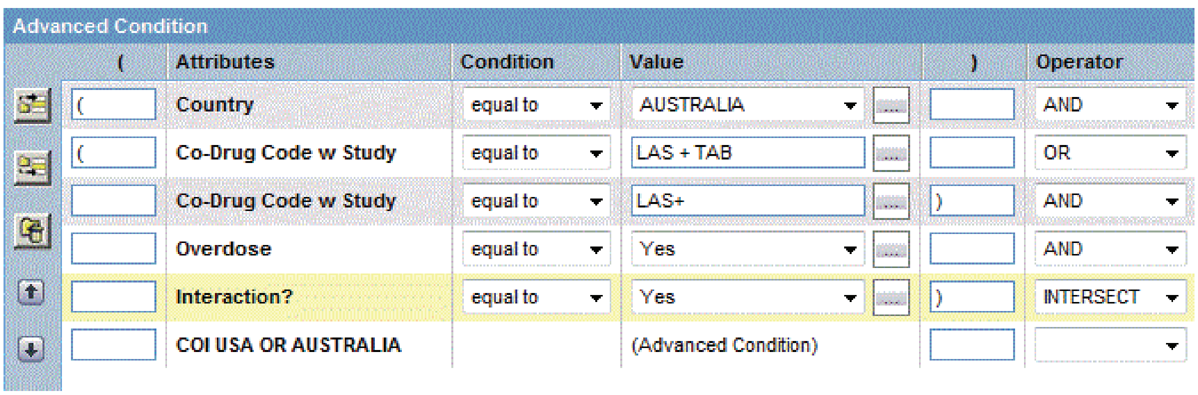
WHERE Country = "United States" OR Country = "Australia"

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



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** (

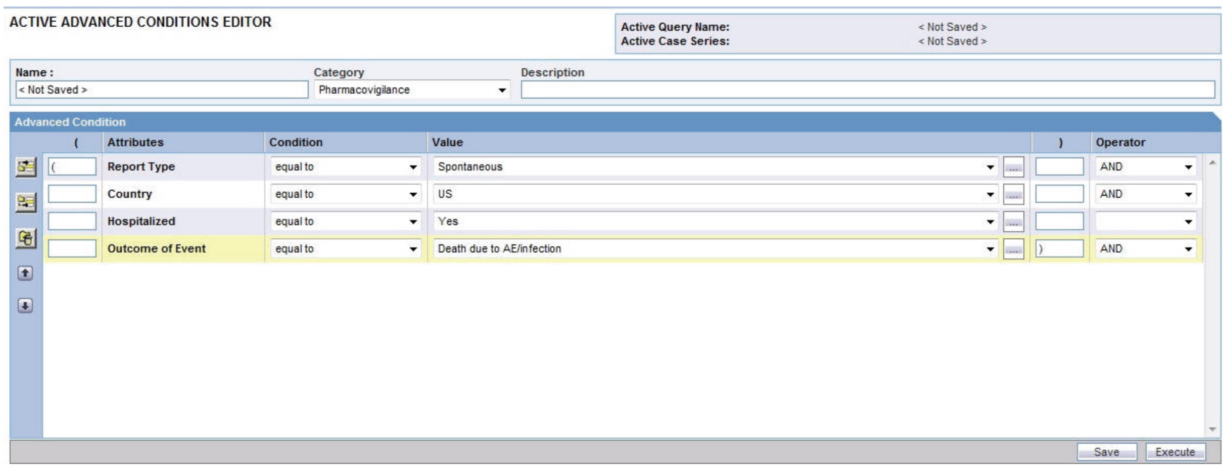
SELECT DISTINCT v_rpt_case.case_id
FROM v_rpt_case
WHERE (v_rpt_case.country_id = 13)
OR (v_rpt_case.country_id = 223))

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

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

   You can also rename an already saved advanced condition, by entering the new name in the **Name** field and clicking **Save**.

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

Task	Description
Modify the attributes in the Advanced Conditions Editor	If required, you can modify the attributes (fields and values) in the Advanced Conditions Editor. See "Creating a New Advanced Condition" on page 5-1 for more information. Click **Save** to save the changed *field* values. This button is only available for a saved active advanced condition.

Task	Description
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.
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 5-1 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

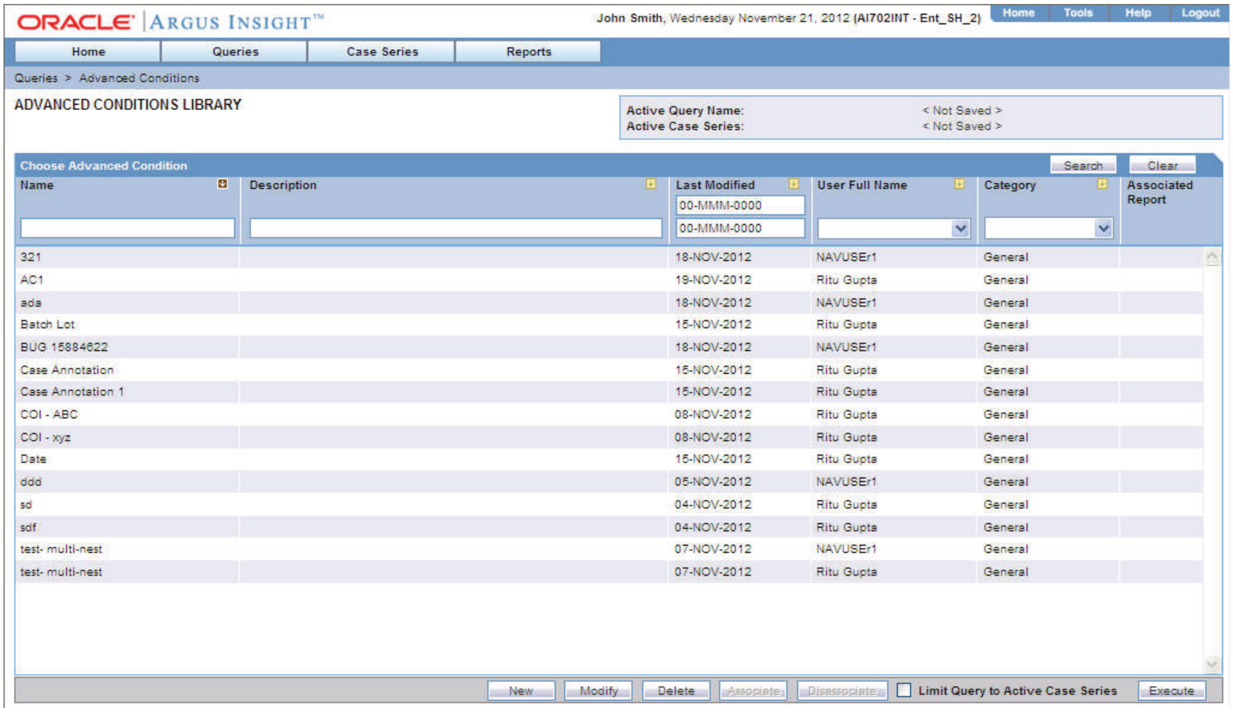
The ADVANCED CONDITIONS LIBRARY page lists all the advanced conditions saved to the system.

To access this page, navigate to **Queries, 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



Searching Saved Advanced Conditions

To search for a saved advanced condition:

1. 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.

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

   ---

2. Click **Search.** 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 5-1 for details.

Modifying an Advanced Condition

To modify an advanced condition:

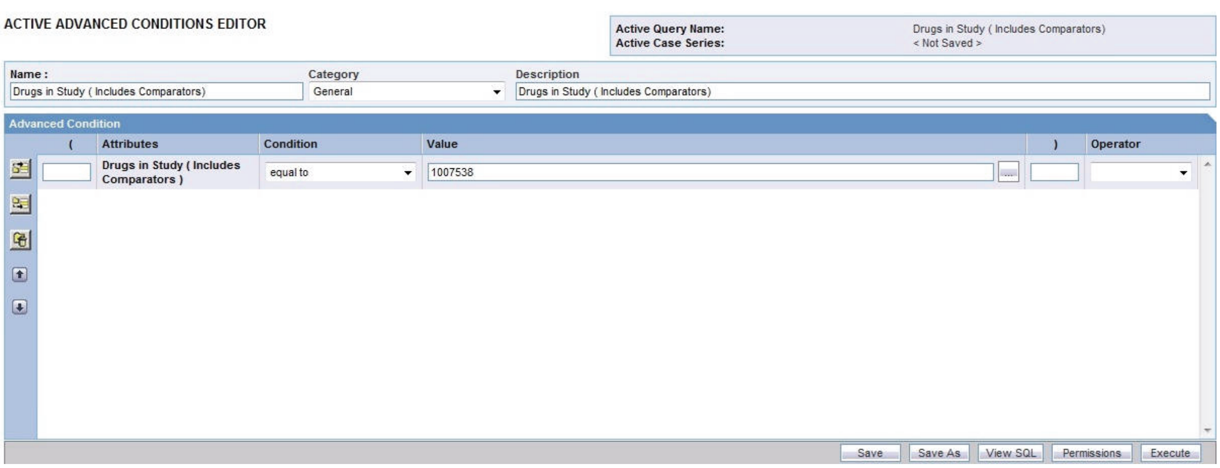
1. Navigate to the ADVANCED CONDITIONS LIBRARY page.
2. Select the advanced condition you want to modify.
3. Click **Modify.**
4. Make your modifications to the advanced condition, as appropriate.
5. Click **Save** to save your changes.

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

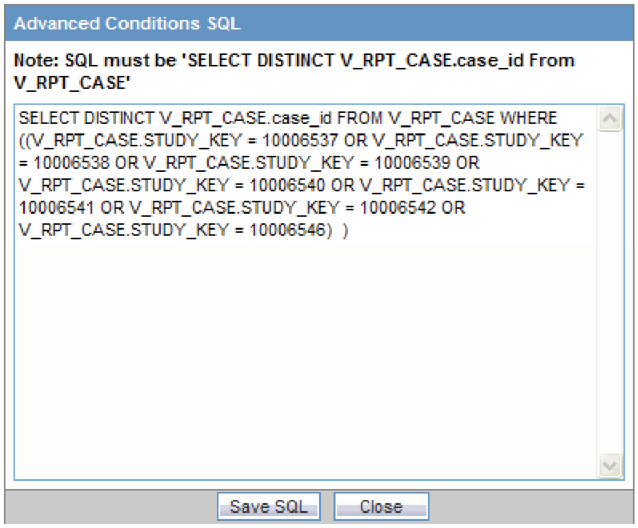
Modifying the SQL of an Advanced Condition

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.

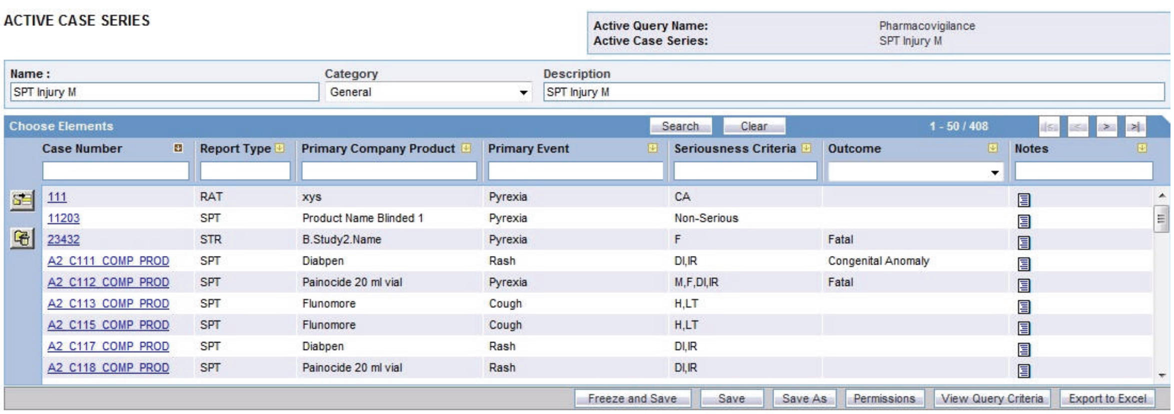
For detailed procedures and more information about associating report groups, see "Scheduling and Associating Reports Against a Query or Case Series" on page 8-9.

> **Note:** To be able to schedule reports, you must have an enterprise login configured in the Business Intelligence tool 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.



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

2. Navigate to **Queries, 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.

6 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

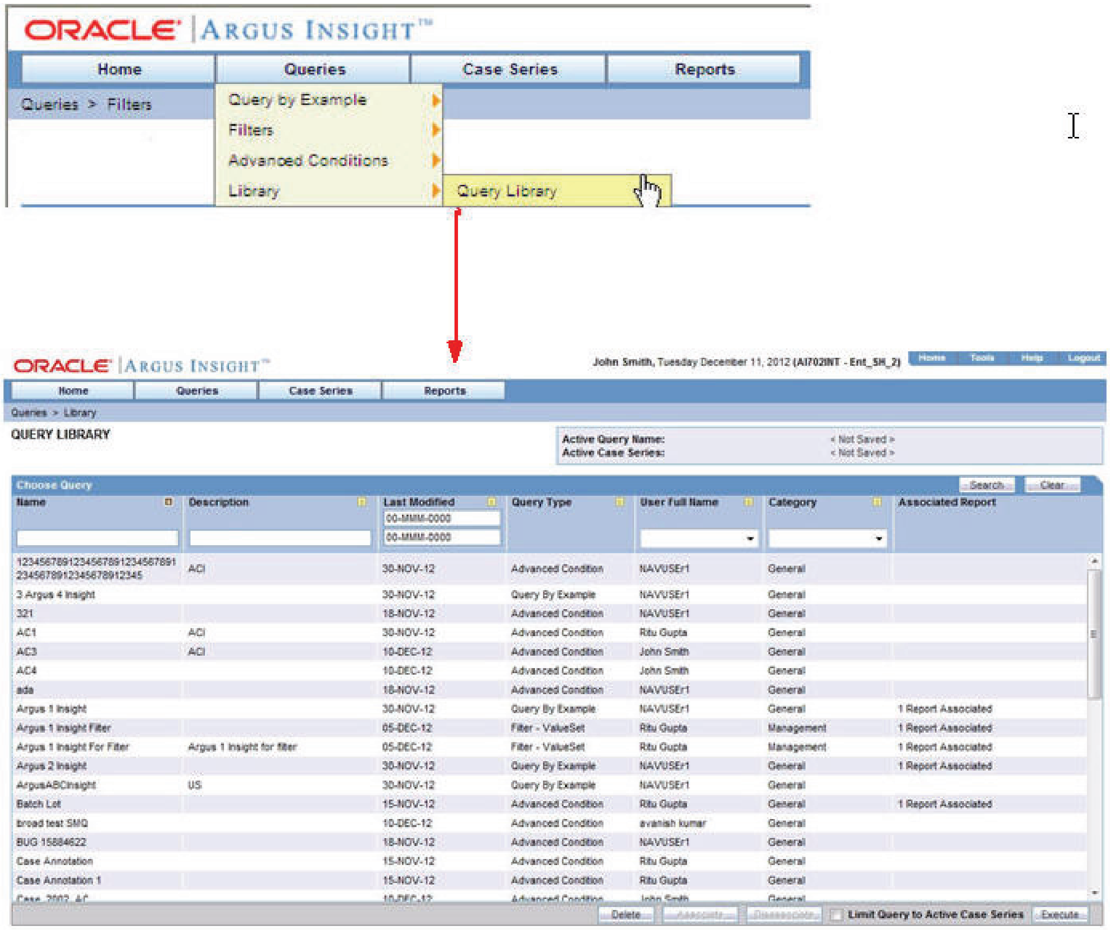
Viewing Save Queries in the Query Library

To view a list of all the saved queries, navigate to **Queries, 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.

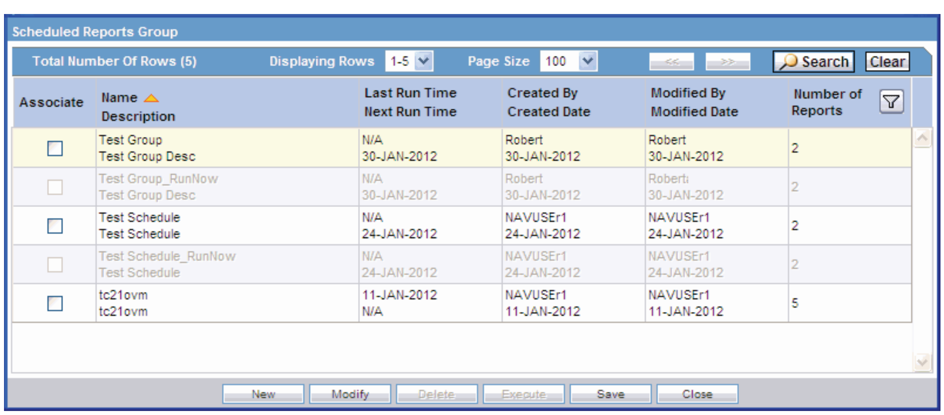
Figure 6–1 QUERY LIBRARY Page



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.



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

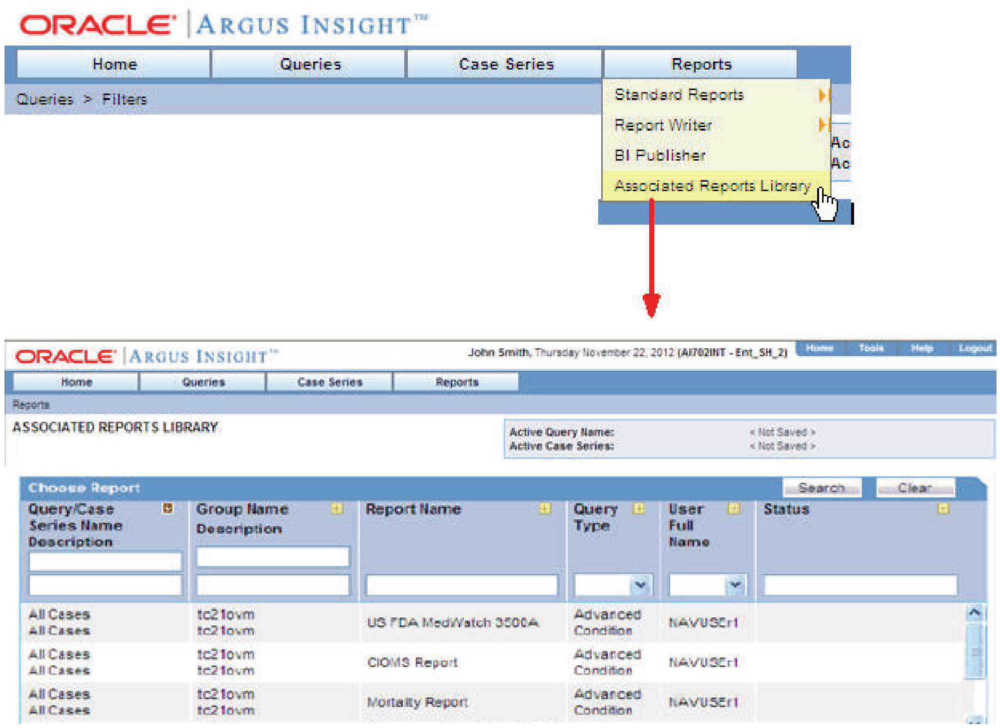
To view a list of all the reports associated with a query or a case series, navigate to **Reports** and select **Associated Reports Library.** The ASSOCIATED REPORTS LIBRARY page opens. See Figure 6–2.

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.

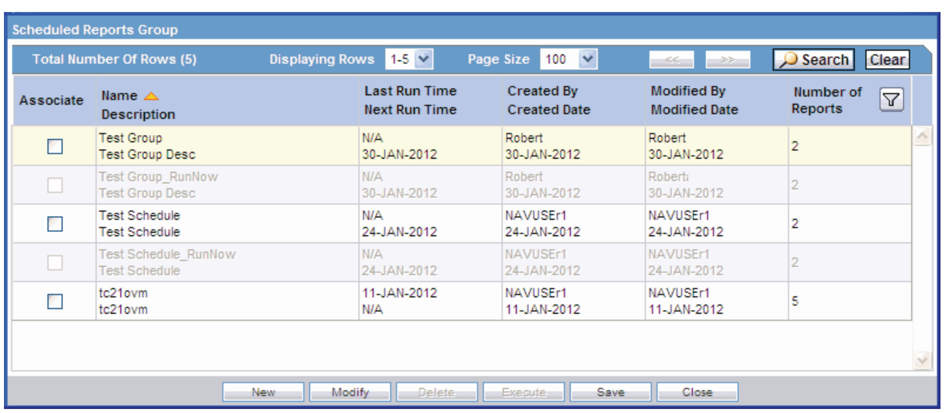
Figure 6–2 ASSOCIATED REPORTS LIBRARY Page



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.



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.**

7

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

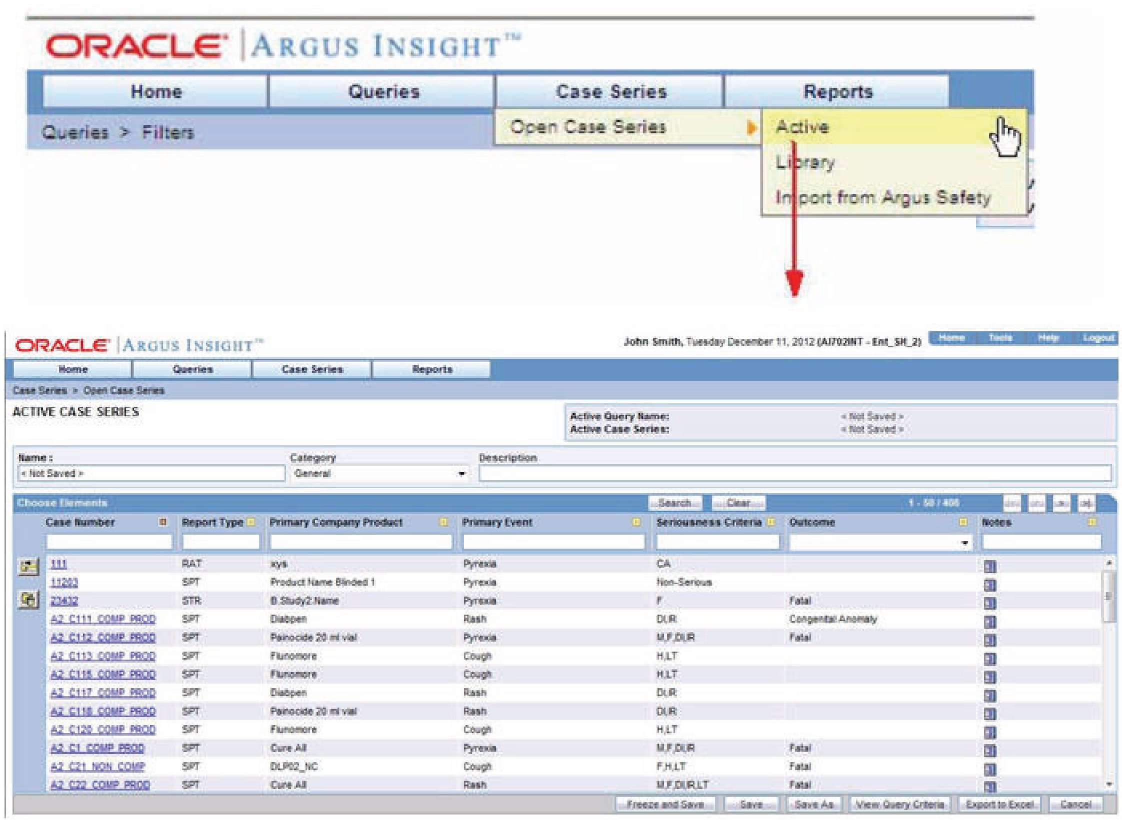
Viewing the Active Case Series

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 **Case Series, Open 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** field displays the text `<Not Saved>` until you save the case series by a name.

  You can enter the name of the case series in the **Name** field and click **Save**.

You can also rename an already saved case series, by entering the new name in the **Name** field and clicking **Save**.

Sorting, Searching, and Navigating

On the ACTIVE CASE SERIES page, use the tools in the table header (see Figure 7–2) to sort, search, and navigate through the list of cases.

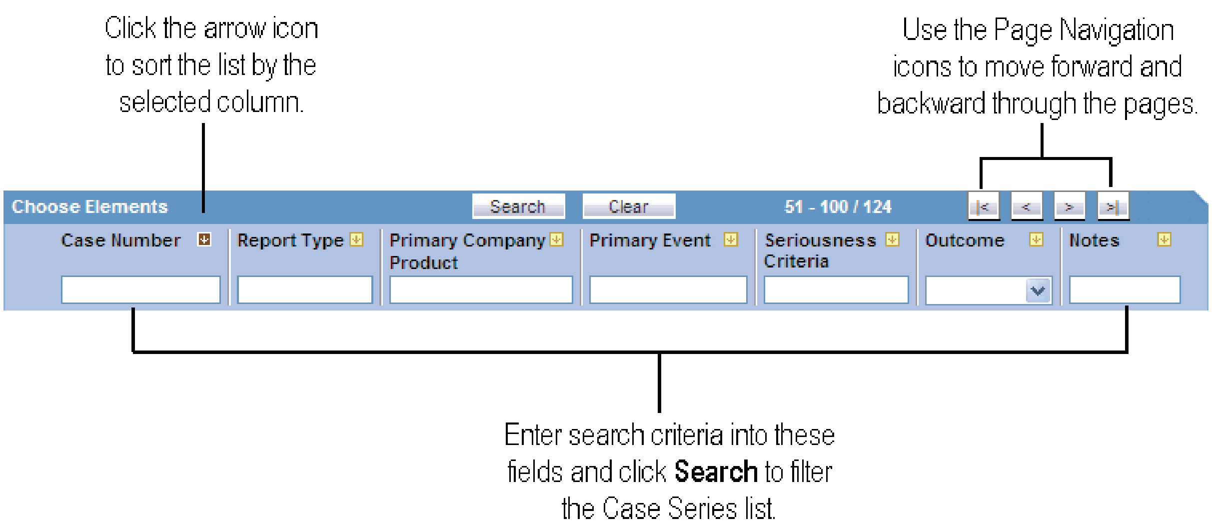
- To sort the list by a specific column, click the arrow icon next to a column heading.
- To filter the list, enter search criteria into one or more of the fields below the column headings, and then click **Search.**

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

- To move forward and backward through the pages of case series, click the Page Navigation icons. A page displays 50 cases.

When you export the data to a Microsoft Excel file, the system retains any changes you made to the sorting and filtering order. See "Exporting a Case Series to Microsoft Excel" on page 7-15 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 **Save As** to assign a name to the case series and save it to the Case Series library.

If you are modifying a case series that is already saved, click **Save** to save your modifications or click **Save As** to save the case series by another name.

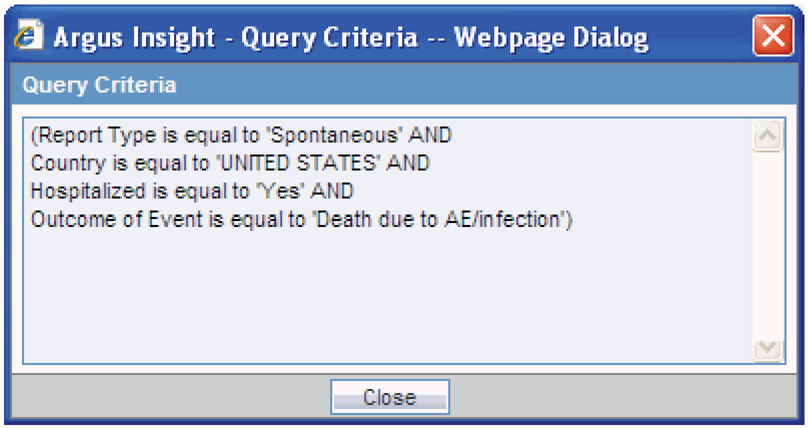
Viewing the Criteria that Generated the Active Case Series

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

- To return to the appropriate *Queries* page (QUERY BY EXAMPLE page, FILTER VALUE SET page, or ADVANCED CONDITIONS EDITOR page) and view the query criteria that generated the case series, click **View Query.**

  The **View Query** button is enabled *only if* the active case series is not yet saved to the system.

- To view the query criteria in a statement format, click **View Query Criteria.** The Query Criteria dialog box opens and displays the query. For example:



Assigning Group-Level Access Permissions

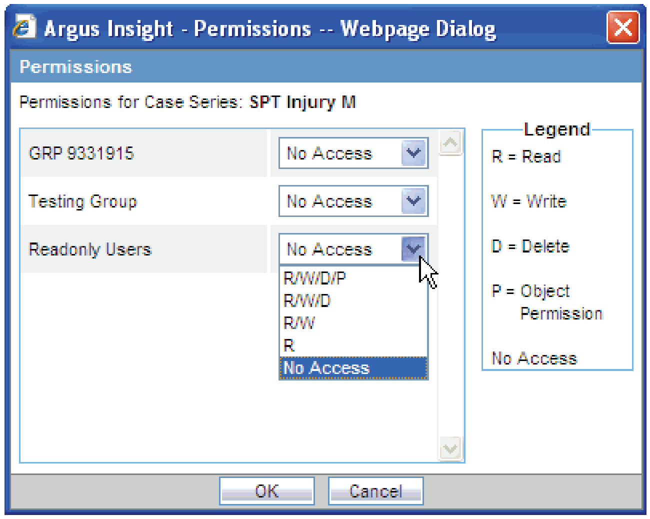
You can assign group-level access permissions for the case series. These permissions determine which user groups will be able to view, modify, or delete a case series.

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

To set case series permissions:

1. Navigate to **Case Series, Open Case Series,** and select **Active.** The ACTIVE CASE SERIES page opens.
2. 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.



3. 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.

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

Adding an Annotation to a Case

A *case annotation* is the addition of notes to a case. For example, you may want to add explanatory notes, critical comments about the case, or updates for the reporter. Adding relevant and important information about a case makes for better understanding of that case.

About Case Annotations

A case annotation:

- Supports a maximum of 200 characters.

- Is saved with the case series. Once entered, an annotation is saved for the case series. You do not need to explicitly save a case series to save the annotations.
- Is applicable for the case in only the same case series where it was saved. It is not applicable even for the same case if the case is in a different case series.
- Is frozen along with a frozen case series. Therefore, you cannot edit, add, or delete an annotation in a frozen case series.
- Is copied to a new case series if the case series where it was created is also copied.
- Is exported to Microsoft Excel when you use the Export to Excel feature.
- Is kept with a case if the case series is subsetted.
- Is retained when the case series merges with another case series. As shown in the following graphic, the Case Series #1 section title on the CASE SERIES MERGE page includes a statement that the notes from this series will be preserved in the merged case series:

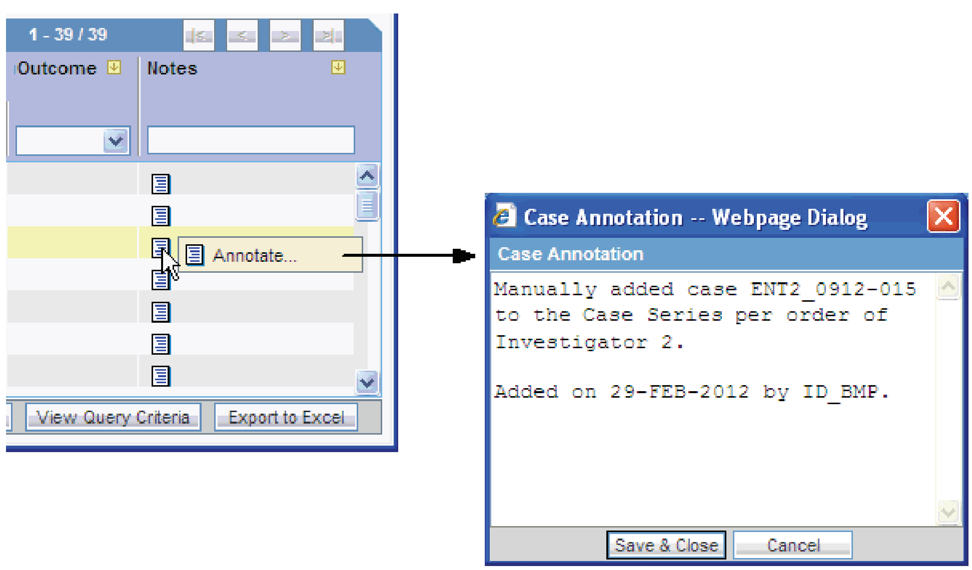
If you can access a case series, you can access its corresponding case annotations.

Annotations in the Active Case Series

For any case in the active case series, you 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.

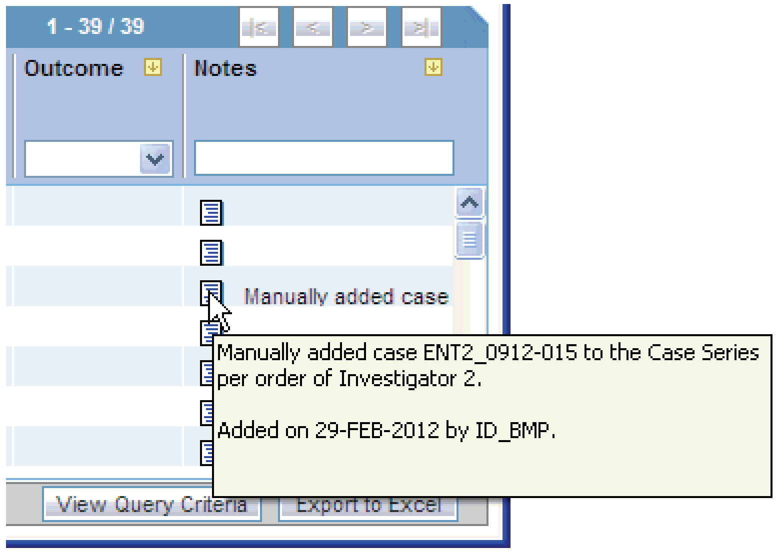


5. Type your notes, comments, or remarks about the case.

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:

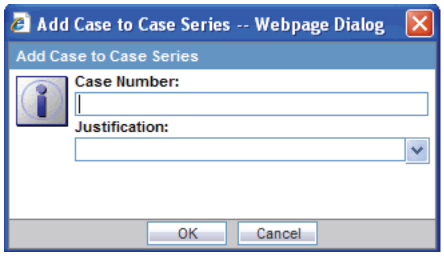
1. Navigate to **Reports, Report Writer,** and select **New.**
2. Navigate to **Report Writer, Case Series,** and select **Case Annotation.**
3. Click **Insert.**

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:

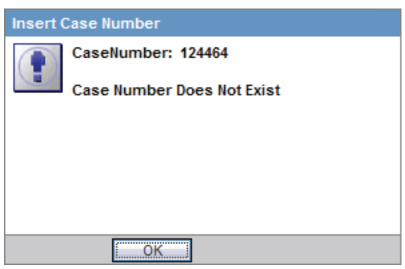
1. Navigate to the ACTIVE CASE SERIES page.
2. Click the **Add Case** icon on the left bar. The Add Case to Case Series dialog box opens.



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:

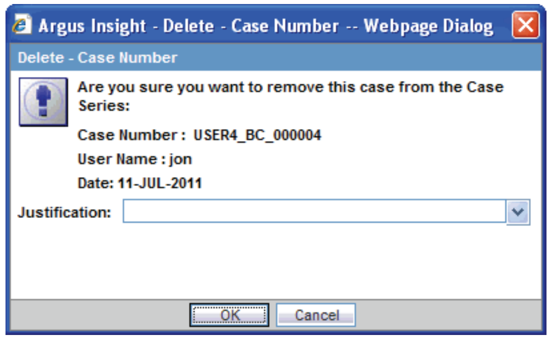


6. Click **OK** to close the message dialog box.

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

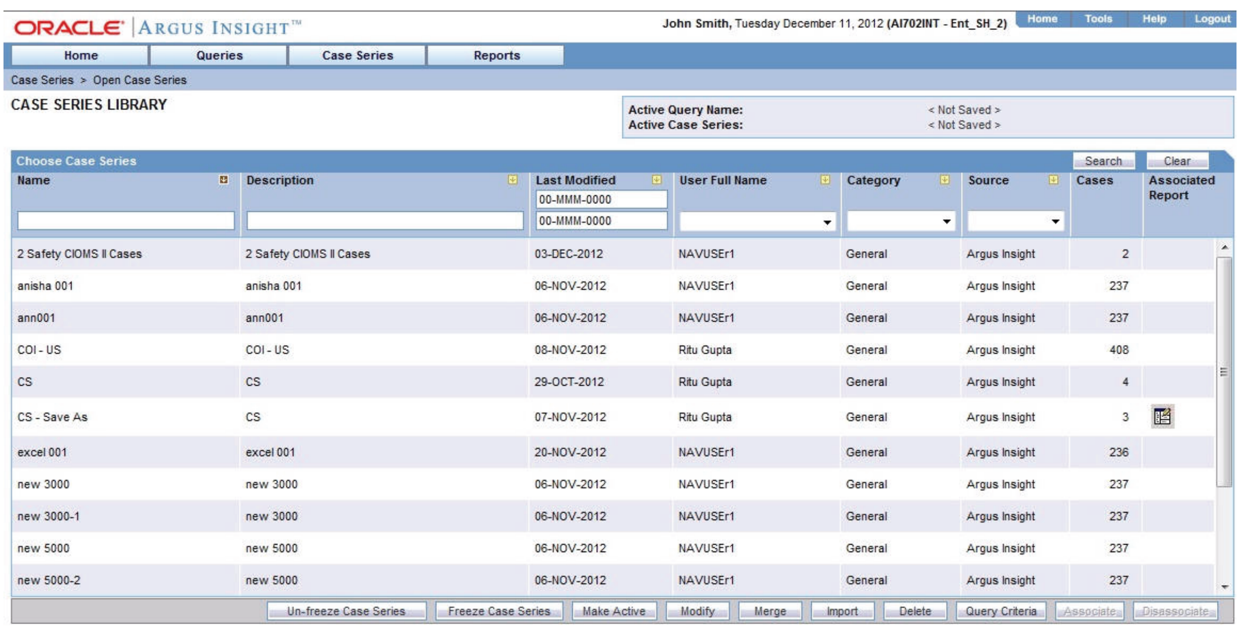
The CASE SERIES LIBRARY page, shown in Figure 7–3, lists all the case series saved to the system.

To open the CASE SERIES LIBRARY page, navigate to **Case Series, Open 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

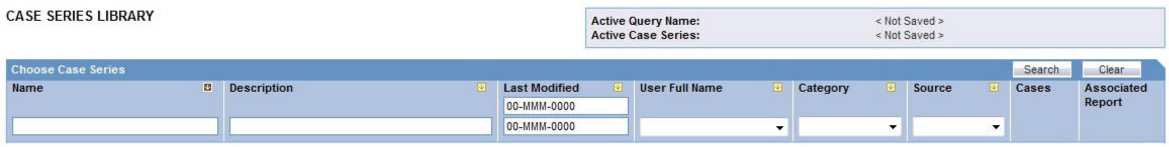


Searching for a Saved Case Series in the Library

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.



To search for a case series:

- By its name, type the name of the case series in the **Name** field.
- By its description, type part of the description in the **Description** field. The system searches for the specified text string in all case series descriptions.
- By its date of modification, enter the modification date in the first **Last Modified** date field. To specify a date range, type the start and end dates in the first and second date fields, respectively.
- By its author, select the author name from the **User Full Name** field.
- By its category, select the category from the **Category** field.
- By its source, select the source from the **Source** field.

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

---

3. Click **Search.** 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 7-1 for detailed information about making modifications to the case series and setting permissions.

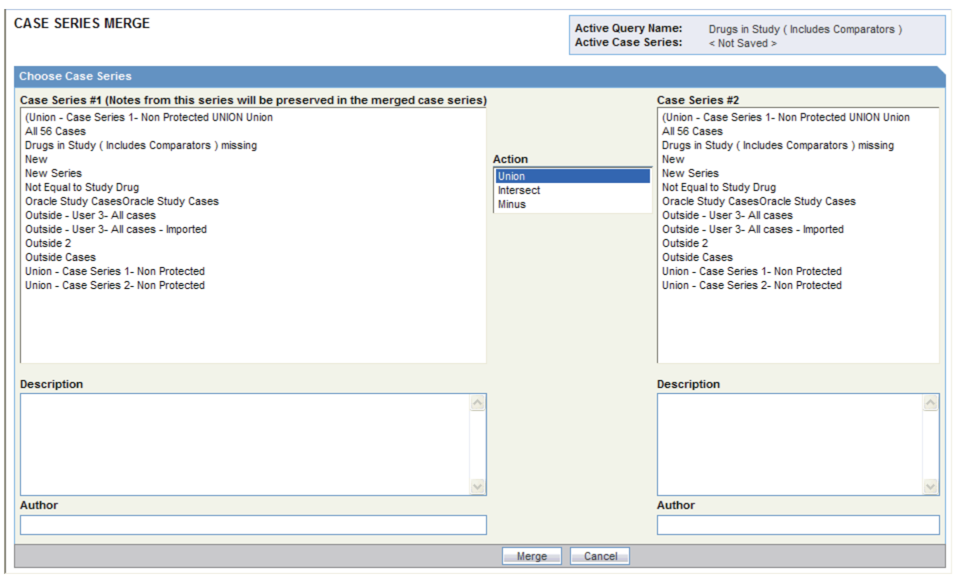
Merging Case Series

Argus Insight lets you create a new case series by merging two case series through a *set operator.* The set operator you select works on the case numbers. The case numbers included in the merged case series depend on the type of set operator you use:

- **Union —** Creates a new case series that contains all the cases in both case series; common case numbers are included, and are listed only once.
- **Intersect —** Creates a new case series that contains only those case numbers that exist in both case series.
- **Minus —** Creates a new case series that contains only those case numbers that are present in the first case series, but are not present in the second case series.

To generate a merged case series:

1. Navigate to the CASE SERIES LIBRARY page.
2. Click **Merge.** The CASE SERIES MERGE page opens.



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.

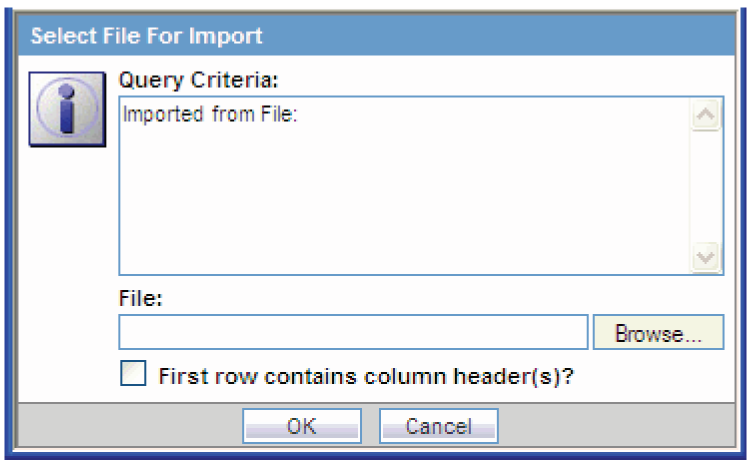
Importing a Case Series from an External Source

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.**

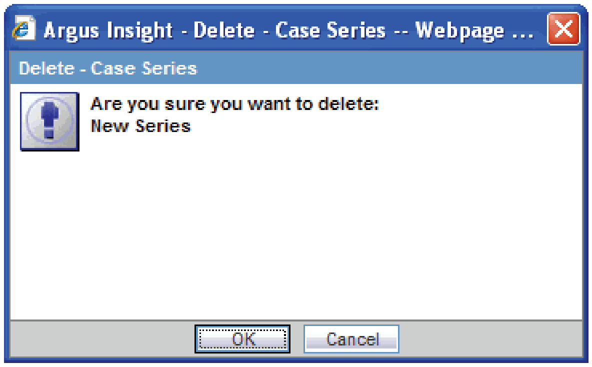
6. Click **OK** to display the imported case series on the ACTIVE CASE SERIES page.

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.

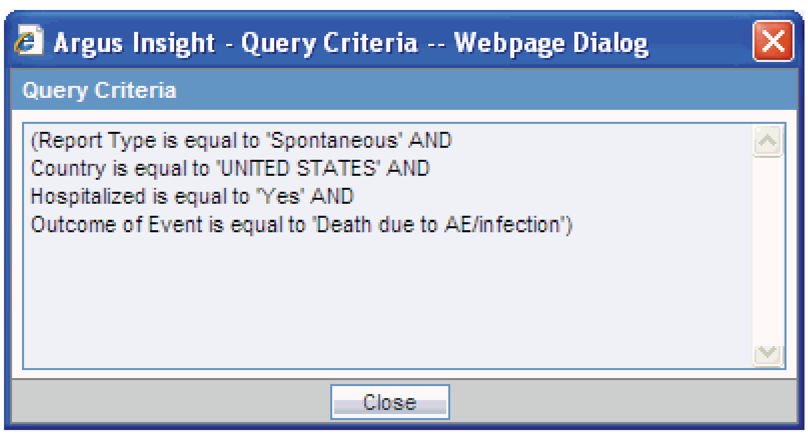


4. Click **OK** to delete the selected case series and return to the CASE SERIES LIBRARY page.

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 8-9.

Note: To be able to schedule reports, you must have an enterprise login configured in the Business Intelligence tool 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 **Case Series, Open Case Series,** and select **Import from Argus Safety.**

   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.

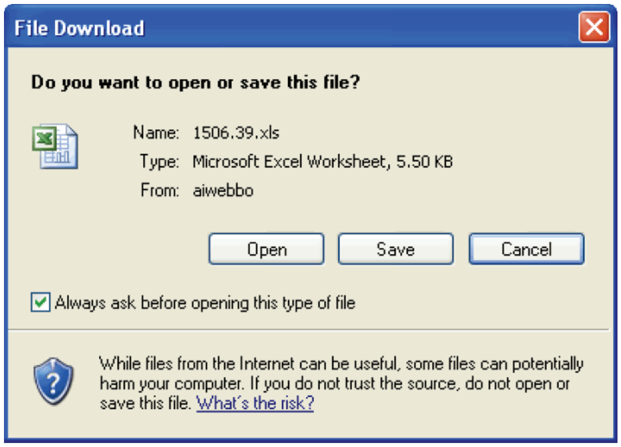
   ---

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.
4. Click **Export to Excel.** The File Download dialog box opens and prompts you to open or save the Microsoft Excel file.

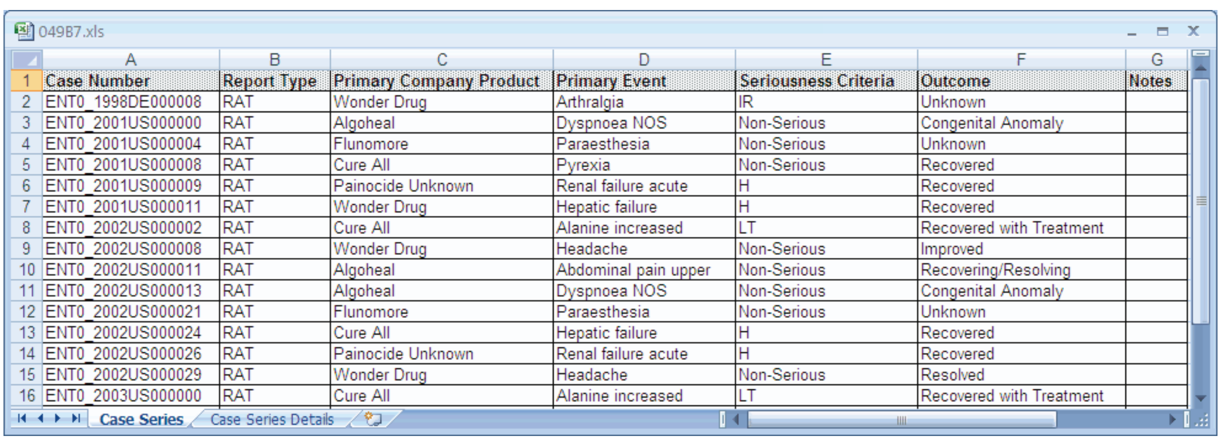


- To open the Excel file and view the case series results, click **Open.**
- To save the Excel file to your system, click **Save.** The system prompts for the location to save the file. Once the file is saved, you can open the file and view the case series results.

The Excel spreadsheet has two tabs:

- The **Case Series** tab provides information about each case in the case series, including the case number, report type, primary company product, primary event, seriousness criteria, and outcome. See in Figure 7–4.
- The **Case Series Details** tab provides information about the entire case series, including the name specified when the case series was saved, the total number of cases in the series, the description specified when the case series was saved, and the query criteria (in SQL-statement format) used to generate the case series.

Figure 7–4 Sample Case Series Exported to an Excel Spreadsheet



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

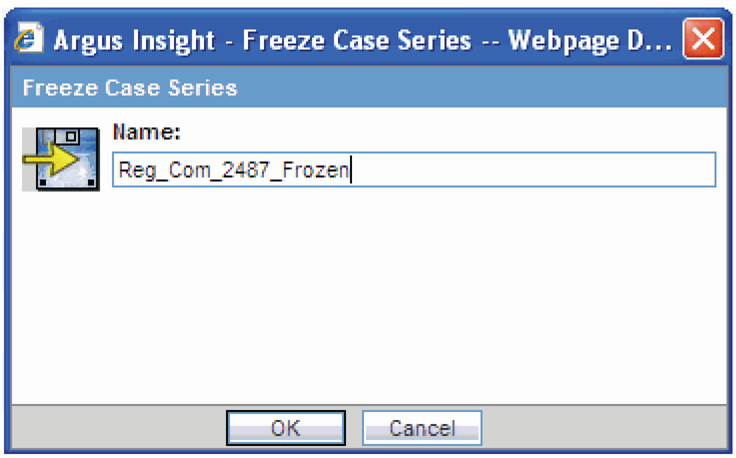
- List Maintenance items are not frozen. Therefore, some reports will have a mismatch of List Maintenance items and the frozen case series data.
- The derivation rules operate against current case data if the List Maintenance rules are modified. The frozen case series are shown if there is a change in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

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

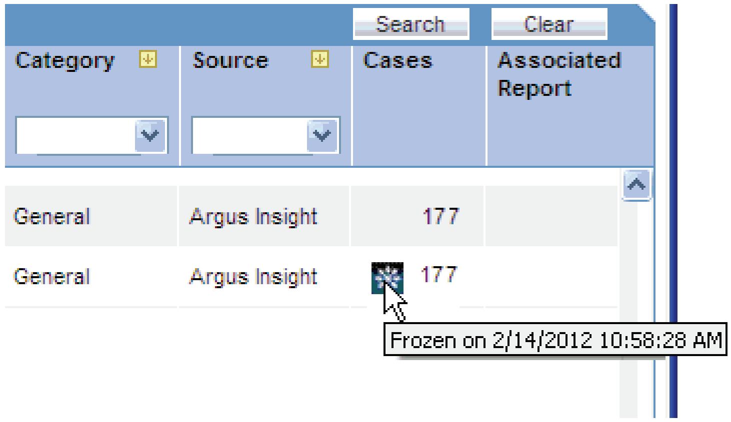


4. Enter a name for this frozen case series.
5. Click **OK.**

   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.



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.**

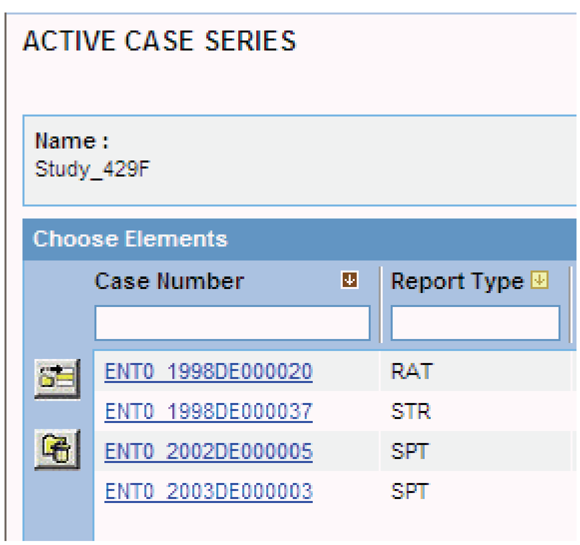
   The system retrieves the latest information for all the cases in the series, refreshes the CASE SERIES LIBRARY page, and displays the updated case series in the list.

   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.`

8

Generating and Scheduling Standard Reports - Cognos

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:

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 11, "Creating Custom Reports - Cognos."

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 3-38
- "Associating a Report Group with a Value Set" on page 4-19
- "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*.

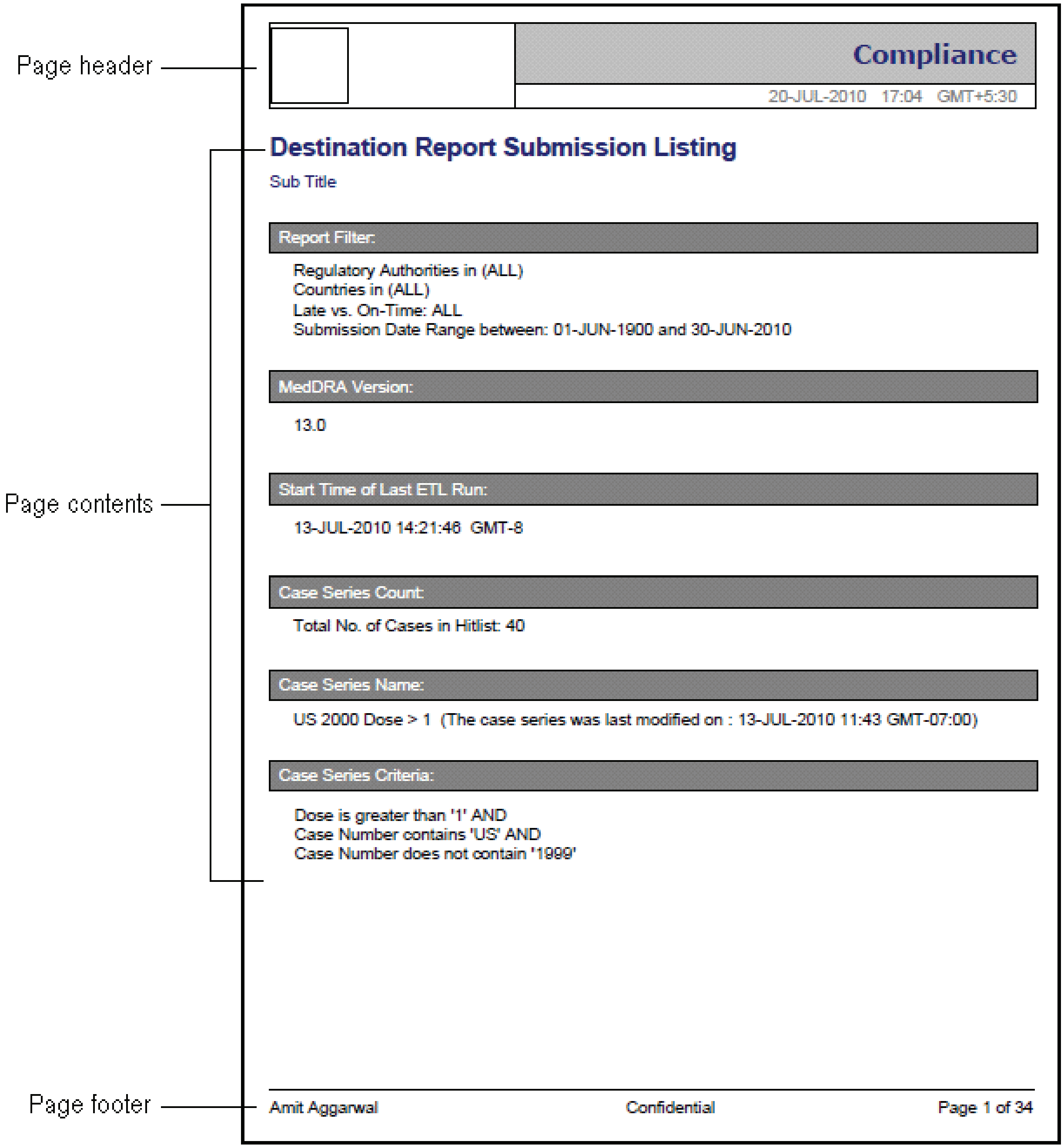
Report Cover Page

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



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 **Reports, Standard Reports,** and select an option.

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

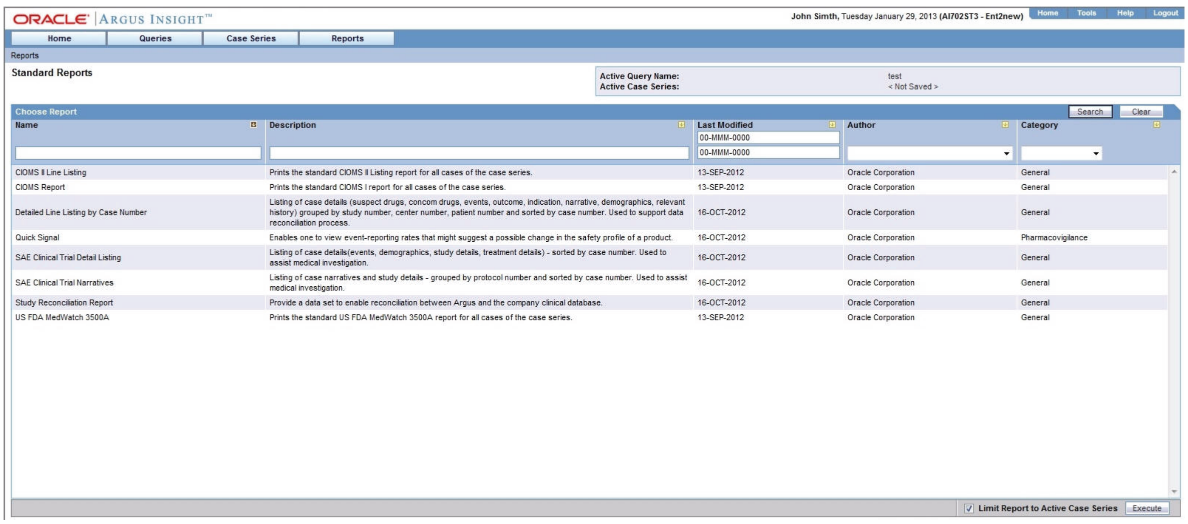
- Name of the report.
- Brief description of the report.
- Date when the report was last modified.
- Author of the report. For standard reports, the author is Oracle Corporation.

- 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

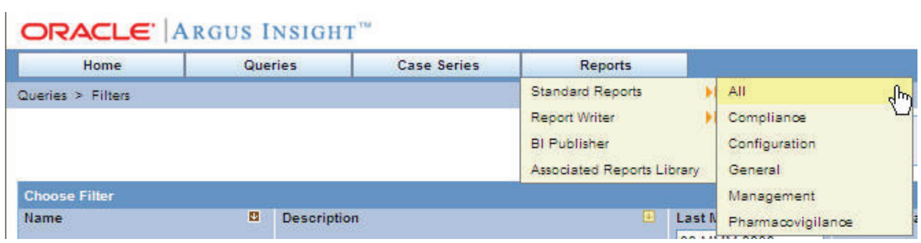
Figure 8–2 Sample Listing on the STANDARD REPORTS Page



Generating Standard Reports

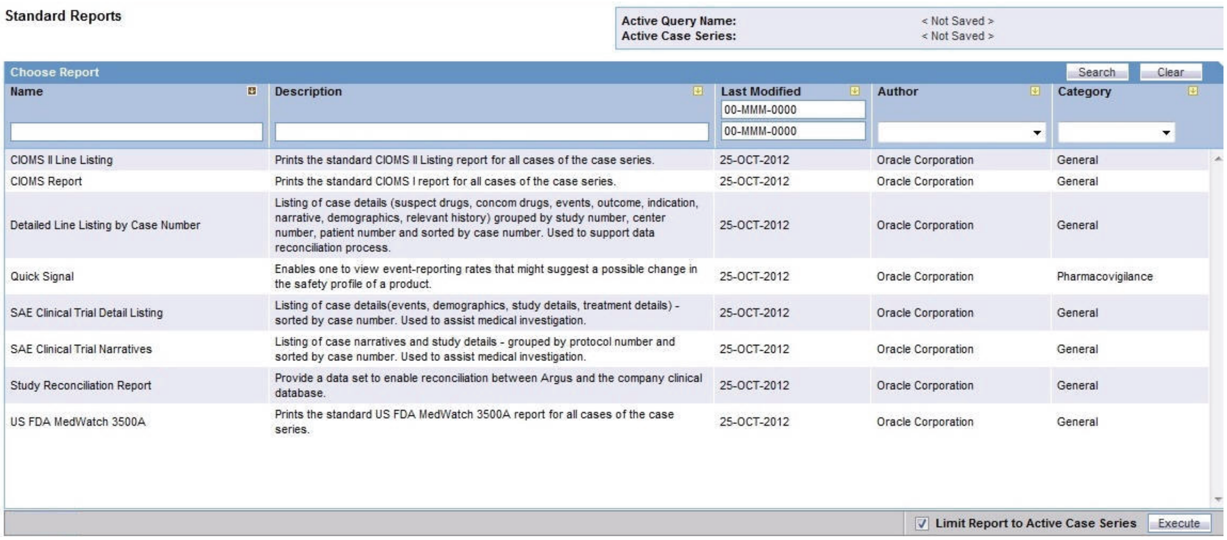
To generate a standard report:

1. Navigate to **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.

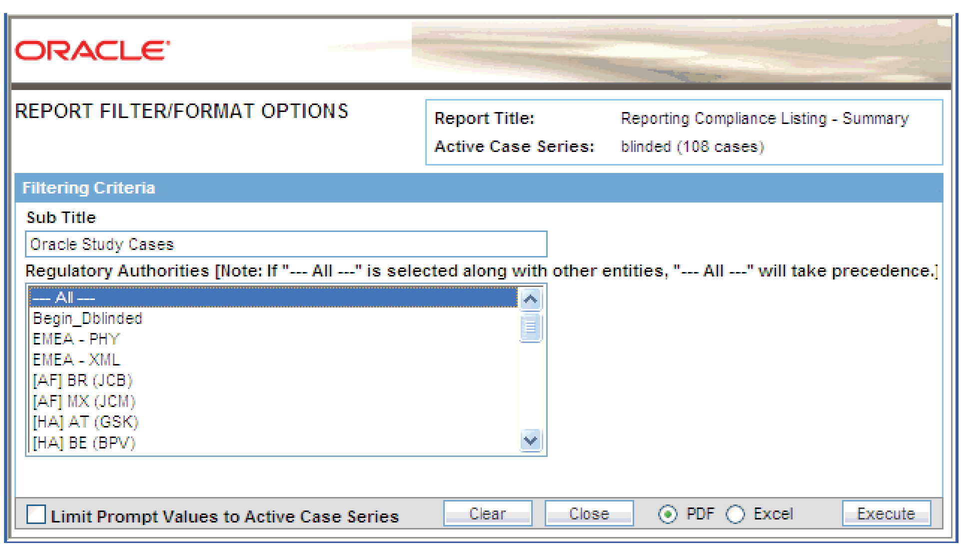
4. Select the **Limit Report to Active Case Series** check box to generate the report on the active case series only.

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 **Case Series, Open Case Series,** and select **Active.** To make a different case series active, navigate to **Case Series, Open 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.**

---

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



6. 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.

7. 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.

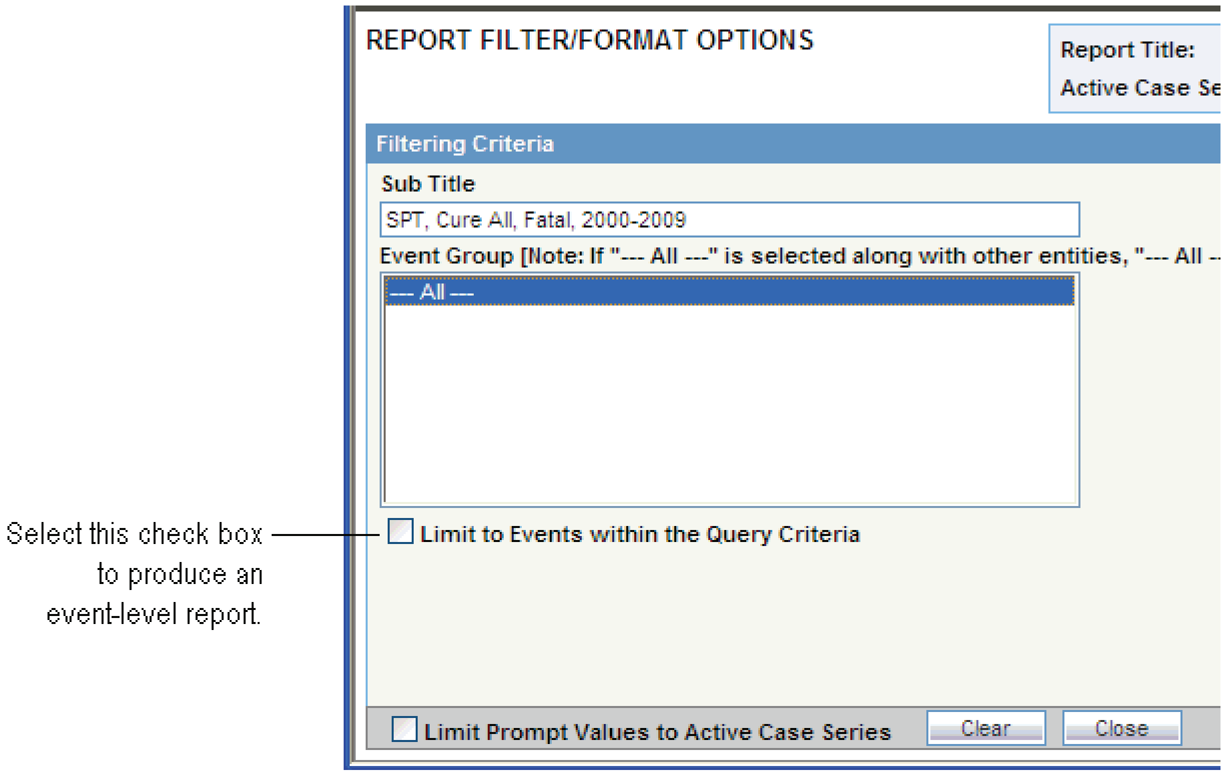
Event-level reporting is available for the following Pharmacovigilance standard reports only:

- 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



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 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.

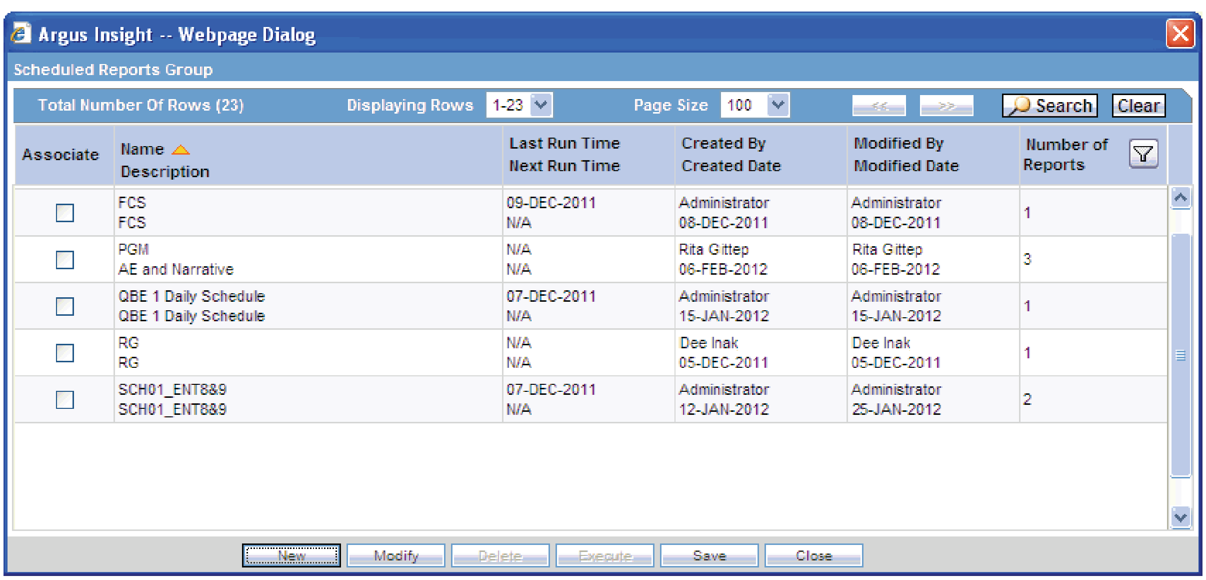
Working in the Scheduled Reports Group Dialog Box

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.

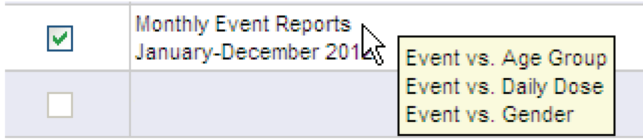
Each group can contain one or more reports. A *report group* means that all the reports are scheduled for the same time for a power query or a case series.

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:

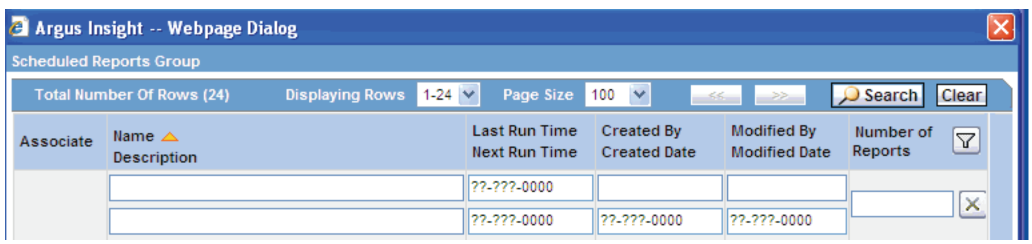


Viewing, Sorting, and Searching the Report Groups

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.

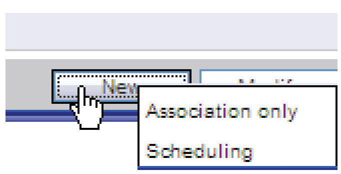
Note: If you search for a text comprising an underscore, it is treated as a wildcard and is replaced by a letter in the displayed results. For example, If you have queries with names - CURE, CORE, and CARE and you search for C_RE, all three queries are displayed in the result.



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.



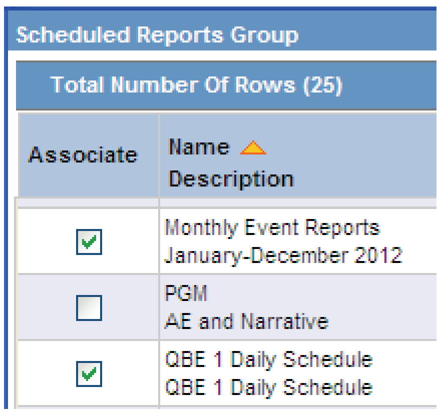
- Click **Modify** to change the settings for an existing scheduled report group.
- Click **Delete** to remove the selected report group. You can delete a report group *only if* the report group is not associated with a query or case series.
- Click **Execute** to close the Scheduled Reports Group dialog 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:

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 associate a report group.
3. Click **Associate.** The Scheduled Reports Group dialog box opens.
4. 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.



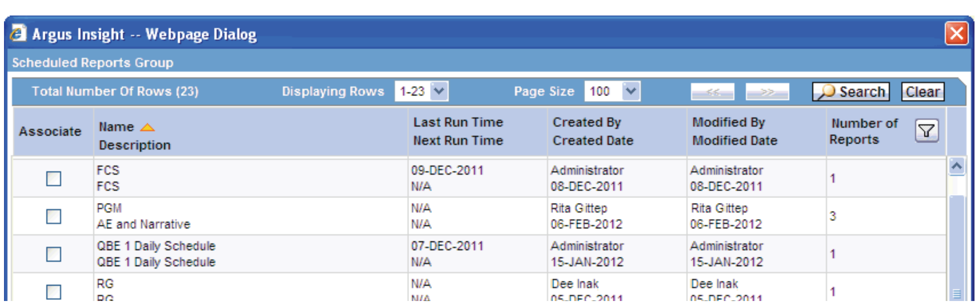
5. Click **Save.** The report groups are now scheduled for the selected query or case series.

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.**

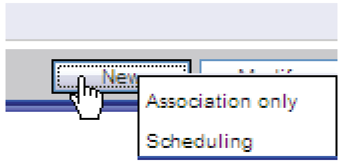
Creating and Scheduling a New Report Group

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.



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

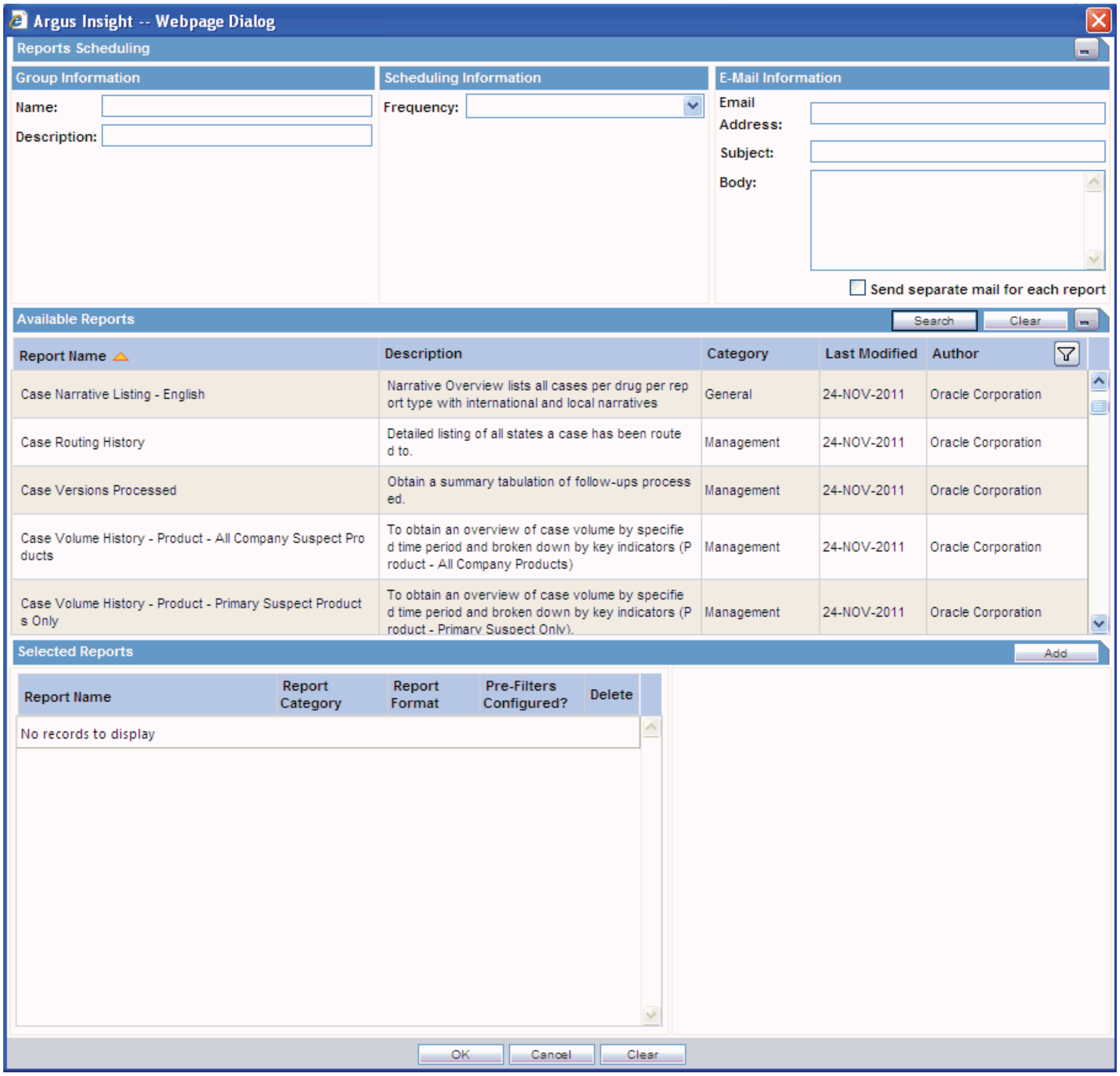
Working in the Reports Scheduling Dialog Box

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



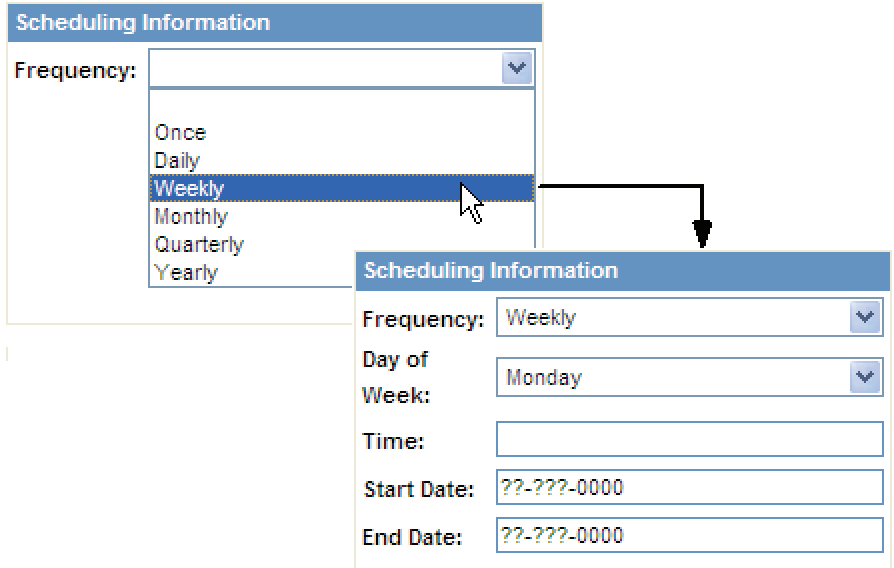
Entering the Report Name and Description

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.



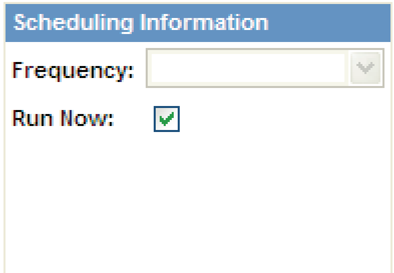
Based on the frequency option you select, enter the additional scheduling information:

- **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.

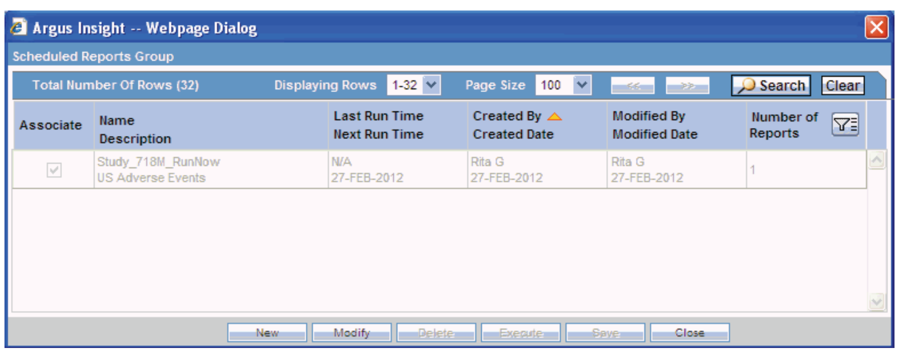


When you select the **Run Now** check box and save the scheduling information, Argus Insight saves the schedule to execute immediately.

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 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:

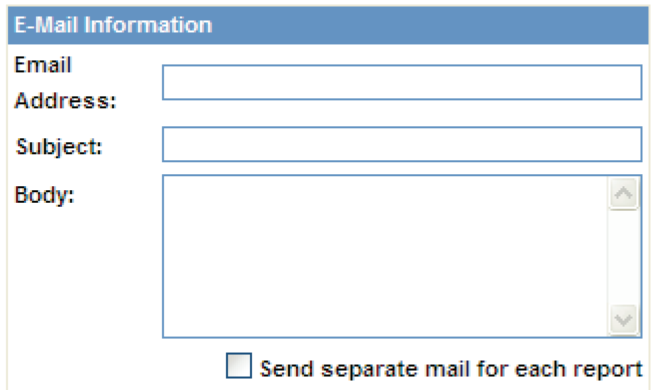


Note that the system:

- 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.



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.

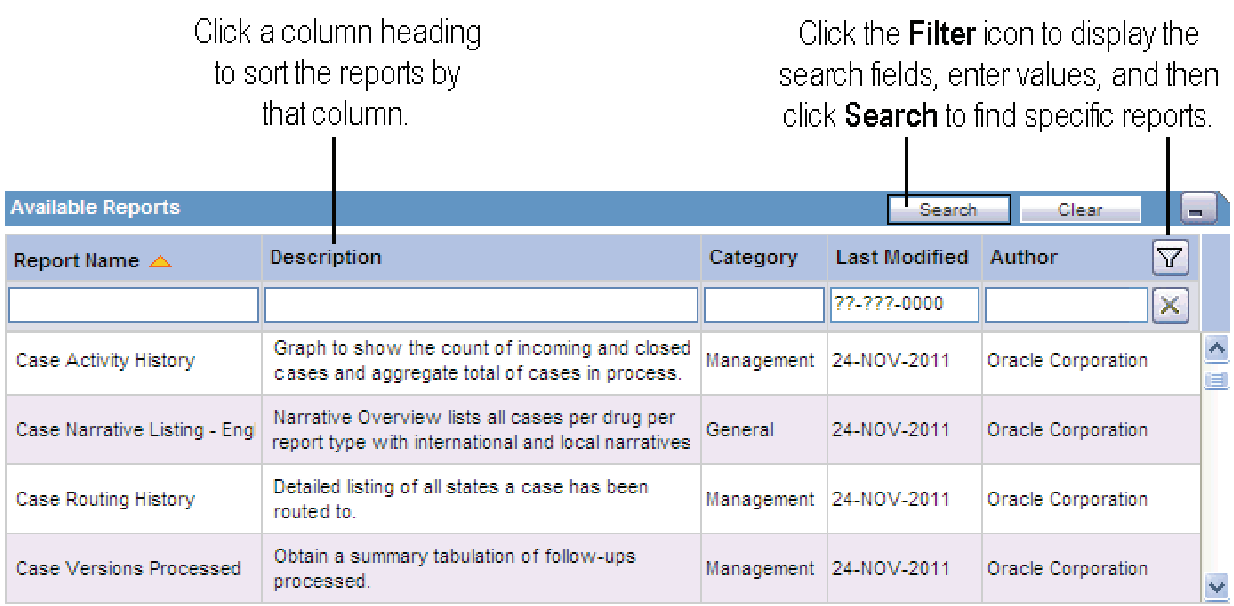
You can schedule multiple reports for a single QBE. Be sure to select the **Send separate mail for each report** check box if you want the system to send an email notification for each report generated.

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.



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.

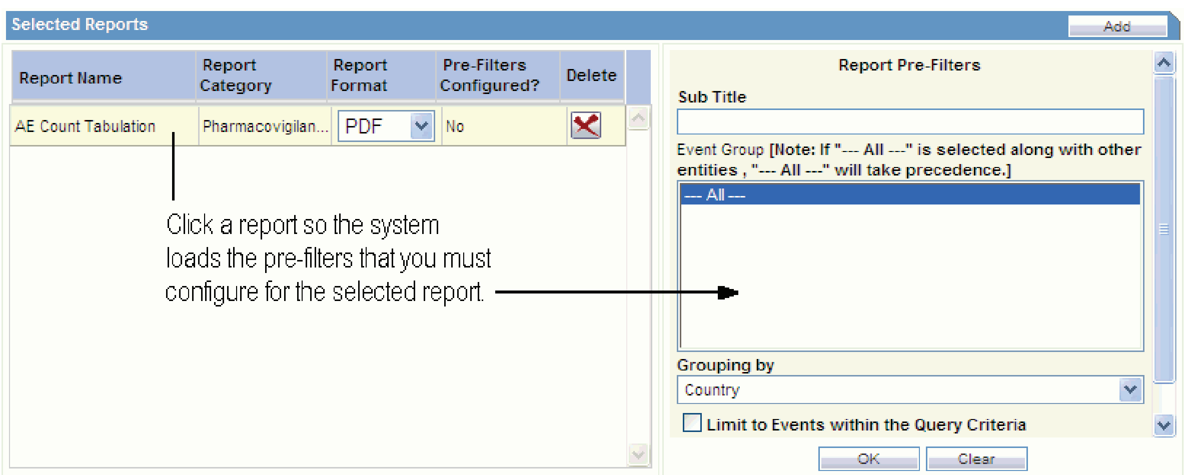
Entering Required Pre-filters and Selecting a Report Format

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.**

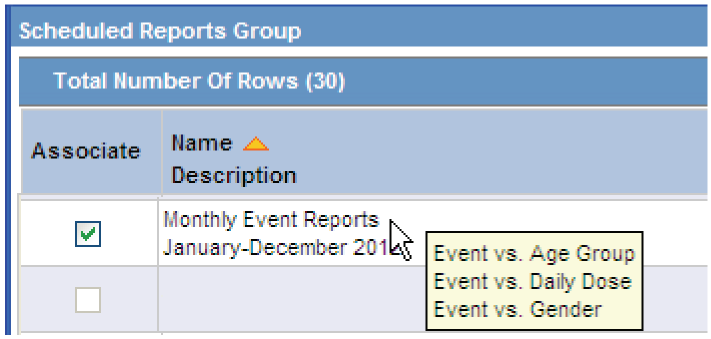
If you want to remove a report from this scheduling, click the **Delete** icon. The system prompts for confirmation before deleting the report.

Saving the Schedule

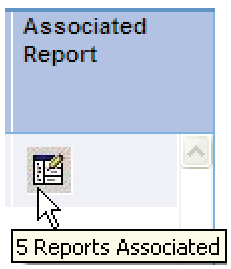
Click **OK** in the Reports Scheduling dialog box to save your report scheduling.

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.



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 **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 8-13 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.

Compliance Reports

There is no report under this category for the Argus Insight 7.0.2 Release.

Configuration Reports

There is no report under this category for the Argus Insight 7.0.2 Release.

General Reports

Table 8–1 describes the standard General reports.

Table 8–1 Standard General Reports

Report Title	Description
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.
Detailed Line Listing by Case Number	Case details (suspect drugs, concomitant drugs, events, outcome, indication, narrative, demographics, relevant history) grouped by study number, center number, and patient number, and sorted by case number. Used to support data reconciliation process.
SAE Clinical Trial Detail Listing	Case details (events, demographics, study details, treatment details) — sorted by case number. Used to assist medical investigation.
SAE Clinical Trial Narratives	Case narratives and study details — grouped by protocol number and sorted by case number. Used to assist medical investigation.
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

There is no report under this category for the Argus Insight 7.0.2 Release.

Pharmacovigilance Reports

Table 8–2 describes the standard Pharmacovigilance reports.

Table 8–2 Standard Pharmacovigilance Reports

Report Title	Description
Quick Signal	List of the event-reporting rates that might suggest a possible change in the safety profile of a product.

9

Generating and Scheduling Standard Reports - BusinessObjects

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 11, "Creating Custom Reports - Cognos."

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 3-38
- "Associating a Report Group with a Value Set" on page 4-19
- "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*.

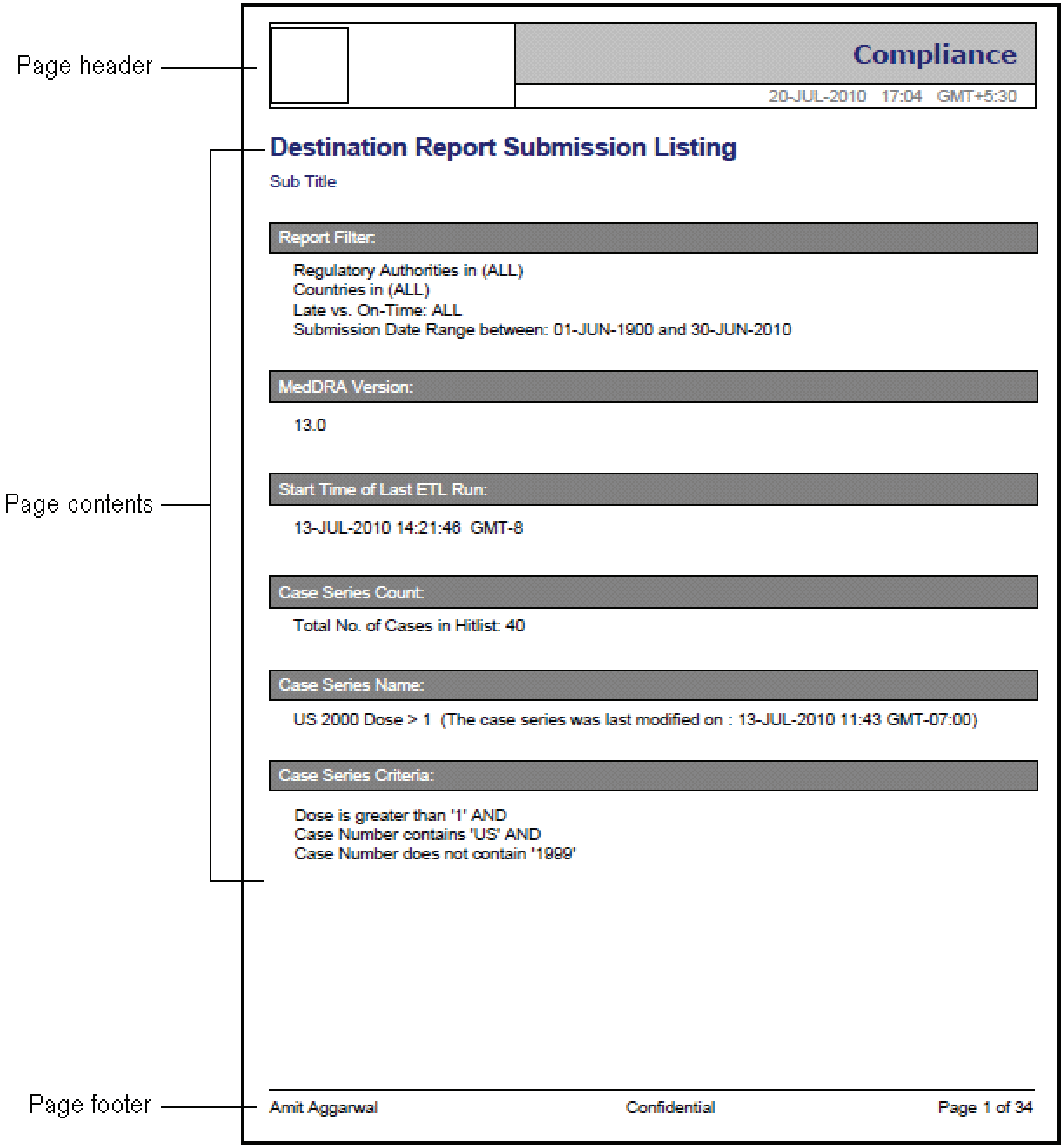
Report Cover Page

Figure 9–1 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 9–1 Sample Report Cover Page



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 9–2, lists all the standard reports built in to Argus Insight.

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

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

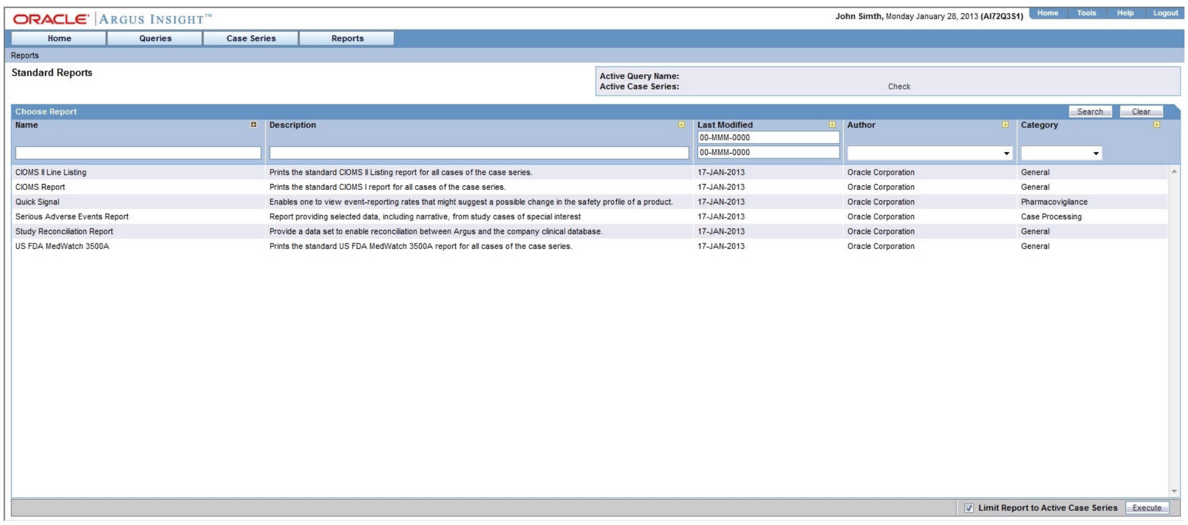
- Name of the report.
- Brief description of the report.
- Date when the report was last modified.
- Author of the report. For standard reports, the author is Oracle Corporation.

- 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.

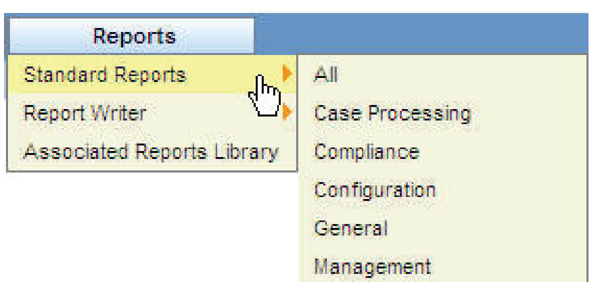
Figure 9–2 Sample Listing on the STANDARD REPORTS Page



Generating Standard Reports

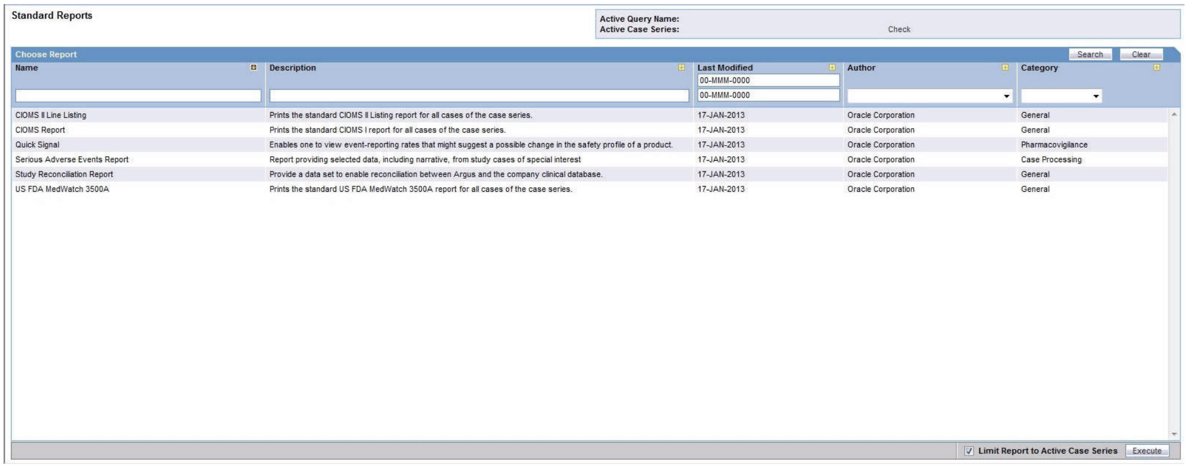
To generate a standard report:

1. Navigate to **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 **Case Series, Open Case Series,** and select **Active.** To make a different case series active, navigate to **Case Series, Open 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.**

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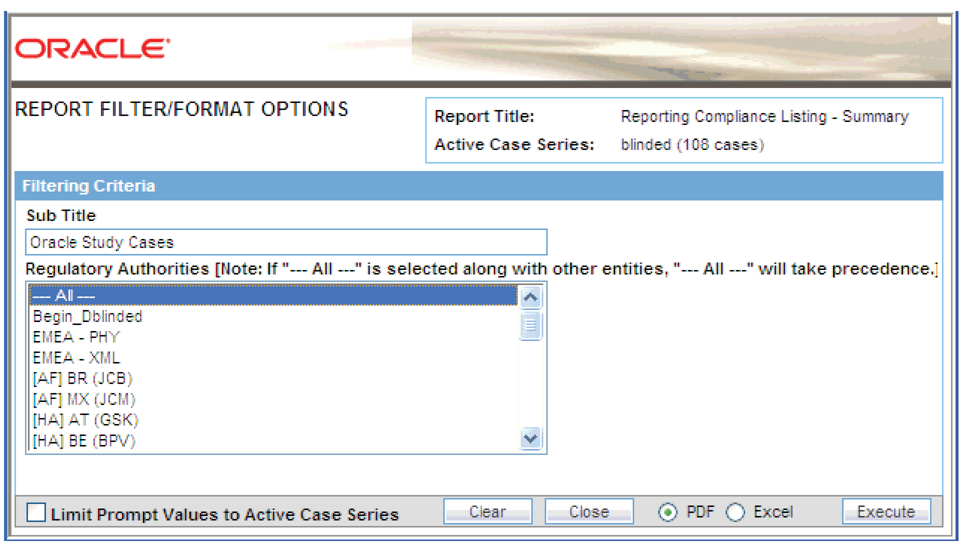
5. Click **Execute.** The system opens a new browser window that displays the REPORT FILTER/FORMAT OPTIONS page.



6. 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.

7. 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.

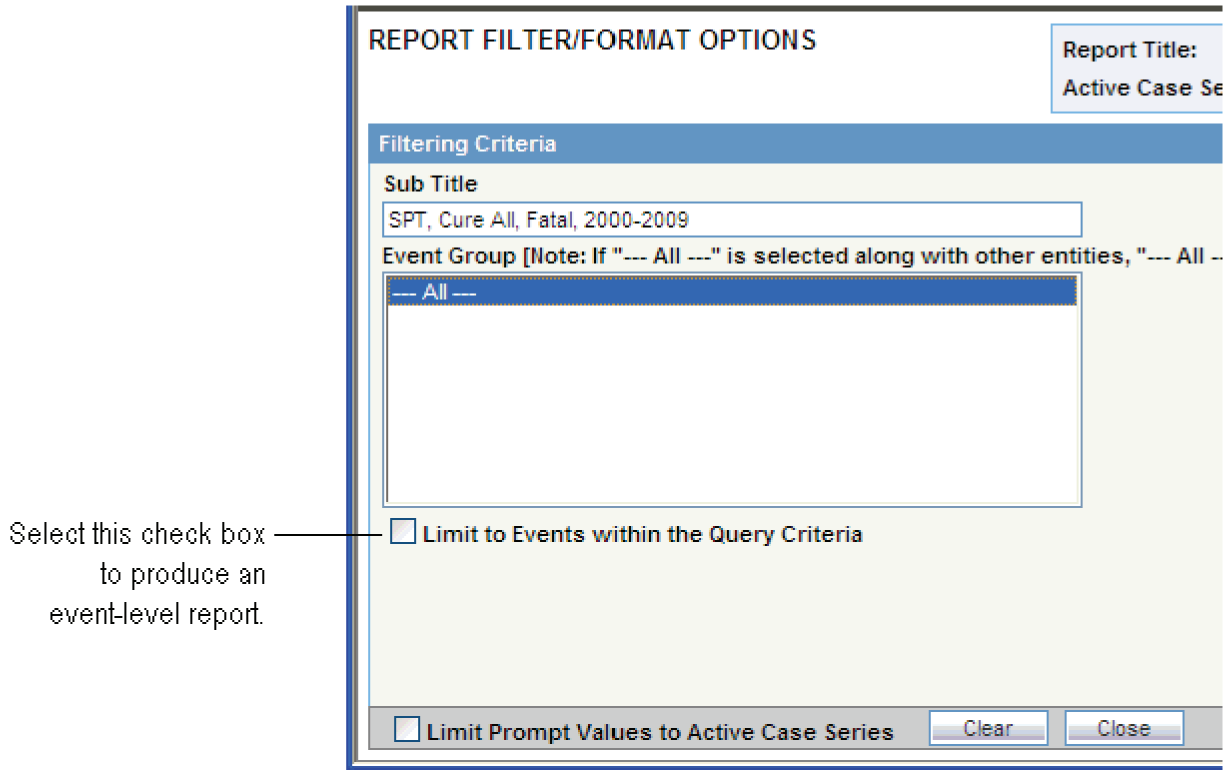
Event-level reporting is available for the following Pharmacovigilance standard reports only:

- 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 9–3.

Figure 9–3 Options for Producing 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 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.

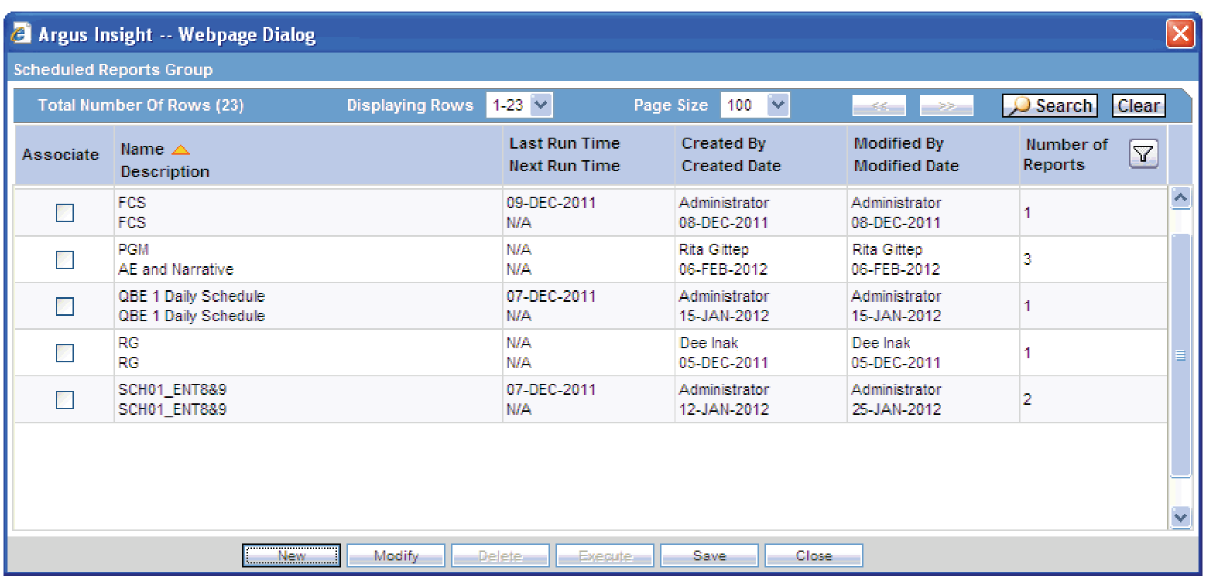
Working in the Scheduled Reports Group Dialog Box

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 9–4.

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.

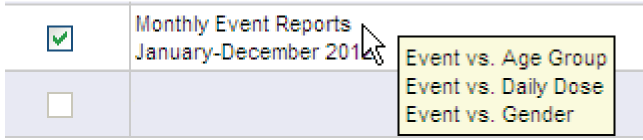
Each group can contain one or more reports. A *report group* means that all the reports are scheduled for the same time for a power query or a case series.

Figure 9–4 Scheduled Reports Group Dialog Box



Viewing the Reports in a Group

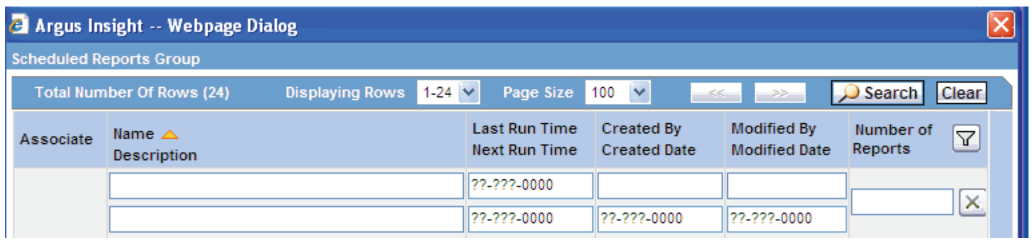
To view a list of the reports in a group, position the cursor over the group name in the Scheduled Reports Group dialog box. For example:



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.

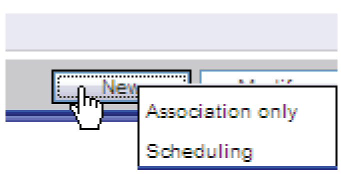


Note: If you search for a text comprising an underscore, it is treated as a wildcard and is replaced by a letter in the displayed results. For example, If you have queries with names - CURE, CORE, and CARE and you search for C_RE, all three queries are displayed in the result.

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.



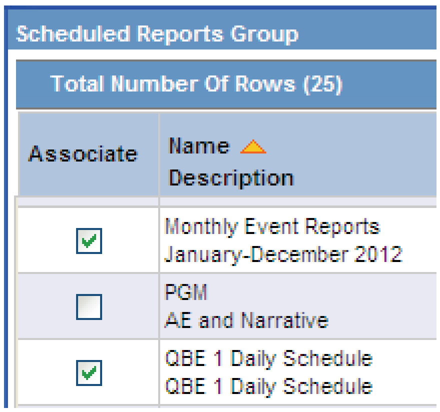
- Click **Modify** to change the settings for an existing scheduled report group.
- Click **Delete** to remove the selected report group. You can delete a report group *only if* the report group is not associated with a query or case series.
- Click **Execute** to close the Scheduled Reports Group dialog 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:

1. Navigate to the QUERY LIBRARY page or CASE SERIES LIBRARY page.
2. Select the query or case series for which you want to associate a report group.
3. Click **Associate.** The Scheduled Reports Group dialog box opens.
4. 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.



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

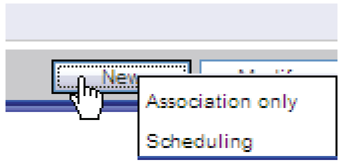
To remove the scheduling of a report group for a selected query or case series, clear the check box in the Associate column and click **Save.**

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.

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 9–5.
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

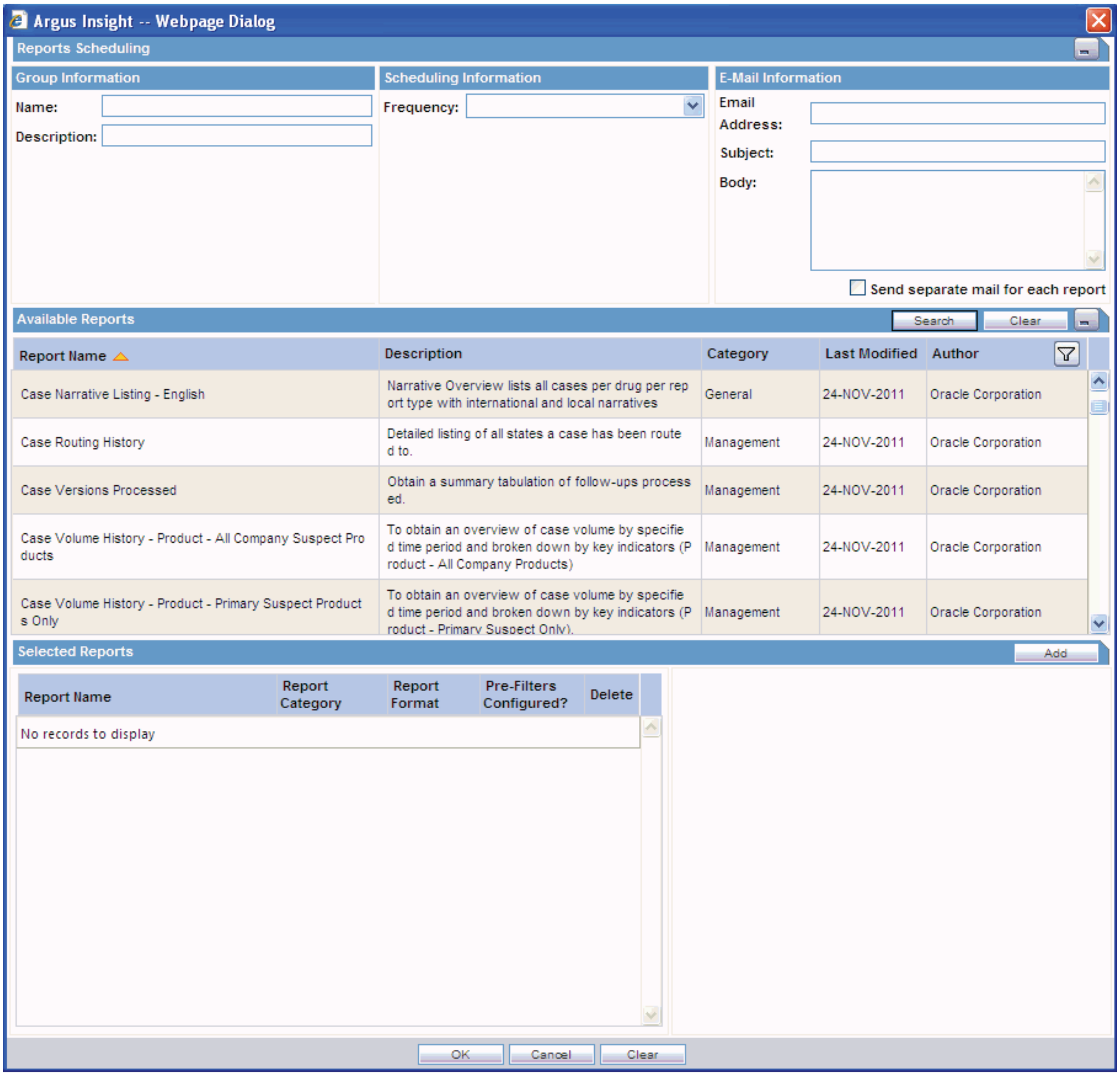
Working in the Reports Scheduling Dialog Box

The Reports Scheduling dialog box is the main scheduling page in Argus Insight. See Figure 9–5. 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 9–5 Reports Scheduling Dialog Box



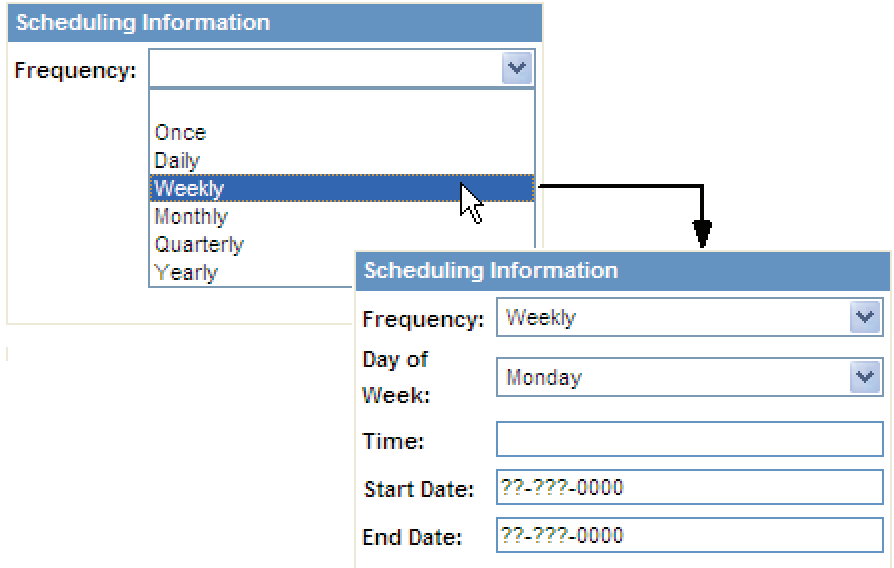
Entering the Report Name and Description

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.



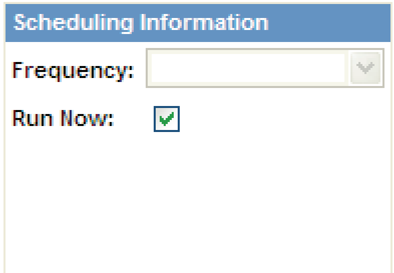
Based on the frequency option you select, enter the additional scheduling information:

- **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.

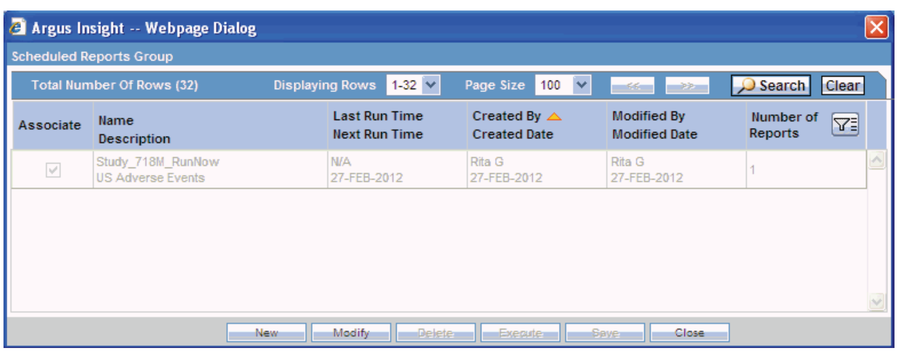


When you select the **Run Now** check box and save the scheduling information, Argus Insight saves the schedule to execute immediately.

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 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:

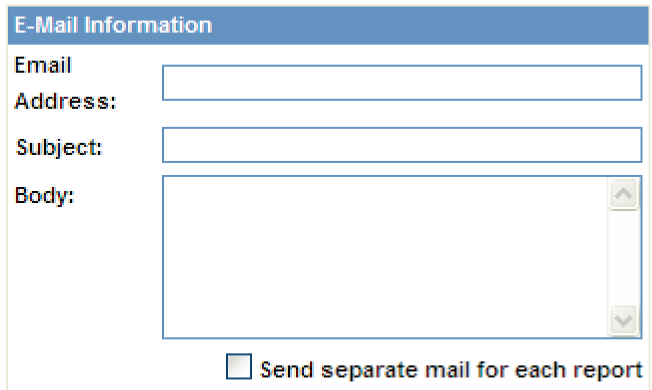


Note that the system:

- 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.



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.

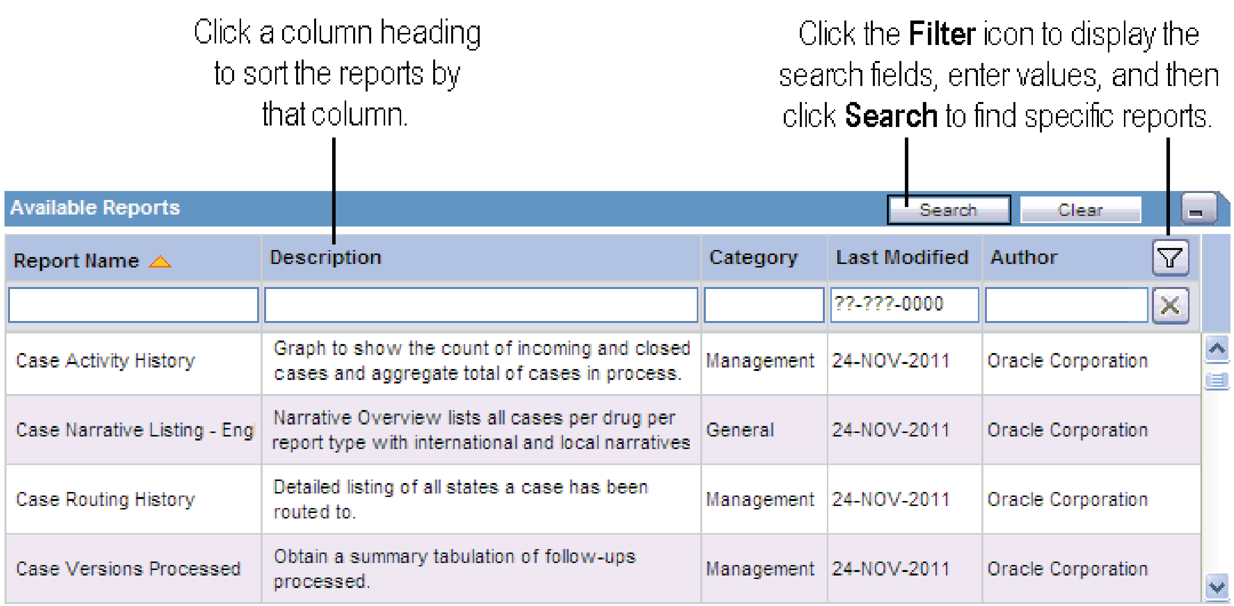
You can schedule multiple reports for a single QBE. Be sure to select the **Send separate mail for each report** check box if you want the system to send an email notification for each report generated.

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.



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.

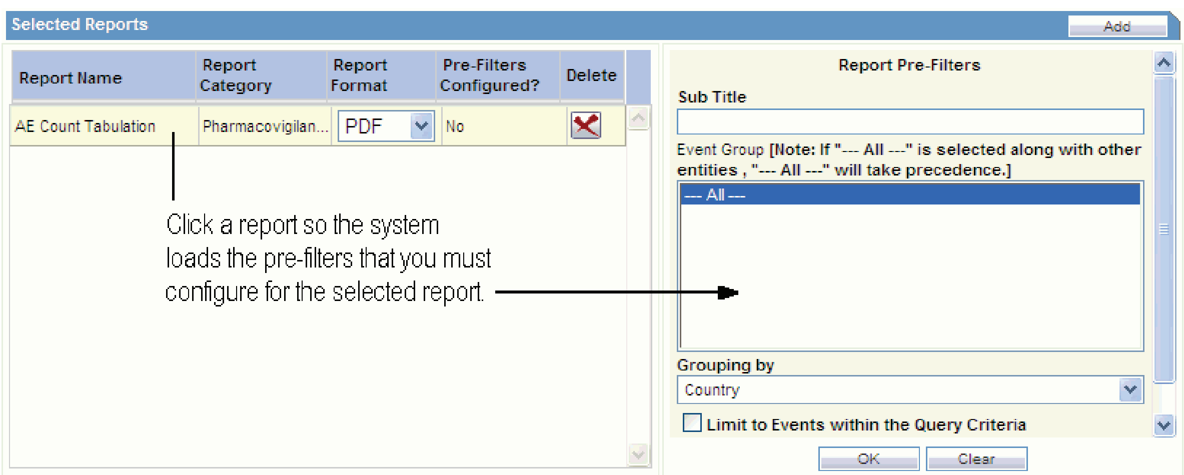
Entering Required Pre-filters and Selecting a Report Format

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.**

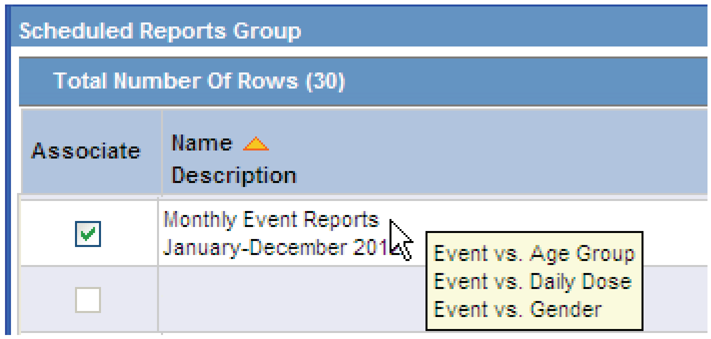
If you want to remove a report from this scheduling, click the **Delete** icon. The system prompts for confirmation before deleting the report.

Saving the Schedule

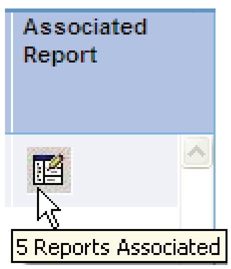
Click **OK** in the Reports Scheduling dialog box to save your report scheduling.

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.



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 **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 9-13 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 9–1 describes the standard Case Processing reports.

Table 9–1 Standard Case Processing Reports

Report Title	Description
Serious Adverse Events Report	A case-wise compilation of selected data, including the narrative, from study cases of special interest.

Compliance Reports

There is no report under this category for the Argus Insight 7.0.2 Release.

Configuration Reports

There is no report under this category for the Argus Insight 7.0.2 Release.

General Reports

Table 9–2 describes the standard General reports.

Table 9–2 Standard General Reports

Report Title	Description
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.
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

There is no report under this category for the Argus Insight 7.0.2 Release.

Pharmacovigilance Reports

Table 9–3 describes the standard Pharmacovigilance reports.

Table 9–3 Standard Pharmacovigilance Reports

Report Title	Description
Quick Signal	List of the event-reporting rates that might suggest a possible change in the safety profile of a product.

10

Generating and Scheduling Standard Reports - BIP

Argus Insight provides built-in Reports that you can run on active case series to analyze your company's safety, workflow, and product data.

This chapter includes the following topics:

- About Standard Reports
- Working in the Reports Page
- Generating Reports
- Scheduling and Associating Reports Against a Query or Case Series

In addition to the preformatted and predefined standard reports, you can create custom reports using the BI Publisher tool. For more information, see Chapter 13, "Creating Custom Reports - BIP."

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.

Browser Configuration

Before using Argus Insight to generate reports, configure the browser as defined in the *Oracle Argus Insight Installation Guide*.

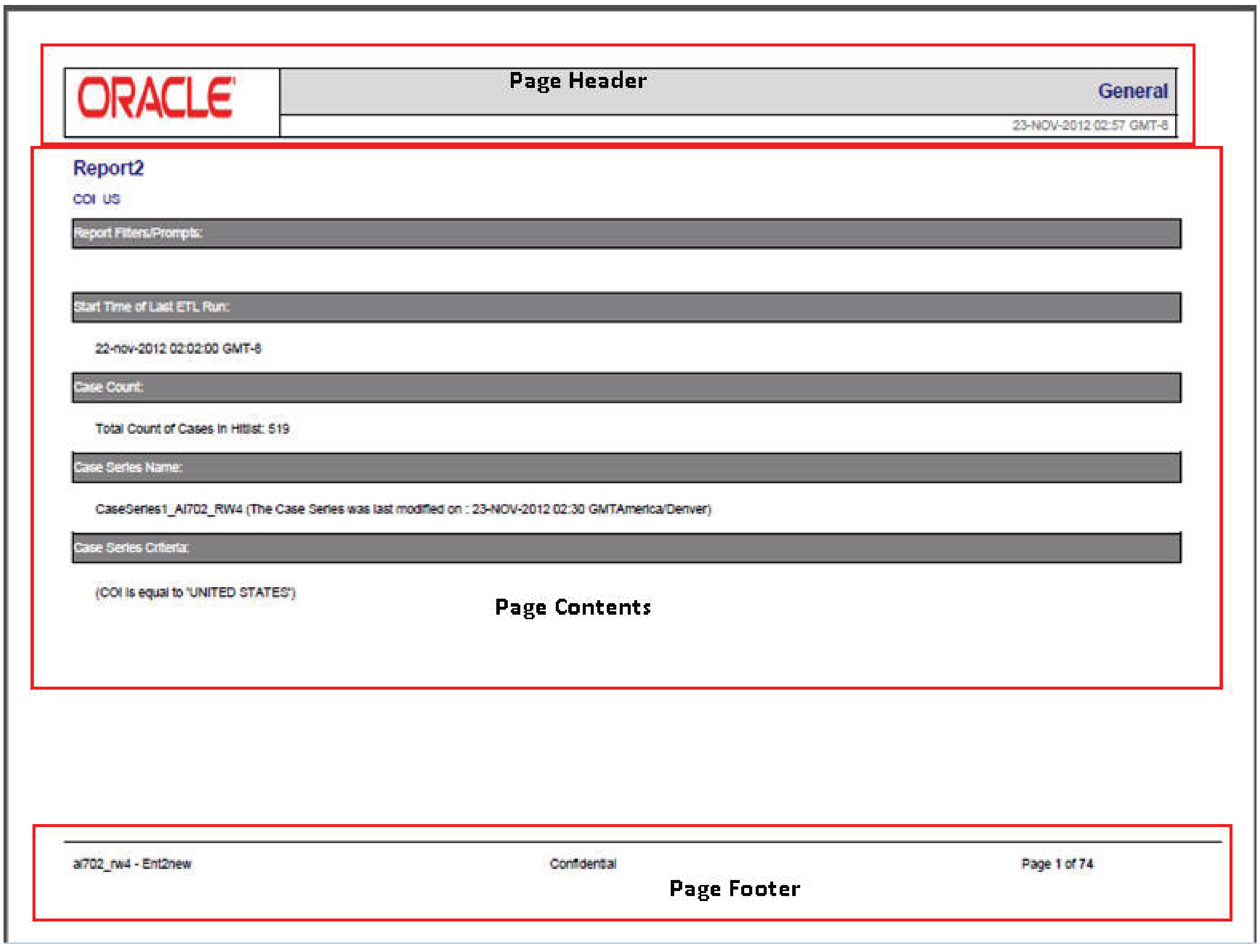
Report Cover Page

Figure 10–1 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 10–1 Sample Report Cover Page



Page Header

The page header of the report cover page includes the following information:

- Company logo. The upper-left box is a placeholder for a logo. You can configure your company logo to print in this space.
- Name of the category to which the selected report belongs. For example, Compliance, Management, or Pharmacovigilance.
- Date and time (Greenwich Mean Time [GMT]) that the report was run.

Page Contents

The page contents of the report cover page includes the following information:

- Title of the selected report.
- Report subtitle. You configure the subtitle when you run the report. Subtitles are useful in further defining the contents of the report. For example, 01-JAN-2000 to 31-DEC-2012.
- Filters defined for the selected report.
- Start date and time (GMT) of the last successful ETL run.
- Count of the total number of unique cases in the case series.
- Name of the saved case series on which the report has been executed.
  - Reports that are run on frozen case series data include the following text next to the case series name on the report:

    `The data in this report was frozen as of` *`date_and_time`*`.`

    Time is the database system time with the GMT offset.
  - Reports that are run on normal case series data include the following text next to the case series name on the report:

    The case series was last modified on *`date_and_time`*.
- Query criteria to get case series on which the report has been executed.

Page Footer

The page footer of the report cover page includes the following information:

- Name of the user who executed the report.
- Confidential text. You can configure the text that prints in the center of the page footer.
- Page number (Page *x* of *y*).

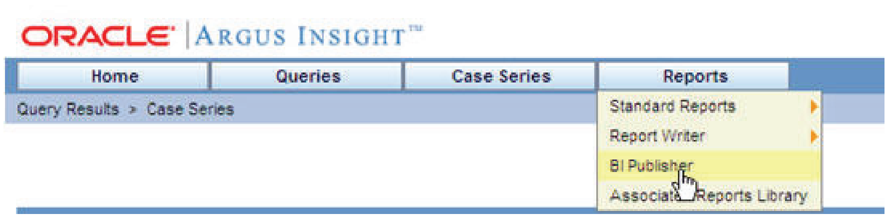
In addition, some reports include a placeholder in the footer for another logo. You can configure the image for the logo.

Working in the Reports Page

The Reports page, lists all the BI Publisher reports built in to Argus Insight.

To display the Reports page, execute the following steps:

1. Select **Reports**, **BI Publisher**, as depicted in the following figure:

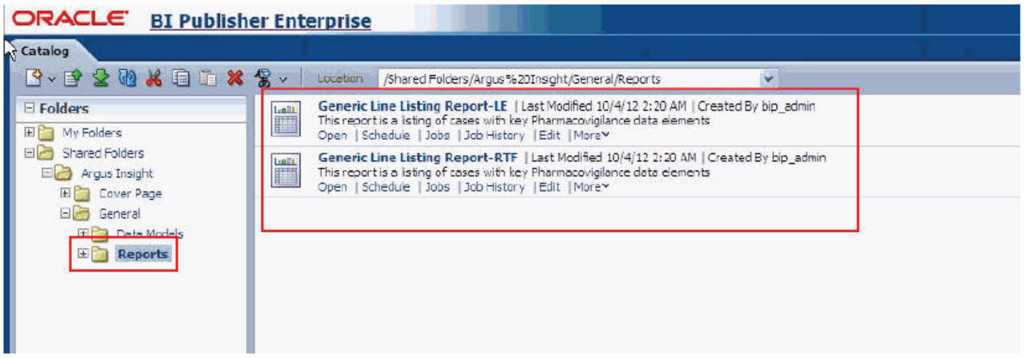


   This displays the BIP login page.

2. Log on to the BI Publisher tool. This displays the BIP Home page.

3. Click **Catalog** on the BIP Home page.

4. In the **Folders** section, navigate to **Shared Folders**, **Argus Insight**, **General**, and select **Reports**. This displays the **Generic Line Listing Report** in **LE** and **RTF** formats in the right pane, as depicted in the following figure:

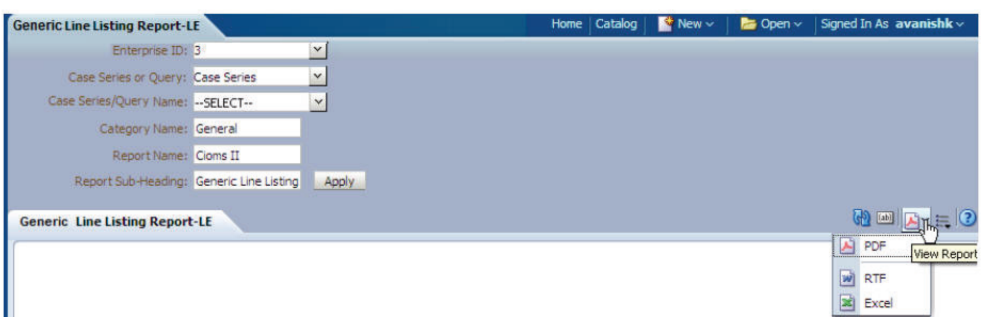


Generating Reports

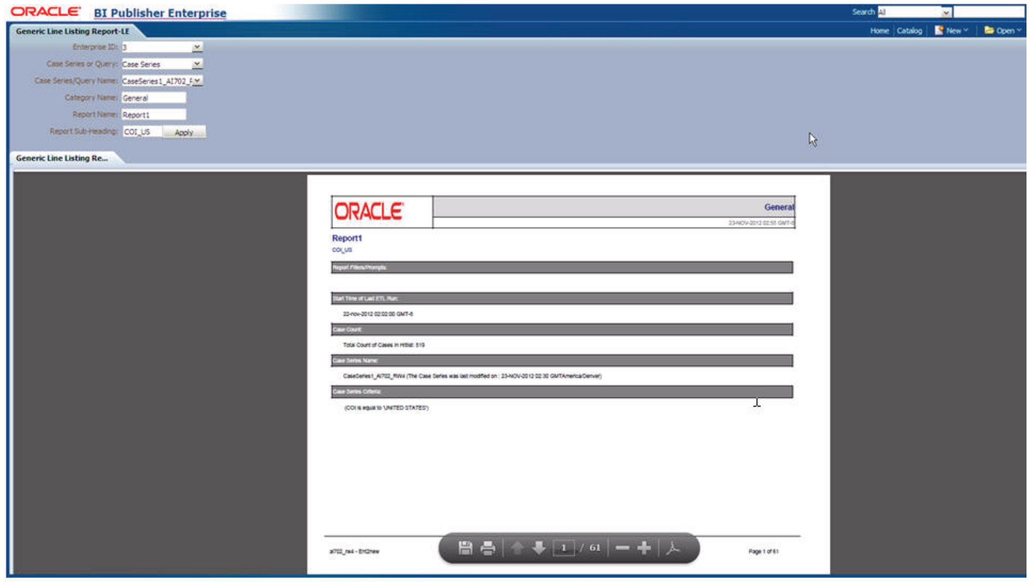
To generate a report using the BI Publisher tool, execute the following steps:

1. Click the **Report link** or **Open** on the **Reports** page. This displays the following screen:

2. Enter the values for all the fields according to the requirements and select the Output Type, as depicted in the following figure:



3. Click **Apply**. The values entered by you are displayed in the generated report, as depicted in the following figure:



For more information on Viewing Reports using the BI Publisher tool, You can refer to the **Viewing a Report** section in the Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Publisher.

Scheduling and Associating Reports Against a Query or Case Series

You can refer to the **Creating Report Jobs** and **Viewing and Managing Report Jobs** sections in the Oracle Fusion Middleware User's Guide for Oracle Business Intelligence Publisher for information on Scheduling and Associating Reports against a query or a case series.

11

Creating Custom Reports - Cognos

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

In this version of Argus Insight, Report Writer uses the features of Cognos 8 Query Studio to let you create custom reports by directly selecting data mart fields and viewing the results (report output) on the fly. 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.

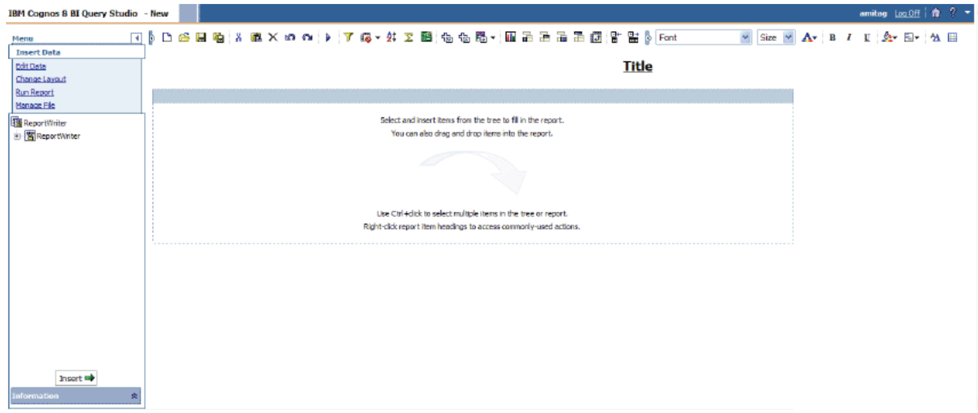
Once you have created your report, you can edit the report, change the report layout, run the report in specific formats, and save the report.

Note: The report author must ensure to not use those enterprise-specific values in the report, which will also be shared with other enterprises.

Creating a New Report

To start Report Writer and create a new report:

1. Navigate to **Reports, Report Writer,** and select **New.** Query Analysis starts. In the left frame, the Insert Data menu option is selected.



2. Select **Active Case Series Filter.**

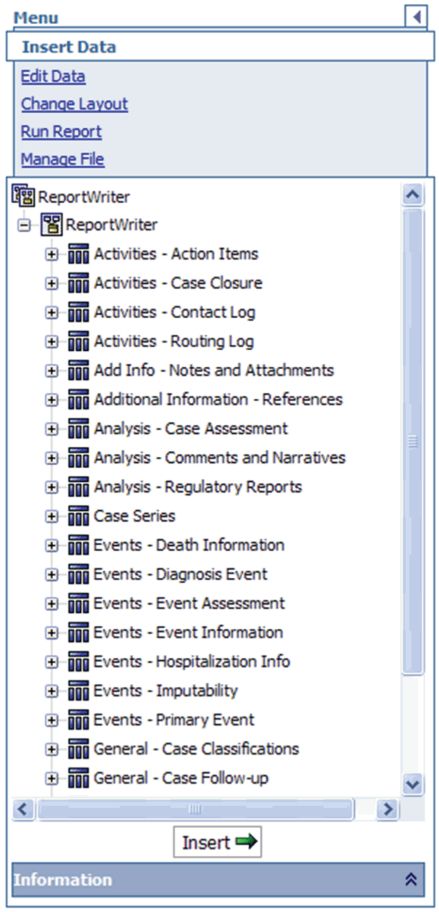
Note: Select the active case series filter before selecting data mart fields for your report. This prevents Report Writer from querying the entire data mart and slowing down the report output generation.

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

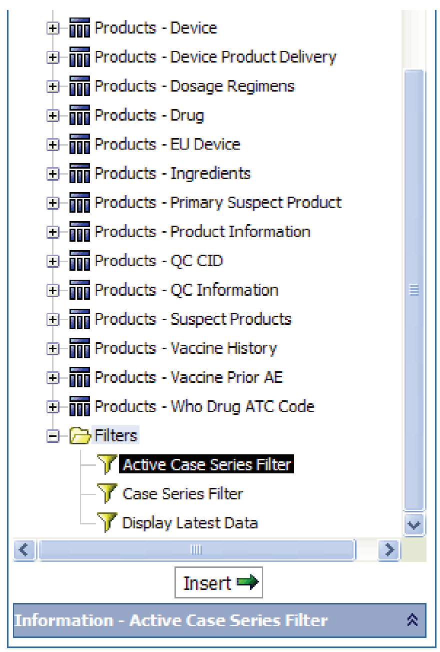
To make a different case series active, navigate to **Case Series, Open Case Series,** and select **Library** in Argus Insight. When the CASE SERIES LIBRARY page opens, select the case series you want to make active and click **Make Active.**

---

3. Expand the **Report Writer** control tree. The various data mart views are displayed.

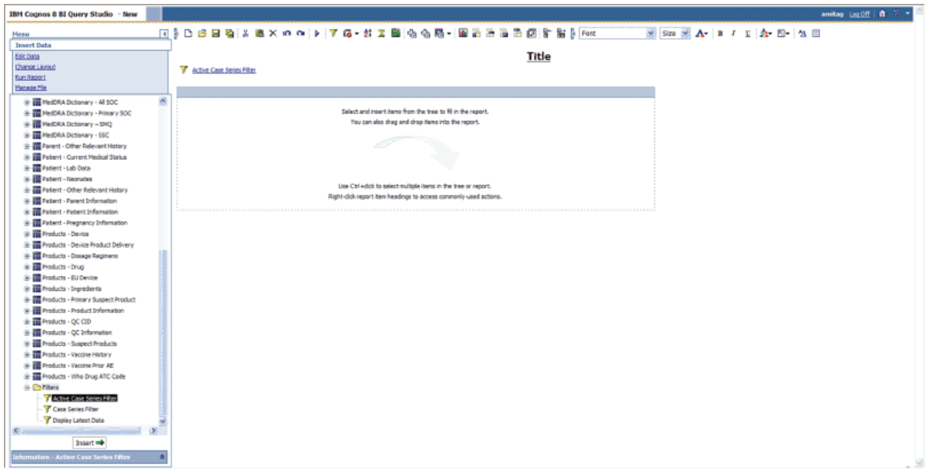


4. Scroll the list of views until the **Filters** folder is visible.
5. Expand the **Filters** folder. The built-in active case series filter is displayed.



6. Select **Active Case Series Filter.**

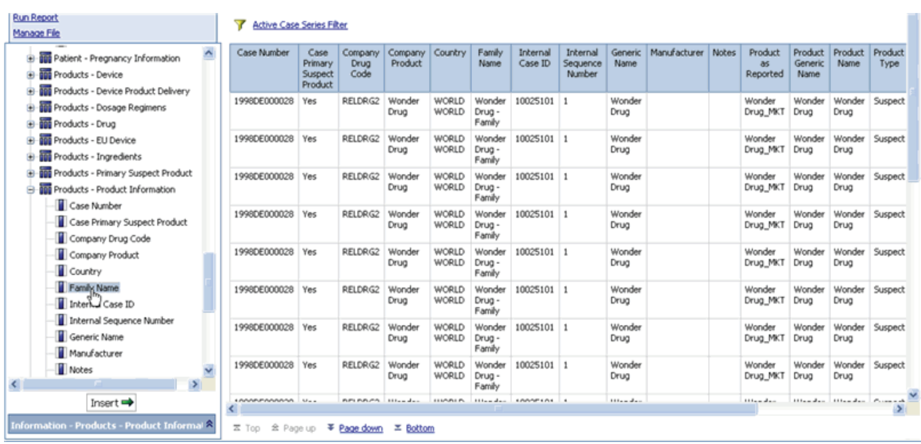
7. Click **Insert.** The system displays the selected filter in the right frame.



8. Select the data mart fields to include in your report.
9. Expand the **Report Writer** control tree. The various data mart views are displayed.
10. Expand the data mart view tree, as appropriate. The data mart fields corresponding to the tree are displayed.
11. Select the data mart fields, as appropriate.

> **Tip:** 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.

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



Tip: Select multiple fields as follows:

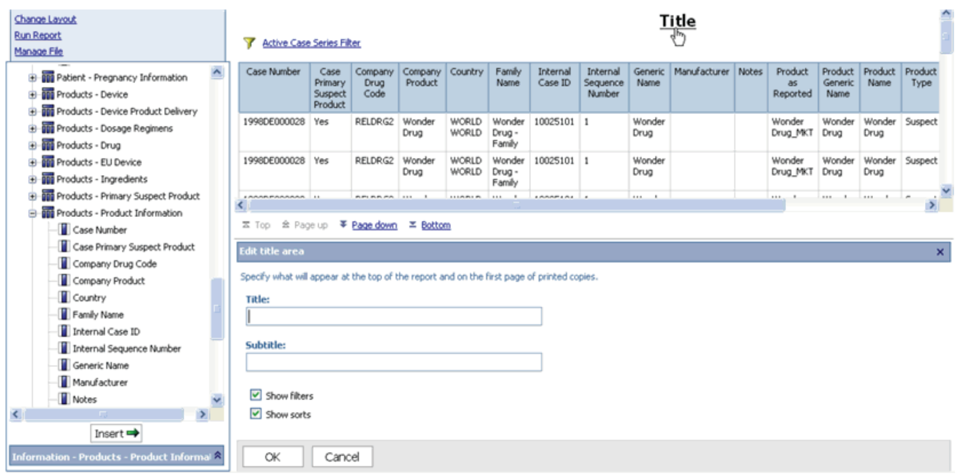
- Hold down the CTRL key and select the fields.
- Insert an entire data mart view in your report by selecting the data mart view entity in the left frame and clicking **Insert.**
- Drag the field entities to the report output area.

13. Repeat the previous steps to insert additional fields into the report.

    Tip: If you want to delete a *column* from the report output, select the column and click **Delete** on the toolbar.

    To revert or repeat any actions you perform in Query Studio, use the **Undo** or **Redo** options on the toolbar, respectively.

14. Enter the report title.
15. Click **Title** above the report output. The **Edit Title** section appears below the report output in the right frame.

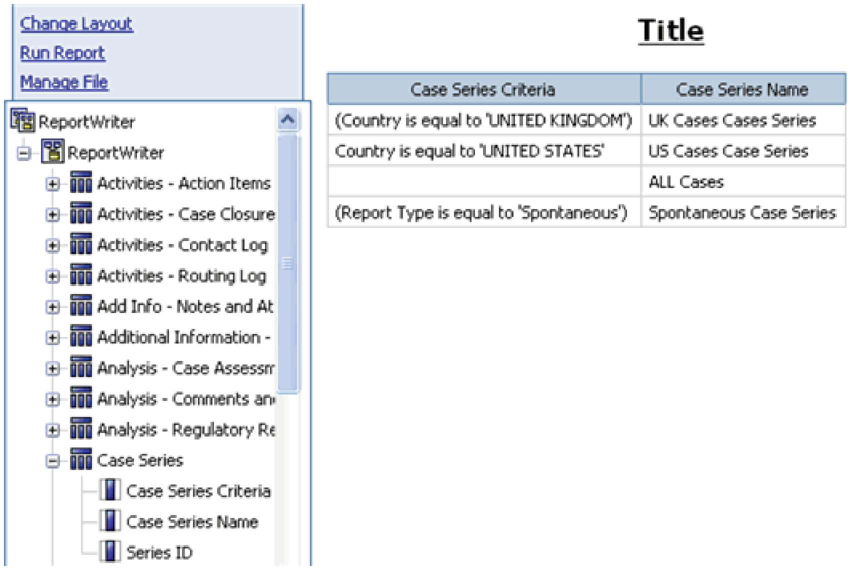


16. Enter the report title and subtitle in the respective fields.
17. Click **OK.** The page refreshes; the titles you entered appear above the report output.

Using Case Series Criteria and Case Series Name in New Report

To generate a report for displaying all the **Case Series Criteria** and **Case Series Name,** select the Case Series Criteria and Case Series Name objects from the Case Series class.

The Report Writer queries the data mart to get all the **Case Series Criteria** and **Case Series Name**.

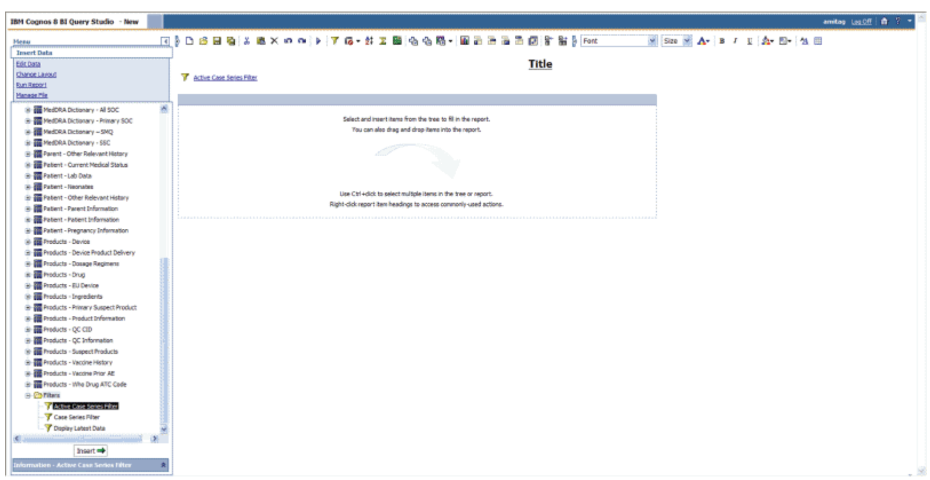


Note: Temporary Case Series Criteria and Case Series names will not be displayed.

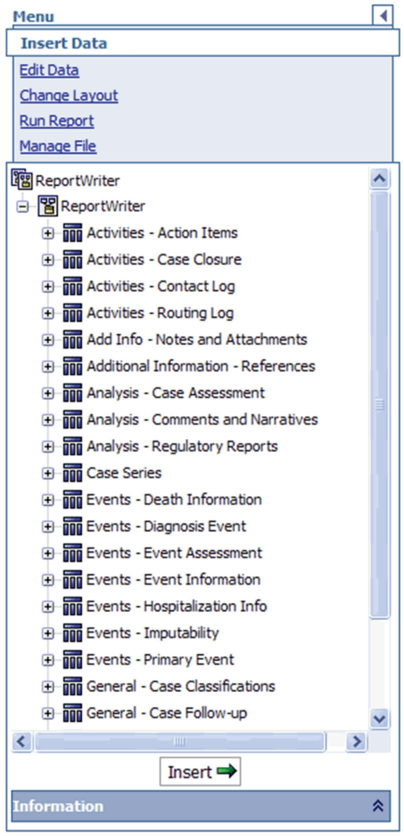
Using Case Series Criteria and Name with Other Objects

To use the Case Series Criteria and Case Series Name with other objects:

1. Expand the class folders under **Report Writer.** The dimensions for the class category are displayed.
2. Scroll the list of views until the **Filters** folder is visible.
3. Expand the **Filters** folder.



4. Select **Active Case Series Filter.**
5. Click **Insert.** The system displays the selected filter in the right frame.
6. Expand the **Report Writer** control tree. The various data mart views are displayed.



7. Expand the data mart view tree, as appropriate.

8. Select the data mart fields, as appropriate along with **Case Series Criteria** and **Case Series Name** from **Case Series** class.

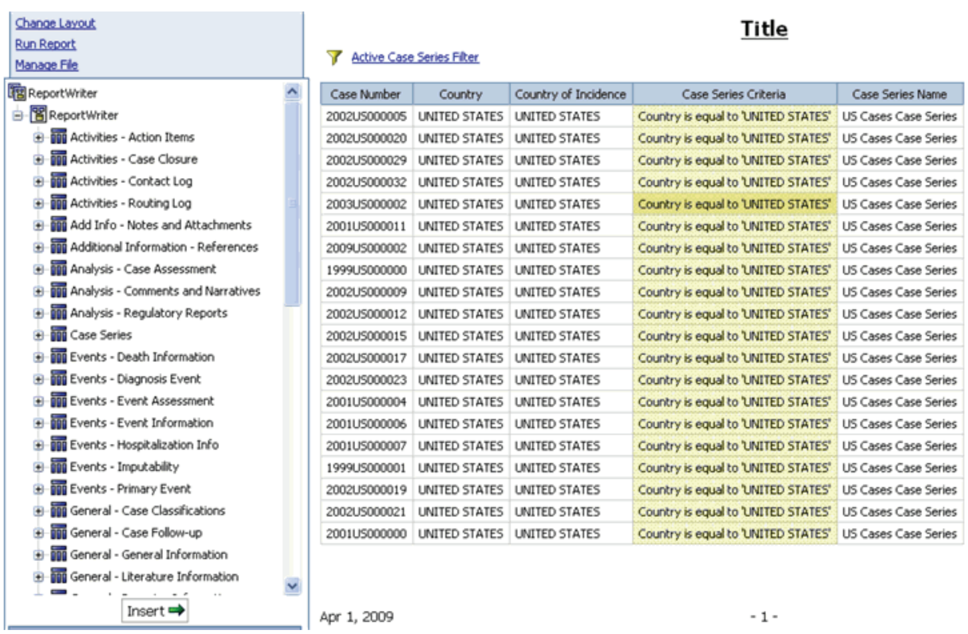
   Tip: If your report consists of fields from the Event and Product tables, it will only display data for those cases where event assessment has been done. This is because event assessment is the only way of defining relationship between an event and a product.

9. Click **Insert.**

   The Report Writer queries the data mart, automatically executes the query for every field you selected, and displays the data for the selected fields in the report output area within the right frame. The fields you selected are displayed as columns in the report output along with **Case Series Criteria** and **Case Series Name.**

> **Tip:** To select multiple fields, hold down the CTRL key and select the fields. To insert an entire data mart view in your report, select the data mart view entity in the left frame and click **Insert.**
>
> You can also drag the field entities to the report output area.

10. Select Case Series Criteria and click Create Sections icon.



11. The **Case Series Criteria** displays as header.

Case Series Criteria: Country is equal to 'UNITED STATES'

Case Number	Country	Country of Incidence	Case Series Name
1999DE000000	UNITED STATES	UNITED STATES	US Cases Case Series
1999US000000	UNITED STATES	UNITED STATES	US Cases Case Series
1999US000001	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000000	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000001	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000002	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000003	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000004	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000005	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000006	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000007	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000008	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000009	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000010	UNITED STATES	UNITED STATES	US Cases Case Series
2001US000011	UNITED STATES	UNITED STATES	US Cases Case Series
2002US000000	UNITED STATES	UNITED STATES	US Cases Case Series
2002US000002	UNITED STATES	UNITED STATES	US Cases Case Series
2002US000003	UNITED STATES	UNITED STATES	US Cases Case Series
2002US000005	UNITED STATES	UNITED STATES	US Cases Case Series
2002US000006	UNITED STATES	UNITED STATES	US Cases Case Series

12. Display the **Case Series Name** as header.

Title

Active Case Series Filter

Case Series Criteria: Country is equal to 'UNITED STATES'

Case Series Name: US Cases Case Series

Case Number	Country	Country of Incidence
1999DE000000	UNITED STATES	UNITED STATES
1999US000000	UNITED STATES	UNITED STATES
1999US000001	UNITED STATES	UNITED STATES
2001US000000	UNITED STATES	UNITED STATES
2001US000001	UNITED STATES	UNITED STATES
2001US000002	UNITED STATES	UNITED STATES
2001US000003	UNITED STATES	UNITED STATES
2001US000004	UNITED STATES	UNITED STATES
2001US000005	UNITED STATES	UNITED STATES
2001US000006	UNITED STATES	UNITED STATES
2001US000007	UNITED STATES	UNITED STATES
2001US000008	UNITED STATES	UNITED STATES
2001US000009	UNITED STATES	UNITED STATES
2001US000010	UNITED STATES	UNITED STATES
2001US000011	UNITED STATES	UNITED STATES
2002US000000	UNITED STATES	UNITED STATES
2002US000002	UNITED STATES	UNITED STATES
2002US000003	UNITED STATES	UNITED STATES
2002US000005	UNITED STATES	UNITED STATES
2002US000006	UNITED STATES	UNITED STATES

Note: Always use Active Case Series Filter while using Case Series Criteria and Case Series Name with other objects. Otherwise, you may receive undesirable results.

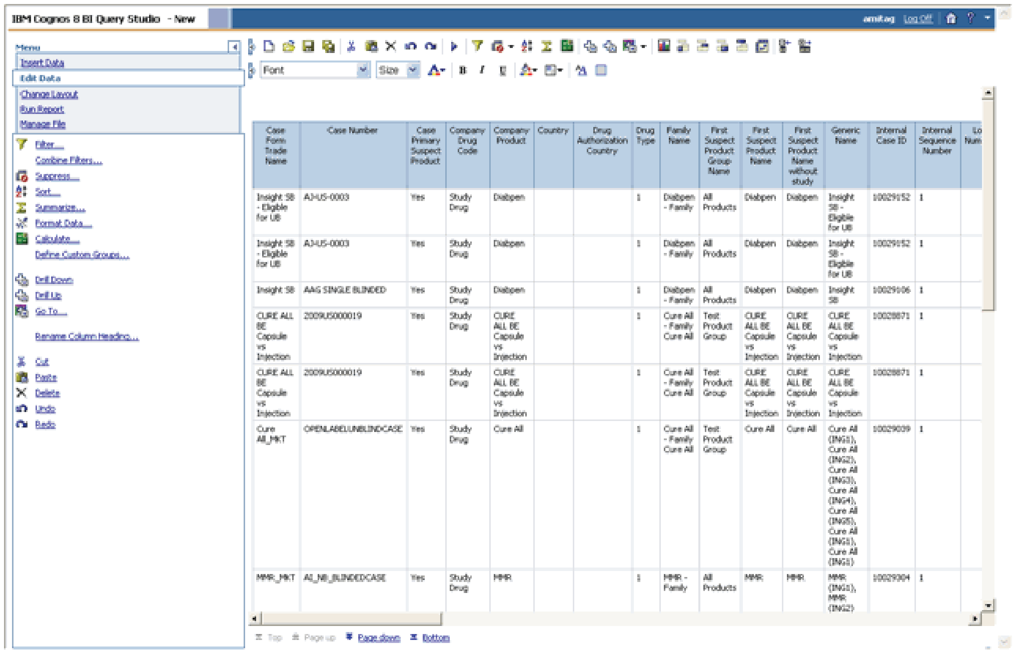
To view the active case series, navigate to **Case Series, Open Case Series,** and select **Active** in Argus Insight.

To make a different case series active, navigate to **Case Series, Open 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.**

After you have selected the required data mart fields and generated the output, you can use the various Query Studio options to edit the report, change the report layout, run the report in specific formats, and save the report.

Editing Reports

To access Query Studio's *report* editing options, select the **Edit Data** menu option. 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.



This topic only explains the basic report editing operations in Query Studio. For detailed information, see the documentation supplied with the Cognos8 products.

Filtering Data

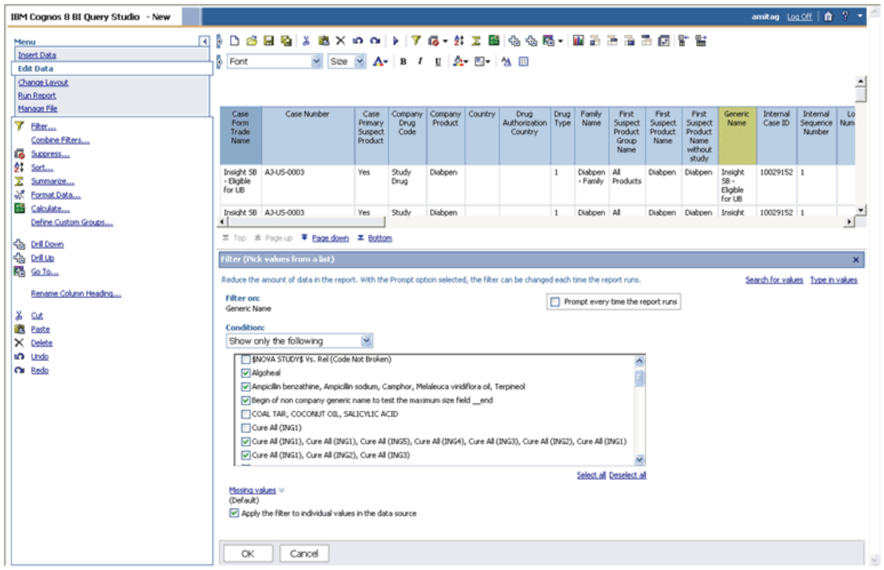
Use the filtering option to reduce data in your report.

To *filter* your report:

1. In the report output area, click within the header of the *column* you want to use to filter the report output. The selected column is highlighted.

First Suspect Product Group Name	First Suspect Product Name	First Suspect Product Name without study	Generic Name	Internal Case ID	Internal Sequence Number
All Products	Diabpen	Diabpen	Insight SB - Eligible for UB	10029152	1
All Products	Diabpen	Diabpen	Insight SB - Eligible for UB	10029152	1
All Products	Diabpen	Diabpen	Insight SB	10029106	1
Test Product Group	CURE ALL BE Capsule vs Injection	CURE ALL BE Capsule vs Injection	CURE ALL BE Capsule vs Injection	10028871	1
Test Product Group	CURE ALL BE Capsule vs Injection	CURE ALL BE Capsule vs Injection	CURE ALL BE Capsule vs Injection	10028871	1

2. Select **Filter** from the **Edit Data** menu options in the left frame. The **Filter** section appears below the report output in the right frame. The **Show only the following** list displays all the values in the column you selected.



3. In the **Show only the following** list, check the values by which you want to filter the report output.

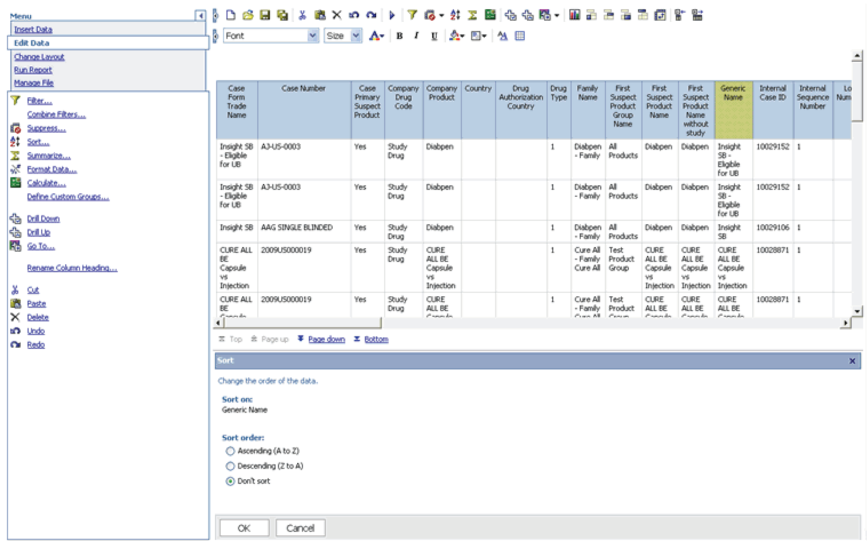
> **Note:** The **Show only the following** list may not display all the values if the list of values is very large. If you cannot find the desired values to filter on, click the **Search for values** link and search for the value by typing the value you are looking for.

4. If you want the system to prompt you to select the filter values each time you run the report, select the **Prompt every time the report runs** check box.
5. If you want the report output to include those records which have a null value (no value) in the selected filter column, select the **Show missing values** check box.
6. Click **OK.** The system refreshes the report and displays the filtered output. The filter information is displayed above the report output.

Sorting Data

To change the sort order in your report:

1. In the report output area, click within the header of the column that contains the values by which you want sort the report output. The selected column is highlighted.
2. Select **Sort** from the **Edit Data** menu options in the left frame. The **Sort** section appears below the report output in the right frame.

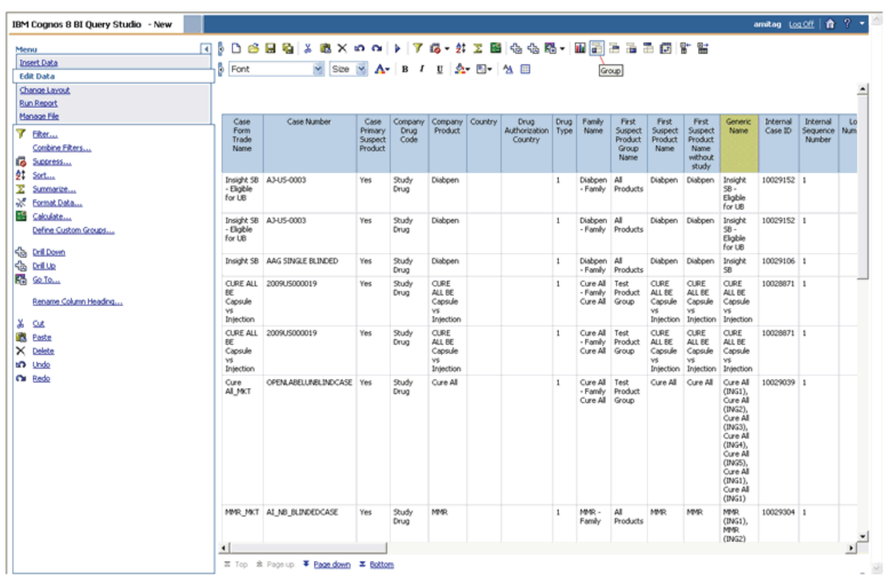


3. Select the required sorting option by using the **Sort Order** option.
4. Click **OK.** The system refreshes the report and displays the sorted output.

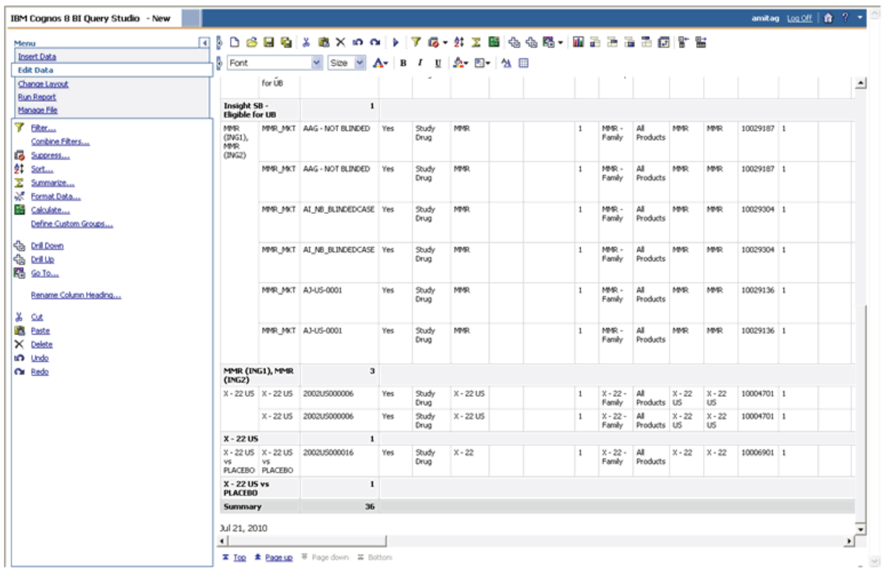
Summarizing Data

Use the predefined summary options to calculate the total, count, maximum, minimum, or average 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.

1. In the report output area, click the column that you want to summarize. The selected column is highlighted.
2. Select the column to be grouped and click on the Group icon placed in the grouping menu in the top panel. The selected column is grouped.



3. Select **Summarize** from the **Edit Data** menu options in the left frame. The **Summarize** section appears below the report output in the right frame.
4. Click the **Summary for footers** drop-down list and select the required summary option. The options available depend on the type of values the select column contains.
5. Click **OK.** The report output displays the column summary at the bottom of the report. Click the **Bottom** link to view the footer. If your report is grouped, the summary values are displayed for each group.



6. To remove summary information, select the relevant column and click **Summarize**. Select **None** from the list and click **OK.**

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 11–1 describes the available formatting options.

Table 11–1 Formatting Options for Data in Reports

Format	Description
Default	The default format is the format of the report item before any formatting is applied in Query Studio. Use default to remove formatting.
Text	Use the text format to specify the number of characters that must be visible in the text string.
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.

Table 11–1 (Cont.) Formatting Options for Data in Reports

Format	Description
Percentage	This format shows a number multiplied by 100, using two decimal places and a percent sign. For example, 0.7356 appears as 73.56%.
Scientific	This format shows a number in exponential notation. For example, the number 224,110 is 2.24110E+05 in scientific notation.
Date and Time	You can choose from a list of date and time formats, including the 12 or 24 hour clock.

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. Select **Format** from the **Edit Data** menu options in the left frame. The **Format** section appears below the report output in the right frame.
4. Select the data format from the **Category** drop-down list, as appropriate. The options for setting the format appear.
5. Set the formatting options, as appropriate.
6. Click **OK.** The report output is refreshed and displays the formatted data.

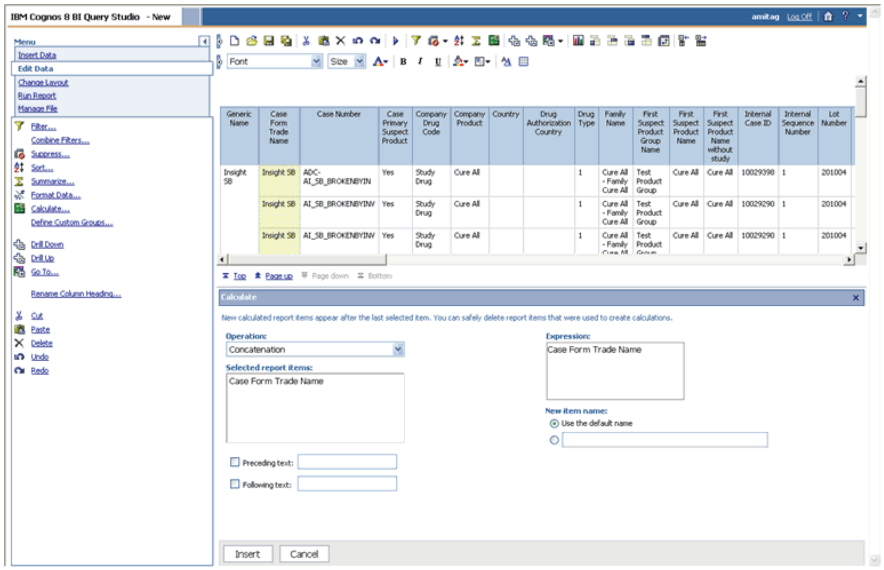
Performing Calculations

While the **Summary** option lets you display calculation results in report footers, the **Calculate** option lets you create a new column that displays the calculation results for one or more columns. For example, you can perform the following types of calculations:

- An arithmetic calculation between several columns in a report
- Analytic operations, such as maximum, minimum, average, or percentile, in grouped reports
- Percentage operations, such as percentage of total or percentage of difference
- Operations on text, such as concatenating text in two columns or abbreviating text in a column

The type of calculations or operations available to you depend on the type of information in a column.

1. In the report output area, select the columns on which you want to perform calculations. The selected columns are highlighted.
2. Select **Calculate** from the **Edit Data** menu options in the left frame. The **Calculate** section appears below the report output in the right frame.

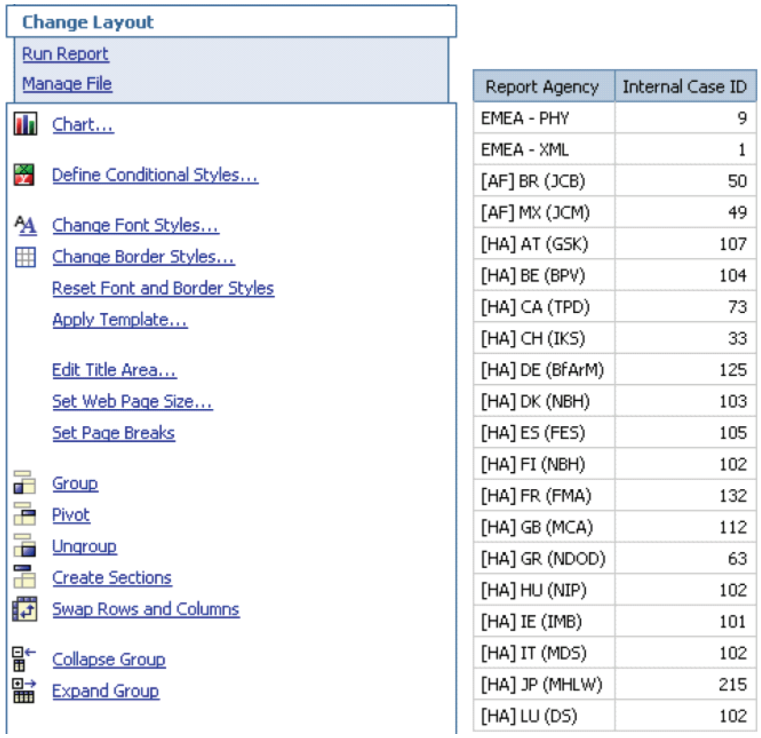


3. Click the **Operation Type** drop-down list and select the type of operation you want to perform. The operation types available depend on the type of information the selected columns contain, such as text or numeric.
4. Click the **Operations** drop-down list and select the operator. The operators available depend on the type of operation you specified.

   Depending on the operator you selected, additional options may appear in the Calculate section. Specify those options.
5. Use the **New item name** options to specify whether you want the result column to have a new header title.
6. Click **Insert.** The system refreshes the report output and displays the calculation result.

Changing the Report Layout

To access Query Studio's *report* layout options, select the **Change Layout** 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. You can also group your report by a specific column, swap rows and columns, or create sections within your report.



The sections explain how to use the various report layout options.

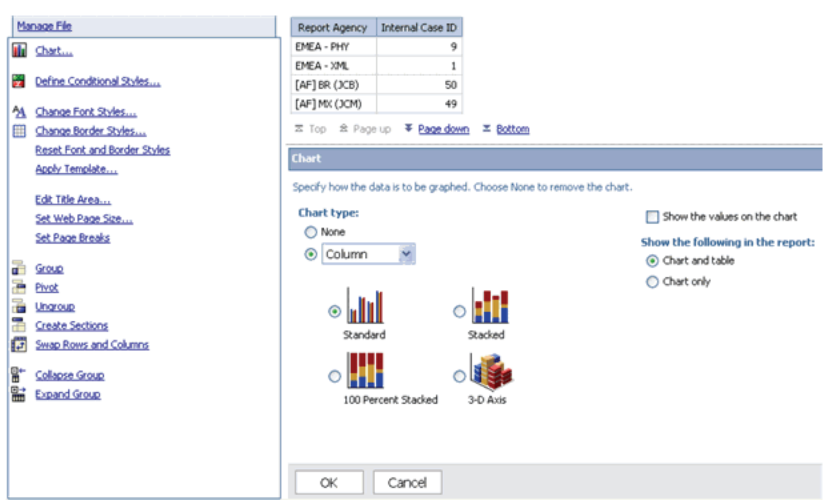
Note: This topic only describes the basic layout operations in Query Studio. For detailed information, see the documentation supplied with the Cognos 8 products.

Creating a Chart

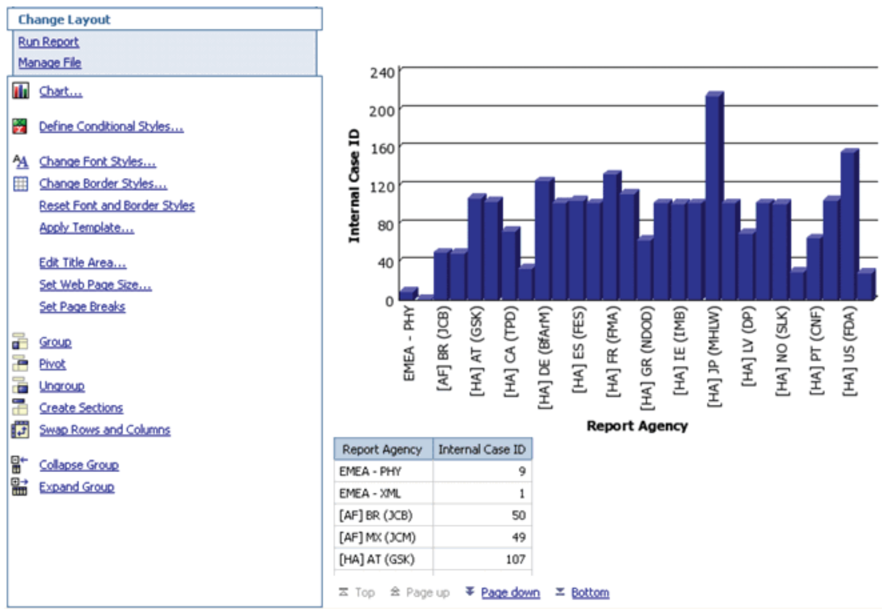
Use the **Chart** option to graphically see patterns and trends in data. Charts can only be created for reports that contain measures (numeric values).

To create a chart from a report:

1. While your report is displayed, select the **Chart** from the **Change Layout** menu options. The **Chart** section appears below the report output in the right frame.



2. Use the **Chart type** drop-down list to select the type of chart you want to create. For example, column, pie, radar, and so on.
3. Check the **Show the values on the chart** check box if you want to display the measure value in the chart.
4. Use the **Show the following in the report** options to specify whether you want the output to display only the chart or both chart and table.
5. Click **OK.** The system refreshes the report output and displays the chart.



Tip: The legends are displayed at the bottom of the screen.

Grouping by Row Headings

Use the **Group** option to reorder the rows of a selected column so that identical values appear together. Grouping also suppresses display of duplicates. You can group only those columns that contain text data or numeric data that is not a measure.

To group a report:

1. In the report output area, click within the header of the column that contains the values you want to use to group the report. The selected column is highlighted.

Case Number	Internal Case ID	Internal Sequence Number	Report Agency	Reporting Affiliate
1998DE000008	10021101	10413701	[HA] US (FDA)	UNITED STATES
1998DE000008	10021101	10413901	[HA] US (FDA)	UNITED STATES
1998DE000008	10021101	10414101	[HA] JP (MHLW)	JAPAN
1998DE000008	10021101	10414301	[HA] JP (MHLW)	JAPAN
1998DE000008	10021101	10414501	[HA] GB (MCA)	UNITED KINGDOM
1998DE000008	10021101	10414701	[HA] DE (BfArM)	GERMANY
1998DE000008	10021101	10414901	[HA] FR (FMA)	FRANCE
1998DE000008	10021101	10415101	[HA] SE (MPA)	SWEDEN
1998DE000008	10021101	10415301	[HA] LV (DP)	LATVIA
1998DE000008	10021101	10415501	[HA] LU (DS)	LUXEMBOURG
1998DE000008	10021101	10415701	[HA] ES (FES)	SPAIN
1998DE000008	10021101	10415901	[HA] BE (BPV)	BELGIUM
1998DE000008	10021101	10416101	[HA] NE (DCBG)	NETHERLANDS
1998DE000008	10021101	10416301	[HA] DK (NBH)	DENMARK
1998DE000008	10021101	10416501	[HA] IT (MDS)	ITALY
1998DE000008	10021101	10416701	[HA] HU (NIP)	HUNGARY
1998DE000008	10021101	10416901	[HA] NO (SLK)	NORWAY
1998DE000008	10021101	10417101	[HA] FI (NBH)	FINLAND
1998DE000008	10021101	10417301	[HA] IE (IMB)	IRELAND
1998DE000008	10021101	10417501	[HA] AT (GSK)	AUSTRIA

2. Select **Group** from the **Change Layout** menu options in the left frame. The system refreshes the report and displays the grouped output.

Reporting Affiliate	Case Number	Internal Case ID	Internal Sequence Number	Report Agency
AUSTRIA	1998DE000008	10021101	10417501	[HA] AT (GSK)
	1998DE000009	10021301	10466501	[HA] AT (GSK)
	1998DE000010	10021501	10462501	[HA] AT (GSK)
	1998DE000011	10021701	10455701	[HA] AT (GSK)
	1998DE000012	10021901	10453101	[HA] AT (GSK)
	1998DE000013	10022101	10449101	[HA] AT (GSK)
	1998DE000014	10022301	10442501	[HA] AT (GSK)
	1998DE000015	10022501	10438501	[HA] AT (GSK)
	1998DE000016	10022701	10433101	[HA] AT (GSK)
	1998DE000017	10022901	10421501	[HA] AT (GSK)
	1998DE000018	10023101	10404501	[HA] AT (GSK)
	1998DE000019	10023301	10396501	[HA] AT (GSK)
	1998DE000020	10023501	10392701	[HA] AT (GSK)
	1998DE000021	10023701	10388901	[HA] AT (GSK)
	1998DE000022	10023901	10386301	[HA] AT (GSK)
	1998DE000023	10024101	10382301	[HA] AT (GSK)
	1998DE000024	10024301	10378301	[HA] AT (GSK)
	1998DE000025	10024501	10374301	[HA] AT (GSK)
	1998DE000026	10024701	10370301	[HA] AT (GSK)
	1998DE000028	10025101	10365501	[HA] AT (GSK)

Ungrouping a Report

To ungroup a report, select the grouped column and select **Ungroup** from the **Change Layout** menu options.

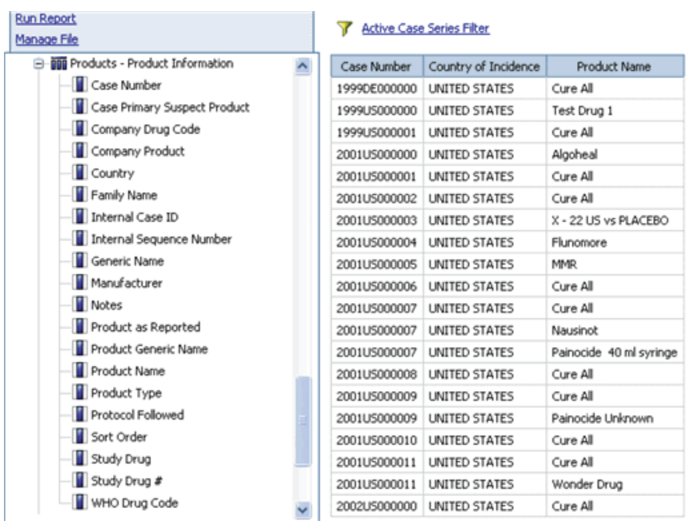
Creating Crosstab Reports

A crosstab report shows a measure at the intersection of each row and column. This type of report is useful when you need to display a large amount of data in a small area. For example, if a report shows Country as columns, Products as rows, and Case Count as the measure, the value at the intersection of each column and row shows the count of cases for that product and that country.

Note: You cannot create crosstab reports directly in Query Studio; you cannot define measures in Query Studio. To create sophisticated reports, such as crosstab reports, use the Cognos 8 Report Studio tool. The steps that follow explain how to create a crosstab report by performing the Count operation on each cell of the Case Number column to convert it into a measure. You can use this method to create similar crosstab reports in Query Studio.

To create a crosstab report using the Count operation:

1. Select the following data mart fields to include in your report.
   - General - General Information, Case Number
   - General - General Information, Country of Incidence
   - Product - Product Information, Product Name
2. The Report Writer queries the data mart, automatically executes the query for every *field* you selected, and displays the data for the selected fields in the report output area within the right frame. The fields you selected are displayed as columns in the report output.

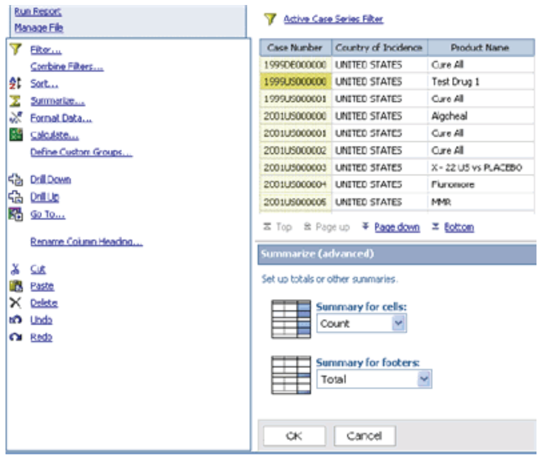


3. Convert the **Case Number** column values into counts.
4. Select the **Edit Data** menu. The **Edit Data** menu options are displayed.
5. Select the **Case Number** column by clicking within the column. The **Case Number** column is highlighted.

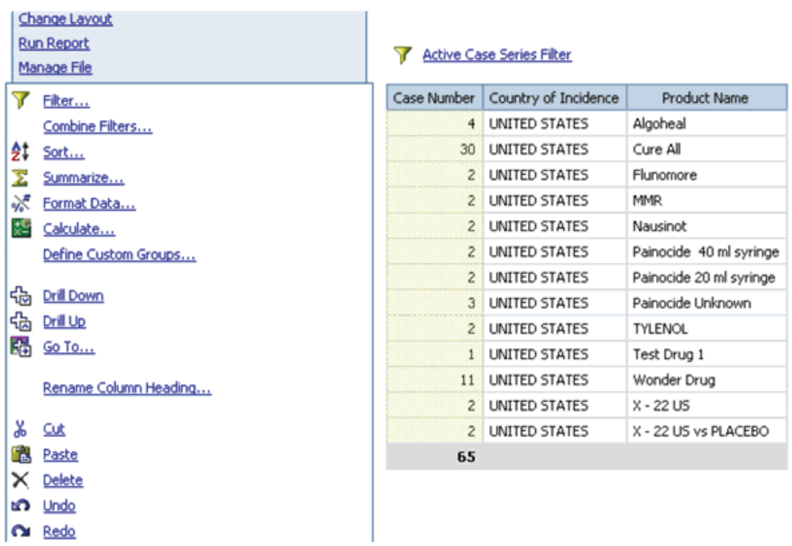
Summarizing the Sections in the Report

To summarize the sections in a report:

1. Select the **Summarize** option from the **Edit Data** menu. The **Summarize** section appears below the report output.
2. Click the **Advanced** link in the **Summarize** section. Additional options appear.



3. Select **Count** from the **Summary for cells** drop-down list.
4. Select **Total** from the **Summary for footers** drop-down list.
5. Click **OK.** The report output refreshes. The **Case Number** column now shows the case count for each row.

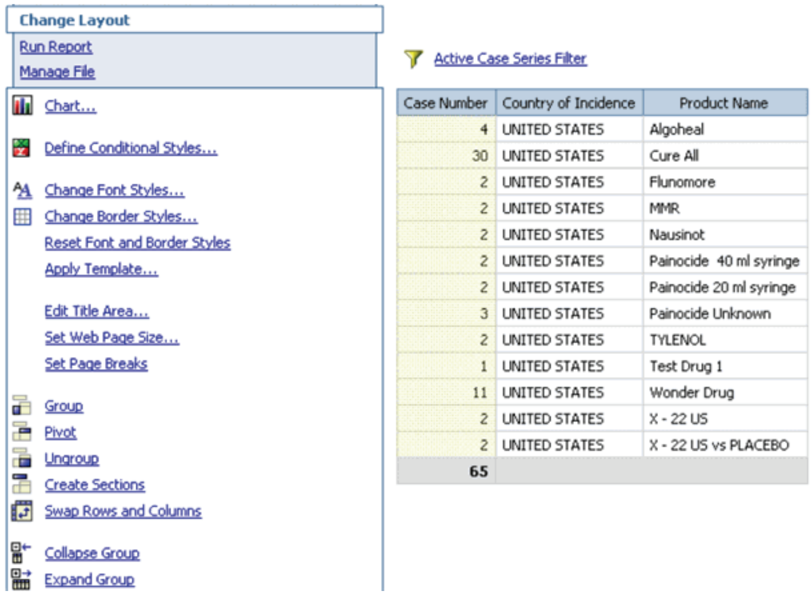


Case Number	Country of Incidence	Product Name
4	UNITED STATES	Algoheal
30	UNITED STATES	Cure All
2	UNITED STATES	Flunomore
2	UNITED STATES	MMR
2	UNITED STATES	Nausinot
2	UNITED STATES	Painocide 40 ml syringe
2	UNITED STATES	Painocide 20 ml syringe
3	UNITED STATES	Painocide Unknown
2	UNITED STATES	TYLENOL
1	UNITED STATES	Test Drug 1
11	UNITED STATES	Wonder Drug
2	UNITED STATES	X - 22 US
2	UNITED STATES	X - 22 US vs PLACEBO
65		

Converting to a Crosstab Report

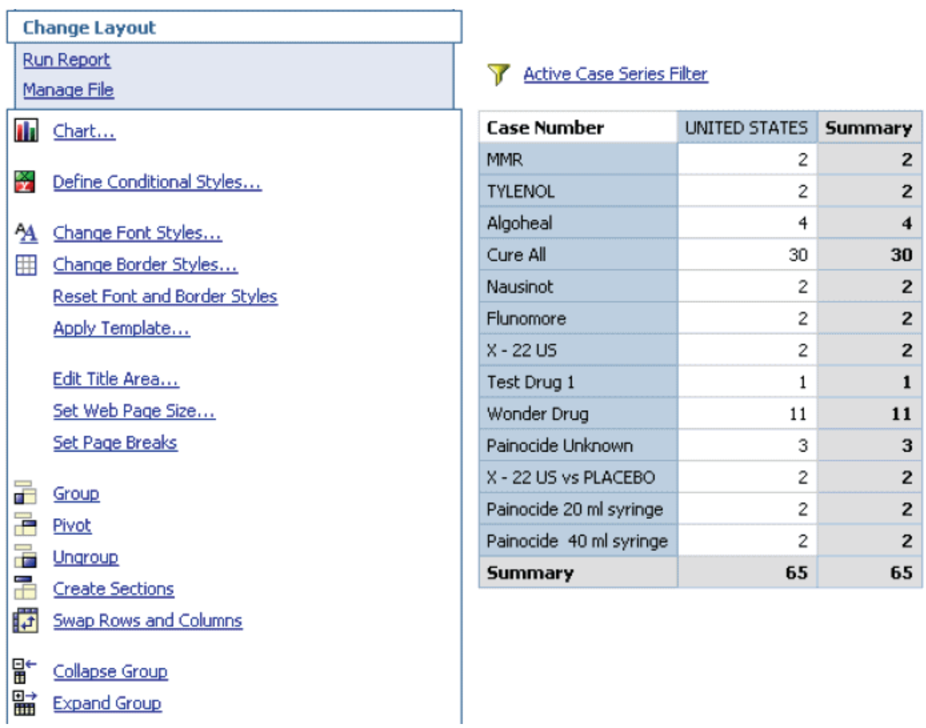
To convert to a crosstab report:

1. Select the **Change Layout** menu. The **Change Layout** menu options are displayed.



2. Select the **Country of Incidence** column in the report output. The column is highlighted. The values of the selected column will appear as columns in your crosstab report.

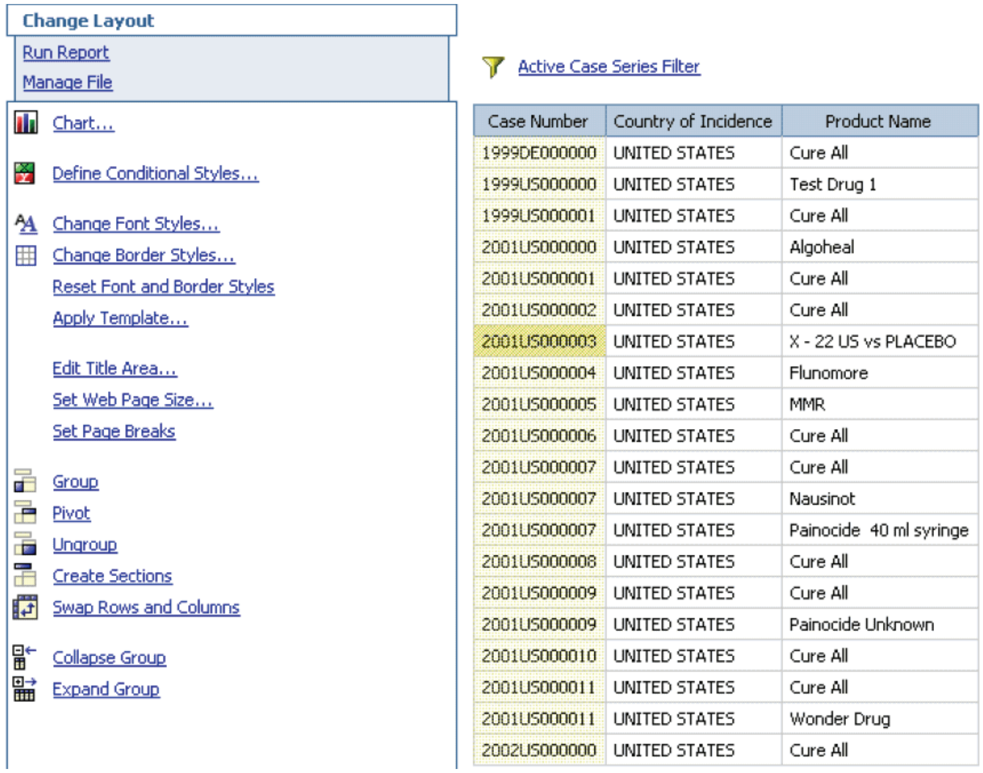
3. Select the **Pivot** from the **Change Layout** menu options. The report output refreshes. The crosstab report is displayed.



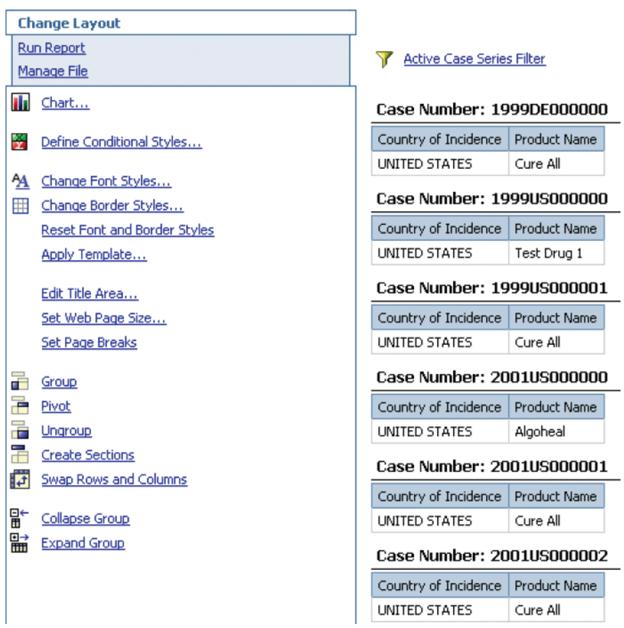
Creating Sections in the Report

Use the **Create Sections** option to group your report into section headings. The section headings are based on the values within a column you select.

1. In the report output area, select the column you want to use for creating sections. The selected column is highlighted.



2. Select **Create Sections** from the **Change Layout** menu options. The report output refreshes. The report is grouped into sections.



Swapping Rows and Columns

The **Swap Rows and Columns** option in the **Change Layout** menu lets you interchange rows and columns in a crosstab report or a chart based on a crosstab. However, this option does not let you swap rows and columns in a list report.

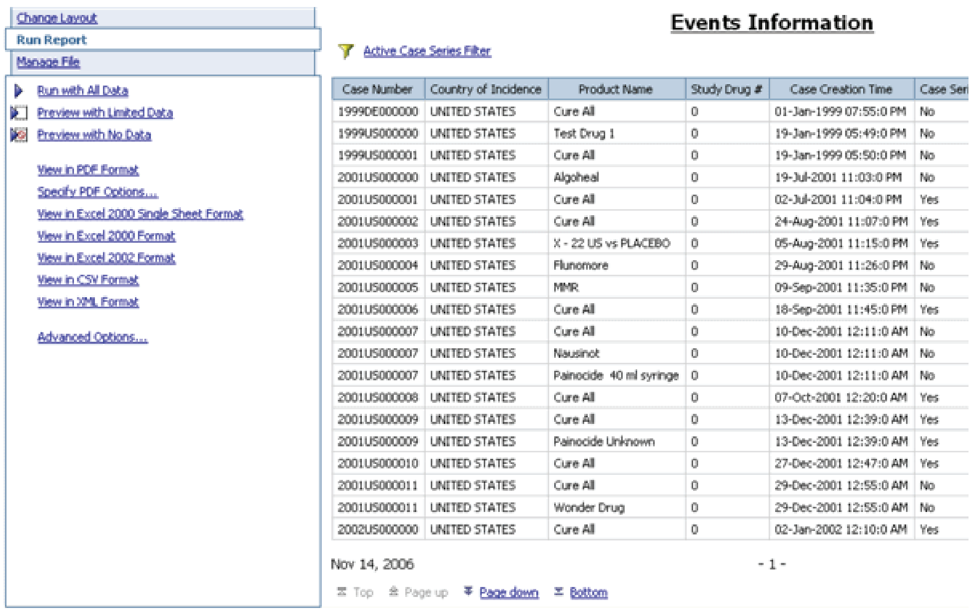
Swapping rows and columns is useful in situations where a crosstab report has few rows and many columns.

For example, to make the report shown in the previous section easier to read, select **Swap Rows and Columns** to interchange rows with columns.

If there are multiple rows or columns in a crosstab report, the outermost rows become the outermost columns, and the outermost columns become the outermost rows.

Running the Report in Specific Formats

Query Studio provides you many options to run or preview a report. You can access its various run and preview options by selecting the **Run Report** menu item. Select the desired option to run the report.



The following table describes the various **Run Report** options available in Query Studio.

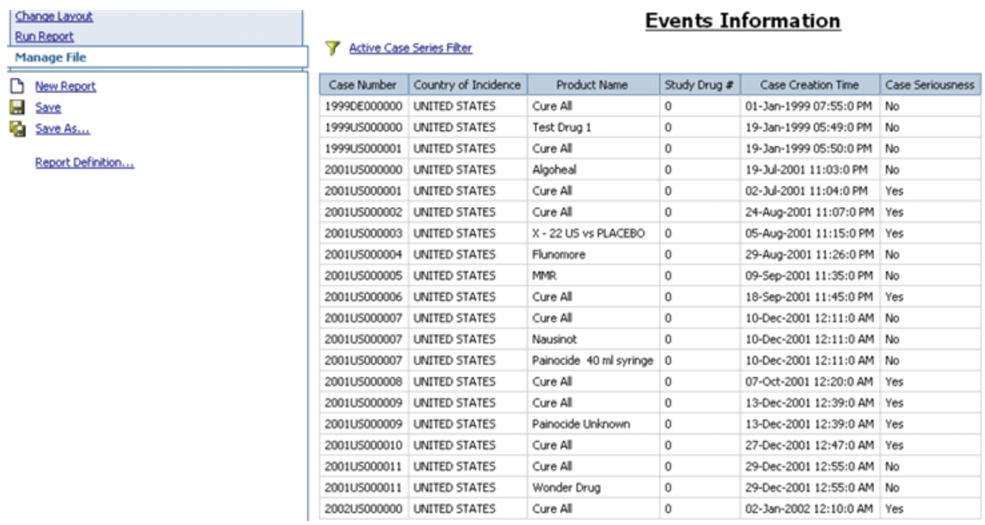
Option	Description
Run with All Data	Select this option to run the report using the full data mart. Running a report with all data can take a long time. If you plan to make several changes to a report, you may run the report by selecting the **Preview with Limited Data** option to limit the rows of data that your report retrieves.
Preview with Limited Data	Select this option to preview the report by retrieving limited data from the data mart. The report output has a torn border at the top and bottom of your report.
Preview with no Data	Select this option to preview your reports with no data. The system displays junk characters in the report and the data mart is not queried at all.
View in PDF Format	Select this option to save a snapshot of your report data in PDF format. Select **Specify PDF Options** to set the display options for the PDF output.
View in Excel Single Sheet Format	Select this option to save a snapshot of your report data in a single data sheet in XLS format.
View in Excel Format	Select this option to save a snapshot of your report data in XLS format.

Option	Description
View in CSV Format	Select this option to save a snapshot of your report data in comma separated values (CSV) format.
View in XML Format	Select this option to view list reports in XML format. You cannot view charts or a crosstab reports in XML format.

Saving and Accessing Saved Reports

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

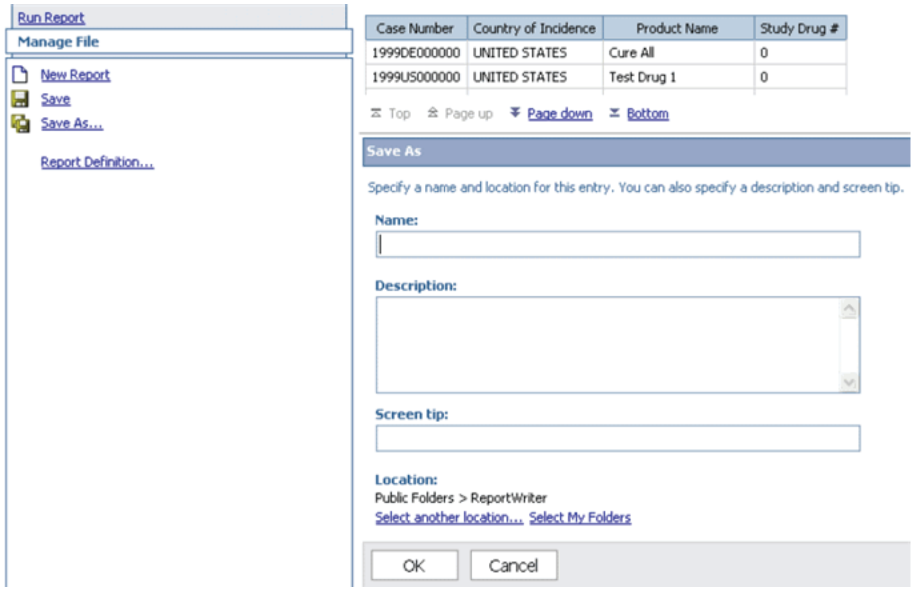
The reports you save are not a snapshot of the data displayed in the report output. Instead, the system stores the specific set of instructions (data mart fields you select) for extracting data from the data mart when you run the report. For example, if you run a report that you saved a week ago, the 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. Select the **Manage File** menu option in the left frame. The options for saving the report appear.
2. Select the **Save** from the **Manage File** menu options. The **Save As** section appears below the report output in the right frame.

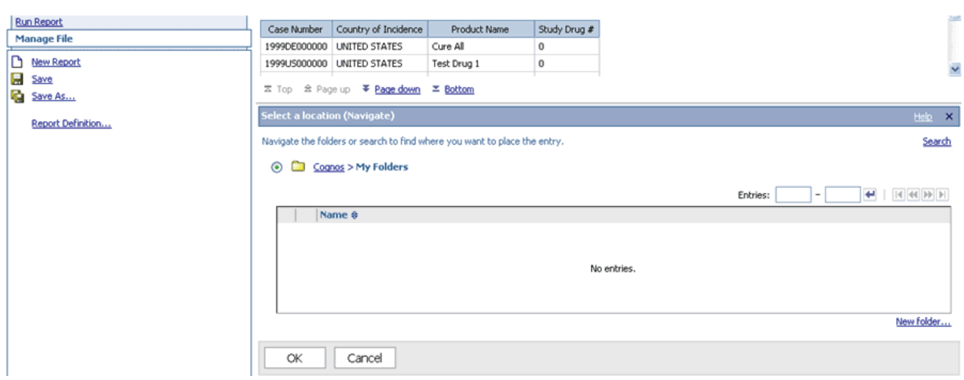


3. Enter the report name in the **Name** field.
4. Enter the report description in the **Description** field.
5. Enter the tip text in the **Screen tip** field. This text displays on the screen when the user points the cursor at the report in the Report Writer.
6. Select a **Location** option to specify where the report needs to be saved.
   - Click **Select another location** if you want all users to be able access the report.
   - Click **Select My Folders** if you want to save the report as a personal document.

Saving a Report in a New Folder

To save a report in a new folder:

1. Click **Select another location.** The **Select a Location** section appears.
2. Select the **Public Folders** or **My Folders** tab, and click the **New Folder.**
3. Specify the name, description, and screen tip for the new folder and click **Finish.**



4. Click **OK** to save the report in the location you specified.

Accessing Report Writer Library

You can access the reports that you saved from the Report Writer library.

To open the Report Writer library, navigate to **Reports, Report Writer,** and select **Library.** My Folders is the default location that appears when you open the Report Writer library. All the reports you save as personal documents are listed in the My Folders location.

To view the reports saved as public documents select the **Public Folders** tab. You can navigate the public folders and display the desired report.

To run the saved report, select the check box next to the report name and click the **Run** icon. If there are any filtering prompts associated with the report, they are displayed. Specify the prompt values and click **OK** to view the report output.

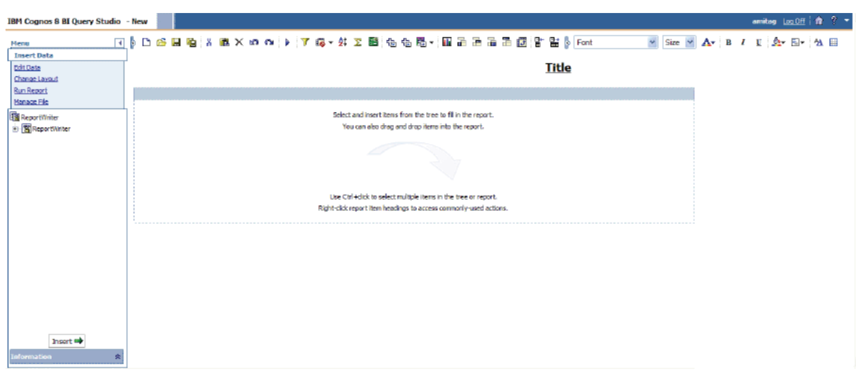
To edit a saved report, click the report name. The report opens in Query Studio. After you edit the report, open the **Manage Files** menu and select **Save As** to save the report by another name.

Using SMQs in Report Writer

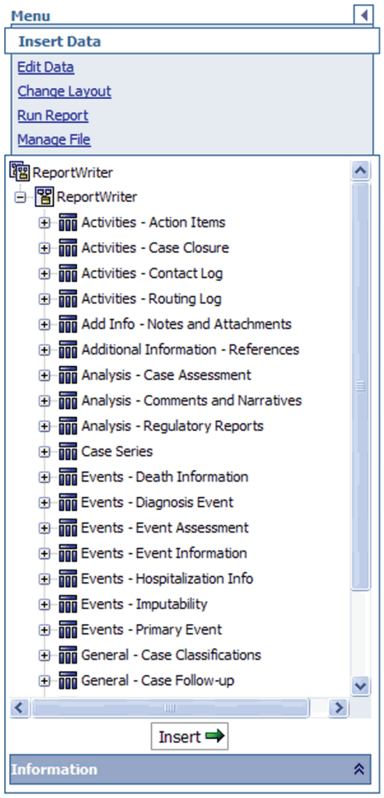
If you select an SMQ, all the cases based on that SMQ are displayed.

To use SMQs in Report Writer:

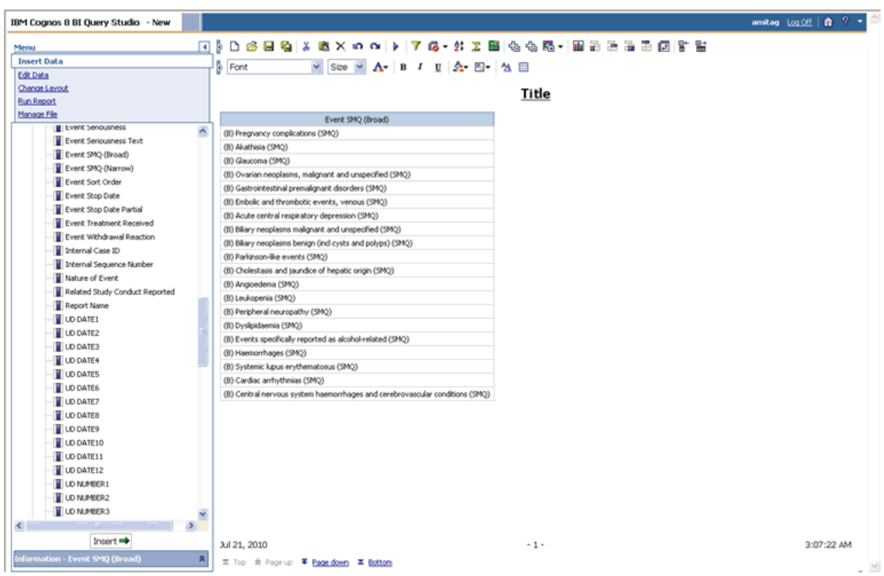
1. Navigate to **Reports, Report Writer,** and select **New.** The following window is displayed.



2. Expand the **Report Writer** control tree to display the various data mart views.



3. Under **Events - Event Information**, either double-click **Event SMQ (Broad)** or drag-and-drop it to the right pane.



4. Perform a similar operation as shown in the previous step for **Event SMQ (Narrow).**

5. Under **Events - Event Information**, either double-click **Case Number** or drag-and-drop it to the **right** pane. This displays all the case numbers that correspond to the selected SMQ.

12

Creating Custom Reports - BusinessObjects

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.

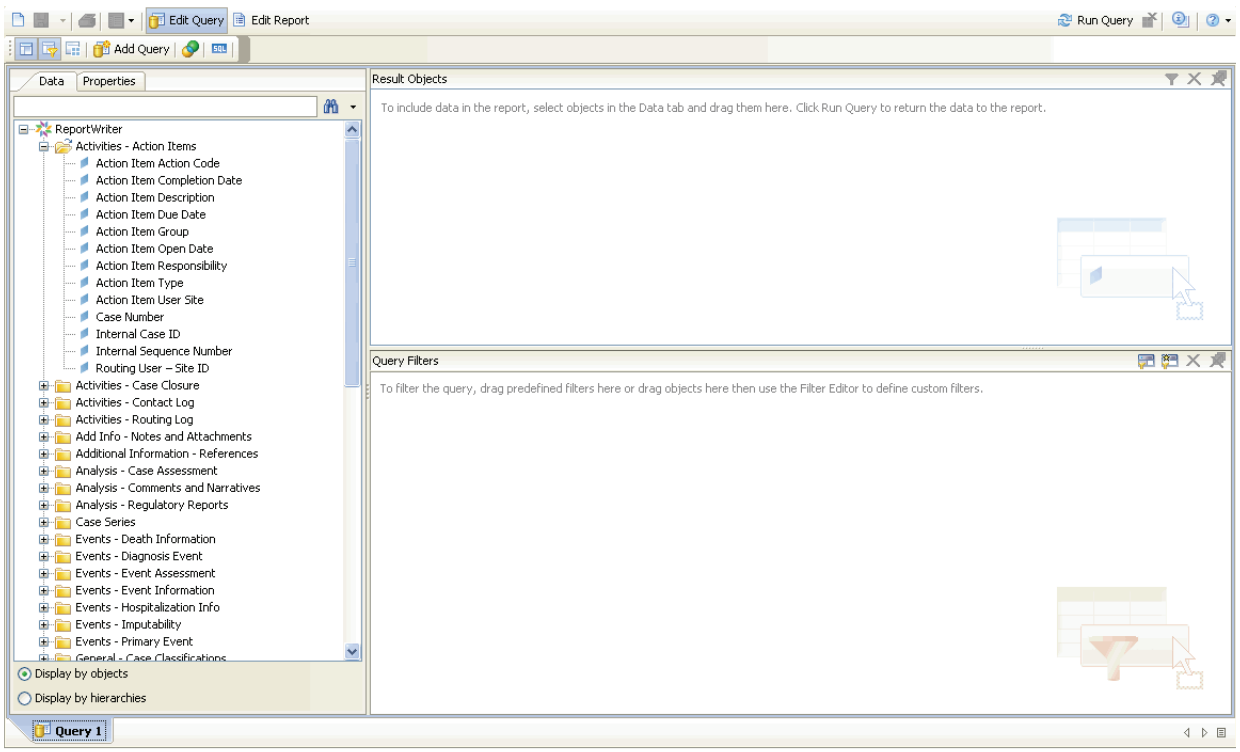
Note: When you finish using the Report Writer to create, edit, and save custom reports, you **must log out** of the BusinessObjects application. If you do not log out of BusinessObjects but you do log out of Argus Insight, another user logging in to Argus Insight has access to BusinessObjects with your 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 **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 **Case Series, Open Case Series,** and select **Active** in Argus Insight.

To make a different case series active, navigate to **Case Series, Open 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.**

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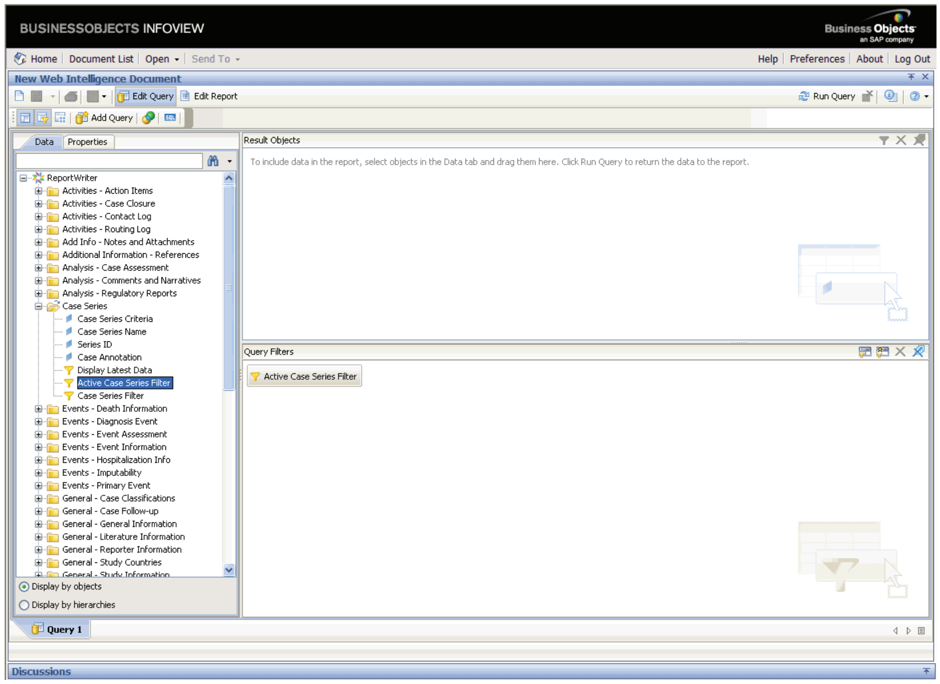
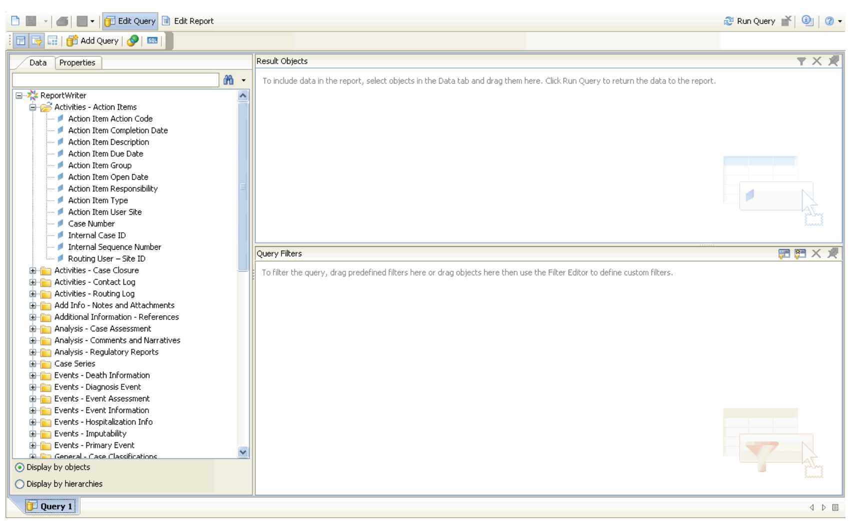
7. Drag and drop the Active Case Series Filter into the Query Filters panel. The selected filter appears in the right frame.



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.

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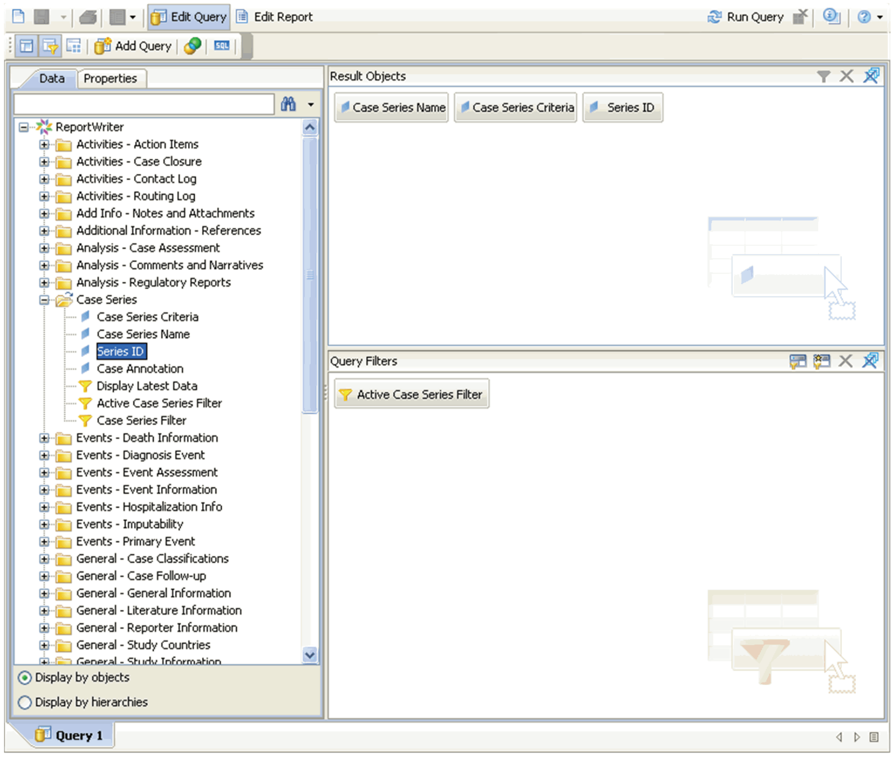
c. Drag and drop fields from the **Report Writer** panel into the **Result Objects** panel.



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.

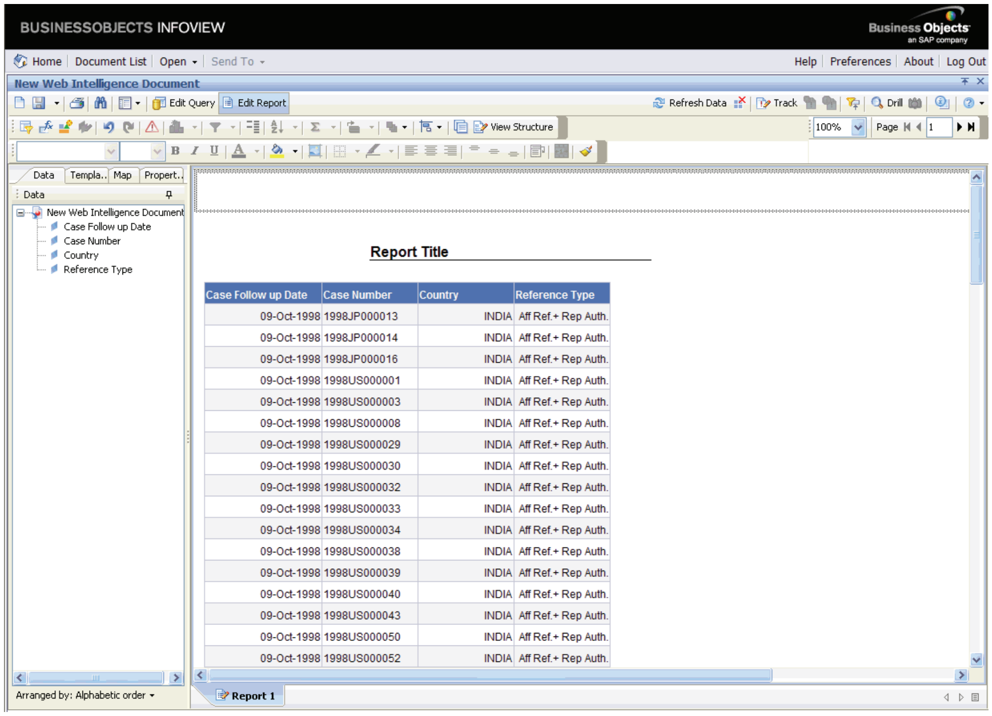
9. Click **Run Query** in the toolbar to execute the query.

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 12–1 shows a sample custom report.

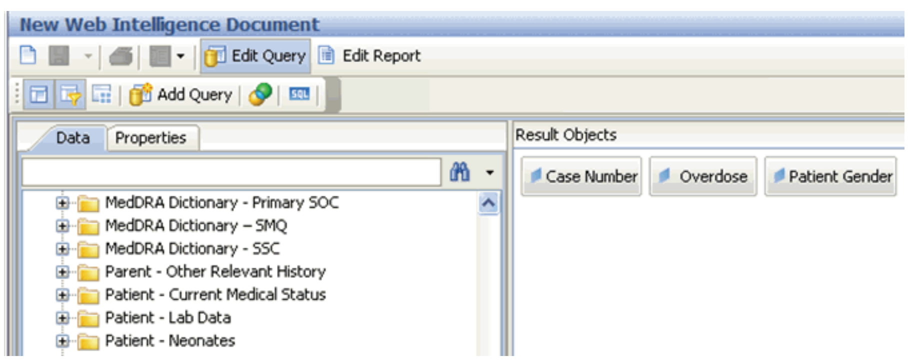
Note: When you finish using the Report Writer to create, edit, and save custom reports, you **must log out** of the BusinessObjects application. If you do not log out of BusinessObjects but you do log out of Argus Insight, another user logging in to Argus Insight has access to BusinessObjects with your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

Figure 12–1 Sample Custom Report



Editing Reports

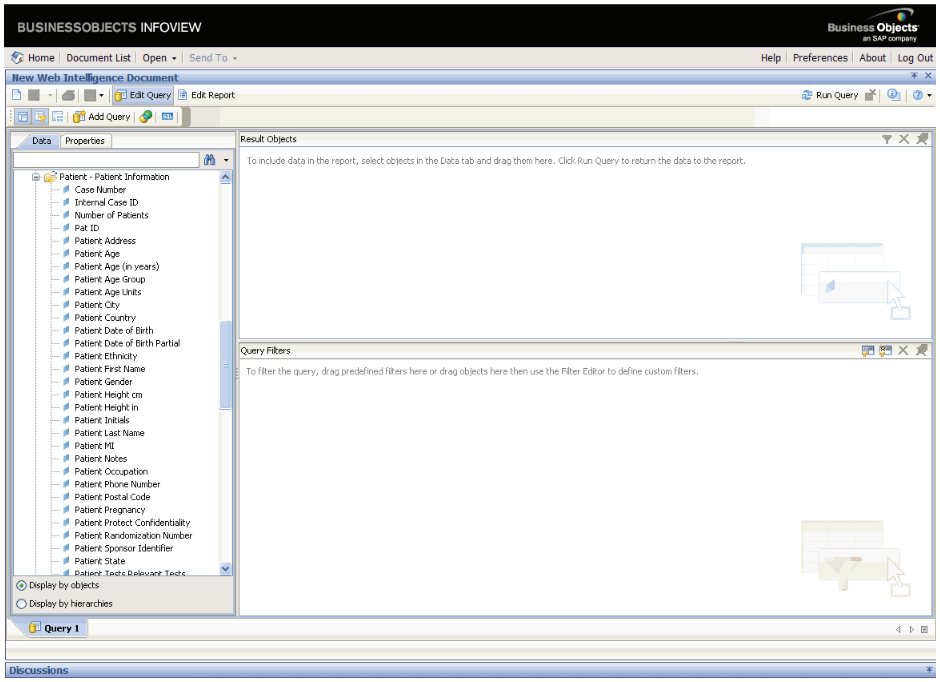
To access the *report* editing options provided by BusinessObjects, select **Edit Query.** The report editing options let you control what data appears in your report as well as how it is formatted, calculated, and sorted. None of the edit operations you perform are stored in the database.



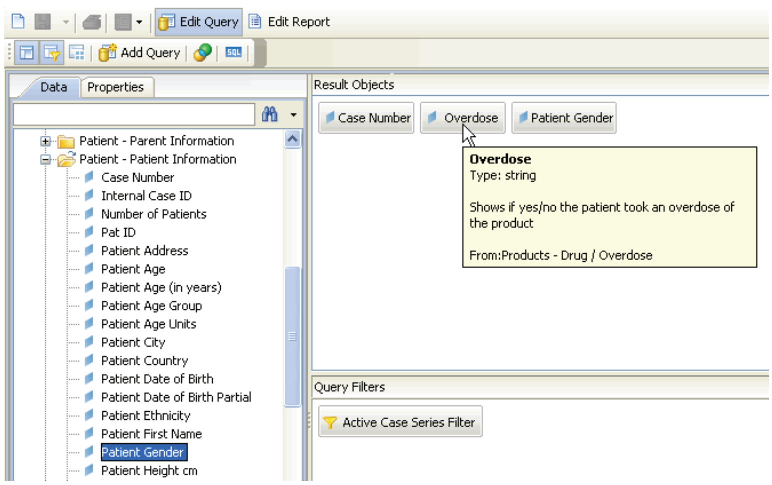
Filtering Data

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

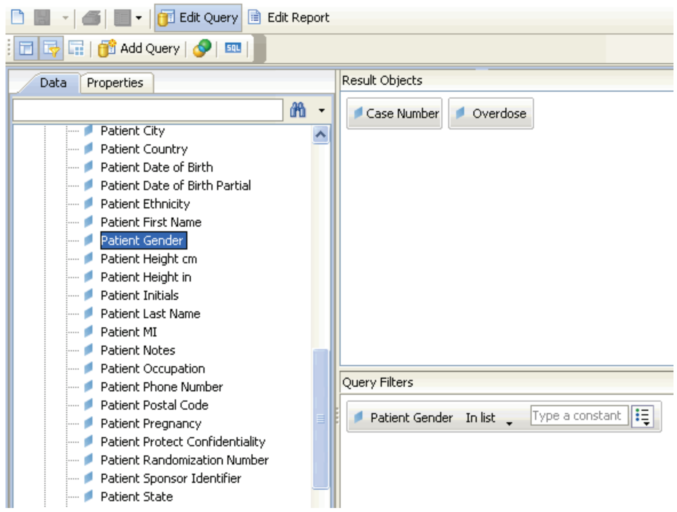
1. Click **Edit Query** to view the Data tab (objects) and the Result Objects panel.
2. Expand **Report Writer** in the Data tab.



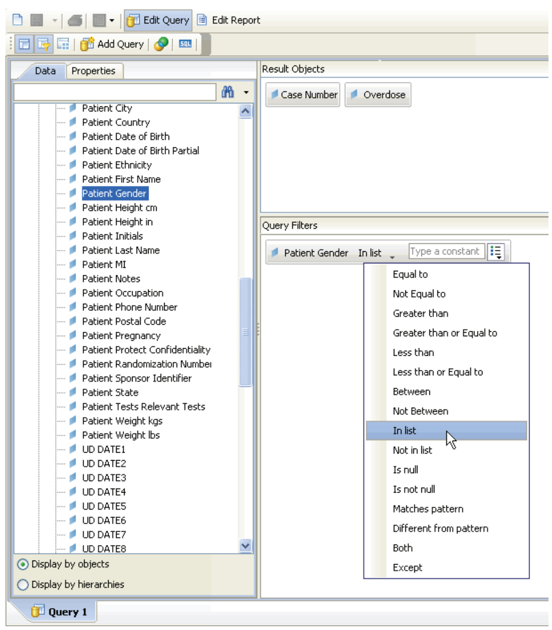
3. Drag and drop the data fields from the Data tab into the **Result Objects** panel.



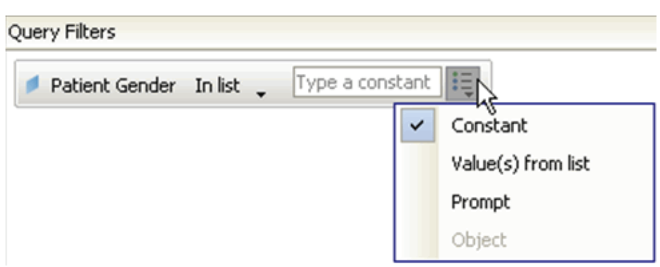
4. Drag and drop the filter criterion from the Data tab into the **Query Filters** panel.



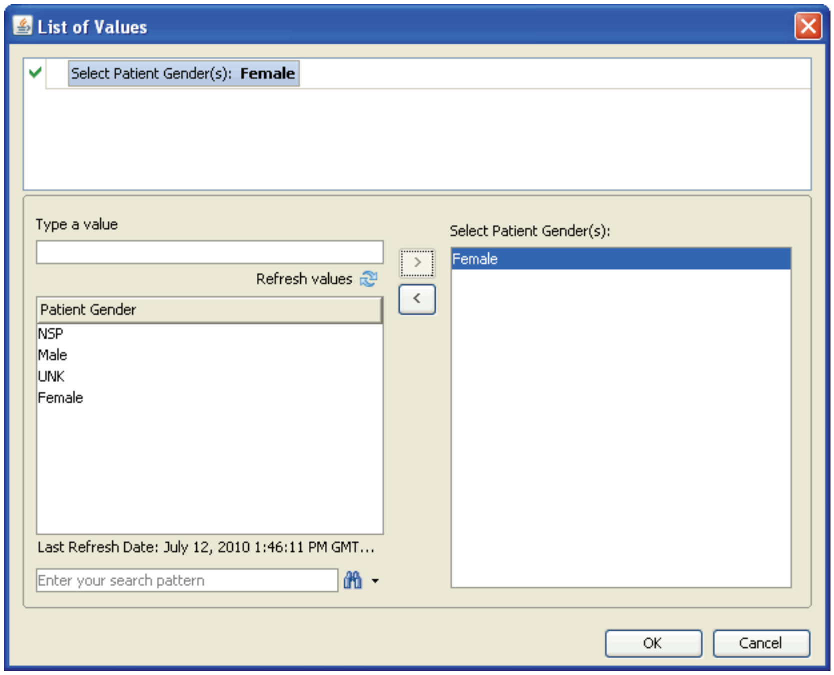
5. Select the **operator type** from the drop-down list. For example, if you select **In list** as the operator, the filter is limited to any one or all of the values defined in the list.



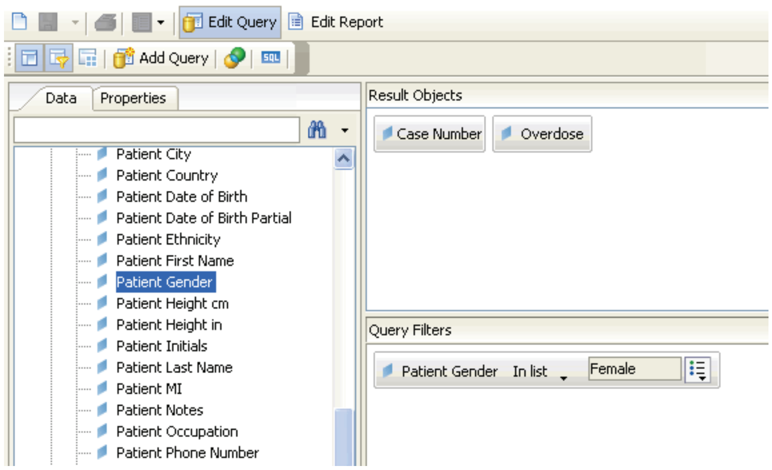
6. Click the icon next to the text field to select the values associated with the selected operator.



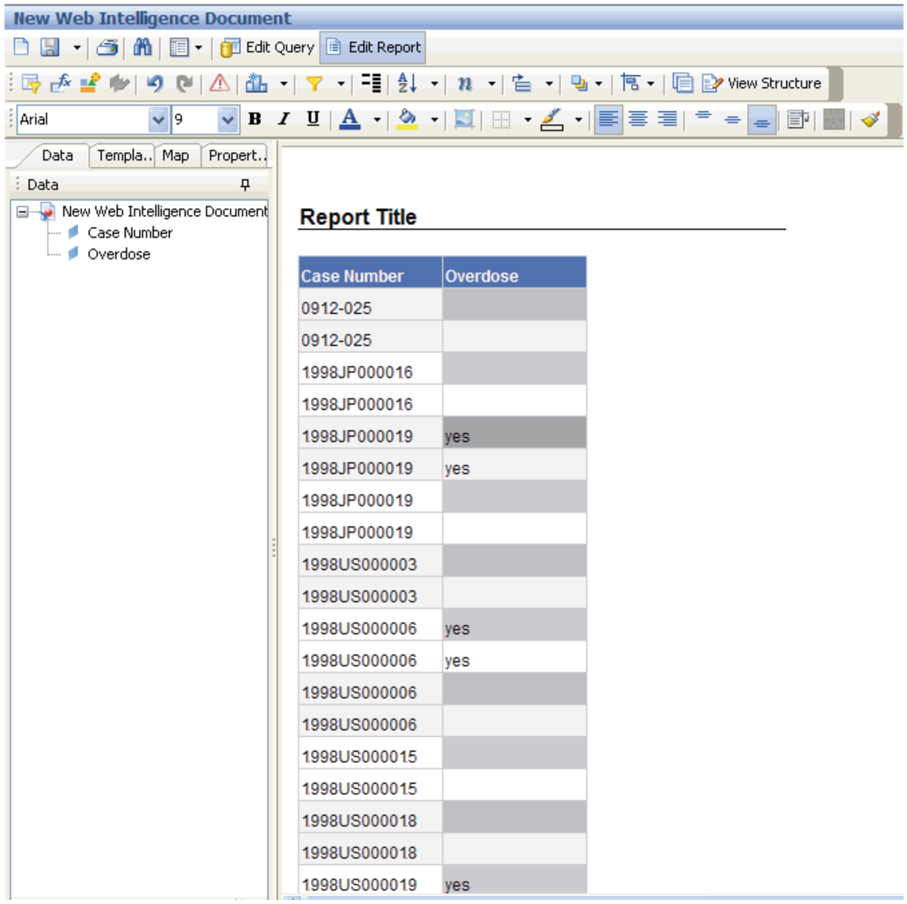
7. Define the value by selecting the term/word to be used as a filtering criterion.



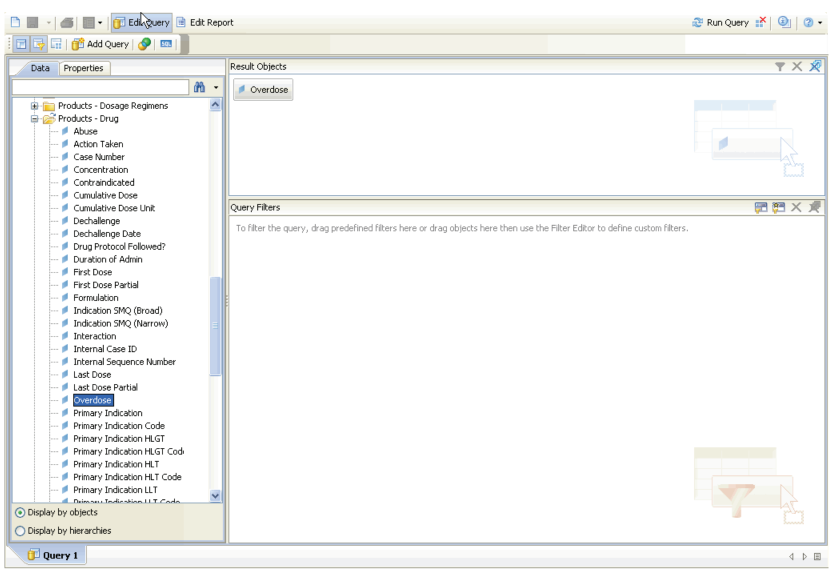
8. Click **OK** to confirm the action. The **Query Filters** panel refreshes automatically to display the complete filtering criterion.



9. 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.

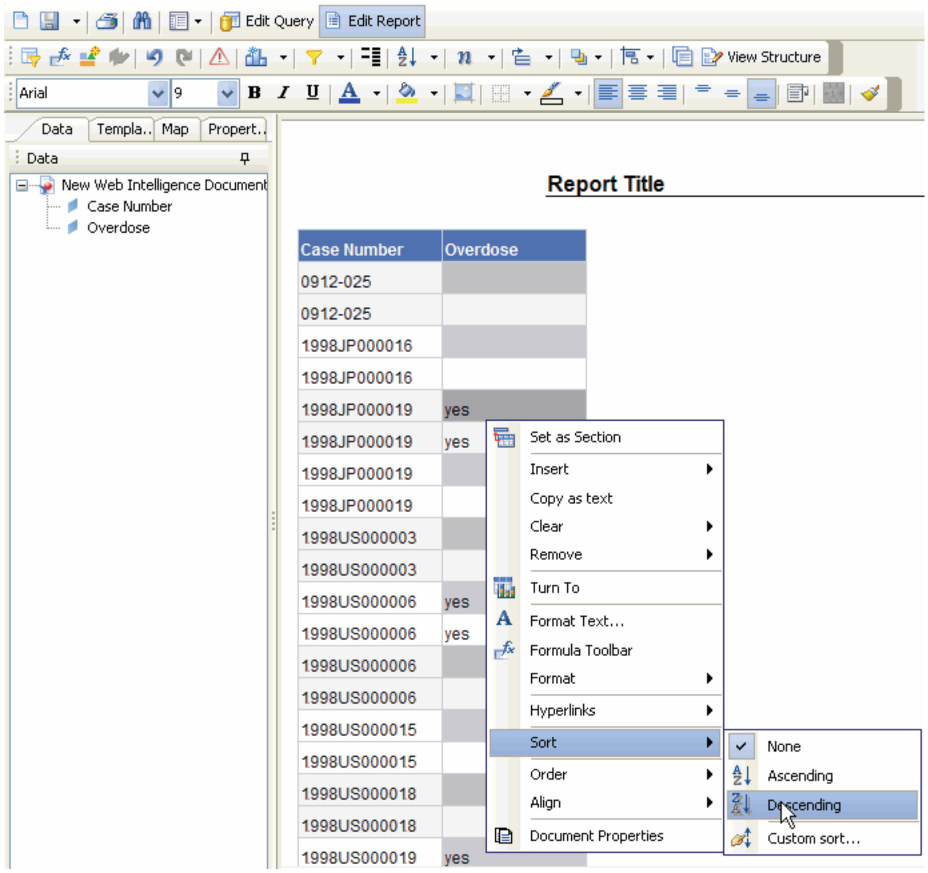


Repeat the procedure to add new data fields and filtering criterion, and then execute the query.

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.

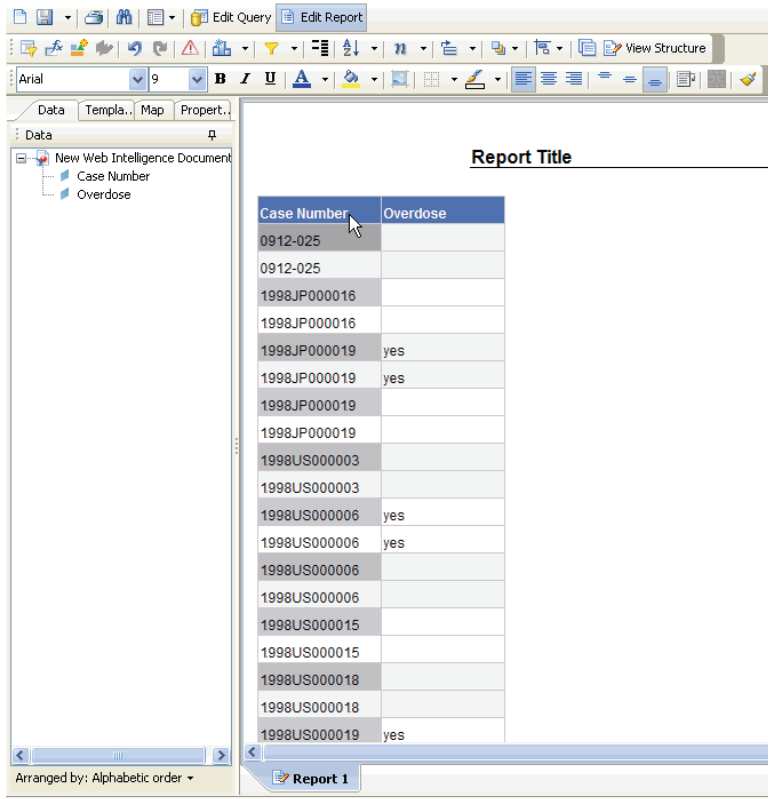
Summarizing Data

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.

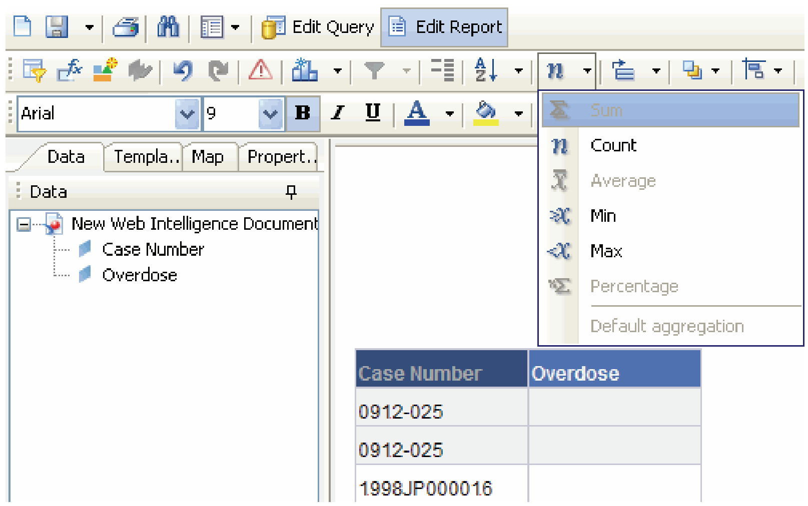
To summarize data:

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

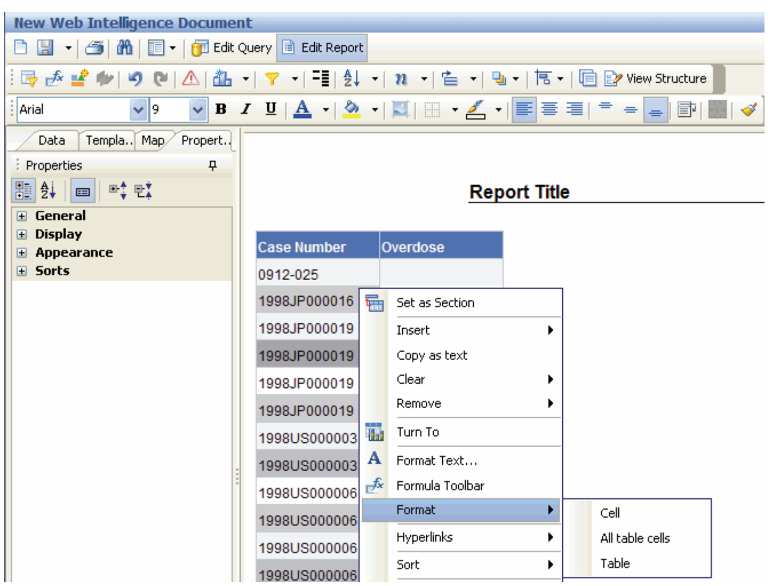
You can use predefined formats to change the appearance of text, numbers, currency, dates, and times in your report. Formatting does not change the underlying data. Table 12–1 describes the available formatting options.

Table 12–1 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.

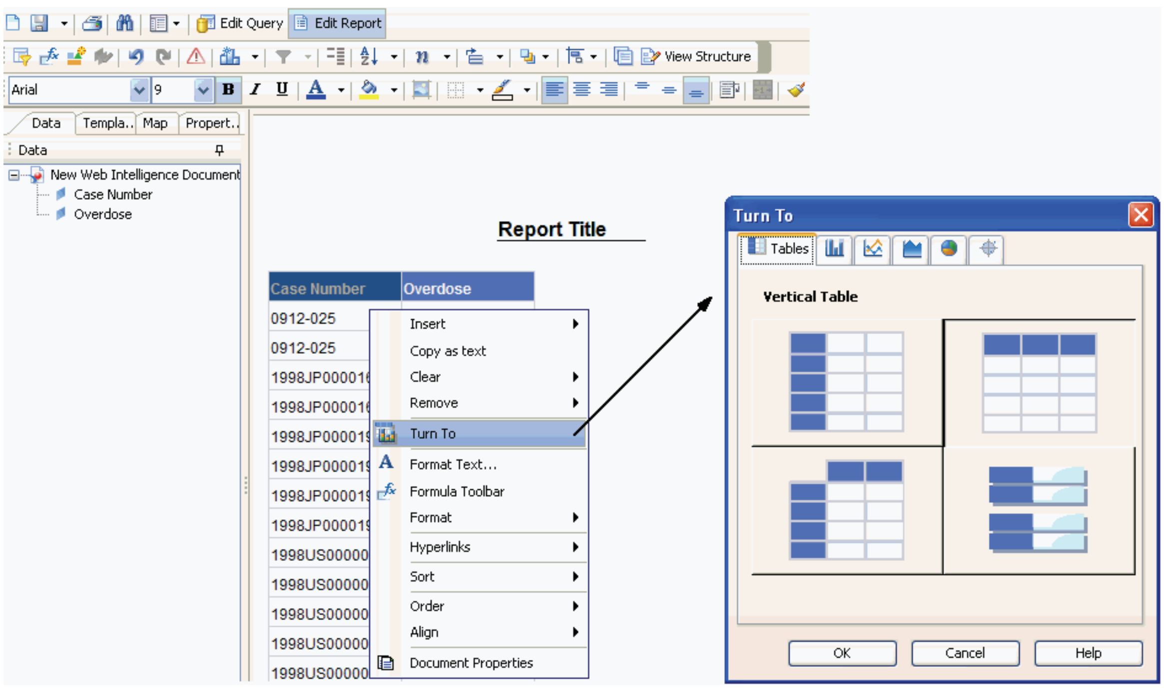
Turning the Report Layout into a Table or Chart

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.

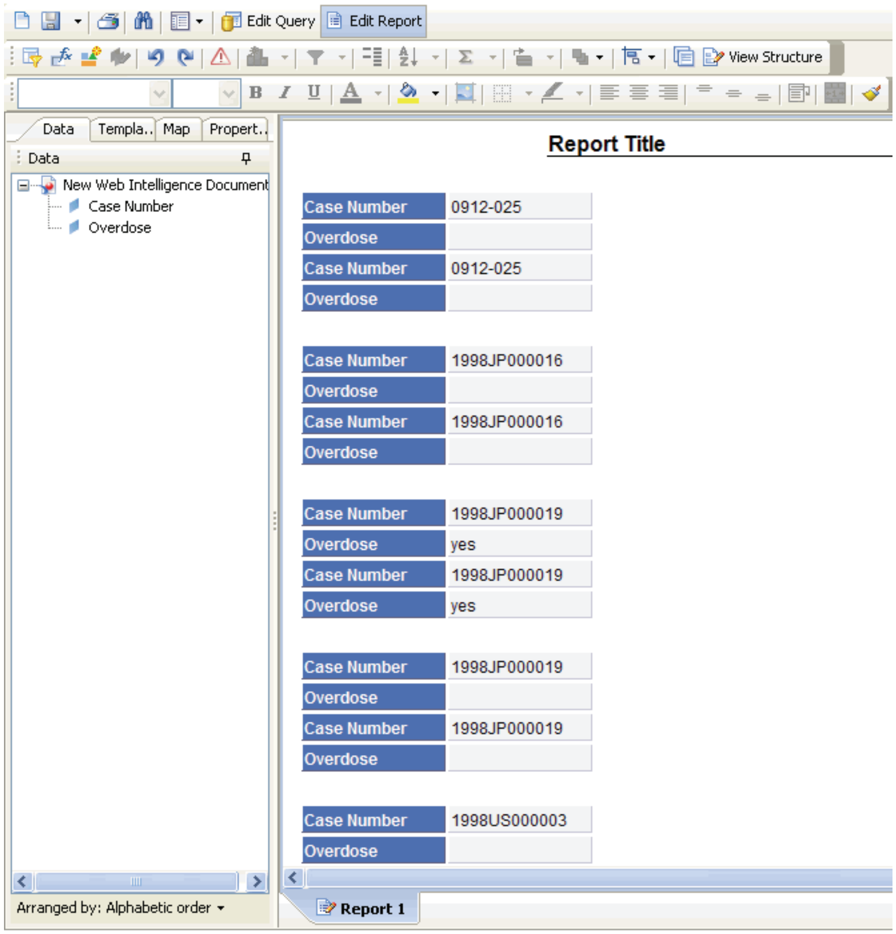
This section describe the basic layout operations. For detailed information, see the documentation supplied with the your BusinessObjects products.

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

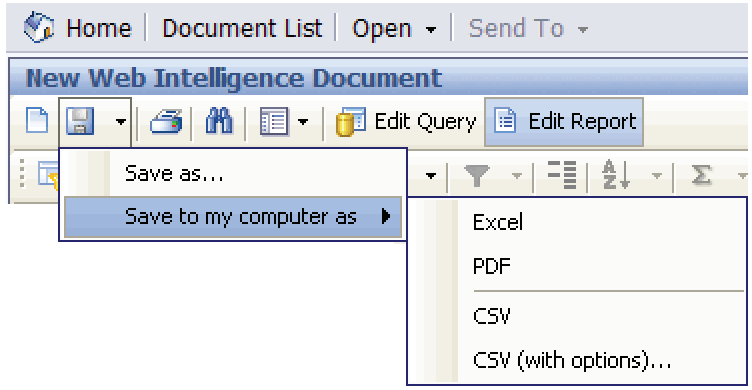
Use the **Save** menu option to save the reports you create by using Report Writer. You can save your reports in either Personal or Public folders.

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

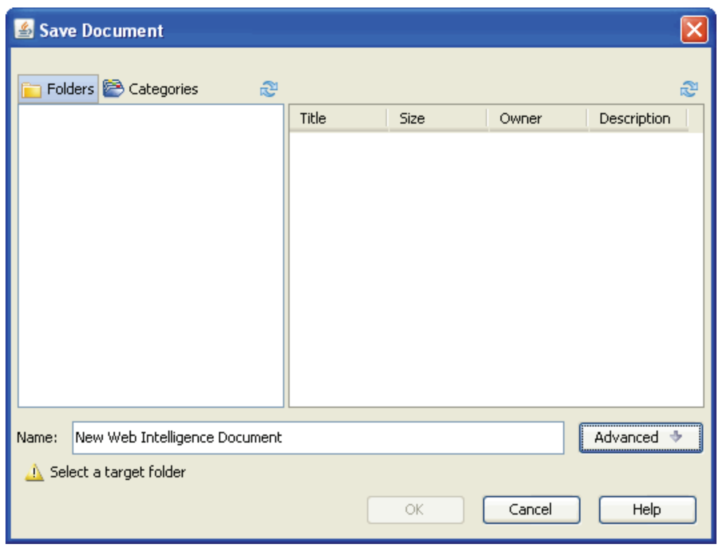
To save a report:

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.

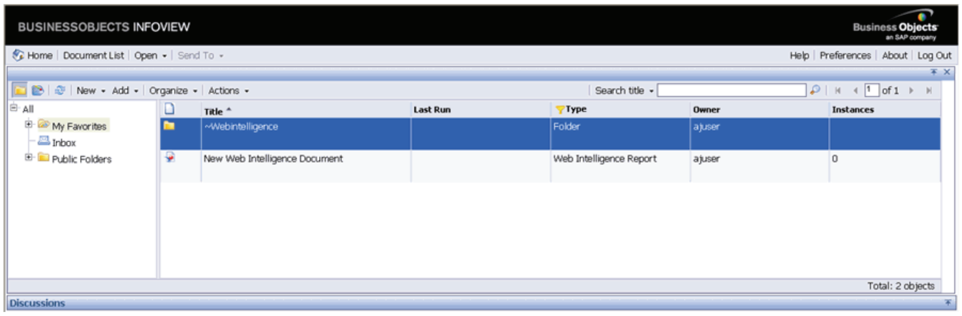
2. Click **Save as** to save the report on your system. The Save Document dialog box opens.



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 **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 **Reports, Report Writer, Library** menu is no longer available in Argus Insight.

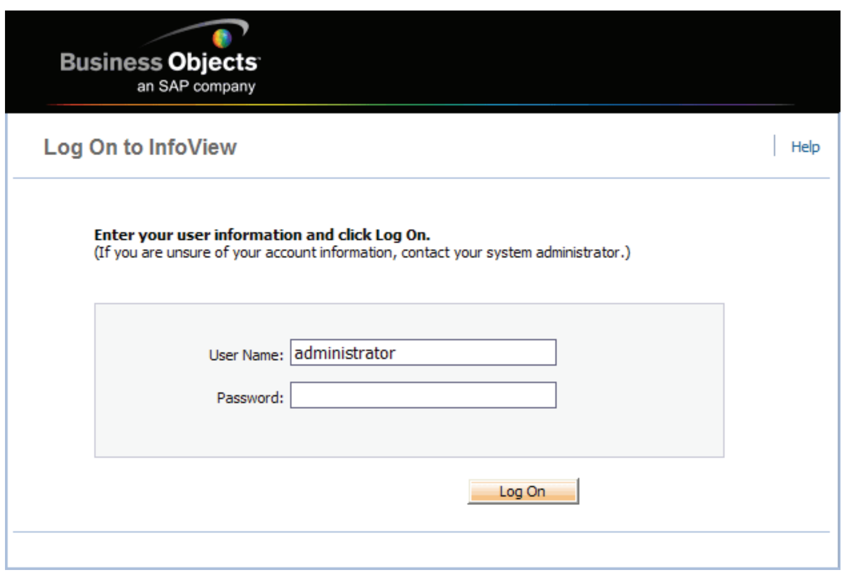
Right-click a report and select **Modify** to edit a saved report. The report opens in the BusinessObjects XI web intelligence interface. After you edit the report, you can save it by another name by using the **Save as** option in the **Save** menu.

Using SMQs in Report Writer

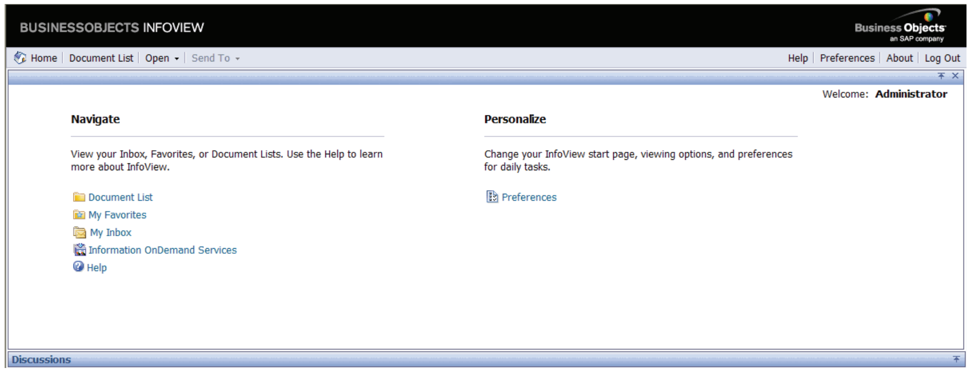
If you select a SMQ, the system displays all the cases based on that SMQ.

To use SMQs in Report Writer:

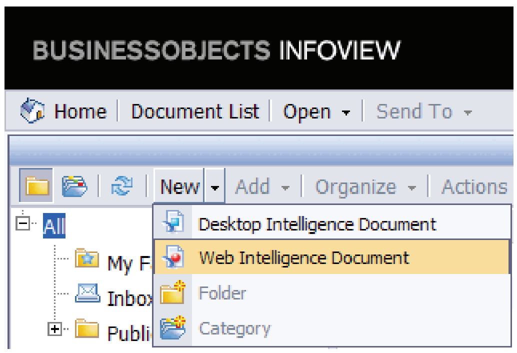
1. Navigate to **Reports, Report Writer,** and select **New.** The BusinessObjects InfoView logon window opens.



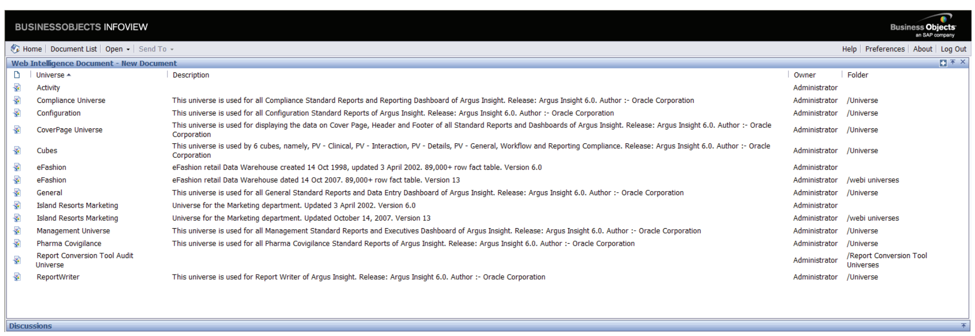
2. Enter your user name and password, and click **Log On.** The home page for BusinessObjects InfoView opens.



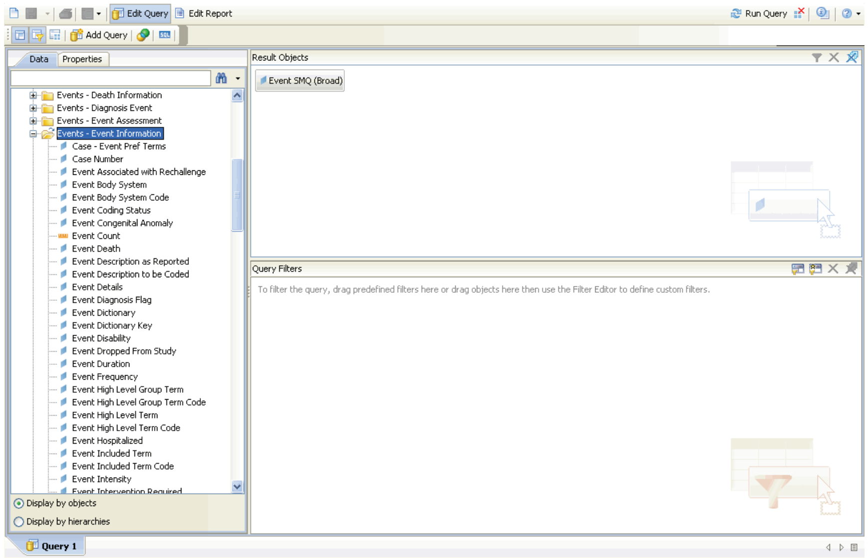
3. Click **Document List.**
4. Open the **New** menu and select **Web Intelligence Document.**



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.



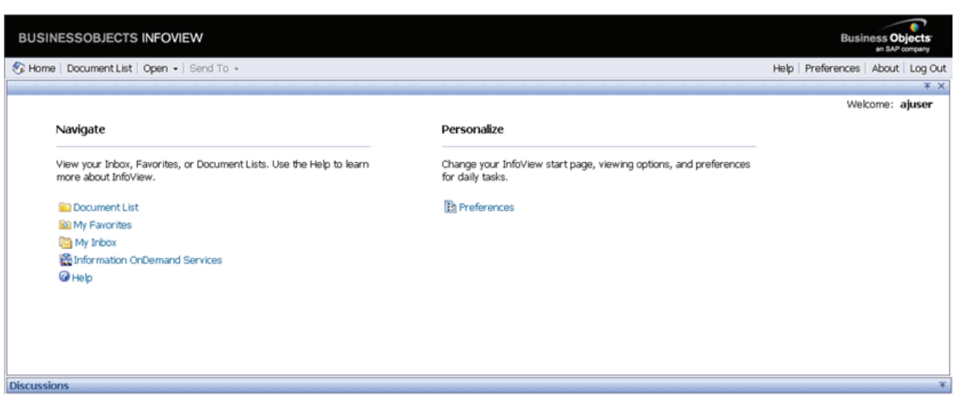
8. Click **Run Query.**
9. Click **Edit Query.**
10. Navigate to **Events - Event Information**, and drag and drop **Event SMQ (Narrow)** into the Result Objects panel.
11. Click **Run Query.**
12. Navigate to **Events - Event Information**, and drag and drop **Case Number** into the Result Objects panel.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

Creating AdHoc Reports

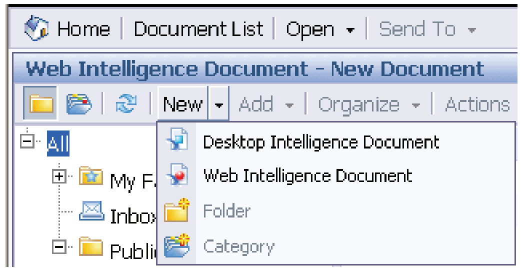
This section describes how to use BusinessObjects InfoView to save the customized reports under the AdHoc Reports menu. *AdHoc Reports* is a repository where all the customized reports are saved. Reports can be shared among different users.

To save AdHoc reports:

1. Log in to Argus Insight.
2. Navigate to **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.

13

Creating Custom Reports - BIP

In addition to the preformatted standard reports, the BI Publisher tool also enables you to create custom reports.

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

- Creating a New Report
- Editing Reports
- Changing the Report Layout

Creating a New Report

Creating a new report using the BI Publisher tool comprises two parts: Creating Reports and Creating Data Models.

For information on creating reports using the BI Publisher tool, refer to the **Creating Reports and Layouts** section of the Oracle Fusion Middleware Report Designer's Guide for Oracle Business Intelligence Publisher.

For information on creating Data Models, refer to the Oracle Fusion Middleware Data Modeling Guide for Oracle Business Intelligence Publisher.

Editing Reports

For information on editing reports, refer to the **Creating and Editing Reports** section of the Oracle Fusion Middleware Report Designer's Guide for Oracle Business Intelligence Publisher.

Changing the Report Layout

For information on changing the Report Layout, refer to the **Creating BI Publisher Layout Templates**, **Creating RTF Templates**, and **Creating RTF Templates Using the Template Builder for Word** sections of the Oracle Fusion Middleware Report Designer's Guide for Oracle Business Intelligence Publisher.

In addition, you can also refer to the following sections of the Oracle Argus Insight Extensibility Guide:

- Extend Current Data Model - This section explains the steps to extend the existing report.
- Add New Data Set - This section explains the steps to add new data set in BIP data model.

- BIP Report Templates - This section explains the steps to add or modify existing layout or report templates.

14

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.

  When Argus Insight is configured for SSO, Cognos still uses the PowerReports namespace.

- **Accessing Argus Insight directly by using URL —** It is expected that customers will pass the internal enterprise ID as a URL parameter for the Argus Insight application to open with the appropriate enterprise context. If the enterprise ID is not passed, the system validates the user against the default enterprise.

- **Global User Management —** To apply updates to the *Synchronizable* fields for all the enterprises in the system, you must maintain some administrative users in Argus Insight. Use the User and Group Administration options in the Security tab on the ADMINISTRATION TOOLS page to modify user accounts and enable access for all enterprises in the system.

- **User-Enterprise Association —** To copy a user account from one enterprise to another, you must have already set up the appropriate user groups in the target enterprise. Otherwise, the user association will fail with an appropriate error message.

- **New User Creation/Association —** Argus Insight lets you use the same user ID to create different users across multiple enterprises. However, use this feature *only if* you do not expect to share the users across enterprises.

  If you expect to share users across multiple enterprises, do not use the same user ID to create different users across different enterprises. Instead, create the user in one enterprise, and then use Global User Management to associate the user to other enterprises.

- **New Enterprise Setup —** It is expected that you will create and choose appropriate enterprises with generic configuration data that can be used as a source for copying the configuration data to create new enterprises.

  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 14–1 describes the modules in Argus Insight as per their data segregation status in Clinical Research Organization mode (CRO mode) and hosting installations.

Table 14–1 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.
Cognos	No	A single Cognos server supports all the enterprises. When you log in to Cognos directly, you can see all the common objects as well as the enterprise-specific objects that are accessible to you. When you run a report, you can access the cases for a specific enterprise only. For reports that you can access, you can run the report against any enterprise data for which you have access.

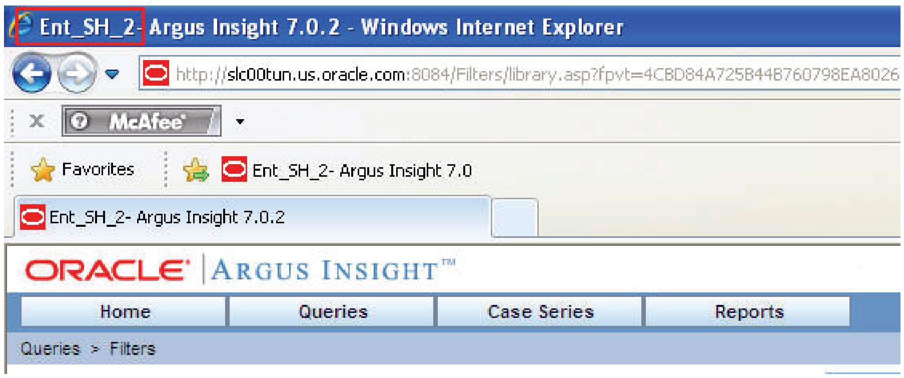
Enterprise Short Name in Argus Insight

The *Enterprise Short Name* is an abbreviated, unique name of a client. You can configure Argus Insight to display the Enterprise Short Name in the title bar for the Argus Insight application.

The **Display Enterprise Short Name in Application Header** check box in Global Enterprise Management controls the display of the Enterprise Short Name.

If this check box is selected, the Enterprise Short Name is displayed in the Argus Safety header along with database name (*DB_Name* – *Enterprise_Short_Name*) where *Enterprise_Short_Name* is the unique short name of the enterprise.

In addition, the Argus Insight application displays the Enterprise Short Name in the title bar. For example, the following illustration shows **ABC Pharma,** which is a sample Enterprise Short Name, in the title bar:



If the **Display Enterprise Short Name in Application Header** check box is not selected, Argus Insight does not display the Enterprise Short Name in the title bar.

Login and Navigation

Clinical Research Organization (CRO) users can operate on only specific enterprises. Users have access to only certain Argus Insight modules.

Note: The default enterprise in Argus Insight is the same as the default enterprise configured in Argus Safety.

Single Sign-On Accounts

Having a single sign-on account (SSO account) for the 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.

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.

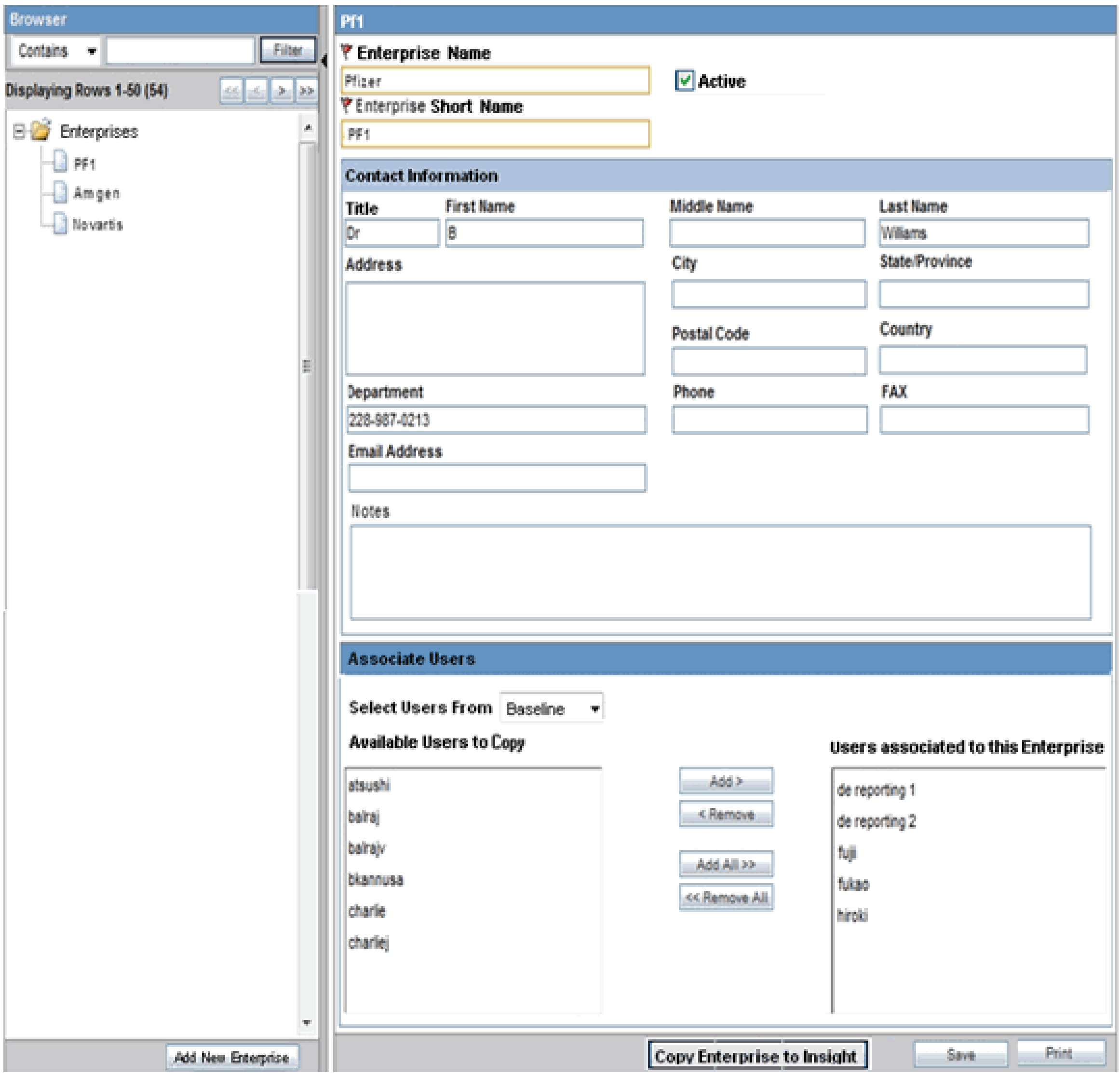
Overview of the Global Enterprise Management Page Layout

The Global Enterprise Management portlet, see Figure 14–1, 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 14–1 Global Enterprise Management Portlet



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.

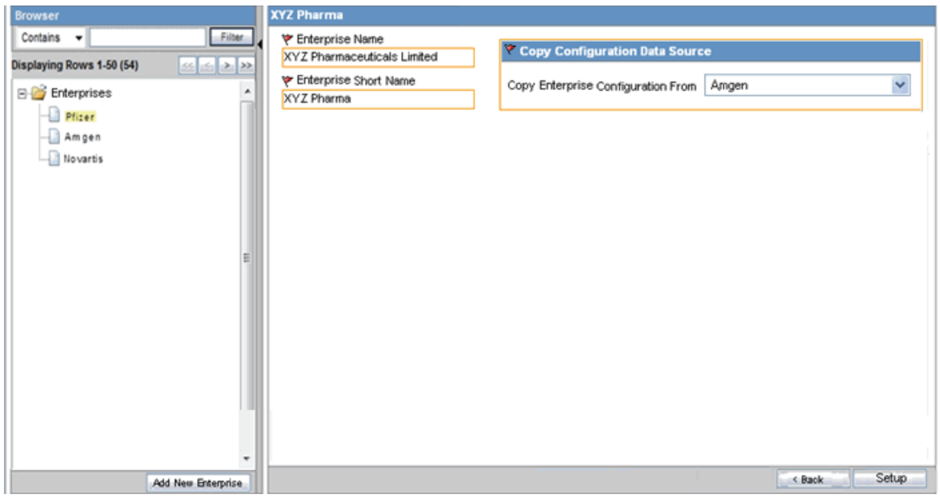
Copying an Enterprise

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

This section comprises the following sub-sections:

- Cognos Reports
- BusinessObjects Reports

Cognos Reports

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

- Standard Reports
- Custom Reports
- Report Writer Reports
- Reports in the Cognos 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 Cognos. Cognos 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 Cognos. 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 Cognos Report Studio 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 Cognos Environment

You can log in to the Cognos 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.

BusinessObjects Reports

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

- 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. BusinessObjects 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 BusinessObjects. 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 BusinessObjects Report Studio 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.

15

Using the Administration Tools

This chapter provides information about using the Argus Insight administration tools. You use the various tabs on the ADMINISTRATION TOOLS page to configure, maintain, and secure Argus Insight.

This chapter includes the following topics:

- Support for Multibyte Characters
- Using Schema Creation Tool
- Opening the ADMINISTRATION TOOLS Page
- Configuring Personal Options
- Maintaining Argus Insight Lists for Cognos
- Maintaining Argus Insight Lists for BusinessObjects
- Running the Extract, Transform, and Load Process
- Securing User Accounts, Groups, and Access Rights
- Viewing the Audit Log

Support for Multibyte Characters

Beginning with Argus 5.1, the database was converted to accommodate multibyte characters. The Argus J structure was merged into Argus Safety 5.1, which included Argus field conversion from VARCHAR to CLOB data type.

To ensure compatibility Argus Safety, Argus Insight 5.1 and later supports the following field changes:

- Schema creation and validation — Data type changed from VARCHAR to CLOB
- Initial ETL and Incremental ETL — Transformation logic changed
- Database upgrade — Data type changed from VARCHAR to CLOB
- Reports — Reports validated and modified
- Report Writer — Design (queries) and model changed
- Power Queries — QBEs, filters, and advanced conditions validated and modified

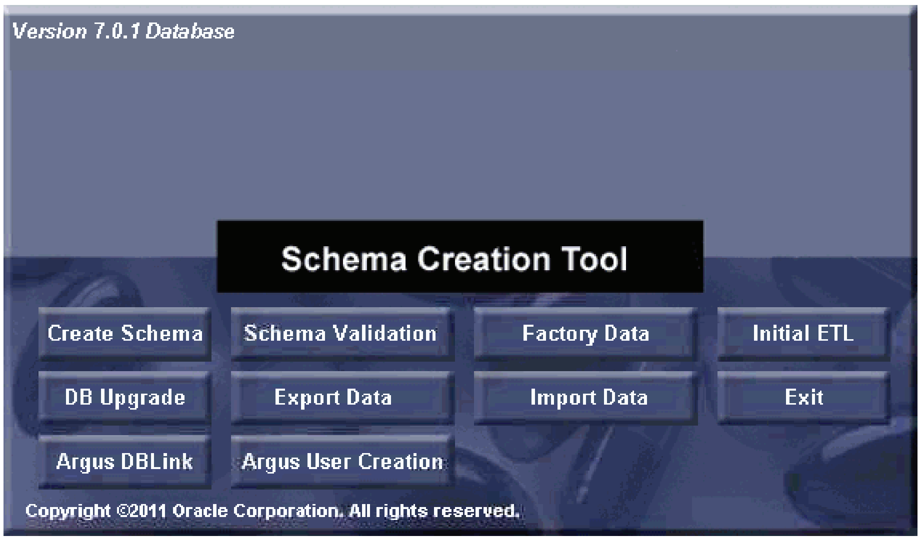
Using Schema Creation Tool

Using the Schema Creation Tool (see Figure 15–1), you create the Argus Insight data mart structure. You create a link between your source Argus database and your new

Argus Insight data mart. The Extract Transform and Load (ETL) process uses this link to transfer data from your Argus database to the Argus Insight data mart for reporting purposes.

During the schema creation process, you create four database users: one user for logging in to the Argus Insight application, two other users who are schema owners, and one user for supporting private database links (DB Links).

Figure 15–1 Schema Creation Tool Main Menu



The Schema Creation Tool provides the following options:

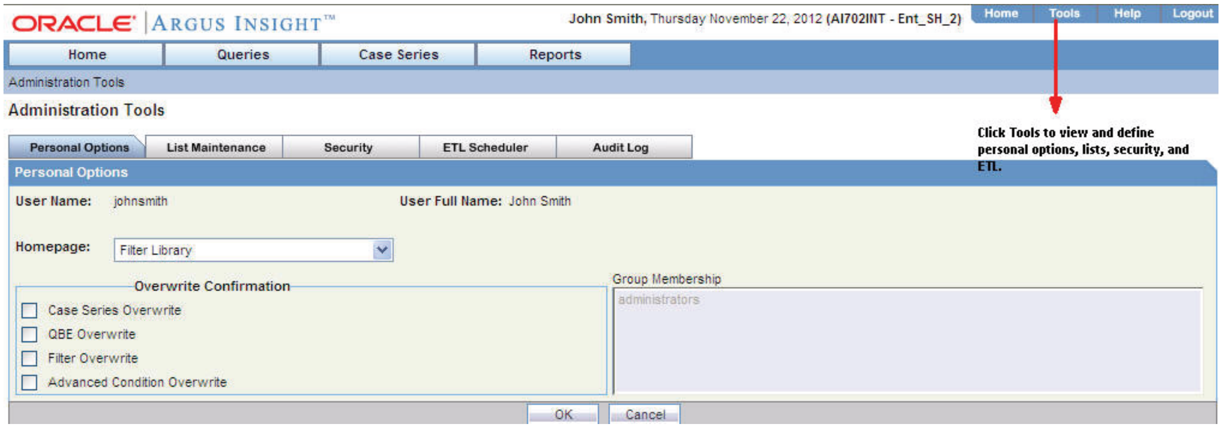
- **Create Schema —** Creates a new database schema for Argus Insight.
- **Schema Validation —** Validates a newly-created database schema.
- **Factory Data —** Loads the factory data into the database.
- **Initial ETL —** Runs the initial process of extracting, transforming, and loading data.
- **DB Upgrade —** Upgrades an existing Argus Insight 7.0 database to an Argus Insight 7.0.2 database.
- **Export Data —** Exports data.
- **Import Data —** Imports data.
- **Argus DBLink —** Creates a link between Argus Insight and Argus Safety.
- **Argus User Creation —** Lets you create Argus Insight users and roles.
- **Exit —** Exits from the Schema Creation Tool.

For detailed information about using the Schema Creation Tool to create the Argus Insight data mart structure, including the database link, users, and roles, see the *Oracle Argus Insight Installation Guide*.

Opening the ADMINISTRATION TOOLS Page

To access the Argus Insight administration tools, click **Tools** on the global toolbar in the upper-right corner of the page. The ADMINISTRATION TOOLS page opens. The Personal Options tab is in focus. See Figure 15–2.

Figure 15–2 ADMINISTRATION TOOLS Page with Personal Options Tab in Focus



Configuring Personal Options

Using the Personal Options tab on the ADMINISTRATION TOOLS page, you can:

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

By default, the Personal Options tab is in focus when you open the ADMINISTRATION TOOLS page. The Personal Options tab is available to all users. For more information about using the Personal Options tab, see "Setting Your Personal Options" on page 2-3.

Maintaining Argus Insight Lists for Cognos

This section describes the following tasks that you can perform using the List Maintenance tab on the ADMINISTRATION TOOLS page:

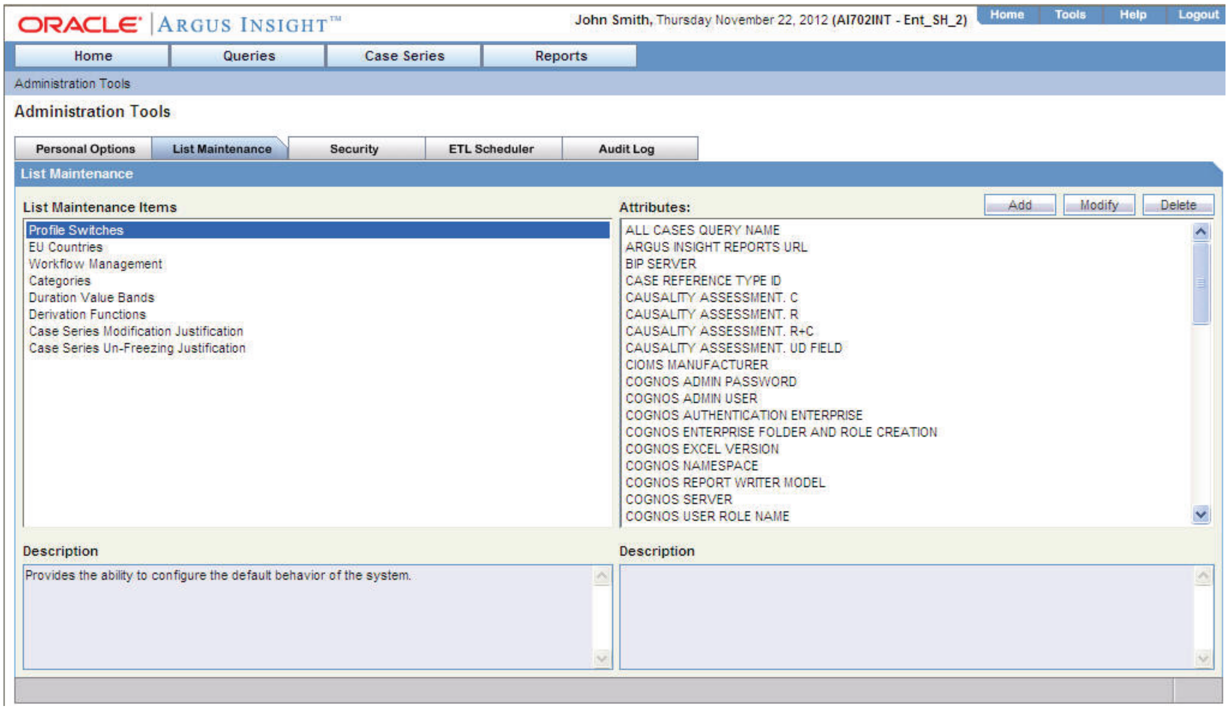
- Configuring the Argus Insight Application Profile Switches
- Configuring European Union Countries
- Mapping Case Workflow States
- Configuring Categories
- Configuring Duration Value Bands
- Configuring Derivation Functions
- Configuring Case Series Modification Justification
- Configuring Case Series Un-freezing Justification

Configuring the Argus Insight Application Profile Switches

Profile switches are a collection of settings that let you configure the default behavior of Argus Insight. The default value of a profile switch can be predefined or based on user input. All profile switch values are case sensitive.

In general, you use the List Maintenance tab on the ADMINISTRATION TOOLS page (see Figure 15–3) to configure existing profile switches and to add new profile switches. However, certain profile switches can only be configured through direct SQL statements.

Figure 15–3 List Maintenance Tab with the Profile Switches



Consult your company's policies and the terminology used before configuring profile switches.

For detailed information about all the profile switches, see the following documents:

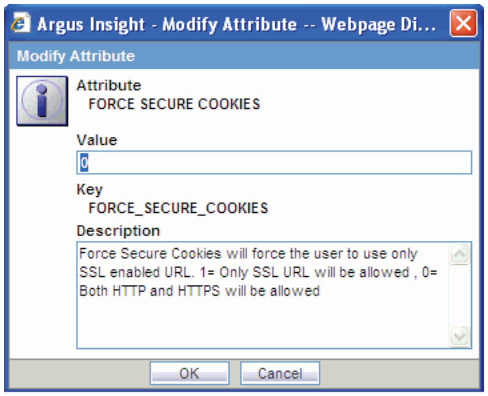
- *Oracle Argus Insight CMN Profile Enterprise Table Guide* (CMN_PROFILE_ENTERPRISE.pdf)
- *Oracle Argus Insight CMN Profile Global Table Guide* (CMN_PROFILE_GLOBAL.pdf)

In addition, the documents have a sample SQL for inserting profile switches and updating their values in the database.

Accessing and Modifying the Profile Switches

To access and modify the Argus Insight profile switches:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page 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 the profile switch that you want to modify.
5. Click **Modify.** The system opens the Modify Attribute dialog box. For example:

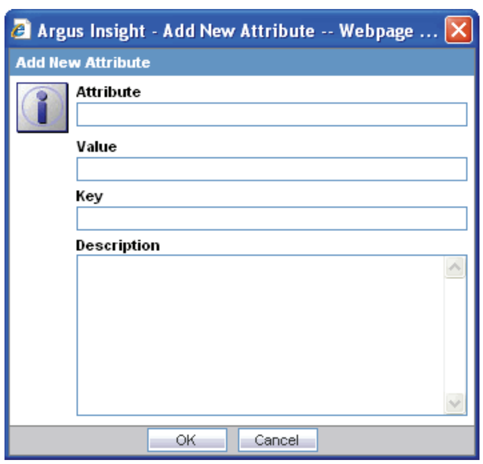


6. Modify the values, as appropriate.
7. Click **OK.** The profile switch is updated.

Adding a New Profile Switch

To add a new profile switch:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page 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 current profile switches.
4. Click **Add.** The system displays the Add New Attribute dialog box.



5. Enter the profile switch name, key, and description, as appropriate.
6. Click **OK.**

Configuring the Excel Version for Cognos Reports

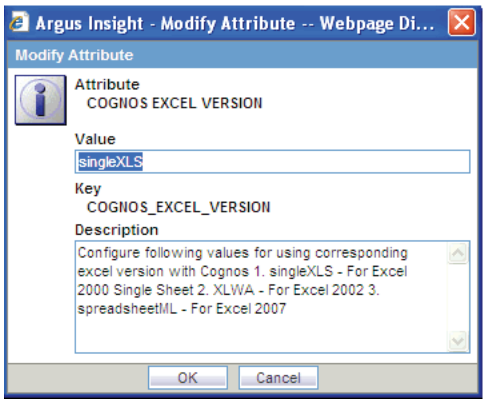
By default, Argus Insight uses Microsoft Excel 2000 (single sheet) to provide proper support for running Cognos reports. This version of Excel is independent of the Excel version on the client machine.

You use the COGNOS EXCEL VERSION profile switch to enable either Excel 2002 or Excel 2007 for Cognos reports. In addition, if you select one of these Excel versions, the same version of Excel *must be installed* on the client machine.

The COGNOS EXCEL VERSION profile switch is available *only if* Cognos is defined as your business intelligence tool.

To set the Microsoft Excel version for Cognos installations:

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 **COGNOS EXCEL VERSION** in the Attributes section.
5. Click **Modify.** The Modify Attribute dialog box opens.



6. Enter the appropriate value depending on your version of Microsoft Excel.
   - **singleXLS —** For Excel 2000 (single sheet format)
   - **XLWA —** For Excel 2002 (multisheet format)
   - **spreadsheetML —** For Excel 2007 (multisheet format)

   Depending on the value you select, Argus Insight determines the Excel version to use to open Cognos reports.
7. Click **OK** to save your changes.

Listing of the Common Profile Switches

Table 15–1 lists the profile switches that you can configure using the options in the List Maintenance tab. For each profile switch, the table specifies the name of the switch, indicates whether the switch is a global-level or an enterprise-level switch, and provides a brief description.

All the global-level switches are displayed, updated, and audit logged in the default enterprise.

For more information about viewing and editing profile switches, see "Configuring the Argus Insight Application Profile Switches" on page 15-3.

Table 15–1 Common Profile Switches

Profile Switch	Switch Level	Description
ALL CASES QUERY NAME	Enterprise	Defines the name of the query that returns All Cases in the data mart for use with reports scheduling.
ARGUS INSIGHT REPORTS URL	Global	Specifies the URL for the Argus Insight application for accessing scheduled reports that cannot be sent to the configured email ID due to the mail size limit.
BITOOL LDAP ENABLED	Global	Specifies whether LDAP is enabled at the Business Intelligence (BI) tool level.
CASE REFERENCE TYPE ID	Enterprise	Used to populate the RPT_CASE.FIRST_REF_NO column.
CAUSALITY ASSESSMENT. C	Enterprise	Used in standard reports for Company Defined Causality.
CAUSALITY ASSESSMENT. R	Enterprise	Used in standard reports for Reporter Defined Causality.
CAUSALITY ASSESSMENT. R+C	Enterprise	Used in standard reports for Reporter Defined Causality and Company Defined Causality.
CAUSALITY ASSESSMENT. UD FIELD	Enterprise	Used in standard reports for user-defined field to determine causality.
CIOMS MANUFACTURER	Enterprise	Defines the manufacturer information that prints on the CIOMS report.
COGNOS ADMIN PASSWORD	Enterprise	Specifies the password for the Cognos administrator. If the password is incorrect, access to the Cognos administration tools for configuring additional security will be denied.
COGNOS ADMIN USER	Enterprise	Specifies the name of the Cognos user who has administrator privileges. This user performs administrative activities, such as security management on Cognos, from the Argus Insight application.
COGNOS AUTHENTICATION ENTERPRISE	Global	Defines the short name of the enterprise from which all users are authenticated for Cognos login. All Argus Insight users must be a member of this template enterprise. On the Cognos Server, Cognos security is enabled only after this switch is configured.
COGNOS ENTERPRISE FOLDER AND ROLE CREATION	Enterprise	Defines the name of the enterprise-specific folder that is created on the Cognos Server (default value is Enterprise Short Name) and defines the role name to give access to users on enterprise-specific objects (default value is Enterprise Short Name_ROLE).
COGNOS EXCEL VERSION	Enterprise	Defines the version of Excel you are using with Cognos.
COGNOS NAMESPACE	Global	Defines the name of the Cognos namespace to use for user authentication. PowerReports is the default namespace for custom Java authentication. If you are using Active Directory or LDAP authentication in Cognos, specify the namespace name used on the Cognos Server.
COGNOS REPORT WRITER MODEL	Enterprise	Defines the name of the Cognos Report Writer model. If this value is incorrect, Report Writer functionality in Argus Insight will not work. Default value is Report Writer.
COGNOS SERVER	Enterprise	Defines either the IP address or the name of the Cognos web server. This value identifies the Cognos server to use. Use the following format to specify the port number along with the server name: *Cognos_server_name:port_number*.
COGNOS USER ROLE NAME	Global	Defines the Cognos role name in which all Argus Insight users are added for accessing reports.
COMPANY LOGO PATH	Enterprise	Defines the location of the company logo on the local server. This logo prints in the report header.

Table 15–1 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
CONFIDENTIALITY TEXT	Enterprise	Defines the confidential text that prints in the running footer on each page in the report.
CUSTOM HELP URL	Enterprise	Defines the URL for your customized online help. If the URL is not valid, users receive the following error message: `Error 404 - Page Not Found`.
CUSTOM ROUTINE AFTER INCREMENTAL ETL	Global	Defines the full path of the custom routine (Oracle stored procedure) to be executed *after* Incremental ETL. If the routine fails or is not found, the administrator receives an email notification.
CUSTOM ROUTINE BEFORE INCREMENTAL ETL	Global	Defines the full path of the custom routine (Oracle stored procedure) to be executed *before* Incremental ETL. If this routine fails or is not found, then the ETL does not run and the administrator receives an email notification.
DATASHEET BPI	Enterprise	Configures the user-defined fields for assessment of BPI Datasheet in the Product tab.
DATASHEET EMEA	Enterprise	Configures the user-defined fields for assessment of EMEA Datasheet in the Product tab.
DATASHEET FLAG	Enterprise	Sets the flag used during Incremental ETL to determine whether to populate the data in the four *DATASHEET* fields (DATASHEET BPI, DATASHEET EMEA, DATASHEET IB, DATASHEET PI) for all the cases or for only the modified cases.
DATASHEET IB	Enterprise	Configures the user-defined fields for assessment of IB Datasheet in the Product tab.
DATASHEET PI	Enterprise	Configures the user-defined fields for assessment of PI Datasheet in the Product tab.
DAYS TO LOCK	Enterprise	Configures the number of days to lock for a case.
DELAY IDENTIFIER	Enterprise	Defines the delay text that ETL uses to populate the RPT_FOLLOWUP.CORE_DELAY_ROUTING_COMMENT field in the Supplier Performance Report and the Process Performance Report - Workflow.
EMAIL SENDER ADDRESS	Enterprise	Defines the email address of the person on whose behalf Argus Insight sends all email messages. If you leave the value blank, then Argus Insight sends no email messages.
ETL DATA EXCLUSION	Global	Specifies whether to continue or cancel the ETL process if cases with erroneous data are found.
ETL EMAIL RECEIVER ADDRESS	Global	Defines the email address of each administrator who will receive email status messages of the ETL process. Use a semi-colon to separate each entry. If you leave the value blank, then Argus Insight sends no email messages.
ETL EMAIL SETUP	Global	Defines whether to send an email only after ETL failure, only after ETL success, or in either case.
FAILED RECIPIENTS STATUS EMAIL ADDRESS	Enterprise	Defines the email address of the user who will receive information regarding undeliverable email messages due to an invalid email ID or other error.
FOLLOW-UP ACTION CODE	Enterprise	Configures the code that indicates a follow-up action is required.
FORCE SECURE COOKIES	Global	Defines whether the user must enter a SSL-enabled URL (HTTPS) to open the Argus Insight application.

Table 15–1 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
LOGO IMAGE	Enterprise	Defines the complete path to the GIF image on the Argus Insight web server that you want to use as the logo for the Argus Reports (CIOMS, CIOMS II Line Listing, and US FDA MedWatch 3500A).
MAX EMAIL SIZE	Enterprise	Defines the maximum size limit (in KB) for mail attachments on the email server.
MAXIMUM EMAIL ATTEMPTS	Global	Defines the maximum number of times the system attempts to send an email.
MEDWATCH MANUFACTURER	Enterprise	Configures the manufacturer information to print on the US FDA MedWatch 3500A report.
POPULATE AFFILIATE DATA	Enterprise	Defines whether to bring affiliate data into the data mart.
POPULATE BLOB DATA	Global	Defines whether to bring BLOB data into the data mart.
POPULATE DLL SLL REPORTS TABLE DATA	Enterprise	Defines whether to populate the RPT_CASE_EVENT_ PRODUCT table required for DLL and SLL.
POPULATE INTERCHANGE CLOB DATA	Global	Defines whether to bring Interchange CLOB data into the data mart.
POPULATE INTERCHANGE DATA	Enterprise	Defines whether to bring Interchange data into the data mart.
POPULATE NARRATIVE LANGUAGES TABLES	Enterprise	Defines whether to populate the RPT_CNL_MLINGUAL table and the RPT_CNL_ENGLISH table.
POPULATE RPT_REG_REPORTS COLUMNS	Enterprise	Defines whether to populate the extra columns of the RPT_REG_REPORTS table.
POPULATE STUDY RECONCILIATION REPORT TABLE DATA	Enterprise	Defines whether to populate the FACT_PROD_LICENSE table required for the Study Reconciliation Report.
PRODUCT LOGO PATH	Enterprise	Defines the full URL path to the image file of the product logo that prints in the header of certain reports.
REPORT FOOTER LOGO PATH	Enterprise	Defines the full URL path to the image file of the product logo that prints in the footer of certain reports.
REPORT PROMPTS	Enterprise	Provides access to the user interface that lets you add new report prompts and modify existing report prompts.
REPORTING TOOL	Global	Represents the name of the Reporting Tool/BI Tool used with the Argus Insight application. The following are the possible values for the Reporting Tool: ■ **BOXI** - For Business Objects and BIP as BI Tool ■ **COGNOS8** - For Cognos 8 and BIP as BI Tool ■ **BIP** - For BIP only as BI Tool.
SET REPORT PRE-FILTER POPULATION	Enterprise	Defines whether the **Limit Prompt Values to Active Case Series** check box on the PRE-FILTER page is selected by default.
UDN Column for SUPPLIER NAME	Enterprise	Defines the user-defined name (UDN) of the column in the Argus Safety CASE_MASTER table that contains the SUPPLIER NAME value.

Table 15–1 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
BIP SERVER	Enterprise	Represents the IP Address or the Name of BIP Web Server. This is used to identify the BIP server to be used. Specify the Port Number of BIP along with the Server Name in the following format: <BIP SERVER NAME>:<Port Number>
KEEP REPORT DATA	Enterprise	Represents a flag to determine if the Report Log Tables need to be populated or not. **Y** - Populate the Report Log Tables **N** - Do not populate the Report Log Tables Default Value - N
LOG REPORT SQL	Global	Identifies if report SQL is to be logged. **0** - No **1** - Yes Default Value - 0

Configuring European Union Countries

From the List Maintenance tab, you can configure the list of European Union countries for reporting purposes. You can add and remove countries as required.

Table 15–2 lists the countries included in the default European Union list.

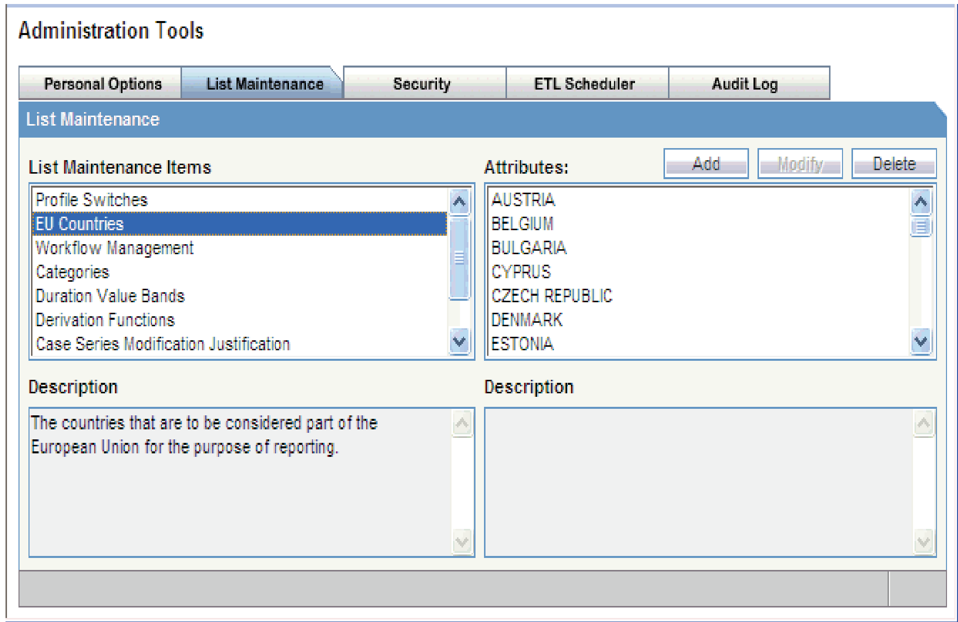
Table 15–2 Countries Included in the Default European Union List

Austria	Finland	Latvia	Portugal
Belgium	France	Liechtenstein	Romania
Bulgaria	Germany	Lithuania	Slovakia (Slovak Republic)
Cyprus	Greece	Luxembourg	Slovenia
Czech Republic	Hungary	Malta	Spain
Denmark	Iceland	Netherlands	Sweden
Estonia	Ireland	Norway	Switzerland
—	Italy	Poland	United Kingdom

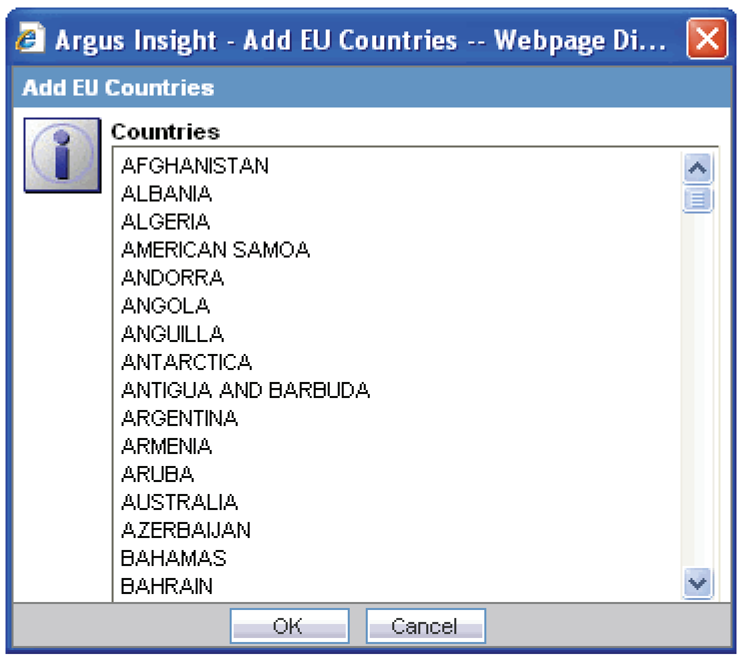
Adding a Country to the European Union List

To add a country to the list of countries in the European Union:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **EU Countries** from the List Maintenance Items section. The system refreshes the screen. The Attributes section displays the countries currently defined in the European Union list.



4. Click **Add.** The system displays the Add EU Countries dialog box.



5. Select one or more countries that you want to add.
   - To select more than one country, press and hold the CTRL key when you click each country.
   - To select a range of countries, press and hold the SHIFT key when you click the start and end country in the range.
6. Click **OK.** The system adds the specified countries to the list of countries in the European Union.

Deleting a Country from the European Union List

To delete a country from the European Union list:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **EU Countries** from the List Maintenance Items section. The system refreshes the screen. The Attributes section displays the countries currently defined in the European Union list.
4. Select the country you want to delete from the list of European Union countries. You can delete only one country at a time.
5. Click **Delete.** The system prompts for confirmation that you want to delete the selected country.
6. Click **OK.**

Mapping Case Workflow States

Workflow is company-specific and your company may not use all the Workflow states.

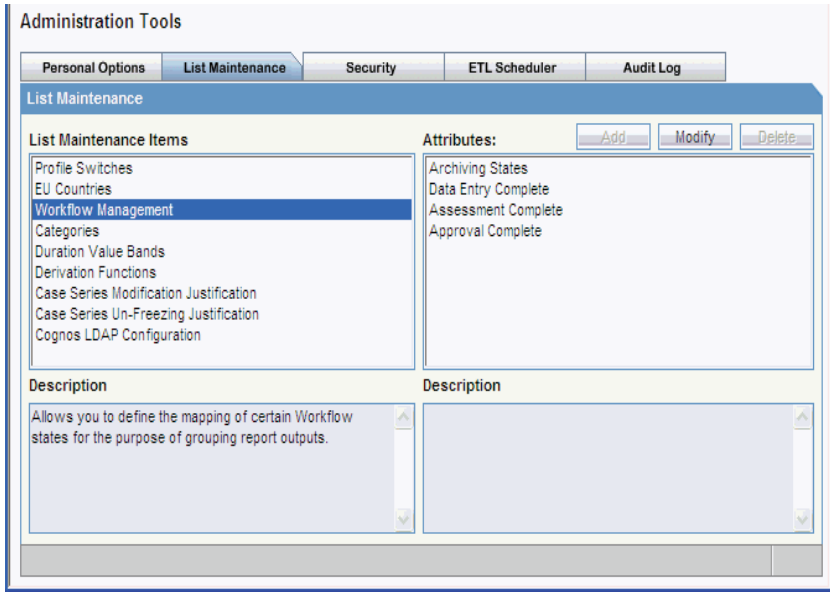
You can map all the site-specific workflow states to the following default groups for the purpose of grouping outputs of certain reports:

- **Archiving States —** All workflow states that are considered as archived/closed in Argus.
- **Data Entry Complete —** All workflow states that indicate completion of data entry in Argus.
- **Assessment Complete —** All workflow states that indicate completion of event assessment in Argus.
- **Approval Complete —** All workflow states that indicate that the case is ready for reporting after being locked in Argus.

Although the workflow mappings are preconfigured during the installation of Argus Insight, you can modify them by adding or removing workflow states from a group as required. However, you cannot add more groups or delete existing ones.

To configure workflow management for the Argus Insight application:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Workflow Management** from the List Maintenance Items section. The Attributes section displays the existing workflow groups.
4. Select the workflow group that you want to change, and click **Modify.** The system opens the appropriate dialog box for the selected workflow group. For example:



5. Modify the mappings, as appropriate.
   - To add a new workflow state to the group, select a state from the list on the left and click the right arrow (>).
   - To remove a workflow state from the group, select a state from the list on the right and click the left arrow (<).
6. Click **OK** to save your changes.

Configuring Categories

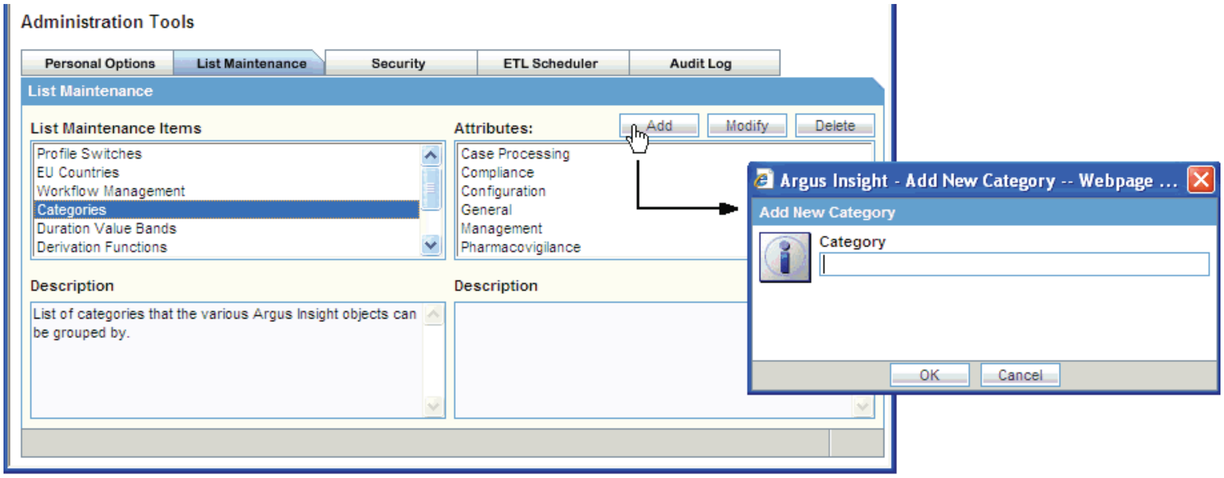
Various Argus Insight objects, such as queries, case series, and standard reports, can be grouped into one of the following default categories:

- Case Processing
- Compliance
- Configuration
- General
- Management
- Pharmacovigilance

You cannot modify or delete the default categories. You can, however, add one or more custom categories. Once added, you can modify or delete a custom category.

To add, modify, or delete custom categories:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Categories** from the List Maintenance Items list. The Attributes list displays the existing categories.
4. Click **Add.** The Add New Category dialog box opens.



5. Enter the category name.
6. Click **OK** to add the new category to Argus Insight.

To change the name of an existing custom category, select the category from the Attributes section and click **Modify.** Change the category name and click **OK.**

To delete an existing custom category, select the category from the Attributes section and click **Delete.** When the system prompts for confirmation, click **OK.**

Configuring Duration Value Bands

In Argus Insight, you can map the following time values (entered in Argus Safety) to specific ranges called Duration Value Bands:

- Time to Onset from First Dose
- Time to Onset from Last Dose

You set the value of these fields in Argus Safety by navigating to Product Tab, Drug Duration of Administration, and Events Tab.

By mapping the time values to Duration Value Bands in Argus Insight, you can specify query criteria for the **Time to Onset from First Dose** field and the **Time to Onset from Last Dose** field based on ranges instead of specific values.

Using the Duration Value Bands item on the List Maintenance tab, you can configure duration value bands in hours, days, weeks, months, and years. For each band, you can specify multiple ranges by entering minimum and maximum values for each range item. Any value that falls within a configured range will map to that range.

Note: Duration Value Band configuration must be done before running the Initial ETL.

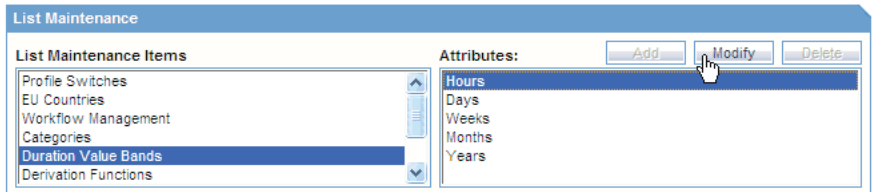
If Duration Value Bands are modified after Initial ETL, you must rerun the Initial ETL.

To modify a duration value band:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.

2. Click the **List Maintenance** tab.

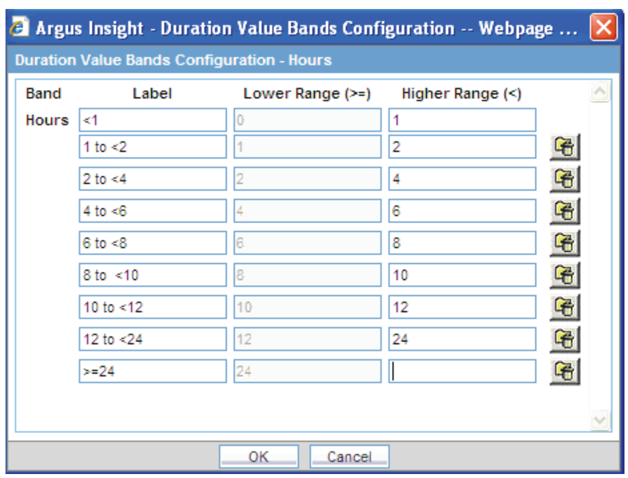
3. Select **Duration Value Bands** from the List Maintenance Items section. The Attributes section displays the valid bands (Hours, Days, Weeks, Months, and Years). You can modify the values of these bands. You cannot, however, add more bands or delete an existing band.



4. Select the duration value band (Hours, Days, Weeks, Months, Years) you want to change, and click **Modify.** The system opens the Duration Value Bands Configuration dialog box and displays the factory-configured ranges.

   Note that:

   - The Label column represents the name of the range.
   - The Lower Range (>=) and Higher Range (<) columns contain the minimum and maximum values, respectively.
   - The highest value band includes all values that are greater than the highest range value specified.



5. Modify the values, as appropriate:

   - To modify an existing range, edit the values in the **Lower Range (>=)** and **Higher Range (<)** fields.
   - To add a range, scroll to the current highest range and click in the blank **Higher Range (<)** field. Enter a value greater than the current highest range and press **Tab** to add a new row.
   - To delete an existing range, click the **Delete** icon next to the row. Note that you cannot delete the lowest band.

     If you delete an intermediate range, the system automatically converts the highest value of the deleted range to the lowest value in the next range. However, the system does not change the range labels.

6. Click **OK** to save your changes.

Configuring Derivation Functions

Argus Insight lets you create a new List Maintenance item and derive specific cases to this item based on case attributes. These attributes are supplied to the system as SQL.

For example, you can create a new List Maintenance item called **Report Type 1** and derive to this item all the cases that have the **Report Type** attribute defined as **Spontaneous, Literature,** or **Compassionate Use.** As a result, Report Type 1 appears as an option in the query tool interface corresponding to the Report Type attribute. When you select Report Type 1 from the Report Type list and execute your query, the system returns only those cases that have the Report Type attribute specified as Spontaneous, Literature, or Compassionate Use.

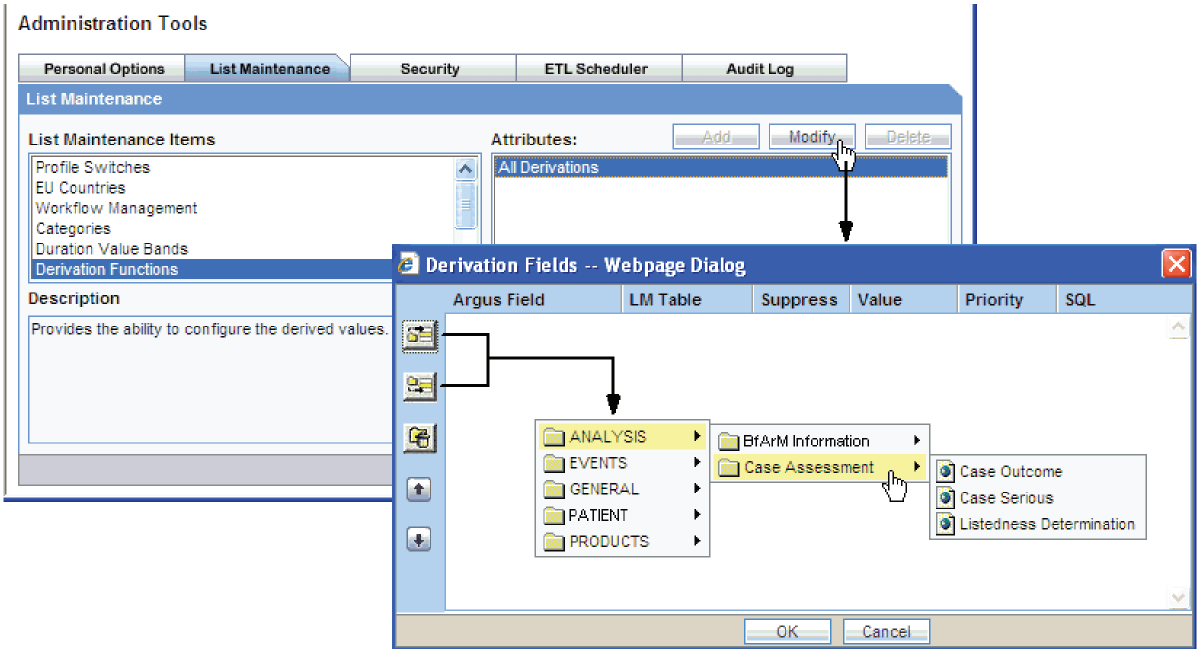
You can specify more than one attribute. For example, you can create a further specialized List Maintenance item called **Report Type 1 US** and derive to this item all the cases that have the **Report Type** attribute defined as **Spontaneous, Literature,** or **Compassionate Use,** *and* the **Country of Incidence** attribute defined as **United States.**

Note: There can be situations where two different List Maintenance items you create contain similar attributes in the SQL criteria. In this case, you can assign a priority level to individual List Maintenance items. The priority level determines which List Maintenance item SQL executes first.

Opening the Derivation Fields Dialog Box

To open the Derivation Fields dialog box and configure derivation functions:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Derivation Functions** from the List Maintenance Items section.
4. Select **All Derivations** from the Attributes section, and click **Modify.** The system opens the Derivation Fields dialog box.



Icons in the Derivation Fields Dialog Box

Table 15–3 describes the icons in the Derivation Fields dialog box that you can use to add, delete, and reorder derivation field elements (rows).

Table 15–3 Icons in the Derivation Fields Dialog Box

Click...	To...
	Add a derivation field element (row) above the currently selected row
	Add a derivation field element (row) below the currently selected row
	Delete the currently selected derivation field element (row)
	Move the selected row up
	Move the selected row down

Field Mapping Derivation Rules

Table 15–4 lists the available field mapping derivation rules for Argus Insight.

Table 15–4 Field Mapping Derivation Rules

Function Category	Function Sub-category	Argus Insight Field
ANALYSIS	BfArM Information	Causality

Table 15–4 (Cont.) Field Mapping Derivation Rules

Function Category	Function Sub-category	Argus Insight Field
ANALYSIS	Case Assessment	Case Outcome Case Serious Listedness Determination
EVENTS	Event Information	Lack of Efficacy
GENERAL	General Information	Derived Pregnancy Report Type
PATIENT	Patient Information	Age Group Gender Patient weight BMI desc
PRODUCTS	Product Drug	Derived Drug Abuse Derived Drug Interaction Derived Overdose Last Daily Dose

Note: Causality, Report Type, Age Group, and Last Daily Dose are comma-separated derivation rules. See

Fields and Check Boxes in the Derivation Fields Dialog Box

This section describes the fields and check boxes in the Derivation Fields dialog box.

LM Table The LM Table field is the table name of the selected Argus field (that is, automatically populated).

Suppress The Suppress check box is available for fields associated with the list maintenance data. When suppress is enabled for a field, the corresponding list maintenance values that are not present in any case are deleted and thus not available for querying.

Note: The Suppress check box is applicable *only if* the condition specified in the SQL text box covers all the cases having the selected List Maintenance field.

Value The Value field captures the value for the new derivation field.

For the following four rules, you must enter the new value for the rule as a comma-separated value:

- Causality
- Report Type
- Age Group
- Last Daily Dose

Note: Make sure that you enter the values for these rules as defined in the following sections. Unexpected results and/or ETL errors may result if the values are not entered as specified.

Causality Rule

Parameters: VALUE, REPORTABILITY

where:

VALUE = New value for the rule

REPORTABILITY = Lower value of the group

Example: NewCausality,1

Report Type Rule

Parameters: VALUE, INC_LIT, INC_TRIAL, ABRV

where:

VALUE = New value for the rule

INC_LIT = 1 if Literature Report Type else 0

INC_TRIAL = 1 if Clinical Trial Report Type else 0

ABRV = A 3-letter abbreviation for the Report Type

Example: NewReportType,0,1,NRT

Age Group Role

Parameters: VALUE, GROUP_LOW, GROUP_HIGH

where:

VALUE = New value for the rule

GROUP_LOW = Lowest value of the age group

GROUP_HIGH = Highest value of the age group

Example: NewAgeGroup,25,50

If you do not want to specify the High Value, then the comma is mandatory in the end.

Example: Unknown,70,

Last Daily Dose Rule

Parameters: VALUE, DAILY_DOSE_SORTING_ORDER

where:

VALUE = New value for the rule

DAILY_DOSE_SORTING_ORDER = 1 or 2 or 3 and so on to define the sorting order if there is more than 1 rule for the Last Daily Dose field

Examples: 1 -> 0to1,1;   2 -> 2to3,2   3 -> 5to8,3

Priority The Priority field captures the priority for a list of derivation rules applied to a single List Maintenance field. Valid values: 1–255.

> **Note:** The priority for derivation rules applicable to a single List Maintenance field must be unique.

SQL

The SQL field specifies the SQL statement to capture the cases for which the derivation rule is applicable.

Note: The SQL statement must follow the correct syntax.

The system does not validate the length of the new values against the database. Make sure that new values being inserted into the data mart do not exceed the limit defined in the database.

Guidelines for correct SQL statement syntax:

- The SQL query configured against a rule cannot contain the table name. It must contain only the primary key column name(s) of the field in the SELECT clause. For example:

  Correct: SELECT CASE_ID FROM RPT_CASE WHERE…

  Incorrect: SELECT RPT_CASE.CASE_ID FROM RPT_CASE WHERE…

- Make sure that there is only one space after the SELECT clause in the SQL query. For example:

  Correct: SELECT CASE_ID, SEQ_NUM FROM RPT_PRODUCT WHERE…

  Incorrect: SELECT   CASE_ID, SEQ_NUM FROM RPT_PRODUCT WHERE…

- Make sure that no Oracle keyword (such as DISTINCT) is used after the SELECT clause in the SQL query. For example:

  Correct: SELECT CASE_ID, SEQ_NUM FROM RPT_PRODUCT…

  Incorrect: SELECT DISTINCT CASE_ID, SEQ_NUM FROM RPT_PRODUCT…

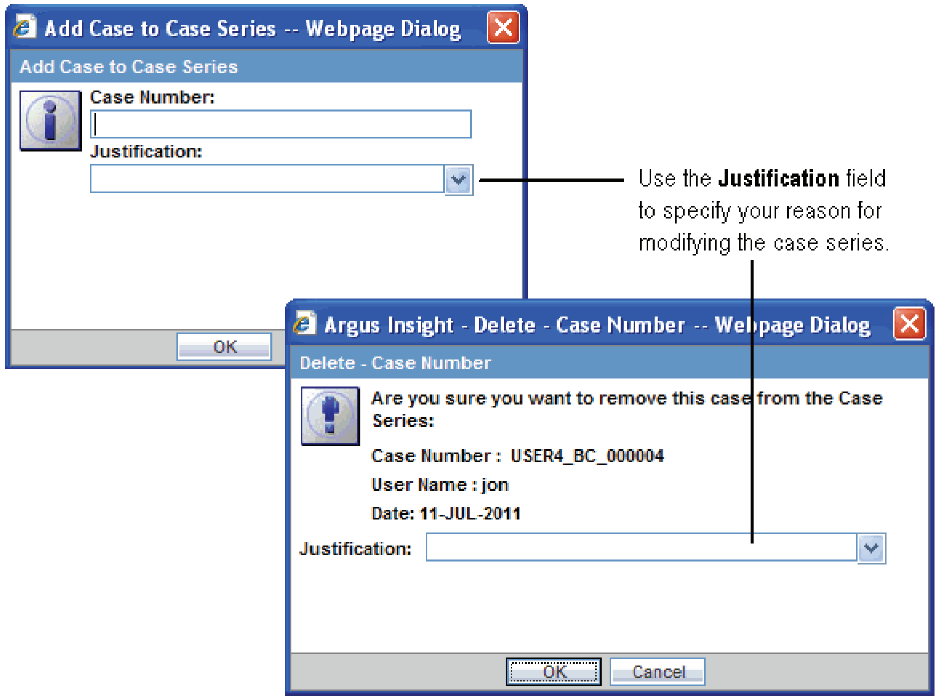
Configuring Case Series Modification Justification

When you modify a case series either by adding a case to the series or by removing a case from the series, Argus Insight prompts for a justification, or reason, for the action. See Figure 15–4. In the **Justification** field, you either type your own reason or select a reason from the list.

Argus Insight does not provide a default list of justifications. However, you can create a set of standard and relevant reasons for Argus Insight to display in the Justification field. Once you create the list of reasons, users can select one of your defined justifications whenever they modify a case series. In addition, users always have the option to type their own justification.

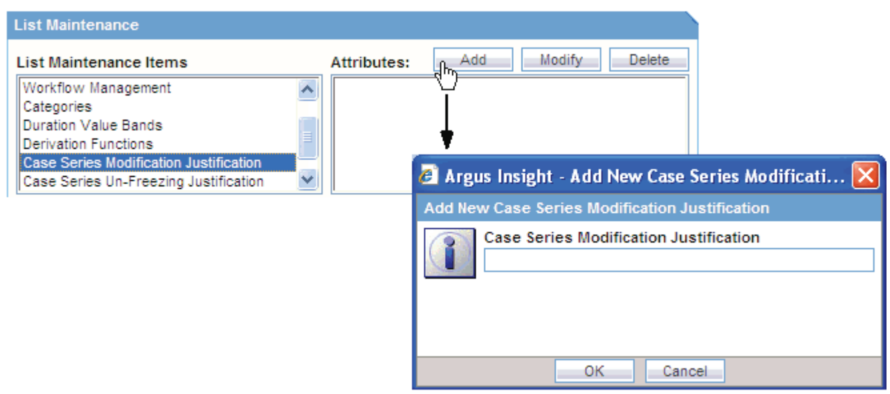
Justifications are important for maintaining the history of a case series.

Figure 15–4 Specifying a Justification when Modifying a Case Series



To create the list of justifications for modifying a case series:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Case Series Modification Justification** from the List Maintenance Items section. The Attributes list displays the existing configured justifications, if any.
4. Click **Add.**



5. Enter the justification text.
6. Click **OK** to save the justification.

To edit an existing justification, select the justification from the Attributes list and click **Modify.**

To delete an existing justification, select the justification from the Attributes list and click **Delete.**

Configuring Case Series Un-freezing Justification

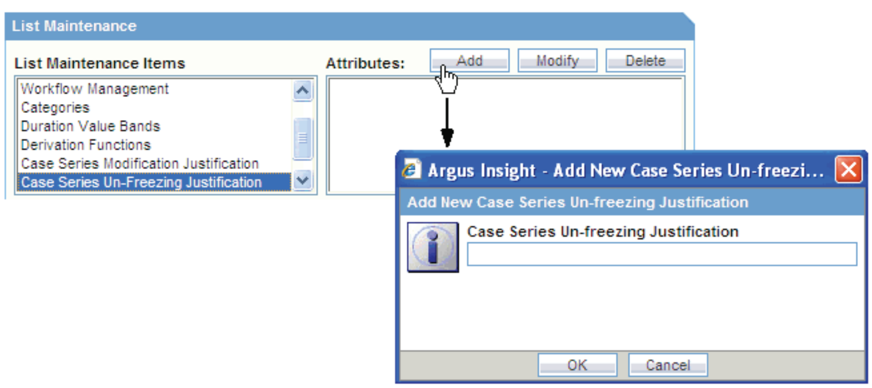
When you unfreeze a case series, Argus Insight prompts for a justification, or reason, for this action. In the **Justification** field, you can either type your own reason or select a reason from the list. For example:

Argus Insight does not provide a default list of justifications. However, you can create a set of standard and relevant reasons for Argus Insight to display in the Justification field. Once you create the list of reasons, users can select one of your defined justifications whenever they unfreeze a case series. In addition, users always have the option to type their own justification.

Justifications are important for maintaining the history of a case series.

To create the list of justifications for unfreezing a case series:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Case Series Un-freezing Justification** in the List Maintenance Items section. The Attributes list displays the existing configured justification text, if any.
4. Click **Add.**



5. Enter the justification text.
6. Click **OK** to save the justification.

To edit an existing justification, select the justification from the Attributes list and click **Modify.**

To delete an existing justification, select the justification from the Attributes list and click **Delete.**

Maintaining Argus Insight Lists for BusinessObjects

This section describes the following tasks that you can perform using the List Maintenance tab on the ADMINISTRATION TOOLS page:

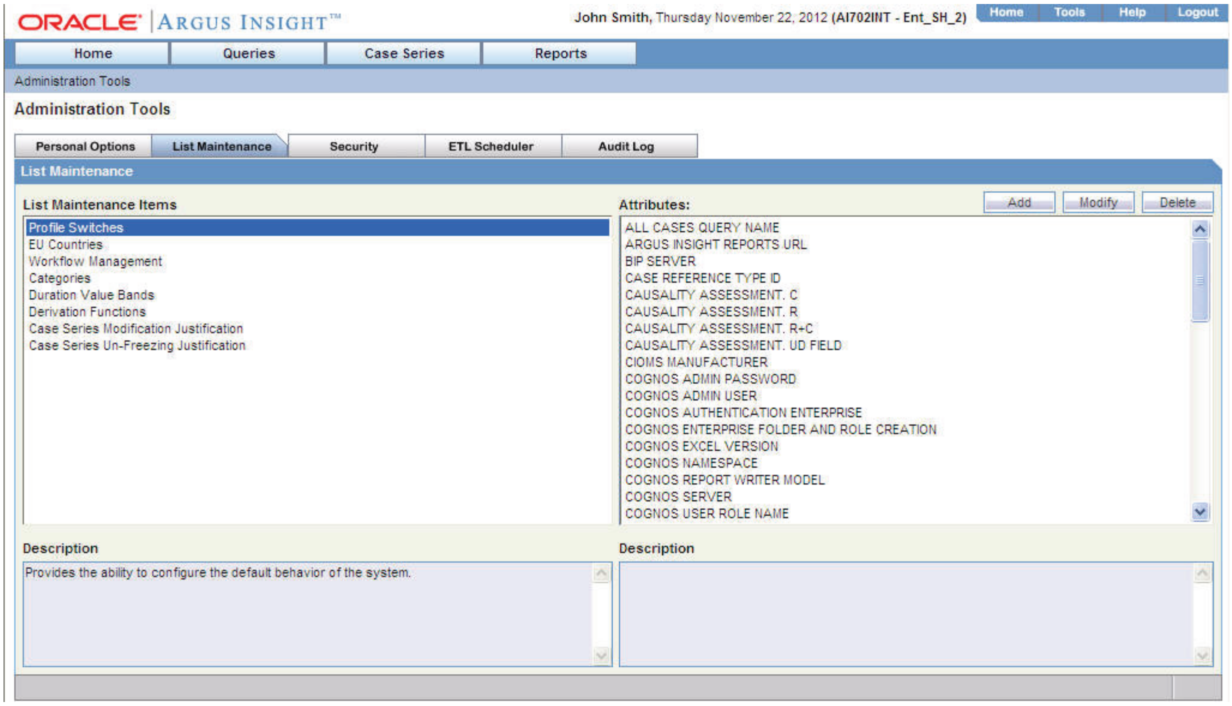
- Configuring the Argus Insight Application Profile Switches
- Configuring European Union Countries
- Mapping Case Workflow States
- Configuring Categories
- Configuring Duration Value Bands
- Configuring Derivation Functions
- Configuring Case Series Modification Justification
- Configuring Case Series Un-freezing Justification
- Configuring Holiday Schedule Management
- Configuring Product Designated Medical Event Configurations
- Configuring Measurable Suppliers
- Configuring Non-Core Sites
- Configuring Acceptable Delay Justifications

Configuring the Argus Insight Application Profile Switches

Profile switches are a collection of settings that let you configure the default behavior of Argus Insight. The default value of a profile switch can be predefined or based on user input. All profile switch values are case sensitive.

In general, you use the List Maintenance tab on the ADMINISTRATION TOOLS page (see Figure 15–5) to configure existing profile switches and to add new profile switches. However, certain profile switches can only be configured through direct SQL statements.

Figure 15–5 List Maintenance Tab with the Profile Switches



Consult your company's policies and the terminology used before configuring profile switches.

For detailed information about all the profile switches, see the following documents:

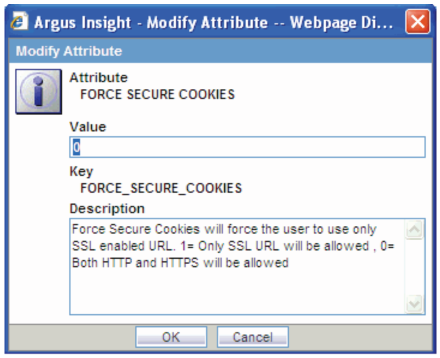
- *Oracle Argus Insight CMN Profile Enterprise Table Guide* (CMN_PROFILE_ENTERPRISE.pdf)
- *Oracle Argus Insight CMN Profile Global Table Guide* (CMN_PROFILE_GLOBAL.pdf)

In addition, the documents have a sample SQL for inserting profile switches and updating their values in the database.

Accessing and Modifying the Profile Switches

To access and modify the Argus Insight profile switches:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page 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 the profile switch that you want to modify.
5. Click **Modify.** The system opens the Modify Attribute dialog box. For example:

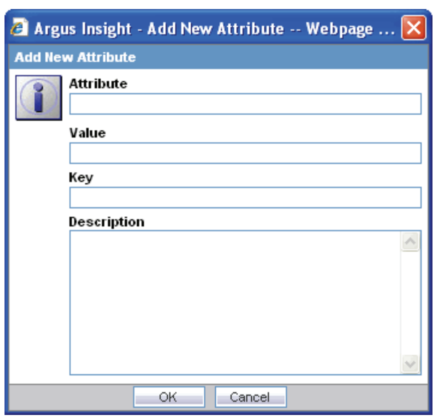


6. Modify the values, as appropriate.
7. Click **OK.** The profile switch is updated.

Adding a New Profile Switch

To add a new profile switch:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page 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 current profile switches.
4. Click **Add.** The system displays the Add New Attribute dialog box.



5. Enter the profile switch name, key, and description, as appropriate.
6. Click **OK.**

Listing of the Common Profile Switches

Table 15–5 lists the profile switches that you can configure using the options in the List Maintenance tab. For each profile switch, the table specifies the name of the switch, indicates whether the switch is a global-level or an enterprise-level switch, and provides a brief description.

All the global-level switches are displayed, updated, and audit logged in the default enterprise.

For more information about viewing and editing profile switches, see "Configuring the Argus Insight Application Profile Switches" on page 15-3.

Table 15–5 Common Profile Switches

Profile Switch	Switch Level	Description
ALL CASES QUERY NAME	Enterprise	Defines the name of the query that returns All Cases in the data mart for use with reports scheduling.
ARGUS INSIGHT REPORTS URL	Global	Specifies the URL for the Argus Insight application for accessing scheduled reports that cannot be sent to the configured email ID due to the mail size limit.
BITOOL LDAP ENABLED	Global	Specifies whether LDAP is enabled at the Business Intelligence (BI) tool level. Your BI tool can be BusinessObjects XI or Cognos 8.
BO ADMIN AUTHENTICATION TYPE	Global	Defines the user authentication type for the BusinessObjects administrator.
BO ADMIN PASSWORD	Global	Defines the password for the BusinessObjects administrator. If the password is incorrect, access to BusinessObjects administration for additional security will be denied.
BO ADMIN USER	Global	Defines the name of the BusinessObjects user who has administrator privileges for tasks such as creating, updating, and deleting user accounts.
BO PORT NUMBER	Global	Defines the BusinessObjects port number used by Infoview.
BO REPORT FOLDER NAME	Global	Defines the name of the report folder that will contain all the objects from Argus Insight. If the folder name does not match the name of the BusinessObjects Reports root folder, then the report listing will not be visible in Argus Insight.
BO REPORT WRITER NAME	Enterprise	Specifies the universe name for the BusinessObjects Report Writer. If this value is incorrect, Report Writer functionality in Argus Insight will not work. Default value is ReportWriter.
BO SERVER	Global	Defines either the IP address or the host name of the BusinessObjects Server to use.
BO USER GROUP NAME	Global	Defines the name of the BusinessObjects user group under which all users will be created in the BusinessObjects repository.
BO USER LICENSE	Global	Defines the type of user license (Named or Concurrent) created in BusinessObjects by Argus Insight. Default value is Named.
BO WEBI SERVER	Global	Defines either the IP address or the host name of the BusinessObjects WEBI Server to use to access Report Writer and Infoview from Argus Insight.
CASE REFERENCE TYPE ID	Enterprise	Used to populate the RPT_CASE.FIRST_REF_NO column.
CAUSALITY ASSESSMENT. C	Enterprise	Used in standard reports for Company Defined Causality.
CAUSALITY ASSESSMENT. R	Enterprise	Used in standard reports for Reporter Defined Causality.
CAUSALITY ASSESSMENT. R+C	Enterprise	Used in standard reports for Reporter Defined Causality and Company Defined Causality.
CAUSALITY ASSESSMENT. UD FIELD	Enterprise	Used in standard reports for user-defined field to determine causality.
CIOMS MANUFACTURER	Enterprise	Defines the manufacturer information that prints on the CIOMS report.
COMPANY LOGO PATH	Enterprise	Defines the location of the company logo on the local server. This logo prints in the report header.

Table 15–5 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
CONFIDENTIALITY TEXT	Enterprise	Defines the confidential text that prints in the running footer on each page in the report.
CUSTOM HELP URL	Enterprise	Defines the URL for your customized online help. If the URL is not valid, users receive the following error message: `Error 404 - Page Not Found`.
CUSTOM ROUTINE AFTER INCREMENTAL ETL	Global	Defines the full path of the custom routine (Oracle stored procedure) to be executed *after* Incremental ETL. If the routine fails or is not found, the administrator receives an email notification.
CUSTOM ROUTINE BEFORE INCREMENTAL ETL	Global	Defines the full path of the custom routine (Oracle stored procedure) to be executed *before* Incremental ETL. If this routine fails or is not found, then the ETL does not run and the administrator receives an email notification.
DATASHEET BPI	Enterprise	Configures the user-defined fields for assessment of BPI Datasheet in the Product tab.
DATASHEET EMEA	Enterprise	Configures the user-defined fields for assessment of EMEA Datasheet in the Product tab.
DATASHEET FLAG	Enterprise	Sets the flag used during Incremental ETL to determine whether to populate the data in the four *DATASHEET* fields (DATASHEET BPI, DATASHEET EMEA, DATASHEET IB, DATASHEET PI) for all the cases or for only the modified cases.
DATASHEET IB	Enterprise	Configures the user-defined fields for assessment of IB Datasheet in the Product tab.
DATASHEET PI	Enterprise	Configures the user-defined fields for assessment of PI Datasheet in the Product tab.
DAYS TO LOCK	Enterprise	Configures the number of days to lock for a case.
DELAY IDENTIFIER	Enterprise	Defines the delay text that ETL uses to populate the RPT_ FOLLOWUP.CORE_DELAY_ROUTING_COMMENT field in the Supplier Performance Report and the Process Performance Report - Workflow.
EMAIL SENDER ADDRESS	Enterprise	Defines the email address of the person on whose behalf Argus Insight sends all email messages. If you leave the value blank, then Argus Insight sends no email messages.
ENABLE COMPANY HOLIDAY	Enterprise	Defines whether to include company holidays in the due date calculation for the Data Entry Performance Over Time Report.
ETL DATA EXCLUSION	Global	Specifies whether to continue or cancel the ETL process if cases with erroneous data are found.
ETL EMAIL RECEIVER ADDRESS	Global	Defines the email address of each administrator who will receive email status messages of the ETL process. Use a semi-colon to separate each entry. If you leave the value blank, then Argus Insight sends no email messages.
ETL EMAIL SETUP	Global	Defines whether to send an email only after ETL failure, only after ETL success, or in either case.
FAILED RECIPIENTS STATUS EMAIL ADDRESS	Enterprise	Defines the email address of the user who will receive information regarding undeliverable email messages due to an invalid email ID or other error.
FOLLOW-UP ACTION CODE	Enterprise	Configures the code that indicates a follow-up action is required.

Table 15–5 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
FORCE SECURE COOKIES	Global	Defines whether the user must enter a SSL-enabled URL (HTTPS) to open the Argus Insight application.
LOGO IMAGE	Enterprise	Defines the complete path to the GIF image on the Argus Insight web server that you want to use as the logo for the Argus Reports (CIOMS, CIOMS II Line Listing, and US FDA MedWatch 3500A).
MAX EMAIL SIZE	Enterprise	Defines the maximum size limit (in KB) for mail attachments on the email server.
MAXIMUM EMAIL ATTEMPTS	Global	Defines the maximum number of times the system attempts to send an email.
MEDWATCH MANUFACTURER	Enterprise	Configures the manufacturer information to print on the US FDA MedWatch 3500A report.
POPULATE AFFILIATE DATA	Enterprise	Defines whether to bring affiliate data into the data mart.
POPULATE BLOB DATA	Global	Defines whether to bring BLOB data into the data mart.
POPULATE DLL SLL REPORTS TABLE DATA	Enterprise	Defines whether to populate the RPT_CASE_EVENT_PRODUCT table required for DLL and SLL.
POPULATE INTERCHANGE CLOB DATA	Global	Defines whether to bring Interchange CLOB data into the data mart.
POPULATE INTERCHANGE DATA	Enterprise	Defines whether to bring Interchange data into the data mart.
POPULATE NARRATIVE LANGUAGES TABLES	Enterprise	Defines whether to populate the RPT_CNL_MLINGUAL table and the RPT_CNL_ENGLISH table.
POPULATE RPT_REG_REPORTS COLUMNS	Enterprise	Defines whether to populate the extra columns of the RPT_REG_REPORTS table.
POPULATE STUDY RECONCILIATION REPORT TABLE DATA	Enterprise	Defines whether to populate the FACT_PROD_LICENSE table required for the Study Reconciliation Report.
PRODUCT LOGO PATH	Enterprise	Defines the full URL path to the image file of the product logo that prints in the header of certain reports.
REPORT FOOTER LOGO PATH	Enterprise	Defines the full URL path to the image file of the product logo that prints in the footer of certain reports.
REPORT PROMPTS	Enterprise	Provides access to the user interface that lets you add new report prompts and modify existing report prompts.
REPORTING TOOL	Global	Represents the name of the Reporting Tool/BI Tool used with the Argus Insight application. The following are the possible values for the Reporting Tool: ■ **BOXI** - For Business Objects and BIP as BI Tool ■ **COGNOS8** - For Cognos 8 and BIP as BI Tool ■ **BIP** - For BIP only as BI Tool.
SET REPORT PRE-FILTER POPULATION	Enterprise	Defines whether the **Limit Prompt Values to Active Case Series** check box on the PRE-FILTER page is selected by default.
UDN Column for SUPPLIER NAME	Enterprise	Defines the user-defined name (UDN) of the column in the Argus Safety CASE_MASTER table that contains the SUPPLIER NAME value.

Table 15–5 (Cont.) Common Profile Switches

Profile Switch	Switch Level	Description
USE BO JOB SERVER	Global	Defines whether to use the Report Server or the BusinessObjects Job Server to run reports.
BIP SERVER	Enterprise	Represents the IP Address or the Name of BIP Web Server. This is used to identify the BIP server to be used. Specify the Port Number of BIP along with the Server Name in the following format: <BIP SERVER NAME>:<Port Number>
KEEP REPORT DATA	Enterprise	Represents a flag to determine if the Report Log Tables need to be populated or not. **Y** - Populate the Report Log Tables **N** - Do not populate the Report Log Tables Default Value - N
LOG REPORT SQL	Global	Identifies if report SQL is to be logged. **0** - No **1** - Yes Default Value - 0

Configuring European Union Countries

From the List Maintenance tab, you can configure the list of European Union countries for reporting purposes. You can add and remove countries as required.

Table 15–6 lists the countries included in the default European Union list.

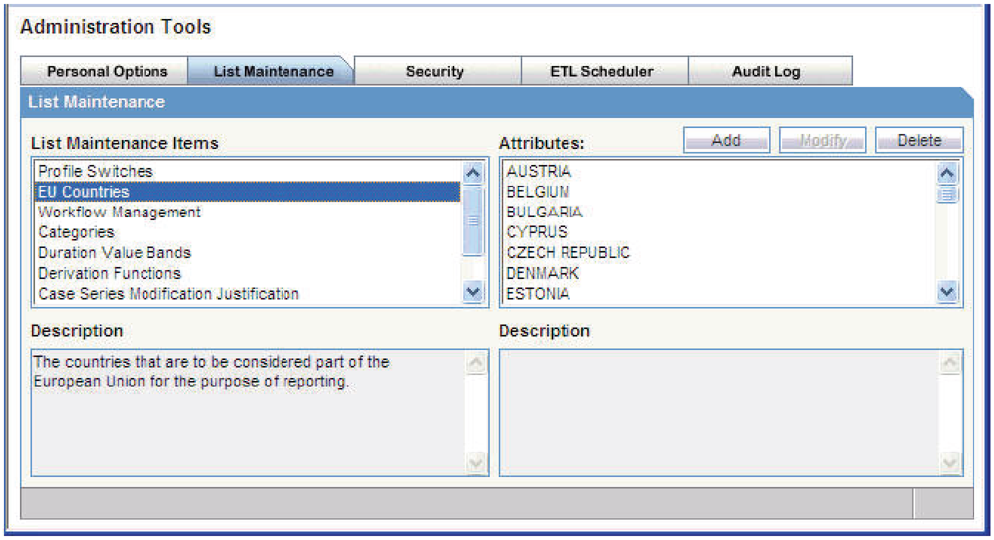
Table 15–6 Countries Included in the Default European Union List

Austria	Finland	Latvia	Portugal
Belgium	France	Liechtenstein	Romania
Bulgaria	Germany	Lithuania	Slovakia (Slovak Republic)
Cyprus	Greece	Luxembourg	Slovenia
Czech Republic	Hungary	Malta	Spain
Denmark	Iceland	Netherlands	Sweden
Estonia	Ireland	Norway	Switzerland
—	Italy	Poland	United Kingdom

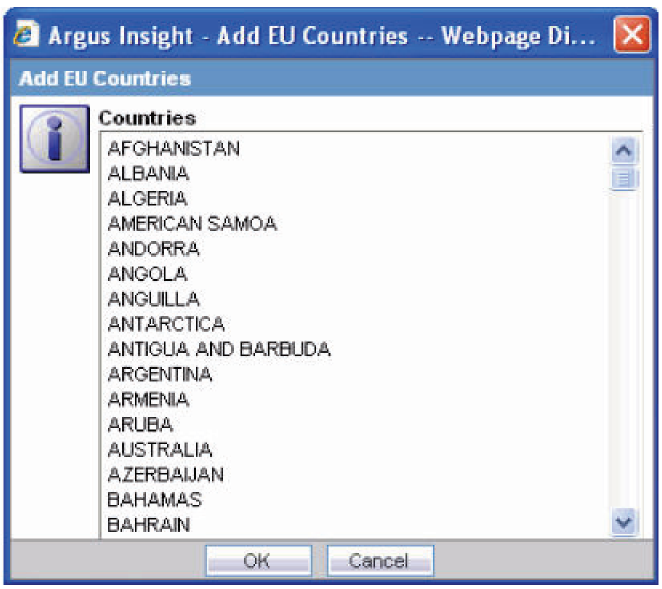
Adding a Country to the European Union List

To add a country to the list of countries in the European Union:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **EU Countries** from the List Maintenance Items section. The system refreshes the screen. The Attributes section displays the countries currently defined in the European Union list.



4. Click **Add.** The system displays the Add EU Countries dialog box.



5. Select one or more countries that you want to add.
   - To select more than one country, press and hold the CTRL key when you click each country.
   - To select a range of countries, press and hold the SHIFT key when you click the start and end country in the range.
6. Click **OK.** The system adds the specified countries to the list of countries in the European Union.

Deleting a Country from the European Union List

To delete a country from the European Union list:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.

3. Select **EU Countries** from the List Maintenance Items section. The system refreshes the screen. The Attributes section displays the countries currently defined in the European Union list.
4. Select the country you want to delete from the list of European Union countries. You can delete only one country at a time.
5. Click **Delete.** The system prompts for confirmation that you want to delete the selected country.
6. Click **OK.**

Mapping Case Workflow States

Workflow is company-specific and your company may not use all the Workflow states.

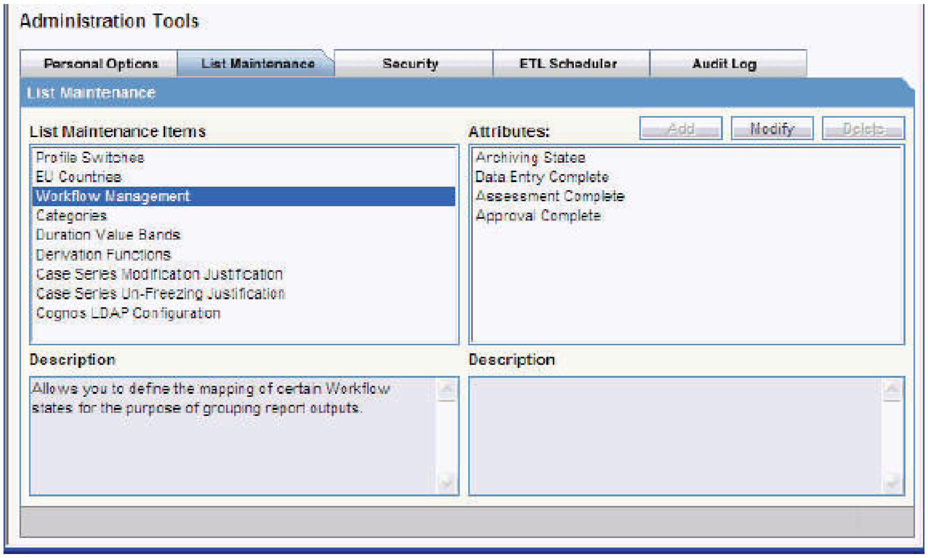
You can map all the site-specific workflow states to the following default groups for the purpose of grouping outputs of certain reports:

- **Archiving States —** All workflow states that are considered as archived/closed in Argus.
- **Data Entry Complete —** All workflow states that indicate completion of data entry in Argus.
- **Assessment Complete —** All workflow states that indicate completion of event assessment in Argus.
- **Approval Complete —** All workflow states that indicate that the case is ready for reporting after being locked in Argus.

Although the workflow mappings are preconfigured during the installation of Argus Insight, you can modify them by adding or removing workflow states from a group as required. However, you cannot add more groups or delete existing ones.

To configure workflow management for the Argus Insight application:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Workflow Management** from the List Maintenance Items section. The Attributes section displays the existing workflow groups.
4. Select the workflow group that you want to change, and click **Modify.** The system opens the appropriate dialog box for the selected workflow group. For example:



5. Modify the mappings, as appropriate.
   - To add a new workflow state to the group, select a state from the list on the left and click the right arrow (>).
   - To remove a workflow state from the group, select a state from the list on the right and click the left arrow (<).
6. Click **OK** to save your changes.

Configuring Categories

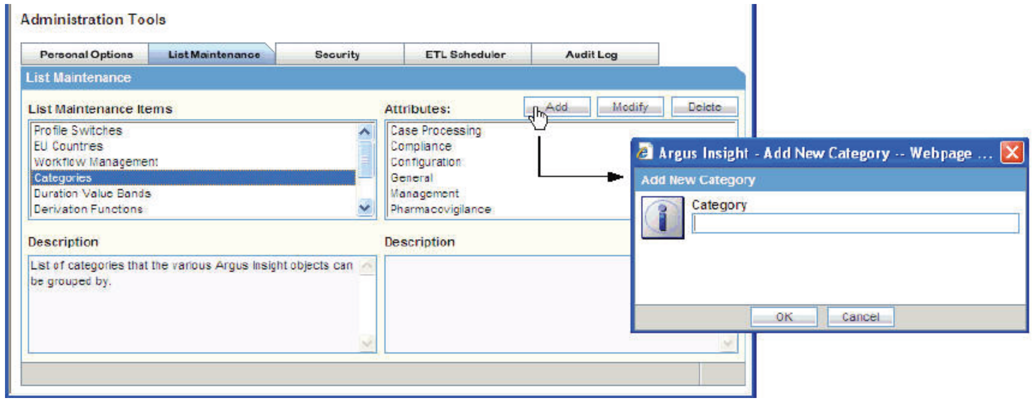
Various Argus Insight objects, such as queries, case series, and standard reports, can be grouped into one of the following default categories:

- Case Processing
- Compliance
- Configuration
- General
- Management
- Pharmacovigilance

You cannot modify or delete the default categories. You can, however, add one or more custom categories. Once added, you can modify or delete a custom category.

To add, modify, or delete custom categories:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Categories** from the List Maintenance Items list. The Attributes list displays the existing categories.
4. Click **Add.** The Add New Category dialog box opens.



5. Enter the category name.
6. Click **OK** to add the new category to Argus Insight.

To change the name of an existing custom category, select the category from the Attributes section and click **Modify.** Change the category name and click **OK.**

To delete an existing custom category, select the category from the Attributes section and click **Delete.** When the system prompts for confirmation, click **OK.**

Configuring Duration Value Bands

In Argus Insight, you can map the following time values (entered in Argus Safety) to specific ranges called Duration Value Bands:

- Time to Onset from First Dose
- Time to Onset from Last Dose

You set the value of these fields in Argus Safety by navigating to Product Tab, Drug Duration of Administration, and Events Tab.

By mapping the time values to Duration Value Bands in Argus Insight, you can specify query criteria for the **Time to Onset from First Dose** field and the **Time to Onset from Last Dose** field based on ranges instead of specific values.

Using the Duration Value Bands item on the List Maintenance tab, you can configure duration value bands in hours, days, weeks, months, and years. For each band, you can specify multiple ranges by entering minimum and maximum values for each range item. Any value that falls within a configured range will map to that range.

Note: Duration Value Band configuration must be done before running the Initial ETL.

If Duration Value Bands are modified after Initial ETL, you must rerun the Initial ETL.

To modify a duration value band:

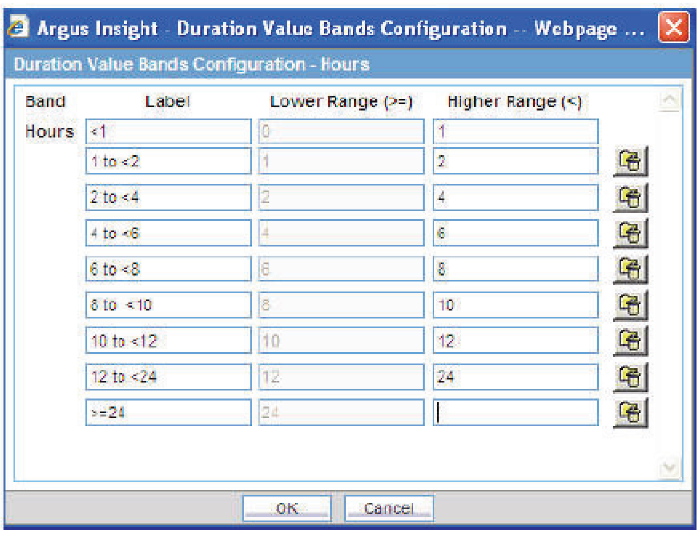
1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Duration Value Bands** from the List Maintenance Items section. The Attributes section displays the valid bands (Hours, Days, Weeks, Months, and

Years). You can modify the values of these bands. You cannot, however, add more bands or delete an existing band.

4. Select the duration value band (Hours, Days, Weeks, Months, Years) you want to change, and click **Modify.** The system opens the Duration Value Bands Configuration dialog box and displays the factory-configured ranges.

   Note that:

   - The Label column represents the name of the range.
   - The Lower Range (>=) and Higher Range (<) columns contain the minimum and maximum values, respectively.
   - The highest value band includes all values that are greater than the highest range value specified.



5. Modify the values, as appropriate:

   - To modify an existing range, edit the values in the **Lower Range (>=)** and **Higher Range (<)** fields.
   - To add a range, scroll to the current highest range and click in the blank **Higher Range (<)** field. Enter a value greater than the current highest range and press **Tab** to add a new row.
   - To delete an existing range, click the **Delete** icon next to the row. Note that you cannot delete the lowest band.

     If you delete an intermediate range, the system automatically converts the highest value of the deleted range to the lowest value in the next range. However, the system does not change the range labels.

6. Click **OK** to save your changes.

Configuring Derivation Functions

Argus Insight lets you create a new List Maintenance item and derive specific cases to this item based on case attributes. These attributes are supplied to the system as SQL.

For example, you can create a new List Maintenance item called **Report Type 1** and derive to this item all the cases that have the **Report Type** attribute defined as **Spontaneous, Literature,** or **Compassionate Use.** As a result, Report Type 1 appears as an option in the query tool interface corresponding to the Report Type attribute. When you select Report Type 1 from the Report Type list and execute your query, the system returns only those cases that have the Report Type attribute specified as Spontaneous, Literature, or Compassionate Use.

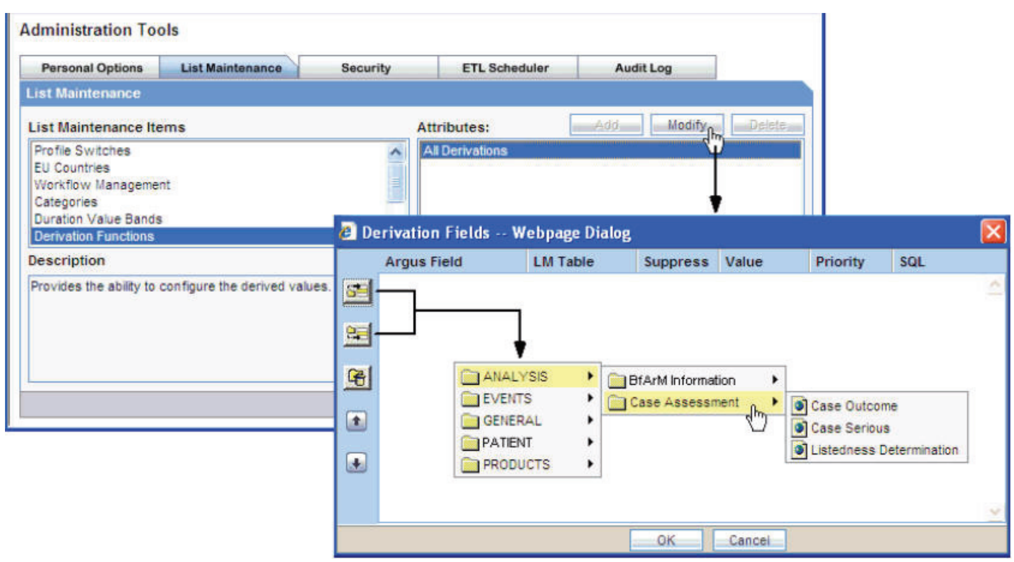
You can specify more than one attribute. For example, you can create a further specialized List Maintenance item called **Report Type 1 US** and derive to this item all the cases that have the **Report Type** attribute defined as **Spontaneous, Literature,** or **Compassionate Use,** *and* the **Country of Incidence** attribute defined as **United States.**

> **Note:** There can be situations where two different List Maintenance items you create contain similar attributes in the SQL criteria. In this case, you can assign a priority level to individual List Maintenance items. The priority level determines which List Maintenance item SQL executes first.

Opening the Derivation Fields Dialog Box

To open the Derivation Fields dialog box and configure derivation functions:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Derivation Functions** from the List Maintenance Items section.
4. Select **All Derivations** from the Attributes section, and click **Modify.** The system opens the Derivation Fields dialog box.



Icons in the Derivation Fields Dialog Box

Table 15–7 describes the icons in the Derivation Fields dialog box that you can use to add, delete, and reorder derivation field elements (rows).

Table 15–7 Icons in the Derivation Fields Dialog Box

Click...	To...
	Add a derivation field element (row) above the currently selected row
	Add a derivation field element (row) below the currently selected row
	Delete the currently selected derivation field element (row)
	Move the selected row up
	Move the selected row down

Field Mapping Derivation Rules

Table 15–8 lists the available field mapping derivation rules for Argus Insight.

Table 15–8 Field Mapping Derivation Rules

Function Category	Function Sub-category	Argus Insight Field
ANALYSIS	BfArM Information	Causality
ANALYSIS	Case Assessment	Case Outcome Case Serious Listedness Determination
EVENTS	Event Information	Lack of Efficacy
GENERAL	General Information	Derived Pregnancy Report Type
PATIENT	Patient Information	Age Group Gender Patient weight BMI desc
PRODUCTS	Product Drug	Derived Drug Abuse Derived Drug Interaction Derived Overdose Last Daily Dose

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Note: Causality, Report Type, Age Group, and Last Daily Dose are comma-separated derivation rules. See

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Fields and Check Boxes in the Derivation Fields Dialog Box

This section describes the fields and check boxes in the Derivation Fields dialog box.

LM Table The LM Table field is the table name of the selected Argus field (that is, automatically populated).

Suppress The Suppress check box is available for fields associated with the list maintenance data. When suppress is enabled for a field, the corresponding list maintenance values that are not present in any case are deleted and thus not available for querying.

Note: The Suppress check box is applicable *only if* the condition specified in the SQL text box covers all the cases having the selected List Maintenance field.

Value The Value field captures the value for the new derivation field.

For the following four rules, you must enter the new value for the rule as a comma-separated value:

- Causality
- Report Type
- Age Group
- Last Daily Dose

Note: Make sure that you enter the values for these rules as defined in the following sections. Unexpected results and/or ETL errors may result if the values are not entered as specified.

Causality Rule

Parameters: VALUE, REPORTABILITY

where:

VALUE = New value for the rule

REPORTABILITY = Lower value of the group

Example: NewCausality,1

Report Type Rule

Parameters: VALUE, INC_LIT, INC_TRIAL, ABRV

where:

VALUE = New value for the rule

INC_LIT = 1 if Literature Report Type else 0

INC_TRIAL = 1 if Clinical Trial Report Type else 0

ABRV = A 3-letter abbreviation for the Report Type

Example: NewReportType,0,1,NRT

Age Group Role

Parameters: VALUE, GROUP_LOW, GROUP_HIGH

where:

VALUE = New value for the rule

GROUP_LOW = Lowest value of the age group

GROUP_HIGH = Highest value of the age group

Example: NewAgeGroup,25,50

If you do not want to specify the High Value, then the comma is mandatory in the end.

Example: Unknown,70,

Last Daily Dose Rule

Parameters: VALUE, DAILY_DOSE_SORTING_ORDER

where:

VALUE = New value for the rule

DAILY_DOSE_SORTING_ORDER = 1 or 2 or 3 and so on to define the sorting order if there is more than 1 rule for the Last Daily Dose field

Examples: 1 -> 0to1,1; 2 -> 2to3,2 3 -> 5to8,3

Priority The Priority field captures the priority for a list of derivation rules applied to a single List Maintenance field. Valid values: 1–255.

Note: The priority for derivation rules applicable to a single List Maintenance field must be unique.

SQL

The SQL field specifies the SQL statement to capture the cases for which the derivation rule is applicable.

Note: The SQL statement must follow the correct syntax.

The system does not validate the length of the new values against the database. Make sure that new values being inserted into the data mart do not exceed the limit defined in the database.

Guidelines for correct SQL statement syntax:

- The SQL query configured against a rule cannot contain the table name. It must contain only the primary key column name(s) of the field in the SELECT clause. For example:

  Correct: SELECT CASE_ID FROM RPT_CASE WHERE…

  Incorrect: SELECT RPT_CASE.CASE_ID FROM RPT_CASE WHERE…

- Make sure that there is only one space after the SELECT clause in the SQL query. For example:

  Correct: SELECT CASE_ID, SEQ_NUM FROM RPT_PRODUCT WHERE…

  Incorrect: SELECT   CASE_ID, SEQ_NUM FROM RPT_PRODUCT WHERE…

- Make sure that no Oracle keyword (such as DISTINCT) is used after the SELECT clause in the SQL query. For example:

  Correct: SELECT CASE_ID, SEQ_NUM FROM RPT_PRODUCT…

  Incorrect: SELECT DISTINCT CASE_ID, SEQ_NUM FROM RPT_PRODUCT…

Configuring Case Series Modification Justification

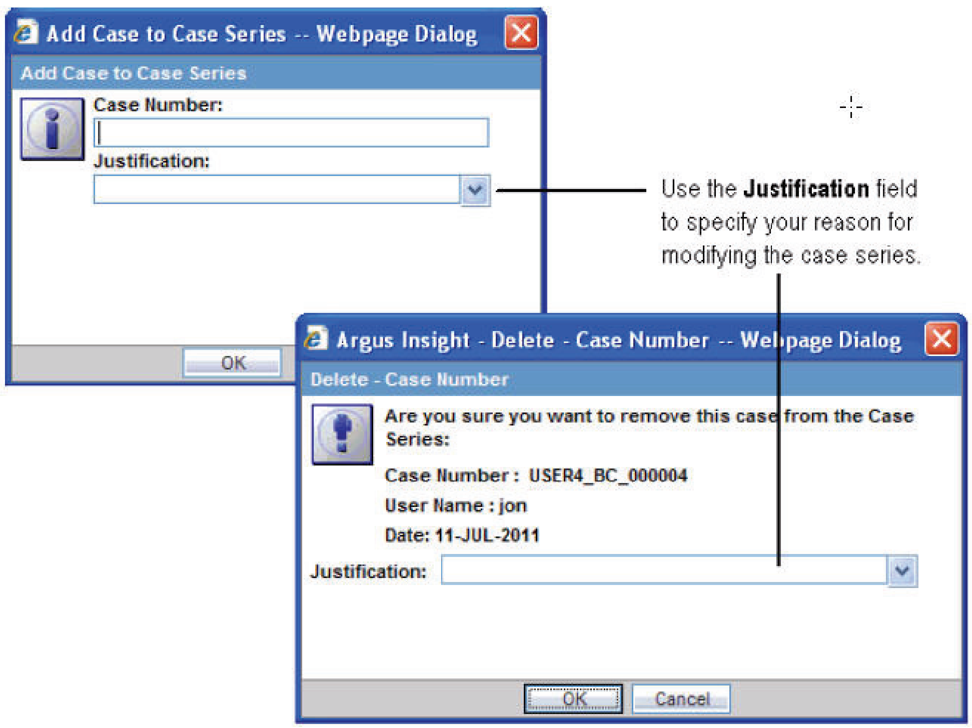
When you modify a case series either by adding a case to the series or by removing a case from the series, Argus Insight prompts for a justification, or reason, for the action.

See Figure 15–6. In the **Justification** field, you either type your own reason or select a reason from the list.

Argus Insight does not provide a default list of justifications. However, you can create a set of standard and relevant reasons for Argus Insight to display in the Justification field. Once you create the list of reasons, users can select one of your defined justifications whenever they modify a case series. In addition, users always have the option to type their own justification.

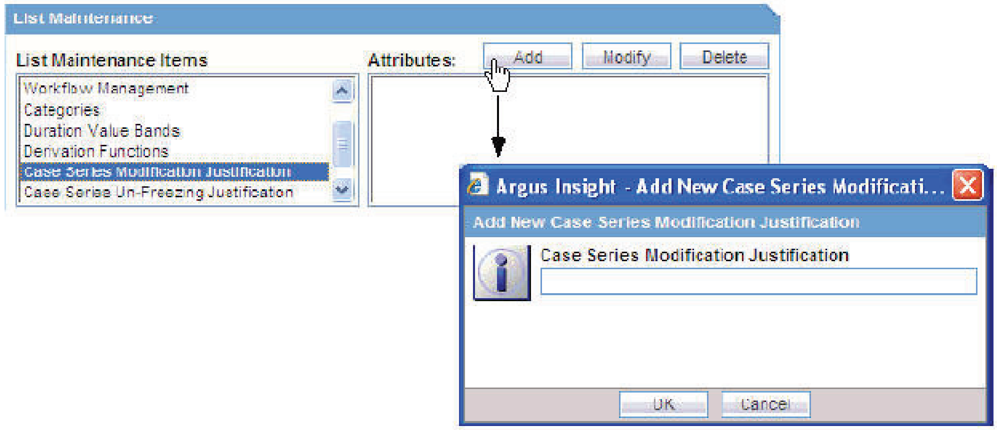
Justifications are important for maintaining the history of a case series.

Figure 15–6 Specifying a Justification when Modifying a Case Series



To create the list of justifications for modifying a case series:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Case Series Modification Justification** from the List Maintenance Items section. The Attributes list displays the existing configured justifications, if any.
4. Click **Add.**



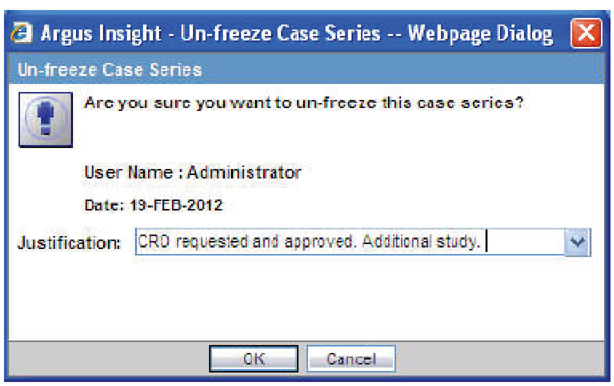
5. Enter the justification text.
6. Click **OK** to save the justification.

To edit an existing justification, select the justification from the Attributes list and click **Modify.**

To delete an existing justification, select the justification from the Attributes list and click **Delete.**

Configuring Case Series Un-freezing Justification

When you unfreeze a case series, Argus Insight prompts for a justification, or reason, for this action. In the **Justification** field, you can either type your own reason or select a reason from the list. For example:



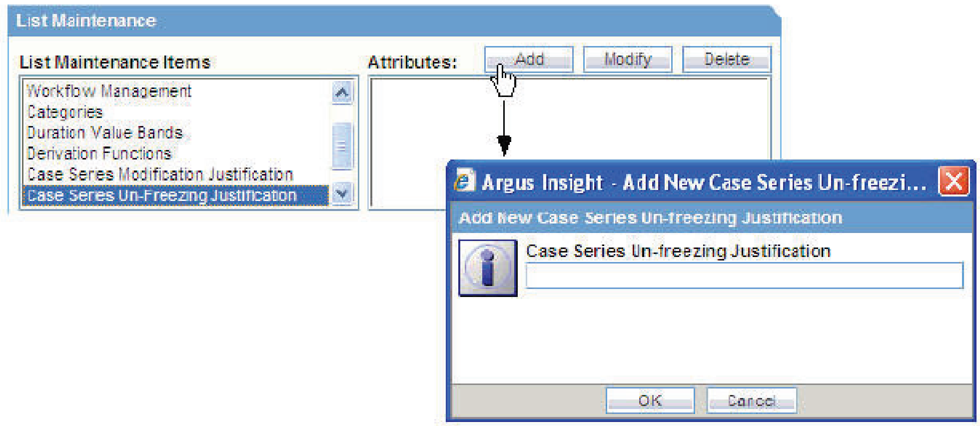
Argus Insight does not provide a default list of justifications. However, you can create a set of standard and relevant reasons for Argus Insight to display in the Justification field. Once you create the list of reasons, users can select one of your defined justifications whenever they unfreeze a case series. In addition, users always have the option to type their own justification.

Justifications are important for maintaining the history of a case series.

To create the list of justifications for unfreezing a case series:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Case Series Un-freezing Justification** in the List Maintenance Items section. The Attributes list displays the existing configured justification text, if any.

4. Click **Add.**



5. Enter the justification text.
6. Click **OK** to save the justification.

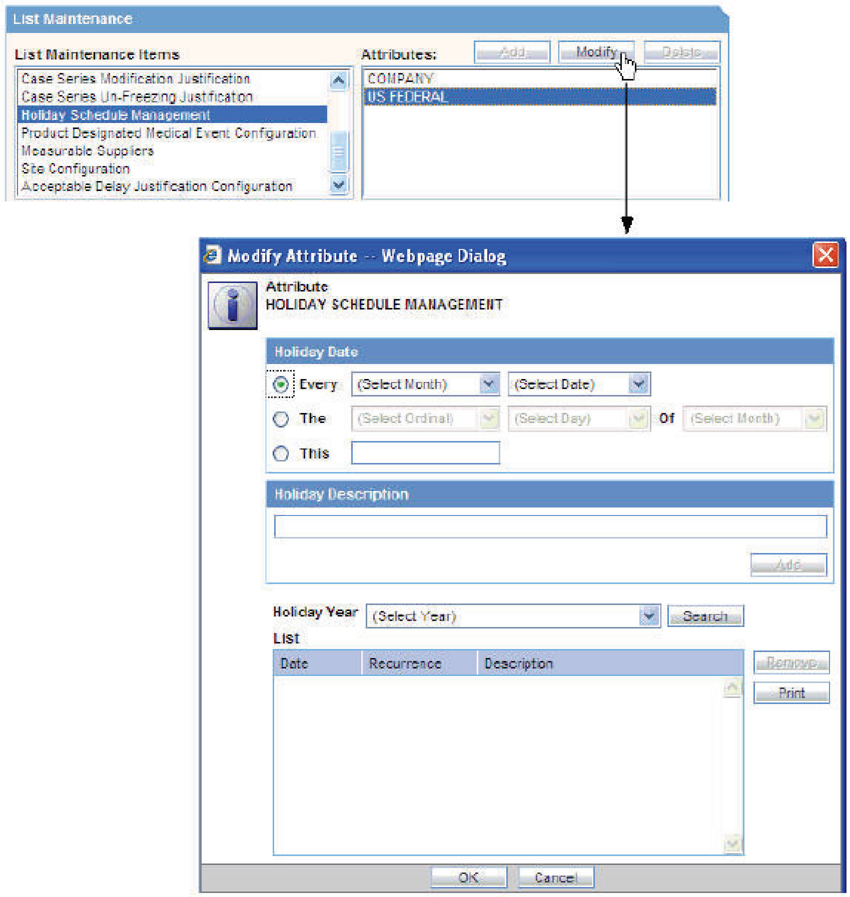
To edit an existing justification, select the justification from the Attributes list and click **Modify.**

To delete an existing justification, select the justification from the Attributes list and click **Delete.**

Configuring Holiday Schedule Management

To configure or manage the schedule of a company's holidays or the US federal holidays:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Holiday Schedule Management** in the List Maintenance Items section.
4. Select **COMPANY** or **US FEDERAL** from the Attributes list.
5. Click **Modify.**

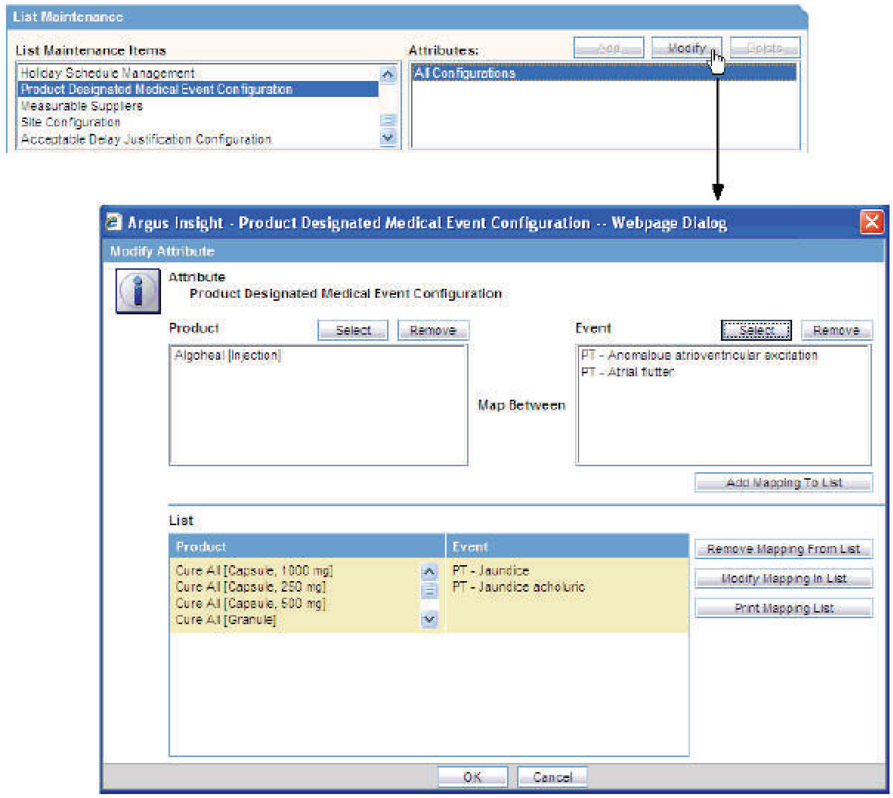


6. Make the required holiday selections, additions, and deletions.
7. Click **OK** to save the holiday schedule.

Configuring Product Designated Medical Event Configurations

To configure or manage Product Designated Medical Event Configurations (PDMEC):

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Product Designated Medical Event Configuration** in the List Maintenance Items section.
4. Select **All Configurations** from the **Attributes** list.
5. Click **Modify.**



6. Select the product to map between one or more events, and then add the mapping to the list.

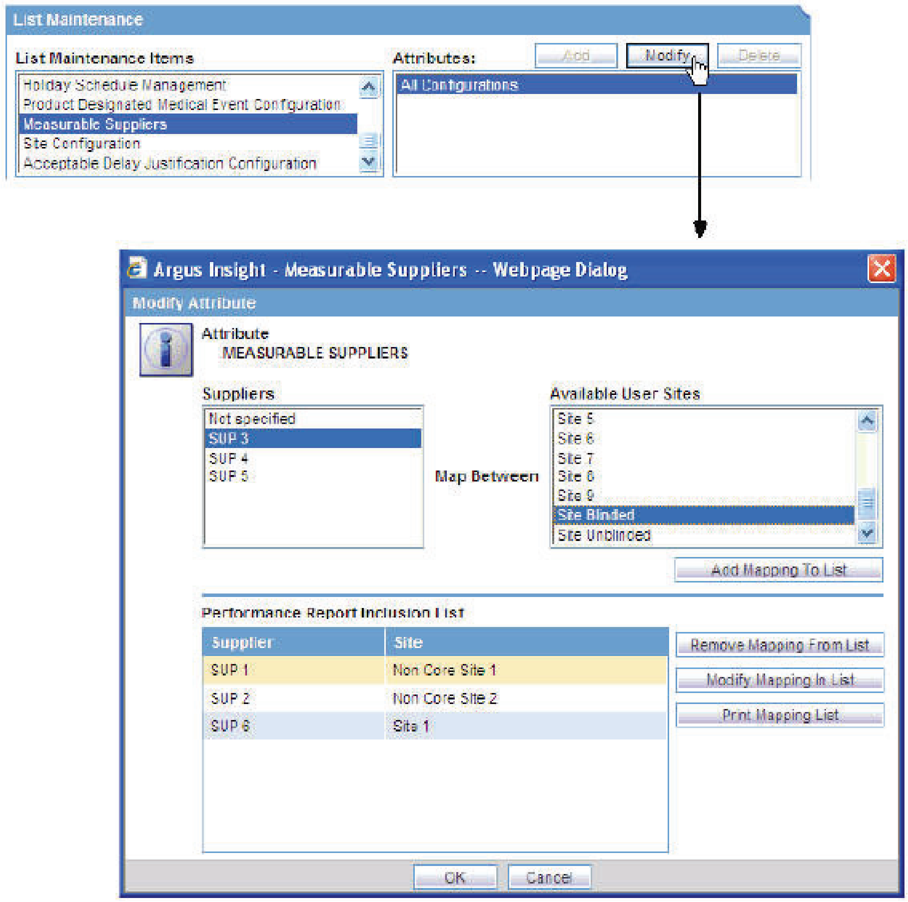
   In addition, you can modify an existing mapping in the list, remove a mapping from the list, and print the mapping list.

7. Click **OK** to save your configuration.

Configuring Measurable Suppliers

To configure or manage measurable suppliers:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Measurable Suppliers** in the List Maintenance Items section.
4. Select **All Configurations** from the Attributes list.
5. Click **Modify.**



6. Configure the mapping between suppliers and available user sites, and then add the mapping to the list.

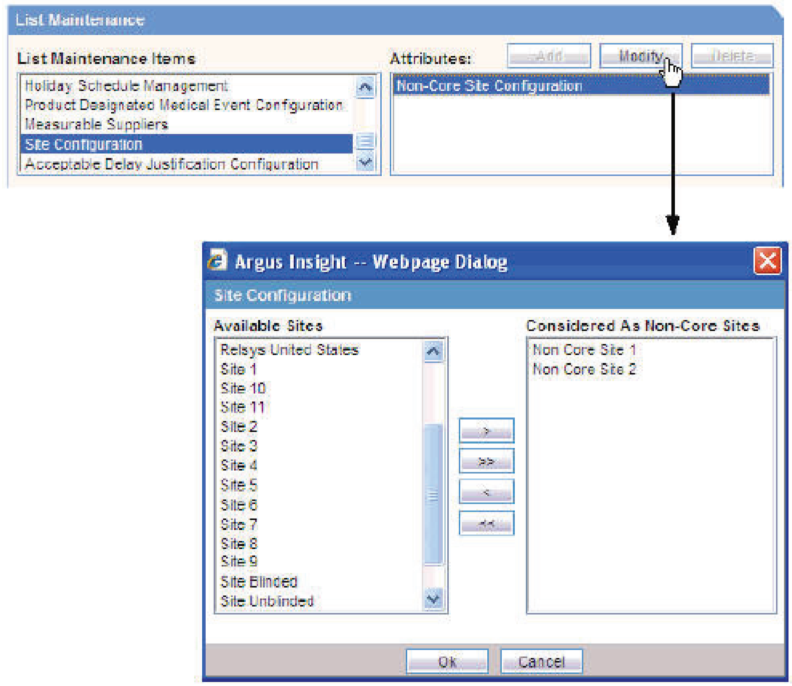
   In addition, you can modify an existing mapping in the list, remove a mapping from the list, and print the mapping list.

7. Click **OK** to save your changes.

Configuring Non-Core Sites

To configure the sites in your installation that are considered non-core sites:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Site Configuration** in the List Maintenance Items section.
4. Select **Non-Core Site Configuration** from the Attributes list.
5. Click **Modify.**

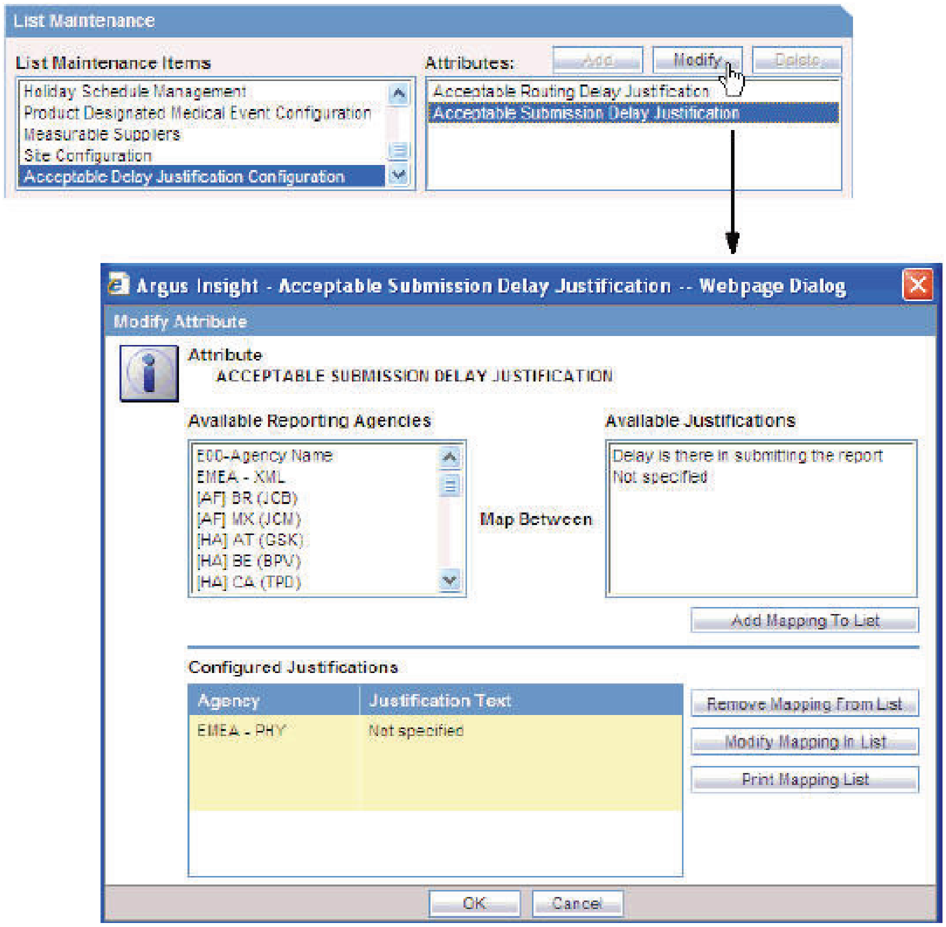


6. Select sites and use the arrow buttons to move sites between the list of available sites and the list of those sites considered to be non-core sites.
7. Click **OK** to save your changes.

Configuring Acceptable Delay Justifications

To configure the justifications for acceptable delays in submission or routing:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **List Maintenance** tab.
3. Select **Acceptable Delay Justification Configuration** in the List Maintenance Items section.
4. Select one of the following options from the Attributes list:
   - To define the justifications for a routing delay, select **Acceptable Routing Delay Justification.**
   - To define the justifications for a submission delay, select **Acceptable Submission Delay Justification.**
5. Click **Modify.**



6. Configure the mapping between available reporting agencies with the available justifications, and then add the mapping to the list.

   In addition, you can modify an existing mapping in the list, remove a mapping from the list, and print the mapping list.

7. Click **OK** to save your changes.

Running the Extract, Transform, and Load Process

The Extract, Transform, and Load (ETL) process enables you to move data from your drug safety database, reformat the data, and then load the data into another database (data mart) for querying, drill-down analysis, and report generation.

Beginning with Argus Insight 7.0, ETL Scheduler is a user role defined in the Security tab on the ADMINISTRATION TOOLS page. This role is available across all enterprises at a global level.

The ETL Scheduler screen can be displayed, updated, and audit logged from the default enterprise in a multi-tenant installation. Only those users who have been assigned the ETL Scheduler role can view this screen.

Data Integrity Checks Before ETL

Argus must complete the following data integrity checks before performing the ETL:

- Every case must have at least one suspect product.

- Every case must have at least one event where the DESC_REPTD column is not null.
- Every case must have one and only one primary event.
- Every case must have a State record (CASE_MASTER.STATE_ID).
- Every case must have a Report Type record (CASE_MASTER.RPT_TYPE_ID).
- Every case must have a Country of Incidence record (CASE_MASTER.COUNTRY_ID).
- Every case must have a Study record (CASE_STUDY).
- Every case must have an Assessment record (CASE_ASSESS).
- Every product in CASE_PRODUCT must have a record in CASE_PROD_DRUGS.
- If there are reporters on the case, there must be only one primary reporter

Initial ETL Versus Incremental ETL

When Argus Insight is installed, the Initial ETL process is run to populate the data mart for the first time. Subsequently, you need to run Incremental ETL processes at specific intervals to update the data mart with the latest data from your drug safety database.

You cannot execute an Initial ETL and an Incremental ETL simultaneously.

Note: Do not run an Incremental ETL for more than 30000 cases. If the number of cases exceeds 30000, run the Initial ETL again. See the *Oracle Argus Insight Installation Guide* for information about running the Initial ETL.

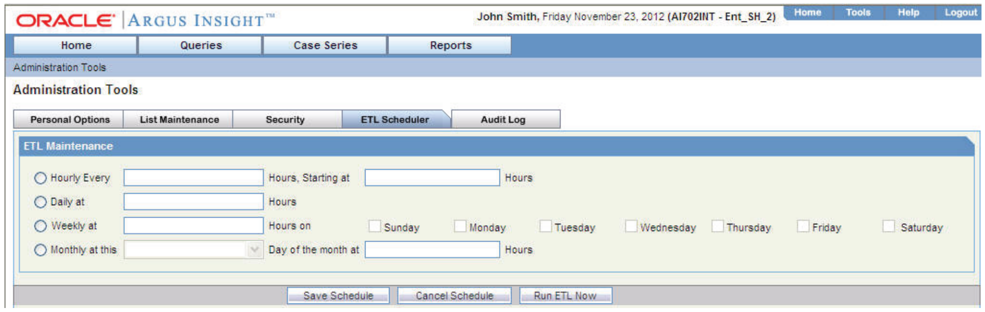
Scheduling the ETL

The **ETL Scheduler** tab lets you schedule the Incremental ETL process to run automatically and update the data mart.

Note: Updating reports table must always be followed by an update to the CASE_MASTER.LAST_UPDATE_TIME. (Updating the CASE_MASTER will result in moving the case along with all the reports to the mart schema.)

To schedule the ETL:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **ETL Scheduler** tab.

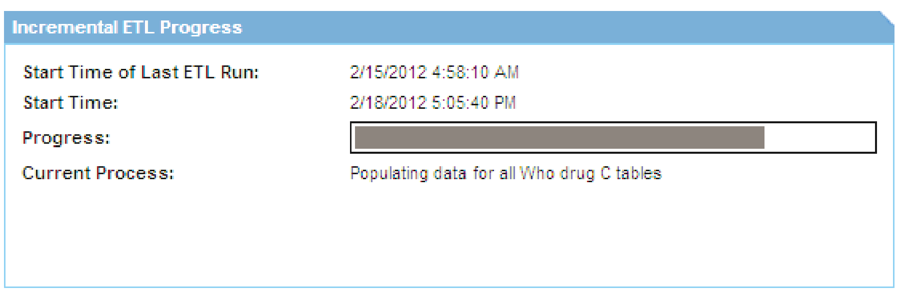


3. Define how often you want to run the ETL by selecting one of the following options:
   - Hourly every so many hours, starting at a specific time
   - Daily at a specific time
   - Weekly at a specific time on a set day of the week
   - Monthly on a set day of the month at a specific time
4. Specify the other parameters, such as the hour of the day when the ETL will run. Use the 24-hour format (HH:MM:SS) when specifying a time value.
5. Click **Save Schedule** to save your settings.

To run the ETL immediately, click **Run ETL Now.** Running the ETL immediately does not affect the scheduled ETL.

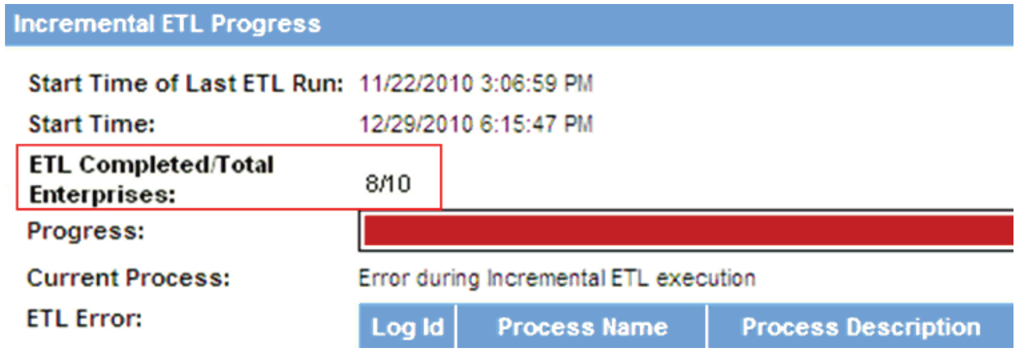
Monitoring the Progress of the ETL

While running the ETL, Argus Insight displays a status bar that shows the progress of Incremental ETL. For example:



The ETL Scheduler screen is only displayed, updated, and audit logged from the default enterprise to the user who is assigned with the ETL Scheduler role.

Beginning with Argus Insight 7.0, the Incremental ETL Progress status screen also displays the ETL Completed/Total Enterprises field. This field displays the number of enterprises for which the ETL has been completed, out of the total number of active enterprises in the system. For example:



If an error occurs during the ETL execution, the ETL stops and the system displays the error message.

- To resume the ETL from the point where the ETL failure occurred, click **Resume ETL.** Note that Argus Insight enables the **Resume ETL** button *only* when the first commit point is reached, after staging has completed. Any ETL failure that occurs before the first commit point will start from scratch.
- To start the Incremental ETL from the beginning again, click **Run ETL Now.**

After the ETL execution is completed, the system generates ETL reports. Navigate to **Reports, Standard Reports,** and select **Configuration** to view the following ETL reports:

- ETL Log Argus to Staging Incremental (execution log for the last Incremental ETL)
- ETL Log Staging to Mart Incremental (execution log for the last Incremental ETL, with the List Maintenance tables and Configuration tables, and case by case log)
- ETL Log Summary (earlier history of all ETL executions)

To check the Initial ETL execution, review the balancing log in the database installation folder.

Securing User Accounts, Groups, and Access Rights

The default user name for the Argus Insight application comes from Argus Safety (admin). Its password is the same as the password of that user in Argus Safety.

Beginning with Argus Insight 7.0, you cannot create a user from Argus Insight. Instead, you create, copy, and delete Argus Insight users from the Argus Safety Console application.

In Argus Insight, however, you can create one or more user groups, and then assign access rights to the group. You can modify an existing user account, assign roles to the user, and add the user as a member of one or more groups.

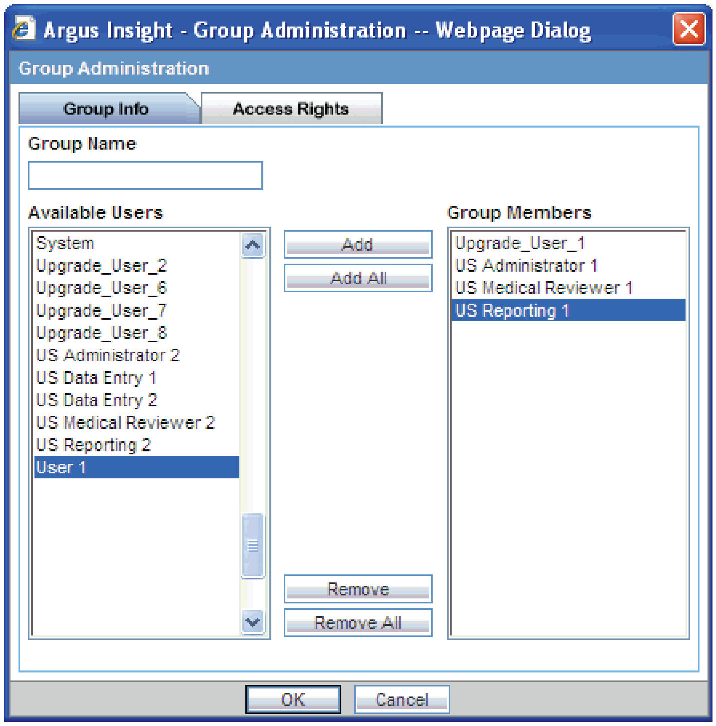
In addition, all the existing Argus Safety user names and their passwords are replicated in Argus Insight.

Note: Any user with access to the custom SQL interface for creating advanced conditions may be able to see any data present in the database. Therefore, restrict the access to this interface to those users who have back-end access or are allowed to see any data from the database.

Creating New User Groups

To create a new user group:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **Security** tab.
3. Click **Add** in the **Groups** section. The Group Administration dialog box opens.



4. Click the **Group Name** field and enter a name for this user group.
5. Define the users who are members of this group.
   - To add one or more users to the group, select the user name from the Available Users list and click **Add.** To add all available users to the group, click **Add All.**
   - To delete one or more users from the group, select the user name from the Group Members list and click **Remove.** To remove all users from the group, click **Remove All.**
6. Define the access rights for all the members of this group.
   a. Click the **Access Rights** tab.
   b. Click **OK** to confirm that you want to create the group.
   c. Select the appropriate check boxes depending on the access rights you want to assign to this group of users.
7. Click **OK.** The list in the **Groups** section in the Security tab displays the name of your newly created group along with the names of the users who are members of the group.

Copying Groups

Once you have created a user group, you can use the Copy functionality to save the existing user group or account by another name while retaining all the access rights, group associations, and user associations. This is useful when you are creating multiple groups or user accounts with similar access rights and associations.

To create a new group or account by copying information from an existing group or account:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **Security** tab.
3. Select a user name or a group name you want to copy.
4. Click **Copy** in the **Groups** section. The Group Administration dialog box opens.
5. Enter a group name in the **Group Name** field.
6. Click **OK.** Settings from the copied group are carried over to the new group.

Modifying Existing Groups

To modify the details and members of a group:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **Security** tab.
3. Select a group name you want to modify.
4. Click **Modify** in the **Groups** section. The Group Administration dialog box opens.
5. Modify the settings, as appropriate.
6. Click **OK** to save the modifications to the selected group.

Deleting Existing Groups

To delete an existing group:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **Security** tab.
3. Select the group that you want to delete.
4. Click **Delete.** The system prompts for confirmation that you want to delete the group.

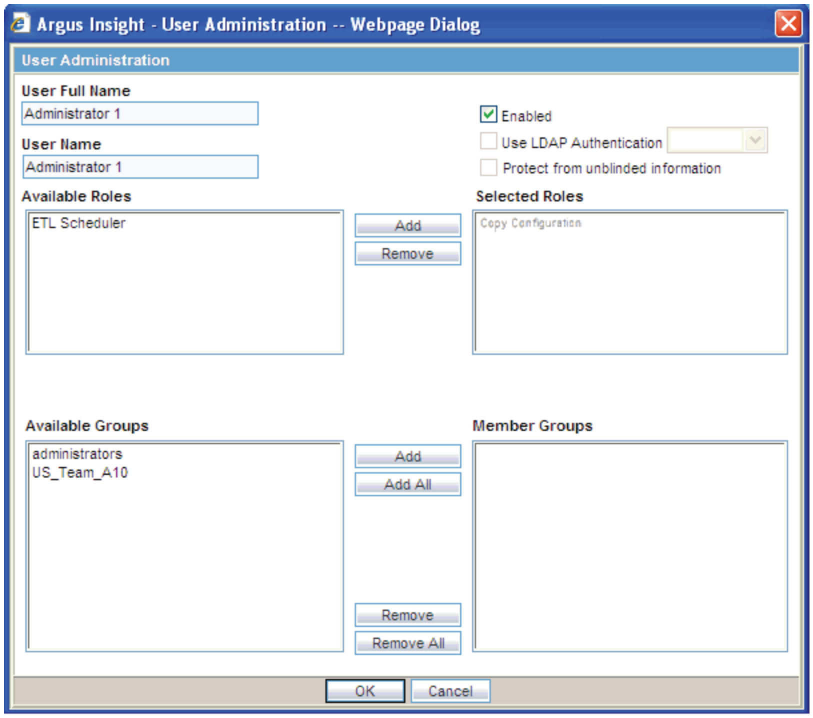
> **Note:** When you delete a user, all the queries and case series that the user saved in Argus Insight are also deleted.

5. Click **Yes** to delete the selected group.

Modifying User Accounts

To modify an existing user account:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **Security** tab.
3. Select the user account that you want to modify.
4. Click **Modify.** The User Administration dialog box opens.



The **User Full Name** field, the **User Name** field, the **Use LDAP Authentication** check box, and the **Protect from unblinded information** check box are read-only in Argus Insight, and are synchronized with their values configured in Argus Console.

5. Define the roles for this user.

   - To assign a role to this user, select the role from the Available Roles list and click **Add.**
   - To remove an existing role for this user, select the role from the Selected Roles list and click **Remove.**

   Note: The Copy Configuration role appears under Selected Roles in read-only mode for the users having this role. Those Argus Insight users who have access to the Copy Configuration role in Argus Safety can copy all the configuration data from the enterprise where they have this role to any new enterprise that they create through the Global Enterprise Management portlet.

   Beginning with Argus Insight 7.0, ETL Scheduler is a user role. This role is only displayed, updated, and audit logged in the default enterprise.

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6. Assign the user to be a member of one or more groups.

   - To make this user a member of a group, select the group name from the Available Groups list and click **Add.** To make this user a member of all groups, click **Add All.**
   - To revoke this user's membership in a group, select the group name from the Member Groups list and click **Remove.** To revoke this user's membership in all groups, click **Remove All.**

7. Click **OK** to save the modifications to the selected user account.

Users who selected the Argus Insight check box (from Argus Console, User Management, Application Access) for an enterprise can access the application for that enterprise.

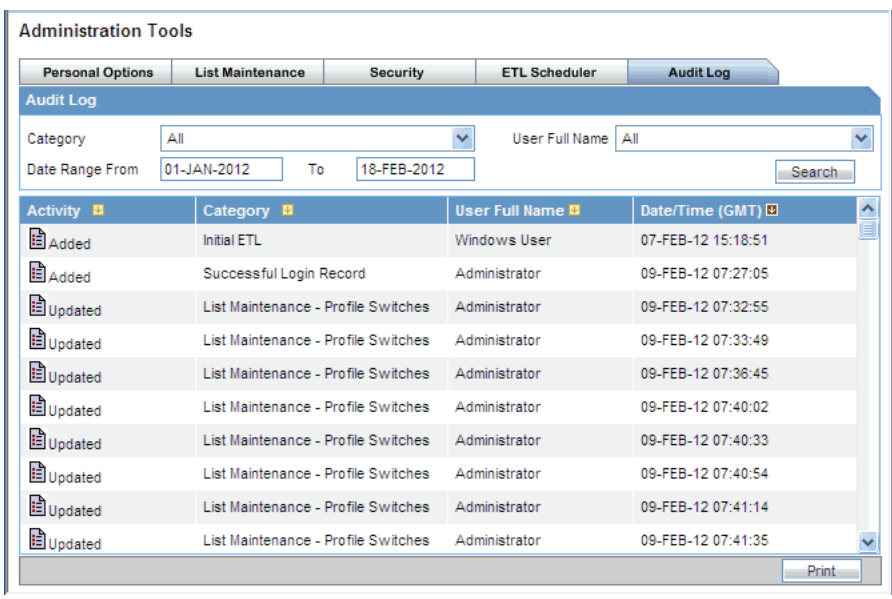
Viewing the Audit Log

From the **Audit Log** tab, you can view the activities performed by an Argus Insight user or by all users during a particular period.

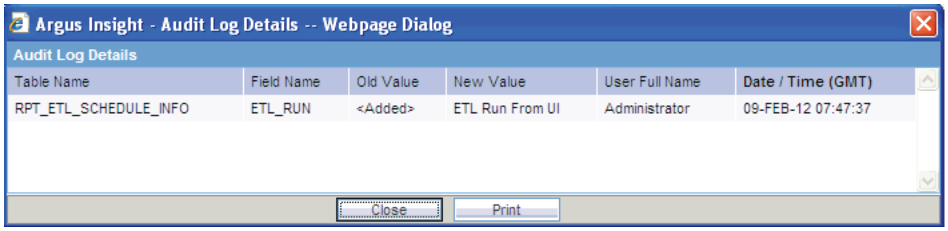
To view the audit log:

1. Click **Tools** on the global toolbar. The ADMINISTRATION TOOLS page opens.
2. Click the **Audit Log** tab.

3. Enter the criteria for the audit logs you want to view.
   a. In the **Category** field, select the activity category or select **All.**
   b. In the **User Full Name** field, select a user name or select **All.**
   c. In the **Date Range From** and **To** fields, enter the date range.
4. Click **Search.** The Audit Log tab displays the list of activities according to the criteria you specified.



- To sort the list of activities, click a column heading.
- To print the list of activities, click **Print.**
- To view more details about an activity, click the Audit Log Details icon in the Activity column. The Audit Log Details dialog box opens and displays additional information about the activity. To print the activity details, click **Print.**


Argus Insight - Audit Log Details -- Webpage Dialog
Audit Log Details
Table Name
Field Name
Old Value
New Value
User Full Name
Date / Time (GMT)
RPT_ETL_SCHEDULE_INFO
ETL_RUN
<Added>
ETL Run From UI
Administrator
09-FEB-12 07:47:37
Close
Print

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.