Oracle® Argus Insight

BOXI Administrator's Guide,

Release 6.0

E18285-01

August 2010

ORACLE®

Oracle Argus Insight BOXI Administrator's Guide, Release 6.0

E18285-01

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Preface

Audience

This document is intended for all Argus Insight administrators.

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Conventions

The following text conventions are used in this document:

Convention	Description
Note	A Note identifies information you should be aware of before proceeding with the current task.
Bold Text	Bold text is used to emphasize words such as does not and must. It is also used to identify user interface elements such as buttons, dialog boxes, check boxes, combo boxes, drop-down lists, labels, option (radio) buttons, tabs, text boxes, etc.
Italic Text	Italic text identifies information that may appear on the screen (such as error message) or information the user must provide.
UPPERCASE TEXT	Uppercase text identifies keyboard keys. For example, SHIFT, ENTER, CTRL, etc.
Bold Underline	Identifies a link indicating that additional information is available.
Initial Capitals	Initial capitals are used to identify modules, applications, proper nouns, etc.

1

Introduction

Argus Insight Overview

This manual describes the various components of Argus Insight and explains the interaction between them.

Argus Insight Overview

This topic explains the typical workflow followed in Argus Insight to generate a *report*.

- Argus Insight Components
- Argus Insight Process Flow

Argus Insight Components

In Argus Insight, you can generate a *report* in either of the following ways:

- Use a *query* to retrieve a specific set of cases (Case Series) from the datamart 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, Cubes and Dashboard Indicators.
- Use Report Writer, Cubes and Dashboard Indicators to:
  - Directly query the datamart
  - Generate reports from the datamart using the Dashboard Indicators component. Dashboard Indicators are pre-configured by the administrator.

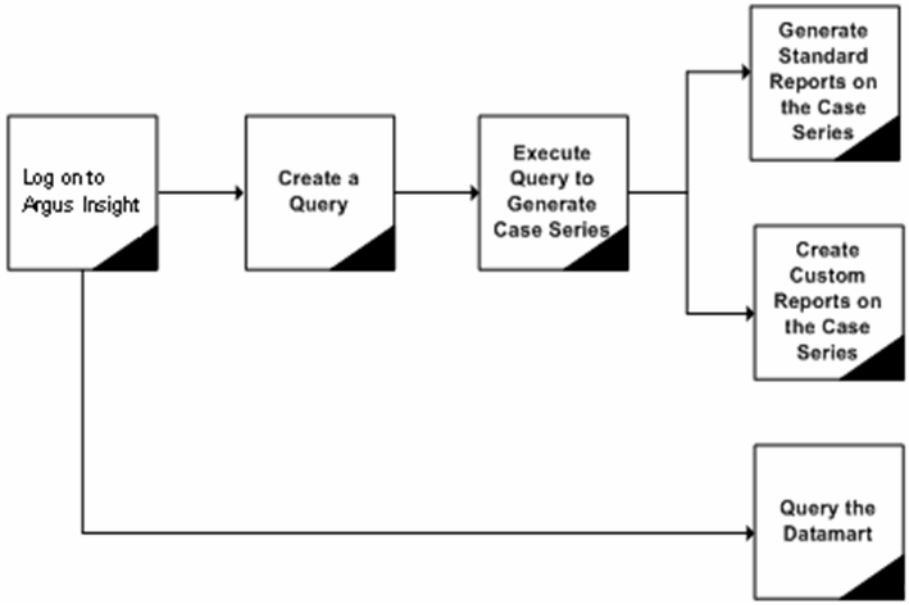
Note: The Report Writer is primarily used to directly query the datamart and create custom reports. However, you can apply the active Case Series*filter* on the reports to reduce the data set and improve report performance. Please note, that the Case Series might become obsolete each time the datamart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

The following table describes the various components of Argus Insight:

Component	Description
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 datamart and applying Boolean and Set operations on them
Case Series	A listing of cases that match the query criteria
Standard Reports	Predefined reports built into Argus Insight These reports are grouped into these categories: Compliance, Management, Pharmacovigilance, Configuration, and General Typically, these reports are run on the Case Series
Report Writer	Lets you directly query the datamart and create custom reports by selecting any datamart 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
Cubes	Lets you run complex queries on the datamart and statistically analyze, drill-down, and explore the results
	Argus Insight has six predefined Cubes: Reporting-Compliance, Workflow, Pharmacovigilance-Detail, Pharmacovigilance-General, Pharmacovigilance-Clinical, and Pharmacovigilance-Interaction
Dashboard Indicators	Special reports that provide an insight into key parameters that let you monitor product performance and workflow efficiency Dashboard Indicator reports are pre-configured by the administrator and are generated directly from the datamart

Argus Insight Process Flow

The following flowchart depicts the set of steps that are typically followed in Argus Insight to generate a *report*. Please refer to your company's guidelines for the exact workflow for generating reports and analyzing data in Argus Insight.



The following table describes the tasks shown in the process flow diagram.

Task	Description
Log on to Argus Insight	Log on 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 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 datamart 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 datamart 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 Datamart	Use the Report Writer, Cubes, or Dashboard Indicators, to directly query the datamart and generate the required report. ■ Use the Report Writer to create new reports ■ Perform data analysis using Cubes ■ View the Dashboard Indicator Reports

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Upgradability and Compatibility

About Upgradability and Compatibility

It is essential for any software to be upgradable to higher versions as well as compatible with multiple versions. This chapter describes about the upgrade and compatibility of Argus Insight.

Upgrade Path

You can upgrade directly to this (6.0) version of Insight from Argus Insight version 5.1 and 5.1.1. After completing the upgrade, you must execute an initial ETL.

Product Compatibility

This version of Insight is compatible with the following products/versions.

- Argus Safety 6.0, 5.1.1, 5.1, and 5.0.3
- Argus Perceptive 6.0

This version of Insight has also been tested for SSL compatibility.

Copy Configuration

You can Import configuration information from the following Insight versions and export it to Argus Insight 6.0.

- Argus Insight 6.0

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Getting Started

Using Argus Insight

Argus Insight, formerly called Power Reports is a highly optimized reporting module that compliments Argus Safety. The Argus Insight Extract Transfer 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 describes the tasks performed when logging into Argus Insight.

Getting Started

The following tasks help you get started with Argus Insight.

To launch the web-based Argus Suite of Products:

1. Open the Web browser.
2. Type the Argus Web URL (Universal Resource Locator) in the address bar.

The system uses the Secure Socket Layers to support third-party digital certificates for secure transmissions at the system level. The System Administrator configures the URL is configured by the System Administrator.

The system opens the login screen.

Single Sign on

Be aware of the following:

- Users can have single-sign on capabilities.
- The Argus Safety Administrator defines access to various modules in User Maintenance. If a user is assigned to more than one group, the system provides the user with the highest access level.
  - Based on module access rights, the system enables / disables the application buttons access rights in the Menu Structure.
  - Group access permissions are assigned in Web Admin.
- A user with access to Argus or Insight can launch the application modules. The system does not ask the user to enter a password again for the PR or Argus modules. This also applies when the user launches other applications.
- In User Maintenance, the administrator can link the Argus, Perceptive, and Insight Mart databases. When a user logs into the system, the system identifies the available application modules for each Argus Instance.
- When the user clicks the application modules, the system opens a **New** dialog where the other application (Insight or Argus Safety) can be worked on.
- When the user launches another application through Argus,or vice versa, the application module buttons **do not appear** in the new dialog windows because the user is already logged into the earlier application.
- The initial login screen is the launching dialog forall other modules.
- Logout is available only on the Parent Application dialog. Logging out of the Main application dialog closes all child dialogs **without** saving information in the child applications.

- Sharing a Case Series

  The system enables a user to share a case series between the following:

  – Perceptive to Insight

    * A case series is available from Perceptive through the Alert Preview and Alert Details.

    * If a case series from Perceptive contains cases not in the Insight data mart (due to latency of the scheduled update), Insight drops these cases from the case series and notifies the user of the dropped cases.

- Insight to Perceptive

  – A case series is available from Insight through the Active Case Series.

  – Case Series tab à Import Cases From Insight is available on the Alert Details screen. This adds the cases from latest (current) Active Case Series for the Insight user to the Case Series in Perceptive.

  – If there are no cases in the Active Case Series in Insight or no Active Case Series exists, Perceptive presents the user with the following message:

    No cases have been exported from Insight

Logging On

The Argus Insight installation program automatically creates an account for the system administrator and assigns the default user name and password as **administrator** and **password**, respectively. The administrator account cannot be deleted. This ensures that the system administrator can always log on to the system. In a given session, only one system administrator can log on to the system.

We recommend that you change the administrator password after logging on to Argus Insight for the first time. You can access Argus Insight through Argus Safety. This feature has been introduced to enable you to use a single login id and password for all Argus Modules. The modules that are enabled when you login to Argus Safety depend on your access right to various Argus modules.

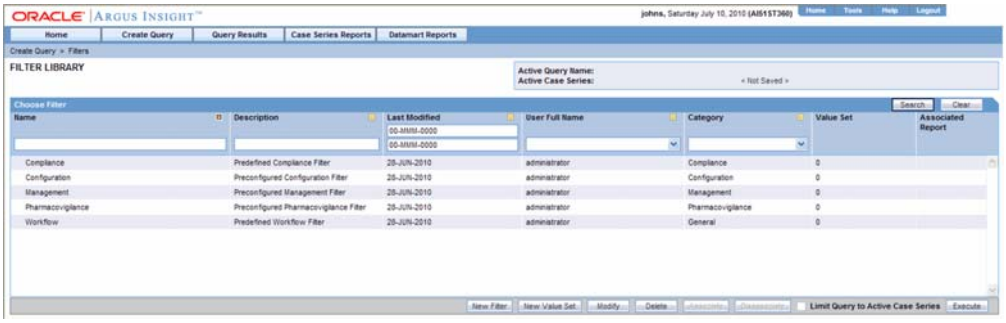
To log on to Argus Insight as an administrator:

1. Start Internet Explorer.
2. Type the Argus Insight Universal Resource Locator (URL) in the address bar.
3. Press Enter. The Argus Insight logon screen appears.

4. Type in the **Username** and **Password**.

> **Note:** Type in **username** as administrator and **password** as password to log in as the administrator.

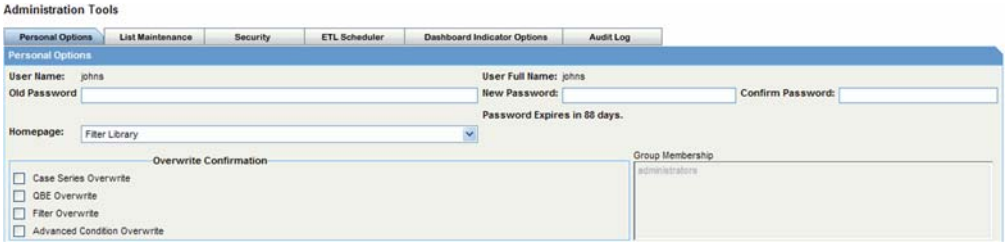
5. Click **Login**. The Argus Insight home page appears.



Changing the Password

Use the following procedure to change the password.

1. Click **Tools** on the global toolbar. The **Administration Tools** page appears with the **Personal Options** tab displayed.
2. In the **Old Password** text box, enter the existing password.



3. In the **New Password** text box, enter a new password. Your new password must be different than your old password.

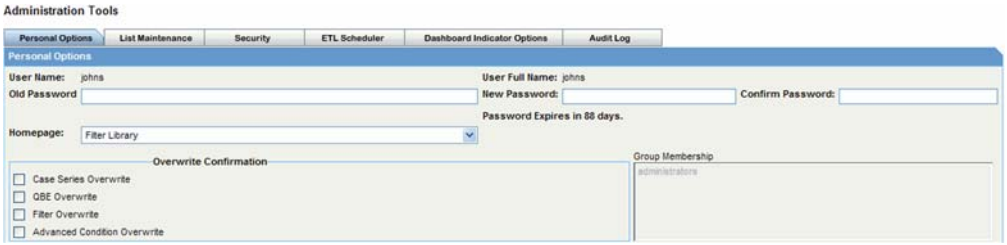
> **Note:** Argus Insight passwords are **case sensitive**. The password requirements are configured by the Administrator.

4. Re-enter the new password in the **Confirm Password** text box.
5. In the **New Password** text box, enter a new password. Your new password must be different than your old password.
6. Click **OK**. The system saves the new password.

Changing the Default Home Page

Use the following procedure to change the default Home page.

1. Click the **Tools** button on the global toolbar. The **Administration Tools** page appears with the **Personal Options** tab displayed.
2. Select a home page from the **Homepage** drop-down list box.



3. Click **OK**. The system changes the default home page to the selected page.

> **Tip:** You can set any page as the default home page, by clicking the **Home Page** button on the global toolbar.
>
> You can make changes to the **Personal Option** tab page to configure the password, default home page, overwrite confirmation, and group membership of users.

Configuring the Argus Insight Application

You may need to configure Argus Insight and change certain factory defaults to conform to the specific business requirements of your organization. Use the following

TheAdministration Toolschapter has information on configuring the following:

- **Personal Options** - password, default home page, overwrite confirmation, and group membership of users.

- **List Maintenance** - profile switches, countries, workflow mappings with Argus, and categories.
- **Security** - creating, modifying, and enabling/disabling user groups and accounts.
- **ETL Scheduler** - configuring ETL.
- **Dashboard Indicators** - assigning specific dashboard reports to users and applying filters to dashboard reports.
- **Audit Log** - monitoring user activities on the system.

Entering Dates in Various Argus Insight Fields

Throughout Argus Insight, you are required to enter dates in several fields. Fields that accept full dates appear in the dd-mmm-yyyy format. You can enter the month using numbers instead of three letters. When you enter a valid month number, the system automatically converts the number to letters corresponding to that month. For example, 03 for the month automatically gets converted to MAR.

> **Tip:** To enter the current date in a date*field*, press the = key on the keyboard

You can enter partial dates in certain fields. Fields that accept partial dates appear in the ??-???-0000 format. 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.

The following fields in the QBE *form*, which is similar to the Argus Case form, accept partial dates.

QBE Form Tab	Field
Patient	Date of Birth
	Other Relevant History
	Start Date
	Other Relevant History
	Stop Date
	Lab Data
	Date
Patient > Parent	Date of Birth
Product	Expiration Date
	Dosage Regimen
	Start Date/Time
	Dosage Regimen
	Start Date/Time
	Summary of all regimens
	First Dose
	Summary of all regimens
	Last Dose

QBE Form Tab	Field
Product > Vaccine History	Date
Product > Device	Date Explanted
	Date Implanted
	Expiration Date
Event	Onset Date
	Stop Date
Event > Death	Death Date
Event > Hospitalized	Start Date
	End Date

The following table lists some examples of partial dates.

Date to be Entered	Partial Date Formats
March, 2005	Enter any one of these sequences: ■ 0032005 ■ 00305 ■ ???305 ■ ??305 ■ /32005 ■ /305 ■ 00MAR2005 ■ 00MAR05 ■ ??32005 ■ ??MAR2005 ■ /MAR2005
2005	Enter any one of these sequences: ■ 00002005 ■ 000005 ■ ??2005 ■ ??05 ■ //2005 ■ //05 ■ ?? ???2005 ■ ?? ???05

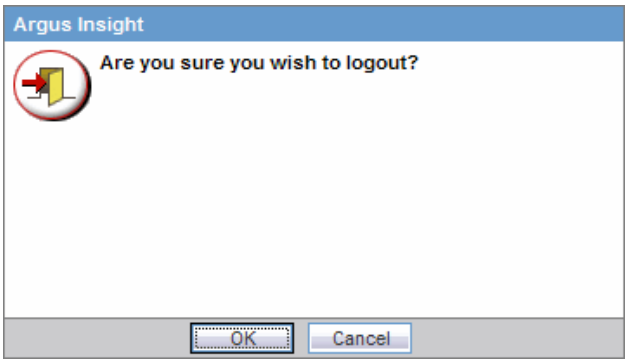
Getting Help

Click the **Help** button on the global toolbar to access the Online Help. You can find information by using the **Contents**, **Index**, or **Search** tabs in the Online Help.

Logging Out

Use the following procedure to log out.

1. Click **Logout** on the global toolbar. A confirmation dialog box appears.



2. Click **OK**. The system logs you out. The Argus Insight logout screen appears.

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Creating Queries

Creating Queries

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

This chapter explains how to use the Argus Insight querying tools and in what situations. Depending on how complex or detailed a query you want to create, you can use these Argus Insight querying tools:

- QBE
- Filters
- Advanced Conditions
- Library

> **Note:** You may be allowed to enter more than 4000 characters in text box, but the query search is limited to the first 4000 characters.

QBE

If you are familiar with the Argus case *form*, you may choose *Query* by Example (QBE) to create simple queries. For a QBE, the querying criteria consists of specific values entered in the fields on the QBE form, which looks substantially like the Argus case form. For example, your QBE may consist of the values in these fields:

QBE Form Tab > *Field*	Value Entered/Selected
General > Country of Incidence	United States
Products > Product Name	Algoheal Injection
Events > Event Description to be Coded	Injection site rash
Events > Seriousness Criteria	Hospitalized

When you execute this QBE, the system retrieves only those cases where the values of **Country of Incidence**, **Product Name**, **CodedEvent Description**, **Event Description to be Coded** and **Seriousness Criteria** are the same as specified in your QBE.

These topics explain how to work with QBE:

- Creating a New QBE
- Working with the Last Modified or Executed QBE
- Working with Saved QBEs
- Using QBEs with Advanced Conditions

Creating a New QBE

Begin creating a QBE by entering values in the QBE *form*. The QBE form has a tab-based interface consisting of eight multiple section tabs.

The first seven tabs in the QBE form let you enter the *query* criteria about a specific aspect of a case:

QBE Form Tab	Type of Information to Enter
General	Lets you enter querying criteria based on general, *study*, reporter, and literature information about the case
Patients	Lets you enter querying criteria based on information about the patient, lab data, other relevant history, and the patient's parent
Products	Lets you enter querying criteria based on product information and dosage regimens
Events	Lets you enter querying criteria based on information about the event and its seriousness criteria
Analysis	Lets you enter querying criteria based on information about case analysis and imputability
Activities	Lets you enter querying criteria based on case activity information, such as contact logs, action items, and case lock/archive dates
Additional Info	Lets you enter querying criteria based on additional information about the case such as references

The eighth tab in the QBE form, **Advanced Conditions**, lets you integrate a QBE with an Advanced condition stored in Argus Insight. You can also convert a QBE into an Advanced Condition. The Using QBEs with Advanced Conditions topic explains this in detail.

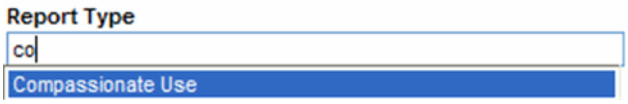
Note: For more sophisticated queries, use Filters or Advanced Conditions.

While specifying the query criteria in Query By Example page (QBE form), Argus Insight provides the functionality of **Type Ahead** in few **fields**. **Type Ahead** functionality offers you to type-in a value and the like values are displayed in the list box. It also enables you to select the desired value from the list of values. The fields having this functionality are as follows:

Accidental Exposure	Action Taken	Action Type	Age Groups	Age Units

Anatomical Locations	Attachment Classification	Birth Type	Case Classification	Causality Category
Condition Type	Contact Type	Delivery Types	Device Subcomponents	Device Type
Dosage Frequency	Dosage Units	Ethnicity	Event Frequency	Event Intensity
Event Outcome	Fetal Outcome	Formulation	Gender	Group (Activities:contact log)
Group (Action item)	Intermediary	Locked or Closed By	Manufacturers	Occupations
Package Units,	Reference Type	Report Media	Report Type	Reporter Type
Routes of Administration	User (Activities:contact log)	User (Action item)		

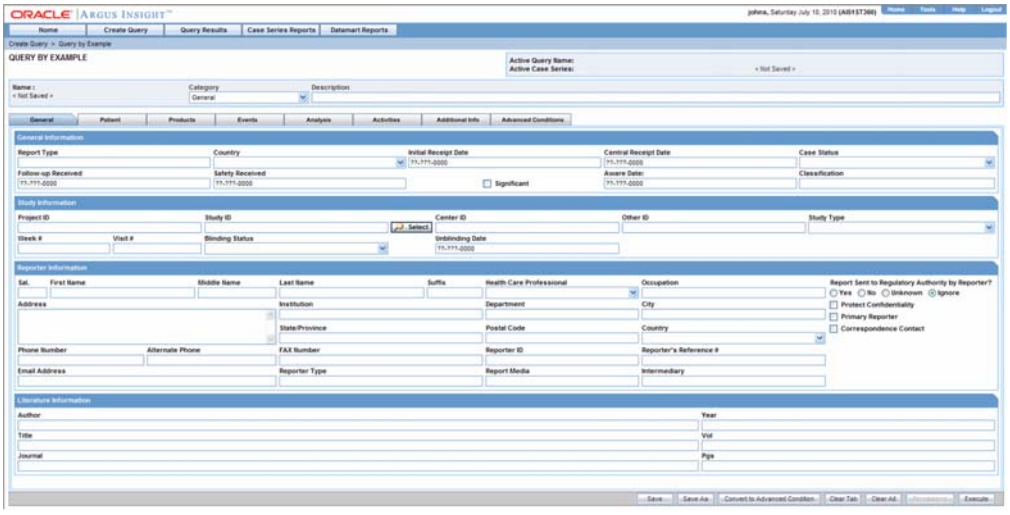
Type Ahead



You can use the type-ahead functionality to select data suggestions by double-clicking on a textbox to display all the suggestions for a field in a list of values. Alternatively, you can also you can type-in a value and suggestions are displayed for the typed value.

Use the following procedure to create a new QBE and work with it. To log out of Argus Insight:

1. Start the new QBE. In Argus Insight, select **Create Query > Query By Example > New**. The **Query By Example** page (QBE form) appears; the **General** tab page is displayed.



2. Specify the querying criteria. Enter values in the fields within the various tab pages, as appropriate.

   Refer to these pages for descriptions of all the fields in the various tab pages of the QBE form:

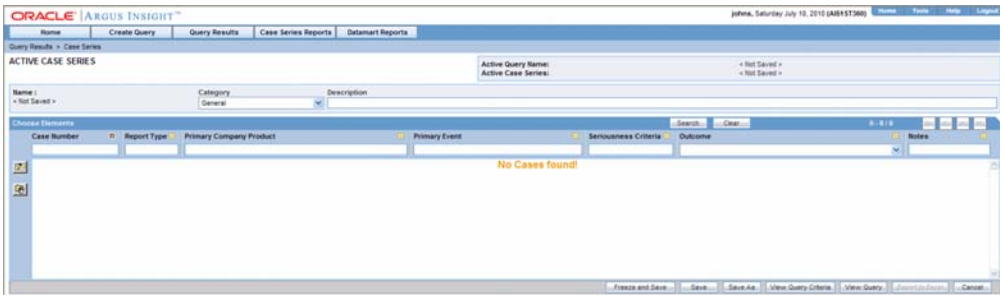
Note: The QBE field labels are displayed as per the field labels configured in Argus

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

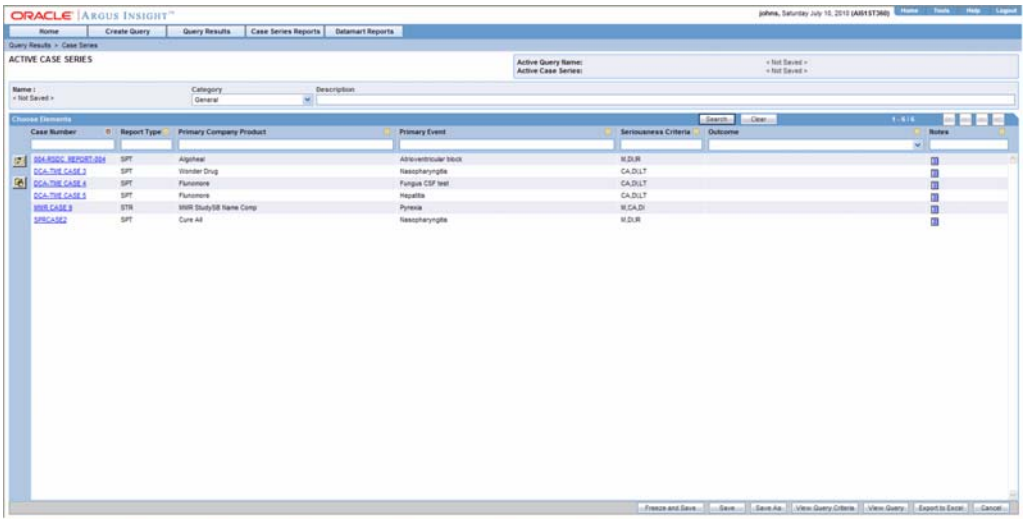
Tip: While entering values in a tab, if you wish to clear all the values you entered, click the **Clear Tab** button. If you wish to clear all the values you entered in all the tabs, click the **Clear All** button.

3. Examine the QBE result.
4. Click **Execute**. While the system searches for matching cases, the following dialog box is displayed.

- If the system does not find any cases that match the querying criteria, the following screen is displayed. Click Cancel to return to the QBE form, modify the criteria and execute the QBE again.



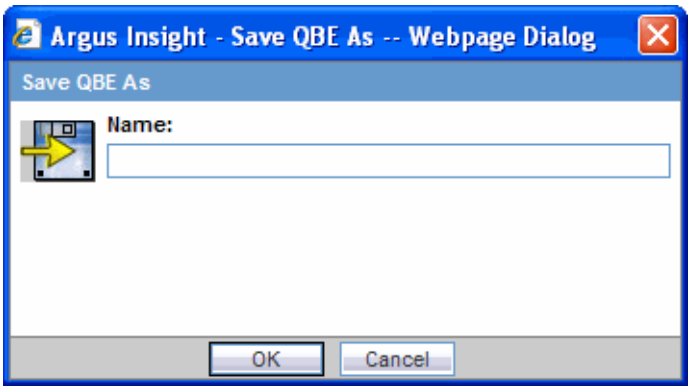
- If the system finds cases that match the query criteria, a list of such cases is displayed in the **Active Case Series** page.



5. Examine the Case Series. If the Case Series is too large, you may want to modify the QBE by specifying additional *field* values in the QBE form to narrow down the Case Series. Alternatively, if you find the Case Series to be appropriate, you can save the QBE to the system.
6. To return to the QBE form, click **View Query** in the **Active Case Series** page. The **Active Query by Example** page appears.

> **Note:** When you save the modifications to a QBE or execute a QBE, the system assigns the Active status to the QBE. Therefore, when you return to the QBE form after executing the QBE, the page title changes to **ActiveQuery By Example**. The field values you specified in the QBE form before executing are retained. See the Working with the Last Modified or Executed QBE topic for details on Active QBEs.

7. If required, modify the QBE and examine the result again or proceed to save the QBE.
8. Save the QBE to the system.
9. Use the **Category** list box to assign a category to the QBE you are going to save. A category indicates the reporting aspect to which your QBE pertains: **Compliance**, **Configuration**, **General**, **Management**, or **Pharmacovigilance**. Specifying the category also helps you in searching the relevant QBEs from a list of all the QBEs saved in the system.
10. Type a description of the QBE in the **Description** text box. For example, you can describe the type of cases the QBE retrieves.
11. Click **Save As** in the **ActiveQuery By Example** page. The **Save QBE** dialog box appears.



12. Type the name of the QBE in the **Name** text box.

> **Note:** A name cannot contain any of the following: % " ' ^ ~,;|#`

13. Click **OK**. The system refreshes the **Query By Example** page. Note that the following new elements appear on the page.
    - 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 of the QBE you specified while saving the QBE.
    - Two new buttons appear at the bottom of the page: Save and Permissions.

> **Note:** All the QBEs that you save to the system are listed in the **Query By Example - Library** page. The Working with Saved QBEs topic explains how to work with saved QBEs.

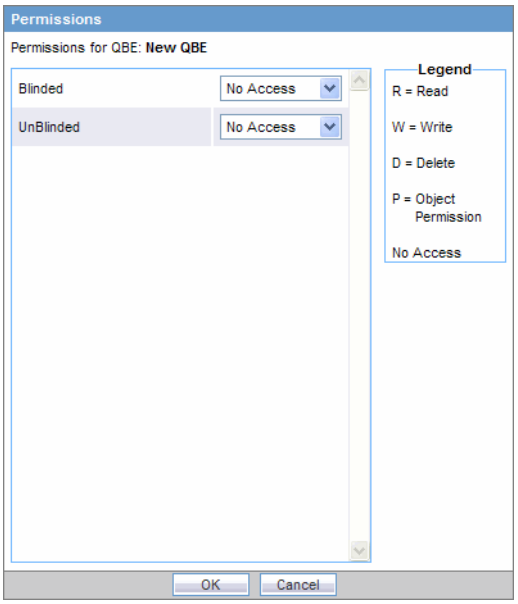
> **Tip:** If you make modifications to the field values after you have saved the QBE to the system, use the Save button to save the changed field values.

Assign group-level permissions on the saved QBE

Use the following procedures to assign group-level permissions to a saved QBE

To assign group-level permissions to a saved QBE:

1. Click the **Permissions** button. The **Permissions** dialog box appears. A list in this dialog box displays the names of all the groups (except the **Administrator** group) that the system administrator has created.



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

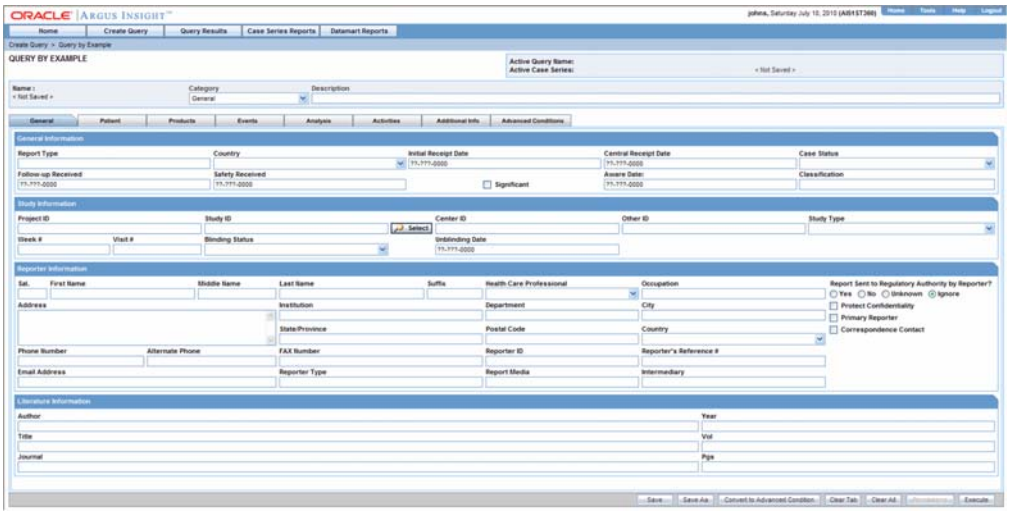
2. Click **OK**. The system saves the permission settings.
3. Execute the QBE.
4. Click **Execute**. The system retrieves the list of cases that match the QBE criteria and displays it in the **Active Case Series** page.

   After generating the Case Series, you can manually modify it or save it. See the Working with Case Series chapter for more information on working with Case Series.

General Page

The **General** page differs from what you might be used to seeing in Argus 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 down the page to view all the fields available.



The following table describes the various fields in the **General** page. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Section	Field	Description
General Information	Report Type	Use this list box to select the case source that the query should look for in cases.
	Country	Use this list box to select the country of incidence that the query should look for in cases.
	Initial Receipt Date	In this date field, enter the date when you company first became aware of the case.
	Central Receipt Date	In this date field, enter the date on which the Central Safety received the case.
	Case Status	Use this list box to select the workflow state that the query should look for in cases.
	Follow-up Received	In this date field, enter the follow-up information receipt date that the query should look for in cases.
	Safety Received	In this date field, enter the date on which follow-up information was received by Central Safety.
	Significant	Check this checkbox to retrieve cases that had a significant follow up.
	Aware Date	In this date field, enter the most recent significant follow-up date or initial receipt date (if there are no follow ups), that the query should look for in cases.

Section	Field	Description
*Study*Information	Study Num	Click the **Select** button associated with this text box to select the study protocol number, study number and center id that the query should look for in cases. See theSelecting the Study Numbersection for details.
	Study Type	Select the study type that the query should look for in cases.
	Other Study ID	In this text box, enter any other ID that can be relevant to the study.
	Study Week	In this text box, enter the week number of the study during which the adverse event occurred. The query will only look for such cases.
	Study Visit	In this text box, enter the visit number of the study during which the adverse event occurred. The query will only look for such cases.
	Study Blinding Status	Use this list box to select the study blinding status that the query should look for in cases.
	Study Broken Date	In this date field, enter the date on which the study was broken. The query will only look for cases with matching study broken date.

Section	Field	Description
Reporter Information	Reporter Sal.	Enter the reporter salutation that the query should look for in cases.
	Reporter First Name	Enter the reporter's first name to look for in cases.
	Reporter Middle Name	Enter the reporter's middle name to look for in cases.
	Reporter Last Name	Enter the reporter's last name to look for in cases.
	Reporter Suffix	Enter the reporter's suffix to look for in cases.
	Health Care Professional	Select an option from this list box to include a query criterion based on whether the reporter is a health care professional.
	Reporter Occupation	Use this list box to select the reporter's occupation that the query should look for in cases.
	Reporter Address	In this text area, enter the report address that the query should look for in cases.
	Reporter Institution	In this text box, enter the reporter's institution that the query should look for in cases.
	Reporter Department	In this text box, enter the reporter's department that the query should look for in cases.
	Reporter City	In this text box, enter the reporter's city that the query should look for in cases.
	Reporter State	In this text box, enter the reporter's state that the query should look for in cases.
	Reporter Postal Code	In this text box, enter the reporter's postal coded that the query should look for in cases.
	Reporter Country ID	In this text box, enter the reporter's country ID that the query should look for in cases.
	Reporter Phone Number	In this text box, enter the reporter's phone number that the query should look for in cases.
	Reporter Alternate Phone	In this text box, enter the reporter's alternate phone number that the query should look for in cases.
	Reporter Fax Number	In this text box, enter the reporter's fax number that the query should look for in cases.
	Reporter ID	In this text box, enter the reporter ID that the query should look for in cases.
	Reporter's Reference #	In this text box, enter the reporter's reference number that the query should look for in cases.
	Reporter Email Address	In this text box, enter the reporter's email address that the query should look for in cases.
	Reporter Type	Use this list box to select the reporter type that the query should look for in cases.
	Report Media	Use this list box to select the report media that the query should look for in cases.
	Intermediary	Use this list box to select the intermediary that the query should look for in cases.
	Report Sent to Regulatory Authority by Reporter	Select the **Yes**, **No**, **Unknown**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where the reporter has already informed a regulatory authority about the event.
	Reporter Protect Confidentiality	Check this checkbox to have the query retrieve only those cases where reporter information is specified as confidential.

Section	Field	Description
Literature Information	Literature Journal	In this text box, enter the literature journal name that the query should look for in cases.
	Literature Author	In this text box, enter the literature author name that the query should look for in cases.
	Literature Title	In this text box, enter the literature title that the query should look for in cases.
	Literature Vol	In this text box, enter the literature volume that the query should look for in cases.
	Literature Year	In this text box, enter the literature publication year that the query should look for in cases.
	Literature Pgs	In this text box, enter the journal page number in which the article appeared. The query will look for this information in cases.

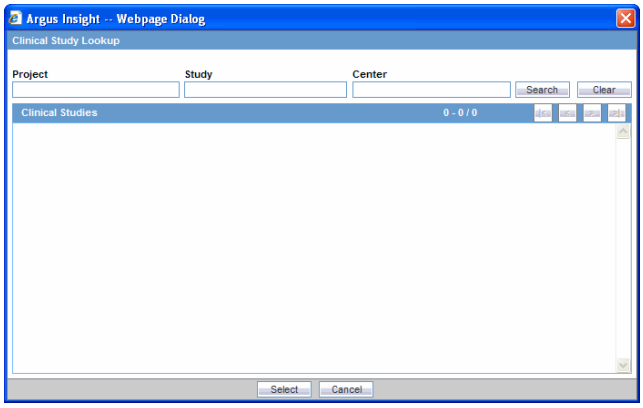
Selecting the Study Number

Argus Insight lets you select the **Study Protocol #, Study Num** and **Center ID** fields in the **Study Information** section, by selecting the study number from the **Clinical Study Lookup** dialog box.

Use the following procedure to select a clinical study:

To select a clinical study:

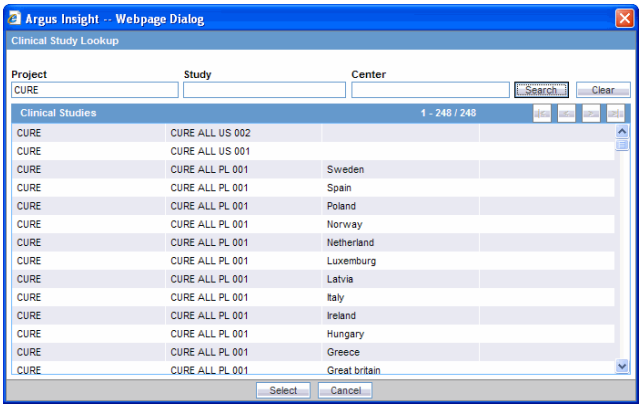
1. Click the **Select** button associated with the **Study Num** field. The **Clinical Study Lookup** dialog box appears.



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

   Tip: If you are not sure about the information you are looking for, as an alternative, click **search** to list all the associated data for **Study Num**.

3. Click **Search**. The system searches for the specified search strings. The **Clinical Study Lookup** dialog box displays the search result in a grid format.



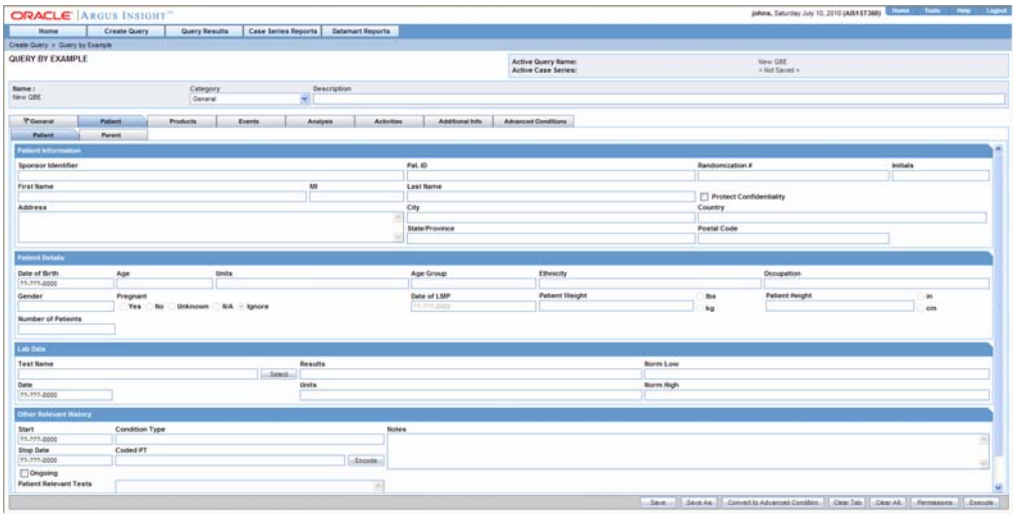
4. Select a study from the **Clinical Studies** listed.
5. Click **Select** in the **Clinical Study Lookup** dialog box. The **Study Protocol # , Study Num (*)** and **Center ID(*)** fields in the **Study Information** section of the QBE *form* are automatically selected.

> **Note:** The **Study Num** and **Center ID** are optional fields.

Patient Page

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

The **Patient** view differs from what you might be used to seeing in Argus in the following ways:



- You can specify information only about one lab data element
- You can specify details of only one relevant history

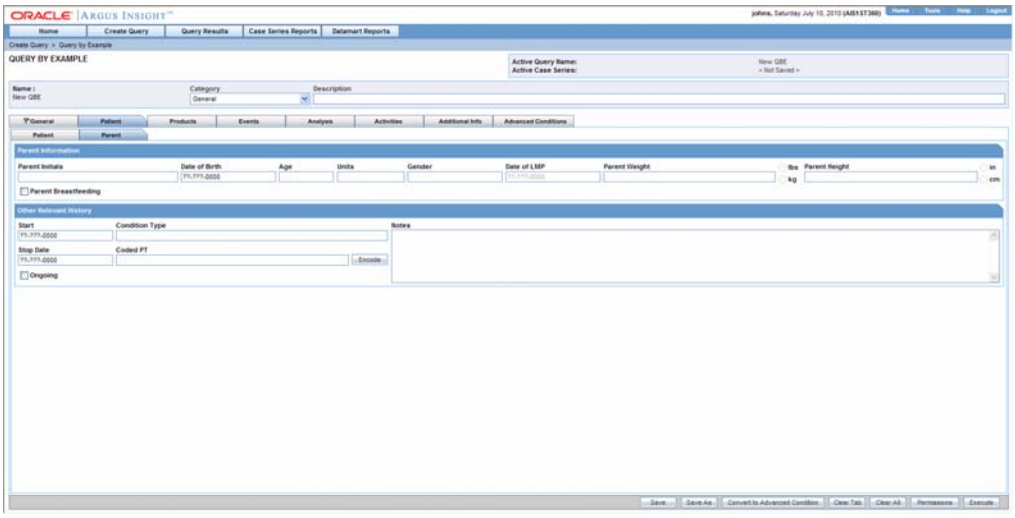
You need to scroll down the page to view all the fields available.

The following table describes the various fields in the **Patient** view of the **Patient** page. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Section	Field	Description
Patient Information	Patient Sponsor Identifier	In this text box, enter the *study* sponsor's ID. The query will look for this information in cases.
	Patient Subject #	In this text box, enter the patient subject number that the query should look for in cases.
	Patient First Name	In this text box, enter the patient's first name that the query should look for in cases.
	Patient Last Name	In this text box, enter the patient's last name that the query should look for in cases.
	Patient MI	In this text box, enter the patient's middle initials that the query should look for in cases.
	Patient Initials	In this text box, enter the patient's initials that the query should look for in cases.
	Patient Randomization Number	In this text box, enter the patient randomization number that the query should look for in cases.
	Patient Protect Confidentiality	Check this checkbox to retrieve those cases where patient information is marked as confidential.
	Number of Patients	In this text box, enter the number of patients.
	Patient Address	In this text box, enter the patient's address that the query should look for in cases.
	Patient City	In this text box, enter the patient's city that the query should look for in cases.
	Patient State	In this text box, enter the patient's state that the query should look for in cases.
	Patient Postal Code	In this text box, enter the patient's postal code that the query should look for in cases.
	Patient Country	In this text box, enter the patient's country that the query should look for in cases.
	Patient Date of Birth	In this date field, enter the patient's date of birth that the query should look for in cases.
	Patient Age	In this text box, enter the patient's age that the query should look for in cases.
	Patient Age Units	Select the age unit for the value you specified in the **Patient Age** text box.
	Patient Age Group	Select the patient age group that the query should look for in cases.
	Patient Gender	Select the patient gender that the query should look for in cases.
	Patient Weight	In this text box, enter the patient weight that the query should look for in cases. Select the **lbs** or **kg** option button, as appropriate.
	Patient Height	In this text box, enter the patient's height that the query should look for in cases. Select the **in** or **cm** option button, as appropriate.
	Patient Ethnicity	Select the patient's ethnicity that the query should look for in cases.
	Patient Occupation	Select the patient occupation that the query should look for in cases.

Section	Field	Description
	Pregnancy	Select the **Yes**, **No**, **Unknown**, **N/A**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where the patient's pregnancy status is specified. This field is available only if you specify the patient gender as Female
	Pregnancy Information Date of Last Menstrual Per.	In this date field, enter the date of last menstrual period that the query should look for in cases.
Lab Data	Lab Data Test Name	Click the associated **Select** button to select the lab test that the query should look for in cases. See theSelecting Lab Testsection for more information.
	Lab Data Result	In this text box, enter the lab data result that the query should look for in cases.
	Lab Data Normal Low	In this text box, enter the lab data normal low value that the query should look for in cases.
	Lab Test Date	In this date field, enter the lab test date that the query should look for in cases.
	Lab Data Result Unit	Enter the lab data result unit for the value you specified in the **Lab Data Result** field.
	Lab Data Normal High	In this text box, enter the lab data normal high value that the query should look for in cases.
Other Relevant Information	Relevant History Start Date	In this date field, enter the relevant history start date that the query should look for in cases.
	Relevant History Condition Type	Select the relevant history condition type that the query should look for in cases.
	Relevant History Notes	In this text box, enter the relevant history notes that the query should look for in cases.
	Relevant History Stop Date	In this date field, enter the relevant history stop date that the query should look for in cases.
	Relevant History Condition	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 theUsing the MedDRA Browser section for details.
	Relevant History Continues	Check this checkbox to retrieve cases where the relevant history condition is continuing/ongoing.
	Patient Relevant Tests	In this text area, enter the relevant patient tests that the query should look for in cases.

This **Parent** view differs from what you might be used to seeing in Argus in the following ways:



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

The following tables describes the various fields in the **Patient** view of the **Patient** page. The system uses the field values you specify the query criteria to retrieve matching cases.

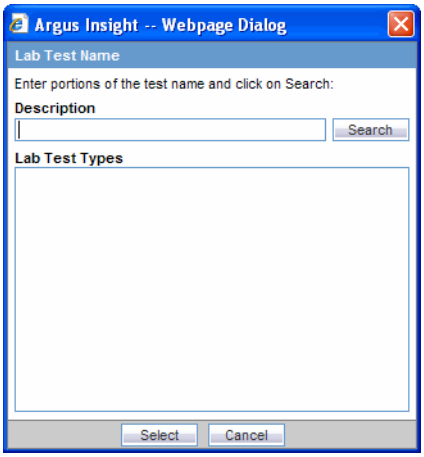
Section	Field	Description
Parent	Parent Initials	In this text box, enter the parent's initials that the query should look for in cases.
	Parent Age	In this text box, enter the parent's age that the query should look for in cases.
	Parent Age Unit	Select the age unit for the value you specified in the **Parent Age** text box.
	Parent Gender	Select the parent gender that the query should look for in cases.
	Parent LMP	In this date field, enter the parent's LMP date that the query should look for in cases. This field is available only if the parent gender is specified as Female.
	Parent Weight	In this text box, enter the parent's weight that the query should look for in cases. Select the **lbs** or **kg** option button, as appropriate.
	Parent Height	In this text box, enter the parent's height that the query should look for in cases. Select the **in** or **cm** option button, as appropriate.
	Parent Breast feeding	Check this checkbox to retrieve cases where parent is breast feeding.

Section	Field	Description
Other Relevant Information	Relevant History Start Date	In this date field, enter the relevant history start date that the query should look for in cases.
	Relevant History Condition Type	Select the relevant history condition type that the query should look for in cases.
	Relevant History Notes	In this text box, enter the relevant history notes that the query should look for in cases.
	Relevant History Stop Date	In this date field, enter the relevant history stop date that the query should look for in cases.
	Relevant History Condition	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 theUsing the MedDRA Browsersection for details.
	Relevant History Continues	Check this checkbox to retrieve cases where the relevant history condition is continuing / ongoing.

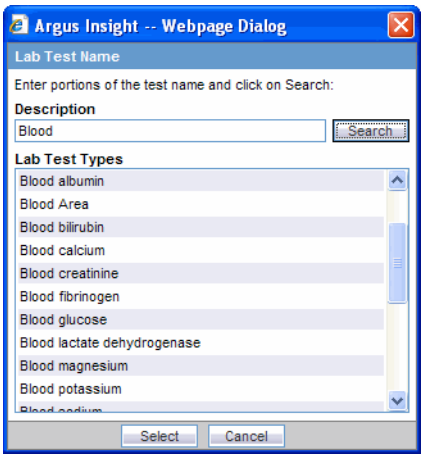
Selecting a Lab Test

Use the following procedure to select a Lab Test:

1. Click the **Select** button associated with the **Lab Data Test Name** field. The **Lab Test Name** dialog box appears.



2. Type a few initial letters of the test name.
3. Click **Search**. The matching test names appear in a list.

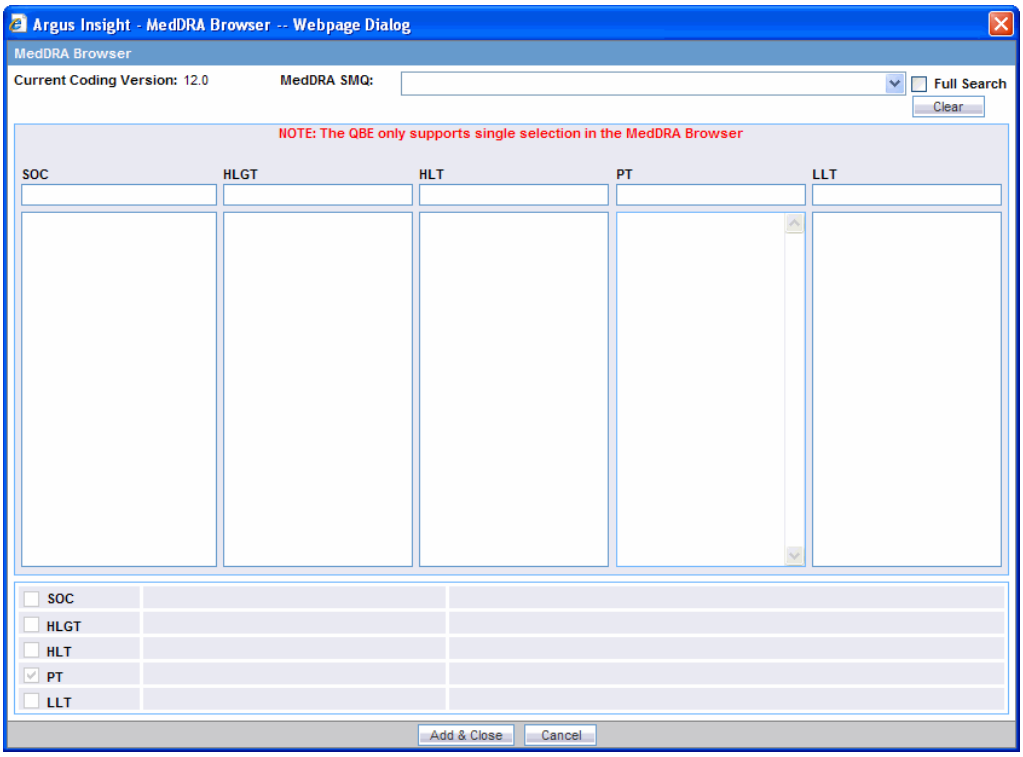


4. Select the required test name.
5. Click **Select**. The test name appears in the **Lab Data Test Name** field in the QBE *form*.

Using the MedDRA Browser

Use the following procedure 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 launch MedDRA browser. The **MedDRA Browser** appears.



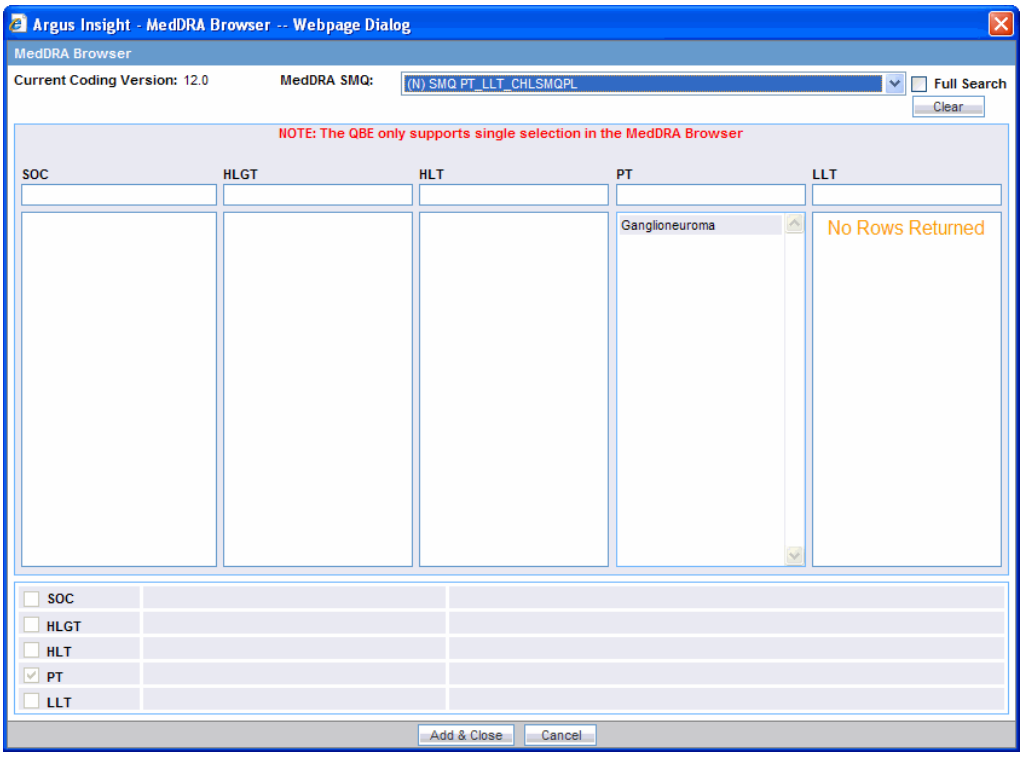
Note: The output returned by the MedDRA browser for the **Patient**, **Product** and **Analysis** tabs of QBE is the **Preferred Term (PT)**. The **Events** tab of QBE provides output for multiple options. You can select and search the required term(s), based on the **Seriousness Criteria**.

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, check the **Full Search** checkbox.

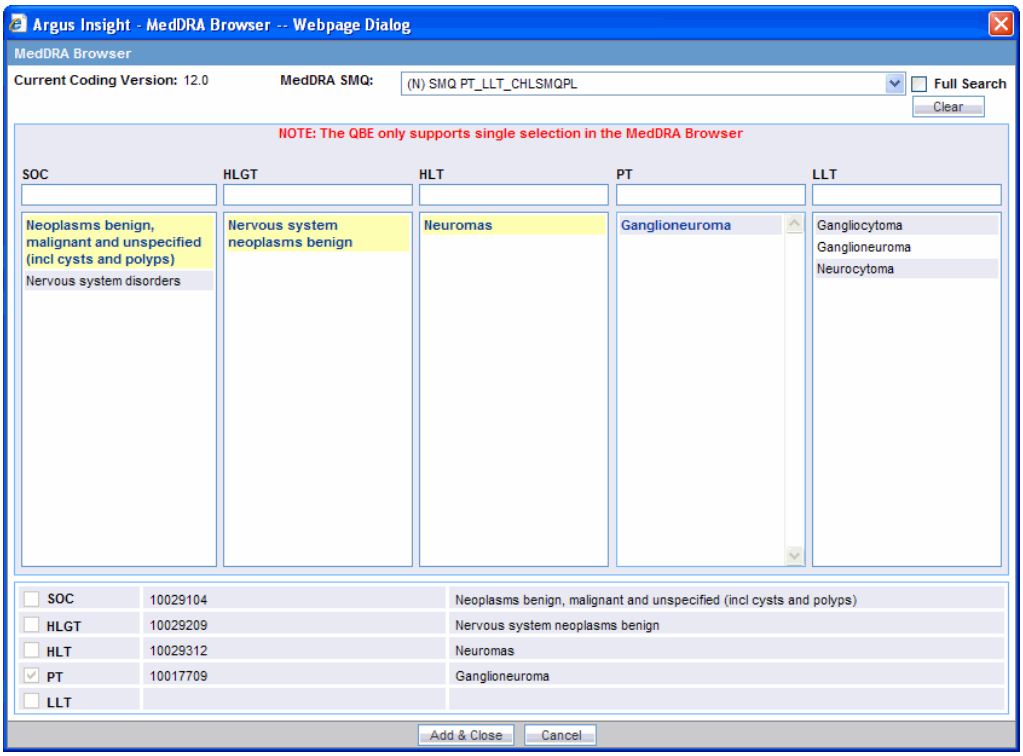
Note: The Special Category drop-down list displays all the SMQs that can be selected. The selected SMQ searches across PT and LLT levels of the MedDRA dictionary.

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 result in a *column* below the text box in which you entered the text string.



4. Select the required event term from the search result. The **SOC**, **HLGT**, **HLT**, **PT**, and **LLT** fields in the MedDRA Browser display the respective terms for the selected event. The fields that are highlighted in the colors listed below have the following significance.



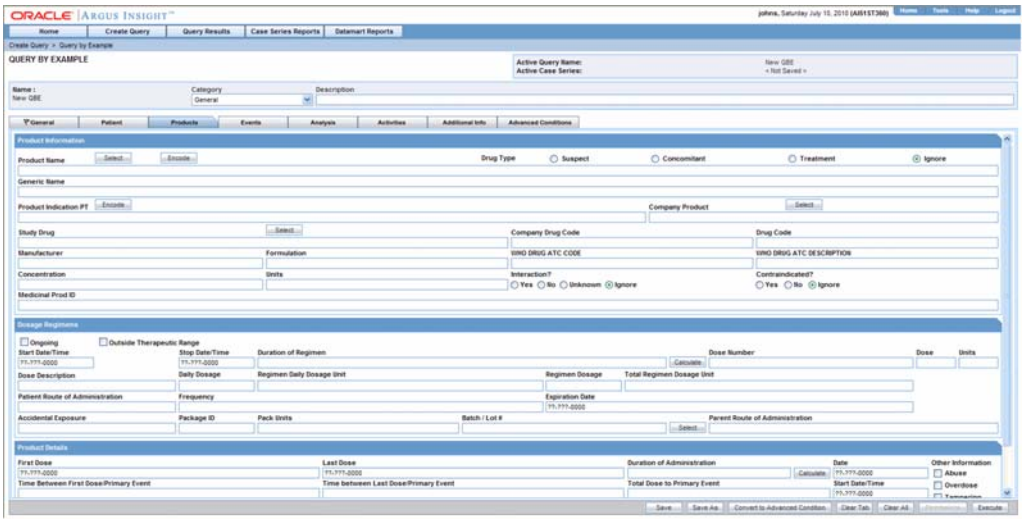
If the row color is...	This signifies...
Yellow	The selected hierarchy is the primary SOC path.
Grey	The selected hierarchy is not the primary SOC path.

5. Check the **SOC**, **HLGT**, **HLT**, **PT**, and **LLT** checkboxes to populate the corresponding fields in the QBE form.
6. Click **Select**.
7. The selected codes for the selected event are displayed in the respective fields in the QBE form.

Products Page

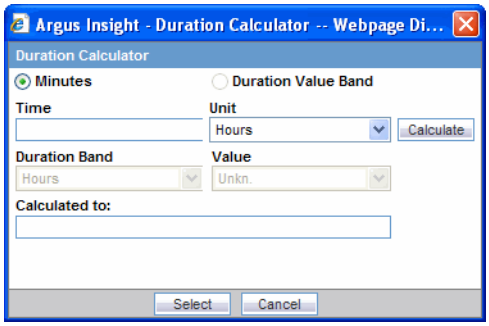
The **Products** page differs from what you might be used to seeing in Argus in the following ways:

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



The following table describes the various fields in the **Products** page. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Section	Field	Description
Product Information	Product Name	Click the associated **Select** button to use the Product Browser to specify the product as the query criteria. Selecting the product name automatically populates the **Product Name**, **Product Generic Name**, and **Company Drug Code** fields in the QBE *form*. See theUsing the Product Browsersection for details.
	Product WHO Drug Code	Click the associated *Encode* button to use the Drug Coding Browser to specify the WHO drug name as the query criteria. See theUsing the WHO Drug Browsersection for details.
	Product Type	Select the **Suspect**, **Concomitant**, **Treatment**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where product type is specified.
	Product Manufacturer	Select the product manufacturer that the query should look 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 theUsing the Study Drug Lookupsection for details.
	ATC Code	Enter the Anatomical, Therapeutic, Chemical (ATC) classification code that the query should look for in cases.
	ATC Description	Enter the Anatomical, Therapeutic, Chemical (ATC) classification description.
	Drug Formulation	Select the drug formulation that the query should look for in cases.
	Drug Concentration	Enter the drug formulation that the query should look for in cases. Select the concentration unit from the **Drug Product Concentration Units ID** list box.
	Drug Primary Indication	Click the associated **Encode** button to use the MedDRA Browser to specify the drug primary indication event term as the query criteria. See theUsing the MedDRA Browsersection for details.
	Drug Interaction	Select the **Yes**, **No**, **Unk**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where drug interaction status is specified.
	Drug Contraindicated	Select the **Yes**, **No**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where drug contraindication status is specified.
Dosage Information	Dosage Regimen Start Date	In this date field, enter the dosage regimen start date that the query should look for in cases.
	Dosage Regimen Stop Date	In this date field, enter the dosage regimen start date that the query should look for in cases.
	Dosage Regimen Ongoing	Check this checkbox to retrieve cases where the dosage regimen is ongoing.
	Dosage Regimen Outside Therapeutic Range	Check this checkbox 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 your Administrator for further company-specific information on the use of this field.

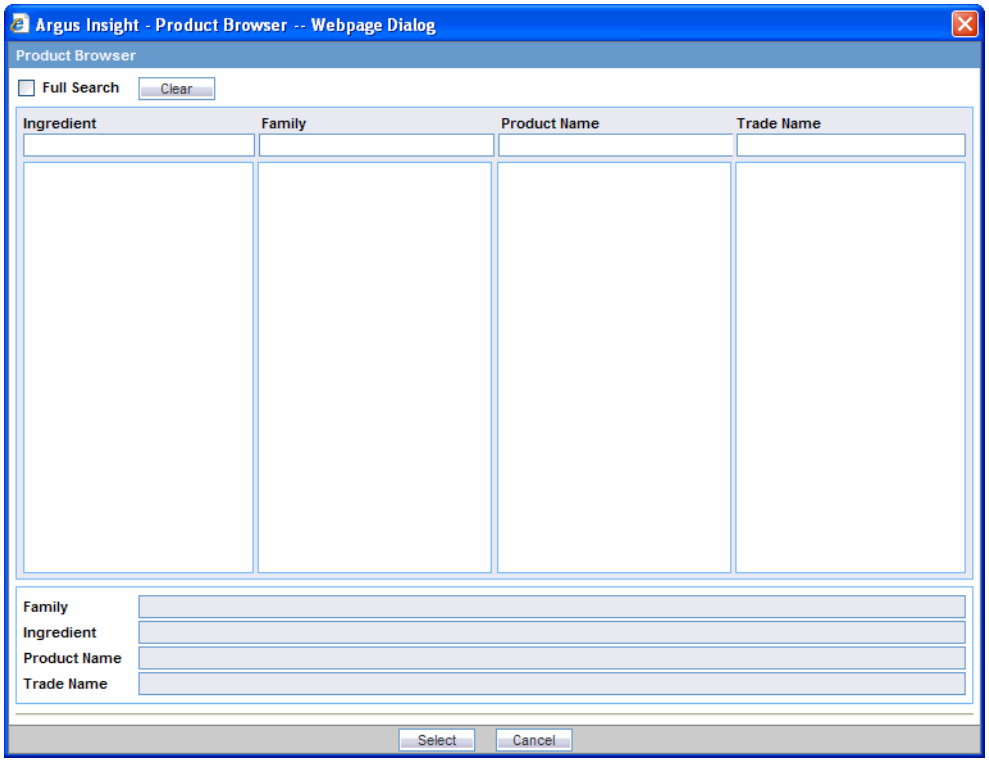
Section	Field	Description
	Dosage Regimen Duration	 In this text box, enter the dosage regimen duration in minutes as the query criteria. OR Click **Calculate** to view the duration calculator, to calculate the dosage regimen duration in minutes or duration value bands. 1. Click the associated **Calculate** button to convert hours, days, weeks, months, or years to minutes 2. Enable the Duration value band option. 3. Select the duration band and its value from the drop-down lists. These ranges are configured by the administrator through List Maintenance. 4. Click **Select** to confirm the operation. The values are displayed in the Products page.
	Dosage Regimen Accidental Exposure	Select the area of accidental exposure as the query criteria.
	Dosage Regimen Dose No.	In this text box, enter the drug dose number as the query criteria.
	Dose	In this text box, enter the drug dose received by the patient as the query criteria.
	Dose Units	Use this list box to specify the units for the value you specified in the **Dose** field.
	Frequency	Use this list box to specify the dosage frequency as the query criteria.
	Dosage Regimen Dose Description	In this text box, enter the dose description based on the values you specified in **Dose**, **Dose Units**, and **Frequency** fields.
	Regimen Daily Dose	In this text box, 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** list box.
	Total Regimen Dosage	daily dose, duration, and frequency
	Total Dosage Regimen Unit	Select the total dose regimen unit based on the values you specified in **Dose**, **Dosage Regimen Duration**, and **Frequency** fields.
	Dosage Regimen Route of Administration	Select the route of dosage administration as the query criteria.

Section	Field	Description
	Dosage Regimen Route (Parent)	Select the route of dosage administration of the parent as the query criteria.
	Dosage Regimen Package ID	Enter the package ID as the query criteria.
	Dosage Regimen Package Units	Select the package units.
	Dosage Regimen Batch/Lot #	Enter the batch/lot number as the query criteria.
	Expiration Date	Enter the product expiration date as the query criteria.
	Drug First Dose	Enter the earliest dosage regimen start date as the query criteria.
	Drug Last Dose	Enter the latest regimen stop date as the query criteria.
	Drug 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.
	Total Drug Dosage	Enter the total drug usage duration as the query criteria.
	Drug Product Total Dose Unit	Enter the total dosage unit as the query criteria. This is based on the daily dose, duration and frequency.
	Product Event Delay	Enter the time between the event onset and the fist dose
	Product Event Latency	Enter the time between the event onset and the last dose
	Drug Cumulative Dose	Enter the total dose for the drug
	Drug Info Action Taken	Select the action taken to mitigate the adverse event
	Other Information	Check the **Drug Abuse**, **Drug Overdose,** and **Tampering** checkboxes
	Drug Taken Previously	Select the **Yes**, **No**, **Unk**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where drug was taken previously.
	Drug *Dechallenge*	Select the **Yes**, **No**, **Unk**, **N/A** or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where drug dechallenge status is specified.
	Drug Dechallenge Date	Enter the drug dechallenge date as the query criteria.
	Drug *Rechallenge*	Select the **Yes**, **No**, **Unknown**, **N/A** or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where drug rechallenge status is specified.
	Drug Rechallenge Start Date	Enter the rechallenge start date as the query criteria.
	Drug Rechallenge Stop Date	Enter the rechallenge stop date as the query criteria.

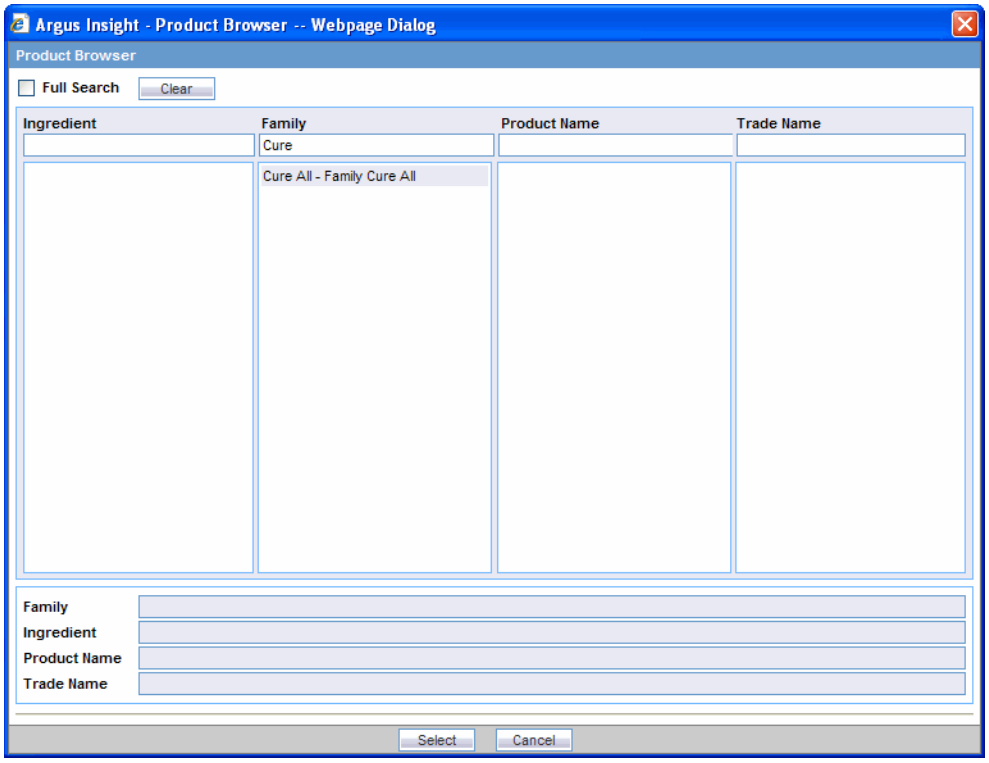
Using the Product Browser

Use the following procedure to explain how to select a product by using the Product Browser.

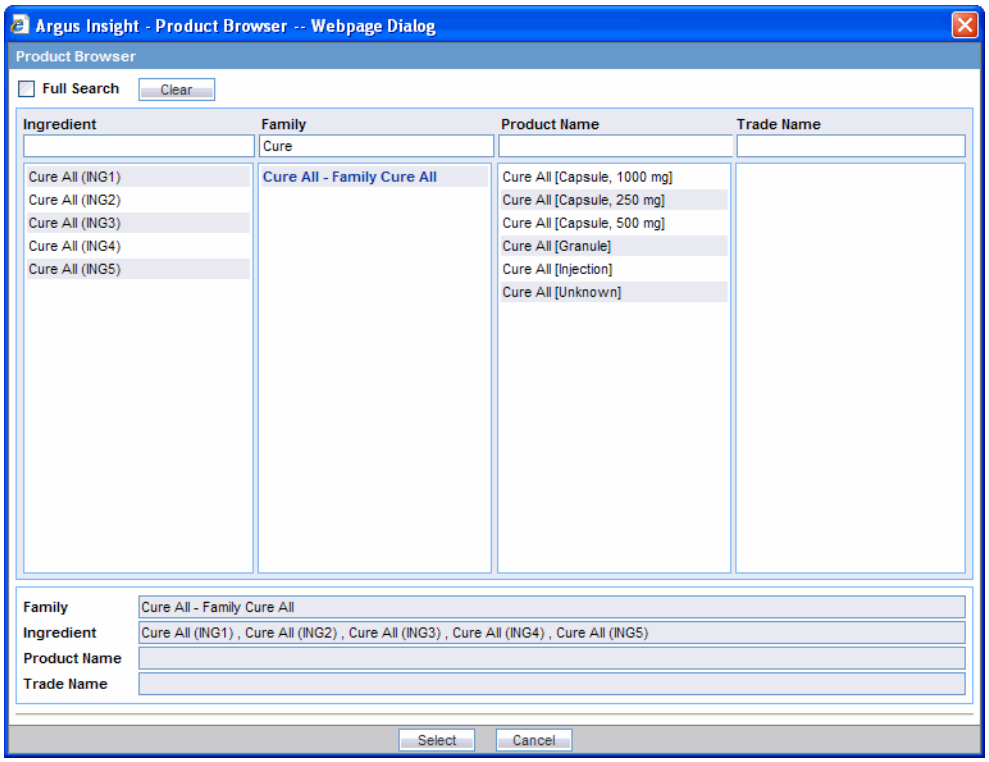
1. Click the **Select** button associated with the **Product Name** field. The Product Browser appears.



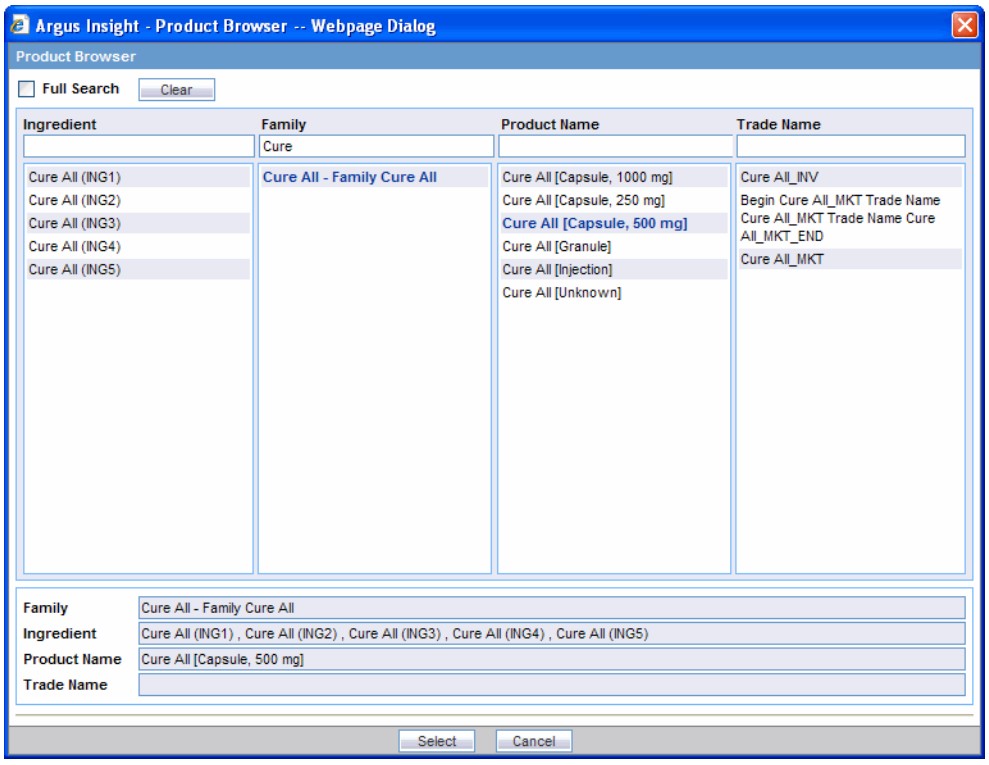
2. Enter the first few letters of the product ingredient, family name, product name, or trade name in the respective text box. If you want the system to search for the specified string in the entire product information, check the **Full Search** checkbox.
3. Press Tab. The system searches the database for the specified search string. The Product Browser displays the search result in a *column* below the text box in which you entered the search string.



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



5. Select the required product name and trade name, as appropriate. The selection is highlighted in the Product Browser.

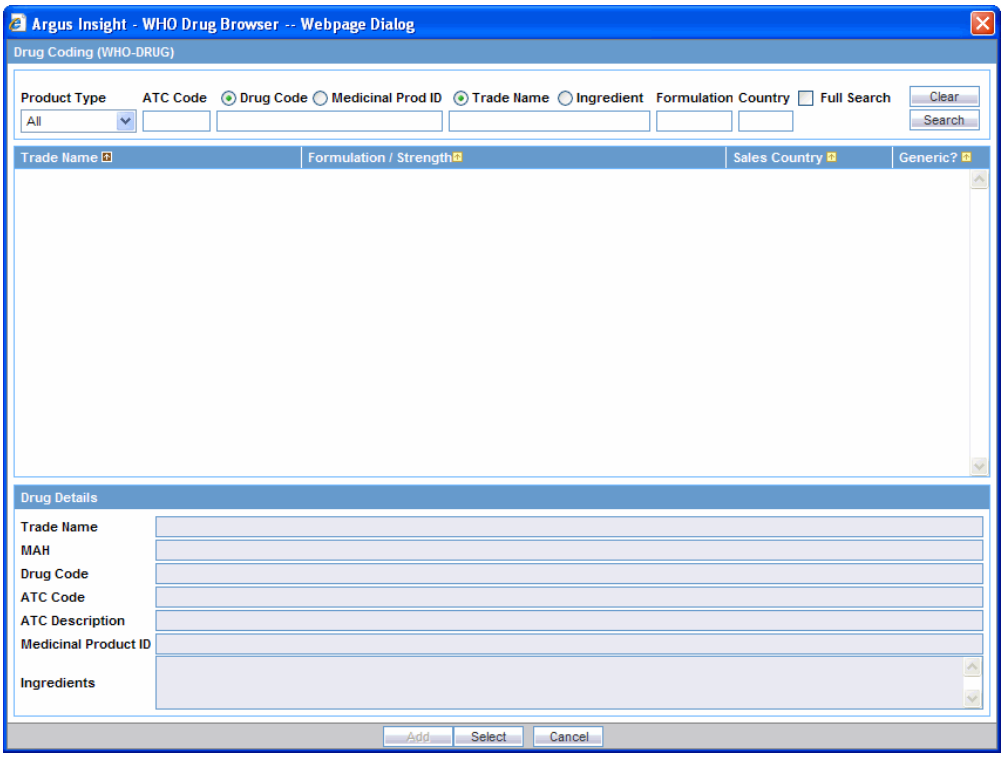


6. Click **Select**. The Product Name, Product Generic Name, Company Drug Code, Drug Formulation, Drug Concentration and Drug Product Concentration Units ID fields in the QBE form are automatically populated with the details of the selected product.

Using the WHO Drug Browser

Use the following procedure to select a WHO drug product by using the WHO Drug Browser.

1. Click the **Encode** button associated with the **Product Name** field. The **WHO Drug Browser** appears.



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

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

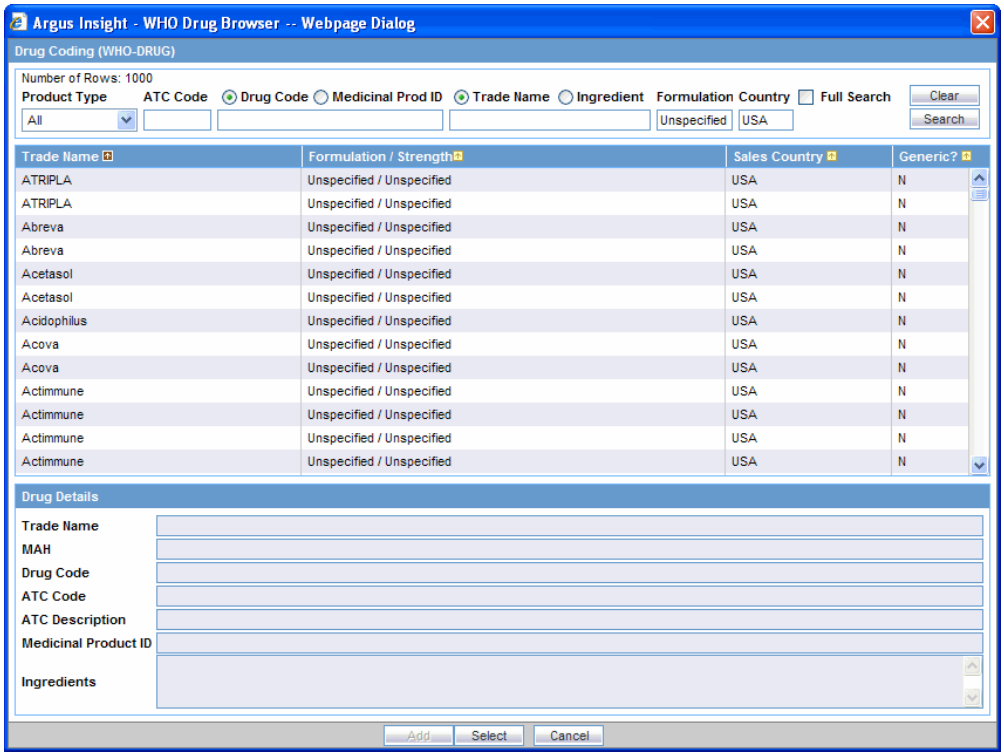
The primary difference between the two browsers is the availability of the following fields in WHO Drug Browser:

- **Product Type:** This is the product type.
- **Medicinal Prod ID**: This is the unique medicinal product id.
- **MAH**: This is the name of the manufacturer.
- **Ingredients**: This is the product substance name.

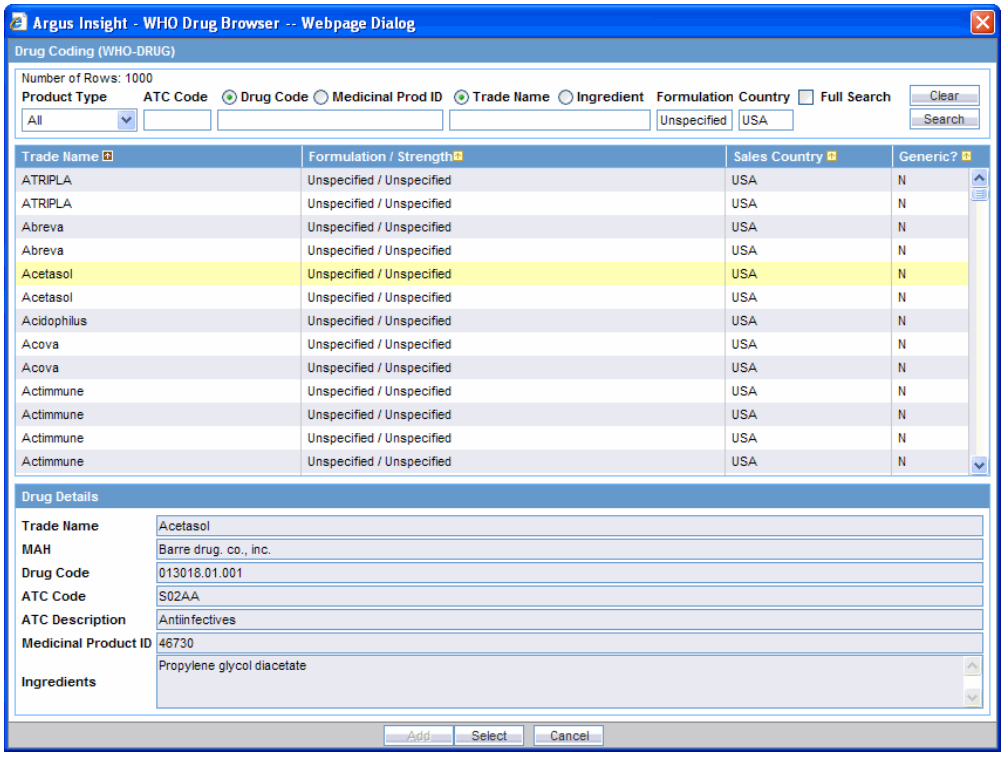
2. Select the **Product Type** as the drug search criteria. The default value is **All**.
3. Enter the first few letters of the **ATC code**, **ATC description**, **Code**, or **Description** in the respective text box. Check the **Ingredient** checkbox to search for the drugs (whose drug ingredients) match the ingredients in the List Maintenance. Click the **SOUNDEX** checkbox to search for drugs, where the exact spelling of the drug is unknown. Example: Enter antiviral in the ATC description field to view the list of drugs starting with the phonetics closest to anti. This returns a list of drugs closest to the phonetic representation (the way it sounds) of the word.
4. Select either the **Drug Code** or **Medicinal Prod ID** radio button as one of the drug search criterion. The default selection is **Drug Code**.
5. Select either the **Trade Name** or **Ingredient** radio button as one of the drug search criterion. The default selection is **Trade Name**. You can also select multiple trade names in the same WHO Drug selection dialog. If multiple trade names are to be

added, the **Add & Close** button is enabled. Click this button to add the selected multiple trade names and ingredients into the **Drug Detail** section.

6. Enter the **Formulation** and **Country** details for the drug to be searched.
7. If you want the system to search for the specified string in the entire product information, check the **Full Search** checkbox.
8. Click **Search**. The system searches the database for the specified search string. The WHO Drug Browser displays the search result in a grid format.



9. Select the required WHO drug. The selected item is highlighted.



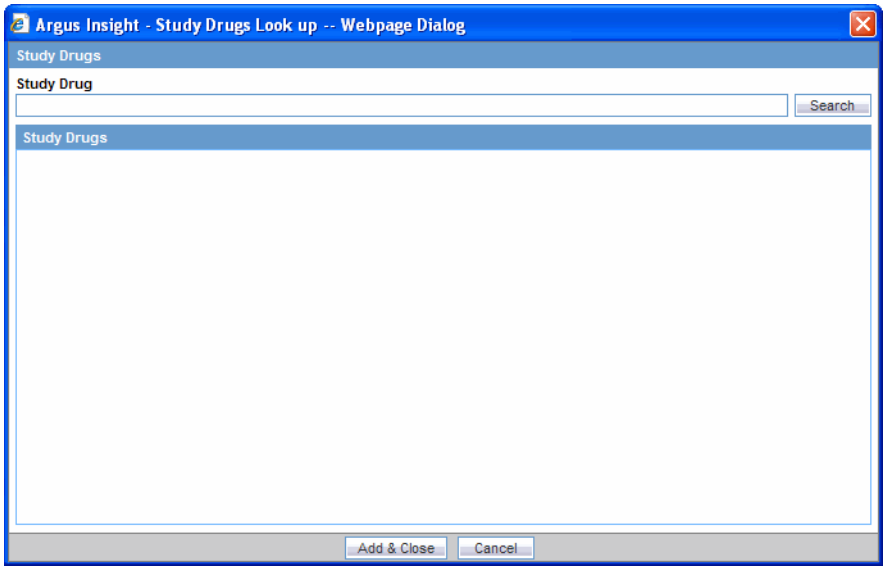
10. Click **Select**. The **Product Name**, **Product WHO Drug Code, Generic Name, ATC Code** and **ATC Text** fields in the QBE form are populated with the selected WHO drug code.

> **Note:** All the Ingredients for the WHO Drug browser are concatenated and displayed in the **Generic Name** for the WHO Drug separated by a ","

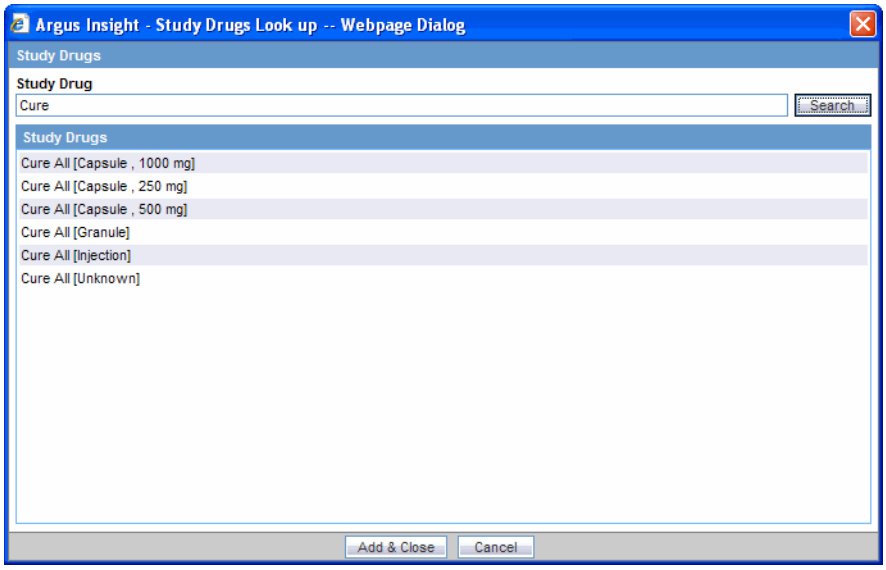
Using the Study Drug Lookup

Use the following procedure to select a study drug:

1. Click the **Select** button associated with the **Study Drug** field. The **Study Drug** dialog box appears.



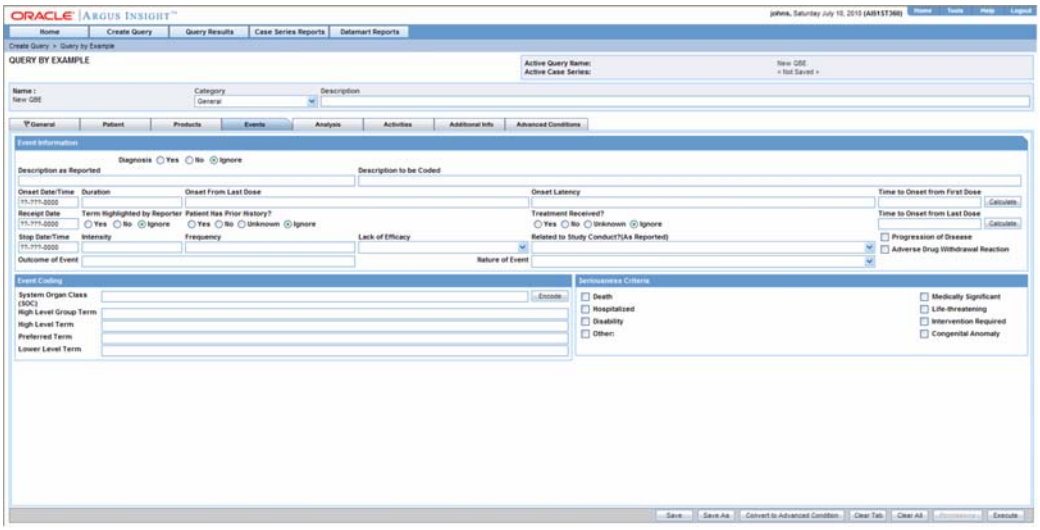
2. Enter the first few letters of the study drug name in the **Study Drug** dialog box.
3. Click **Search**. The system searches the database for the specified search string. The **Study Drug** dialog box displays the search result in a grid format.



4. Select the required study drug from the search result list.
5. Click **Add & Close**. The system populates the **Study Drug** field with the selected study drug.

Events Page

The **Events** page differs from what you might be used to seeing in Argus in that details of only one event can be specified. You must scroll down the page to view all the available fields.



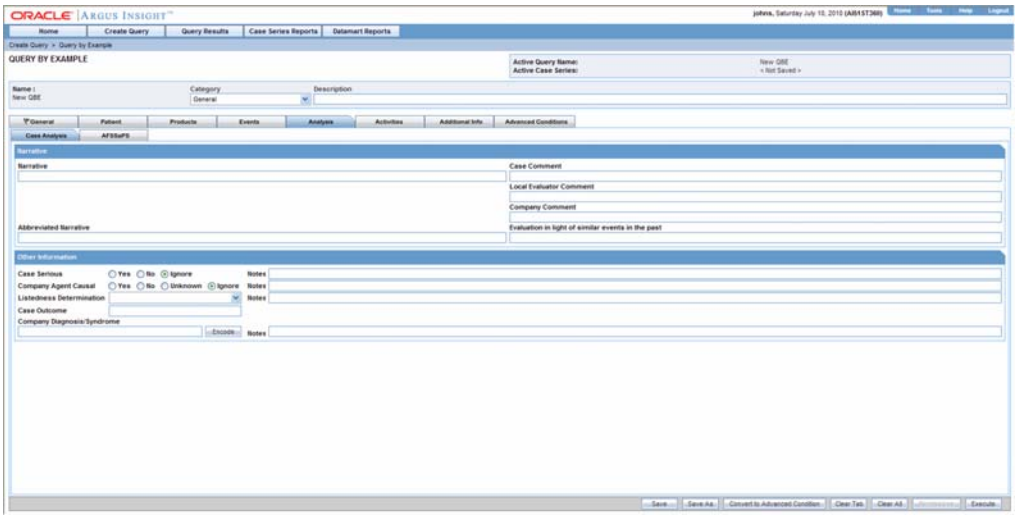
The following table describes the various fields in the **Events** page. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Section	Field	Description
Event Information	Event Description as Reported	In this text box, enter the reported event description that the query should look for in cases.
	Event Diagnosis Flag	Select the **Yes**, **No**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where event diagnosis flag is set.
	Event Description to be Coded	Tab out from this field to use the MedDRA Browser to specify an event term as query criteria. See theUsing the MedDRA Browsersection for details. The MedDRA event terms for the selected term are displayed in the **Seriousness Criteria** section. The query is restricted to the terms displayed.
	Event Past History	Select the **Yes**, **No**, **Unknown**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where event past history is specified.
	Event Onset Date	In this date field, enter the event onset date that the query should look for in cases.
	Event Onset from Last Dose	In this text box, enter the event onset duration from last dose as the query criteria.
	Event Stop Date	In this date field, enter the event stop date that the query should look for in cases.
	Event Duration	In this text box, enter the event duration that the query should look for in cases.
	Event Onset Latency	In this text box, enter the event onset latency duration that the query should look for in cases.
	Time to Onset from First Dose	In this text box, enter the duration from first dose to the event onset as the query criteria. OR Click the associated **Calculate** button to view theDuration Calculatoras displayed in the Products Tab Dosage Information.

Section	Field	Description
	Time to Onset from Last Dose	In this text box, enter the duration from last dose to the event onset as the query criteria. OR Click the associated **Calculate** button to view theDuration Calculatoras displayed in the Products Tab Dosage Information.
	Event Intensity	Select the event intensity option that the query should look for in cases.
	Event Frequency	Select the event frequency option that the query should look for in cases.
	Related to *Study* Conduct (As Reported)	Use this list box to select the **Yes**, **No**, **Unknown**, or **N/A** option, as appropriate, to indicate whether the query should look for cases where the event is related to a study.
	Event Treatment Received	Select the **Yes**, **No**, **Unknown**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where patient received treatment for the event.
	Outcome of Event	Select the event outcome that the query should look for in cases.
	Event Receipt Date	In this date field, enter the event receipt date that the query should look for in cases.
	Event Reported Serious	Select the **Yes**, **No**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where case seriousness status is specified.
	Event Lack of Efficacy	Check this checkbox to retrieve cases where Event Lack of Efficacy is selected.
	Event Progression of Disease	Check this checkbox to retrieve cases where Event Progression of Disease is selected.
	Event Withdrawal Reaction	Check this checkbox to retrieve cases where Event Withdrawal Reaction is selected.
Seriousness Criteria	Seriousness Criteria checkboxes	Check one or more associated checkboxes to specify the seriousness criteria that the query should look for in cases.
	Event Term fields	Click the associated *Encode* button to use the MedDRA Browser to specify event terms as query criteria. See theUsing the MedDRA Browsersection for details.

Analysis Page

The **Analysis** page 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.

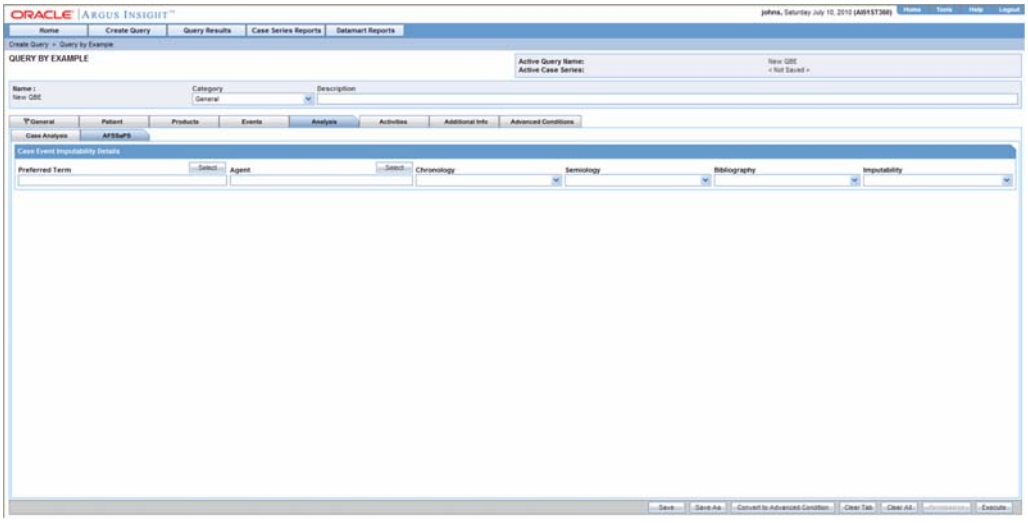


The following table describes all the fields in the **Case Analysis** view. The field values you specify are used as the *query* criteria to retrieve matching cases.

Section	Field	Description
Narrative	Narrative	In this text box, enter the case narrative that the query should look for in cases.
	Case Comment	In this text box, enter the case comment that the query should look for in cases.
	Local Evaluator Comment	In this text box, enter the local evaluator' comment that the query should look for in cases.
	Abbreviated Narrative	In this text box, enter the abbreviated case narrative that the query should look for in cases.
	Company Comment	In this text box, enter the company's comment that the query should look for in cases.
	Evaluation in Light of Similar Events	In this text box, 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.

Section	Field	Description
Other Information	Case Seriousness	Select the **Yes**, **No**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where case seriousness status is specified.
	Case Seriousness Notes	In this text box, enter the case seriousness notes that the query should look for in cases.
	Company Agent Causality	Select the **Yes**, **No**, **Unknown**, or **Ignore** option button, as appropriate, to indicate whether the query should look for cases where the company agent causality status is specified.
	Company Agent Causality Notes	In this text box, enter the company agent causality notes that the query should look for in cases.
	Case Listedness	Select the case listedness status that the query should look for in cases.
	Case Assessment Listedness Notes	In this text box, enter the case assessment listedness notes that the query should look for in cases.
	Case Outcome	Select the case outcome that the query should look 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 theUsing the MedDRA Browsersection for details.
	Company Diagnosis/Syndrome Notes	In this text box, enter the company diagnosis notes that the query should look for in cases.

The following table describes all the fields in the **AFSSaPS** page. The field values you specify are used as the query criteria to retrieve matching cases.

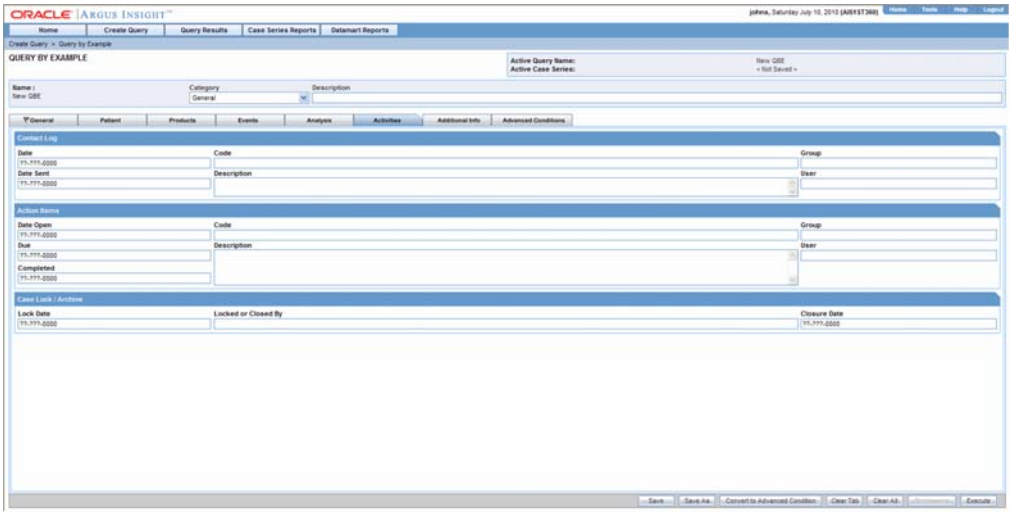


Section	Field	Description

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 theUsing the MedDRA Browsersection for details.
	Agent	Select the *suspect product* that the query should look for in cases.
	Chronology	Select the imputability chronology code that the query should look for in cases.
	Semiology	Select the imputability semiology code that the query should look for in cases.
	Bibliography	Select the imputability bibliography code that the query should look for in cases.
	Imputability	Select the imputability score that the query should look for in cases.

Activities Page

The **Activities** page differs from what you might be used to seeing in Argus 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

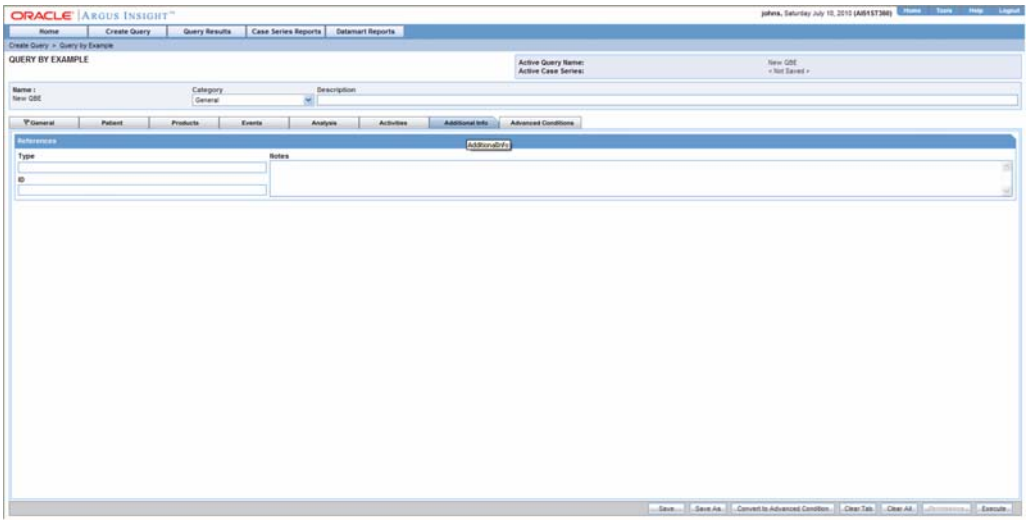
The following table describes all the fields in the **Activities** page. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Section	Field	Description

Contact Log	Contact Log Date	In this date field, enter the contact log date that the query should look for in cases.
	Contact Log Code	Select the contact log code that the query should look for in cases.
	Contact Log Group	Select the contact log group that the query should look for in cases.
	Contact Log Description	In this text area, enter the contact log description that the query should look for in cases.
	Contact Log Responsibility	Select the user responsible for the contact log. The query will look for the user name you select.
	Contact Log Date Sent	In this date field, enter the sent date for the contact.
Action Items	Date Open	In this date field, enter the action item opening date that the query should look for in cases.
	Action Type	Select the action type that the query should look for in cases.
	Group	Select the responsible group that the query should look for in cases.
	Due Date	In this date field, enter the action item due date that the query should look for in cases.
	Description	In this text area, enter the action item description that the query should look for in cases.
	User	Select the user responsible for the action item. The query will look for the specified user name.
	Completed	In this date field, enter the action item completion date that the query should look for in cases.
Case Lock/Archive	Locking Date	In this date field, enter the case lock date that the query should look for in cases.
	Archive Date	In this date field, enter the case archive date that the query should look for in cases.
	Closed By	Select the user that closed the case.

Additional Info Page

This **Additional Information** page differs from what you might be used to seeing in Argus in the following ways:



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

The following table describes all the fields in the **Additional Information** page. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

Section	Field	Description
References	Reference ID #	In this text box, enter the referenced case ID that the query should look for in the cases.
	Reference Type	Select the reference type that the query should look for in cases.
	Reference Notes	In this text area, enter the reference notes that the query should look for in cases.

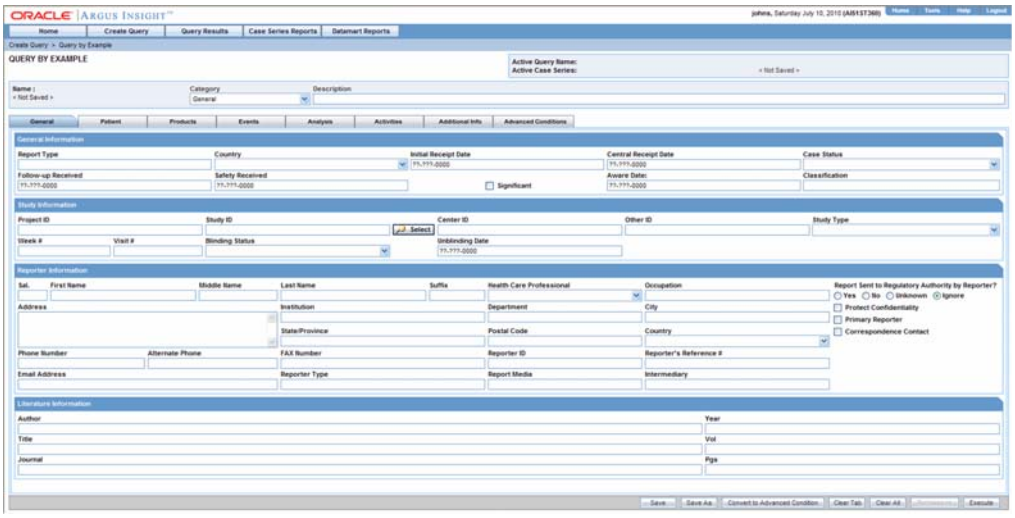
Working with the Last Modified or Executed QBE

This topic explains how to view the QBE 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.

Use the following procedure to view an Active QBE.

1. Select **Create Query > Query by Example > Active**.
2. The **Active Query by Example** page displays the QBE *form* for the last QBE you executed.



If the Active QBE was saved to the system before executing, the name of the QBE appears next to the **Active Query Name** and **Name** label. However, if the Active QBE was not saved to the system before executing, the text **<Not Saved>** is displayed next to the **Active Query Name** label.

From the **Active Query by Example** page, you can perform the following tasks:

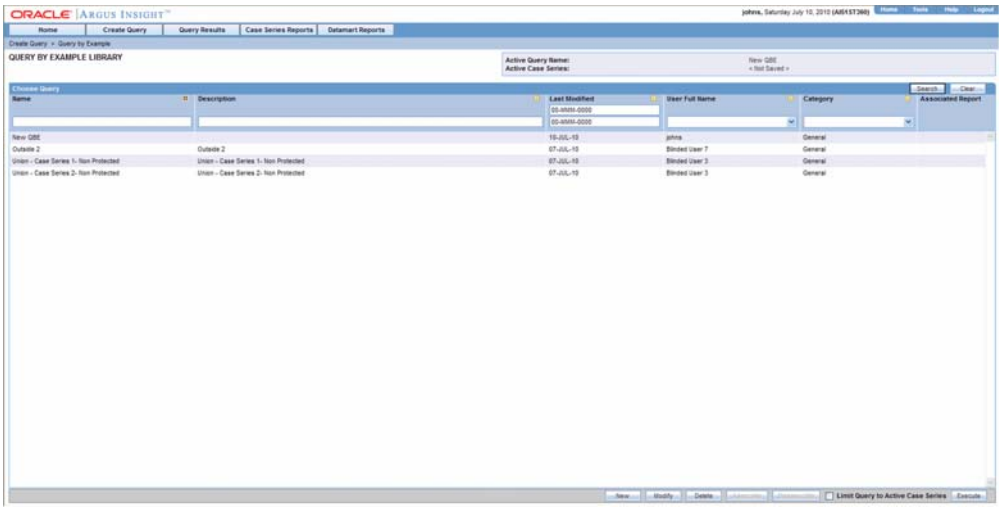
Task	Description
Modify the values in the QBE form	If required, you can modify the *field* values in the QBE form. See theCreating a New QBEtopic for information on entering values in the QBE form. While entering values in a tab, if you wish to clear all the values you entered, click the **Clear Tab button.** If you wish to all values you entered in all the tabs, click the **Clear All** button. Use the **Save** button to save the changed field values. This button is only available for a saved Active QBE.
Save Active QBE with another name	Click **Save As** to save the Active QBE with a different name. The QBEs that you save to the system are listed in the **Query By Example - Library** page. TheWorking with Saved QBEstopic explains how to work with saved QBEs.
Convert QBE to Advanced Condition	Click **Convert to Advanced Condition** to convert the QBE to an Advanced Condition. TheUsing QBEs with Advanced Conditionstopic explains how to do this.
Assign Permissions	Click **Permissions** to set the group-level access permissions on the QBE. See theCreating a New QBEtopic for information on setting permissions. The **Permissions** button is only available for saved Active QBEs.
Change the Description of the Active QBE	You can change the description of the Active QBE by modifying the text displayed in the **Description** text box. Click **Save** to store the changed description.
Execute 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 in case 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 of the QBEs saved to the system. Use the following procedure to access this page.

1. Select **Create Query > Query by Example > Library**. The system opens the Query By Example Library page.



The **Query By Example - Library** page displays a list of the saved QBEs in a grid format. The descriptions of the grid columns follow.

Column	Description
Name	Displays the name of the QBE you specified while saving
Description	Displays the QBE description you entered while saving
Last Modified	Displays the date when the QBE was last modified
User Full Name	Displays the name of the user who created the QBE
Category	Displays the category you assigned to the QBE while saving it
Report Name	The icon indicates that a report is associated with the QBE See theAssociating a QBE with a Reportsection below for more information

Searching for a Saved QBE

Use the following procedure 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** list box.

- To search for a QBE by its category, select the category from the **Category** list box.

2. Click **Search**. Based on your search criteria, the system displays the search result in a list.
3. You can sort the search result list by clicking the sort icon next to the column headers in the list.
4. To clear the search result and display all the saved QBEs in the list, click the **Clear** button.

Creating a New QBE

Instead of selecting **Create Query > Query By Example > New**, you can directly open a new QBE *form* by clicking **New** in the **Query By Example - Library** page.

Modifying a Saved QBE

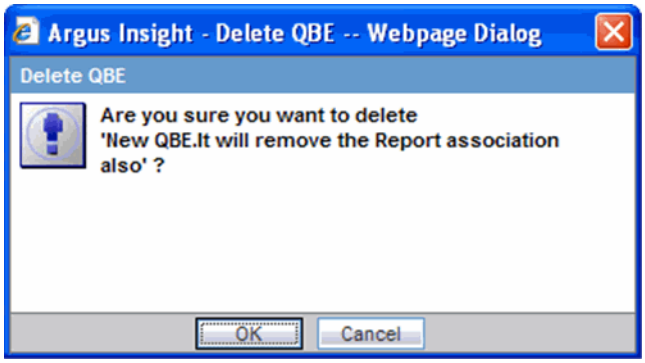
Use the following procedure to modify a saved QBE:

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. You can modify the field values in the QBE form and save the changes by clicking **Save**. You can also save the selected query by another name by clicking **Save As** in the QBE form.

Deleting a Saved QBE

Use the following procedure 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 **Delete QBE** dialog box appears.



3. Click **OK** to delete the QBE. The system deletes the selected QBE; the **Query By Example - Library** page appears.

Associating a QBE with a Report

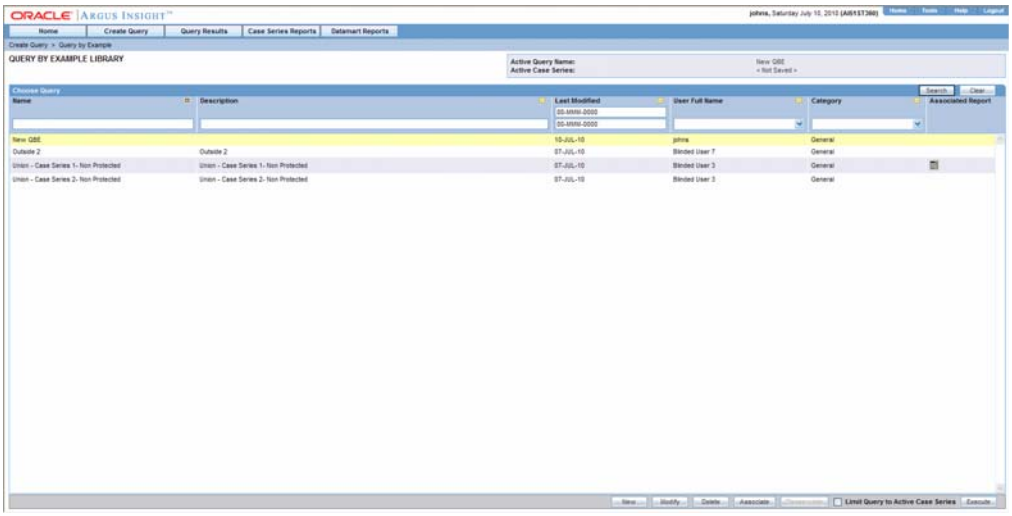
Argus Insight lets you associate a QBE to a particular Standard Report and schedule a time when the report needs to be generated and sent to another user through email. This is helpful in situations when you need to generate the latest Case Series and run a report on it each time the datamart is refreshed. Instead of manually executing the QBE to generate the latest Case Series and running the report, you can use the report association functionality of Argus Insight.

Note: The user who is scheduling reports should have an enterprise login configured in Cognos to schedule the report.

It is not possible to associate multiple reports with a query by a user. If user associates multiple reports against the same query, the scheduling information is overwritten by the latest schedule mentioned by the user.

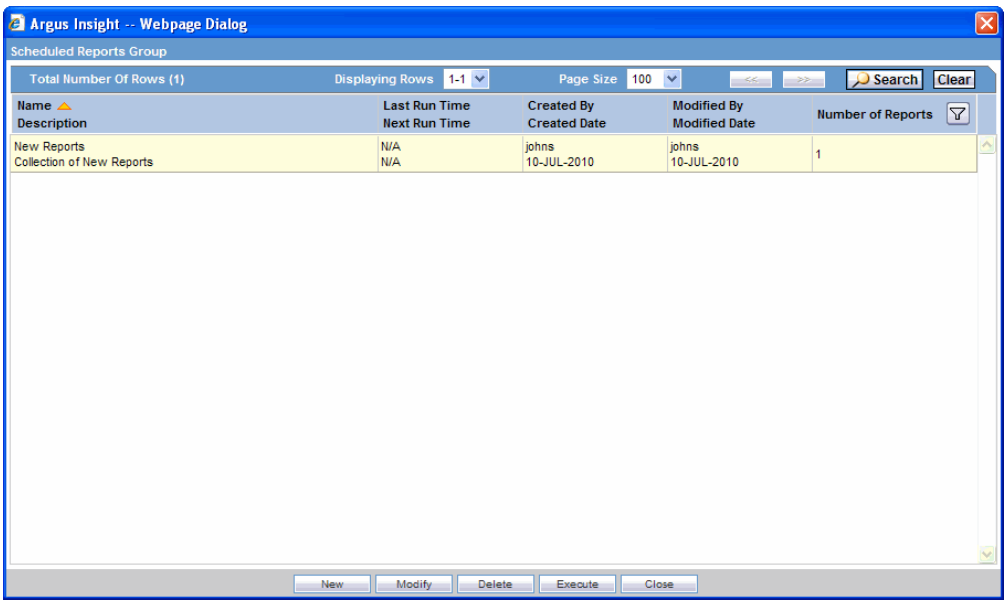
Use the following procedure to associate a QBE with a Standard Report:

1. In the **Query By Example - Library** page, select the QBE that you wish to associate with a Standard Report.

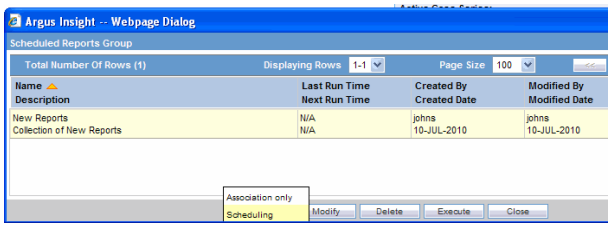


2. Associate the QBE with a Standard Report.

3. Click **Associate**. The **Scheduled Report Groups** window appears. This window displays the information of all the report groups that have been scheduled by the logged-in user.

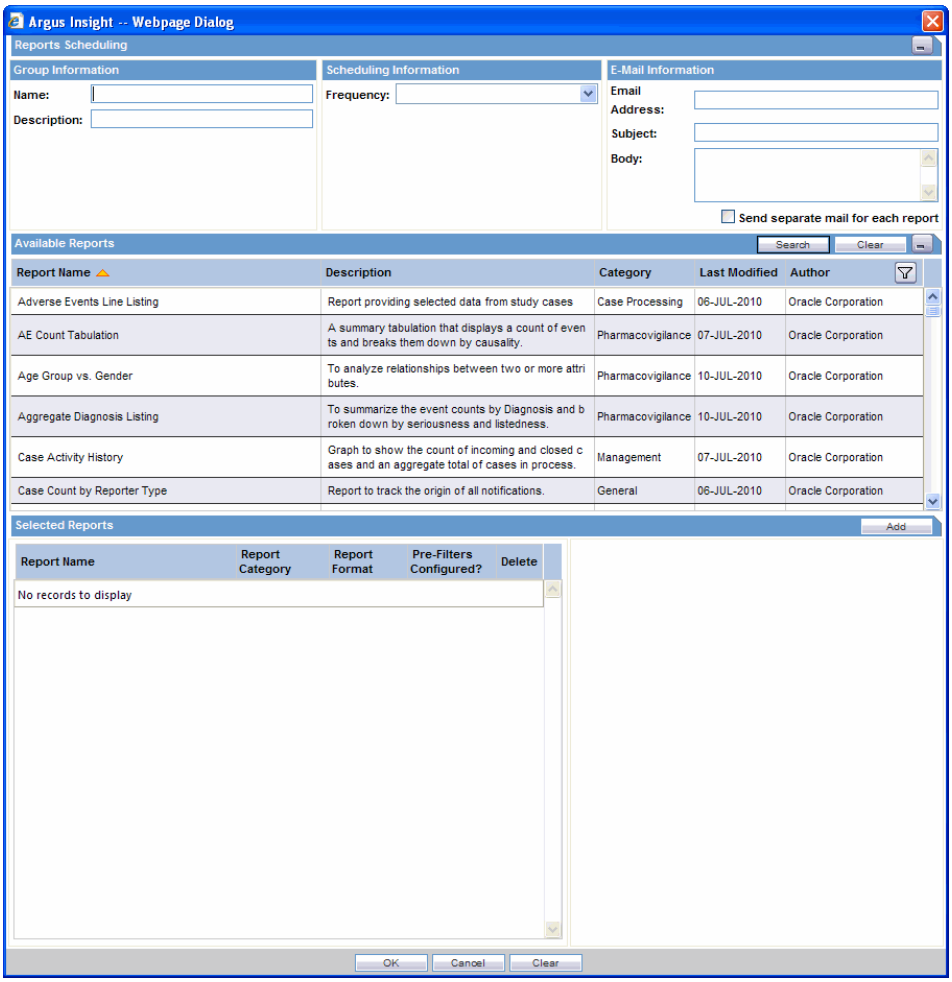


4. Click **New**. It enables you to either do Report **Association Only** or to perform Report **Scheduling**.



5. Schedule the report.

6. Click the **Scheduling** tab. The **Reports Scheduling** page appears.



7. Enter the **Name** and **Decription** of the report.

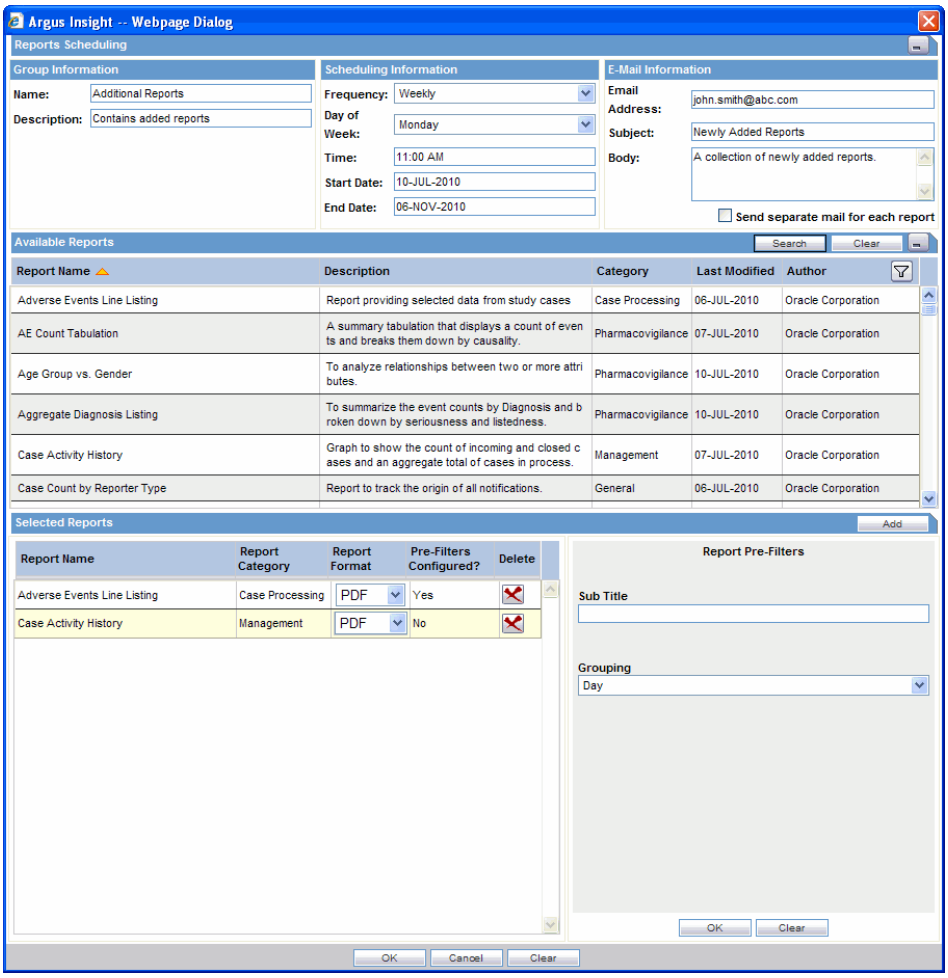
8. Use the **Frequency** list box to specify how often you wish to have the system run the selected QBE and generate the selected report. The options available are: **Once**, **Daily**, **Weekly**, **Monthly**, **Quarterly**, and **Yearly**.

9. Specify the start time in the **Time** field.

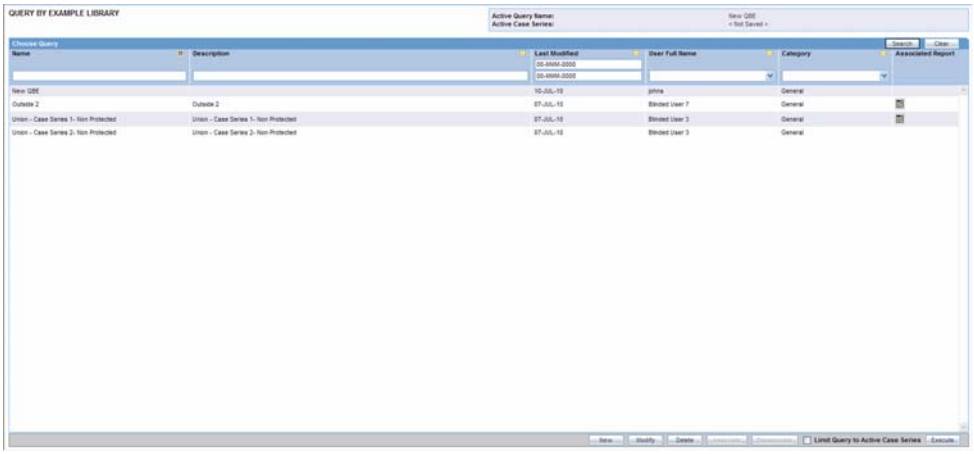
10. Based on the option you selected in the step above, specify the instant when you want the report generated as described in the table below.

Frequency Option Selected	Additional Scheduling Information to Specify
Once	In the **Date** text box that appears, enter the date when you want to have the report generated.
Daily	In the **Time** text box that appears, enter the time when you want to have the report generated. The time must be entered in the HH:MM AM/PM format. Hours should be between 1 and 12.
Weekly	From the **Day of Week** option button group that appears, select the day of week on which you want to have the report generated. Also, specify the time in the **Time** text box.
Monthly	Use the **Day** list box to select the day of the month on which you want to have the report generated. Also, specify the time in the **Time** text box.
Quarterly	Quarterly reports are generated on the first day of the quarter. In the **Time** text box, enter the time when you want to have the report generated on the first day of the quarter.
Yearly	In the **Date** and **Time** text boxes, specify the date and time when you want to have the yearly report generated.

11. In the **Start Date** and **End Date** fields, enter the start and end dates for this activity, respectively.
12. Specify the email recipients of the report you scheduled.
13. In the **Email Address** text box, type the email address of the report recipient. If there are multiple recipients, use a semicolon to separate their email addresses.
14. Type the subject line in the **Subject** text box.
15. Type the email body text in the **Body** text box.
16. Select the report(s) from under **Available Reports** and click **Add**. The selected reports are displayed under **Selected Reports**.
17. Click the selected report(s) under **Selected Reports**. The prompts are loaded in the right pane.



18. Enter the sub title for the report pre-filter and click OK.
19. Click OK in the Reports Scheduling window. In case of Association only, the scheduling steps are not required.
20. Click **OK**. The system associates the QBE with the selected report and saves the scheduling information; **Query By Example - Library** page **appears**. The icon displayed in the **Report** column indicates that the QBE is associated with a report.

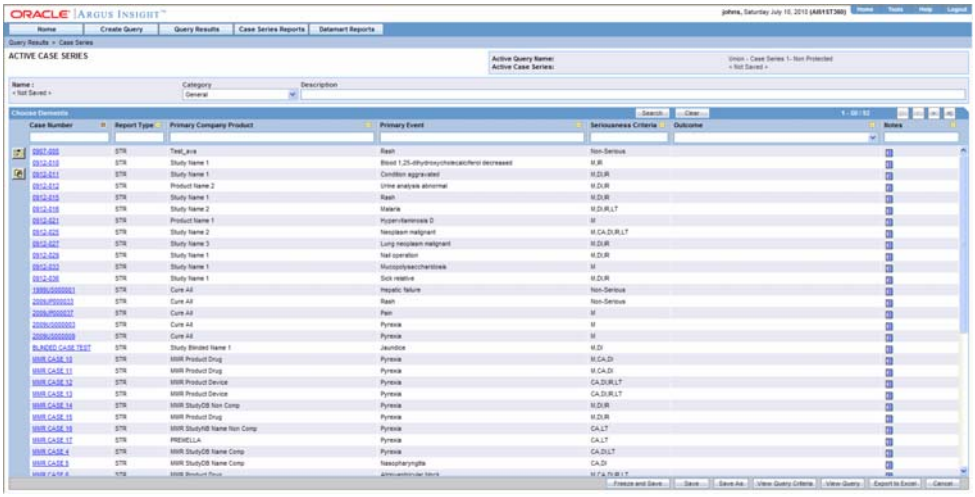


Note: Refer to the Associated Library and Query Library sections in the Library chapter, to view the steps on how to disassociate reports in those libraries

Executing a Saved QBE

Use the following procedure to execute a saved QBE.

1. Select a QBE from the list of QBEs in the **Query By Example - Library** page.
2. Click **Execute**. The system executes the QBE; the **Active Case Series** page appears.



3. If a **report** is associated with the saved QBE, click on **Execute** button. The **Active Case Series** page and **Pre Filter** page of the associated report is displayed.
4. Enter the prompts value in the **Pre Filter** page.
5. Click on the **Execute** button to generate the report.
6. After generating the Case Series, you can manually modify it or save it. See theCase Serieschapter for more information on working with Case Series.

Note: You can also export the Case Series results into an excel file. For details see Exporting Case Series to Excel.

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.

Use the following procedure to narrow down the list of cases in 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 datamart and generating a new Case Series.

1. Generate the Case Series on which you wish to run another QBE:
   - If the Case Series on which you wish to run another QBE is not yet generated / active, you can either create aNew QBEand execute it or execute a saved QBE as explained in the previous section. 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 wish to run another QBE is already saved in the system, select Query Results > Case Series > Library. In the Case Series Library page that appears, select the Case Series title and click Make Active.

2. Select Create Query > Query by Example > Library. The Query By Example - Library page appears.
3. Select the query you want to run on the Active Case Series you generated in step 1.
4. Check the Limit Query to Active Case Series checkbox.
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. In Argus Insight, Advanced Conditions are created 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).

In Argus Insight, QBE is integrated with Advanced Conditions to let you perform the following tasks.

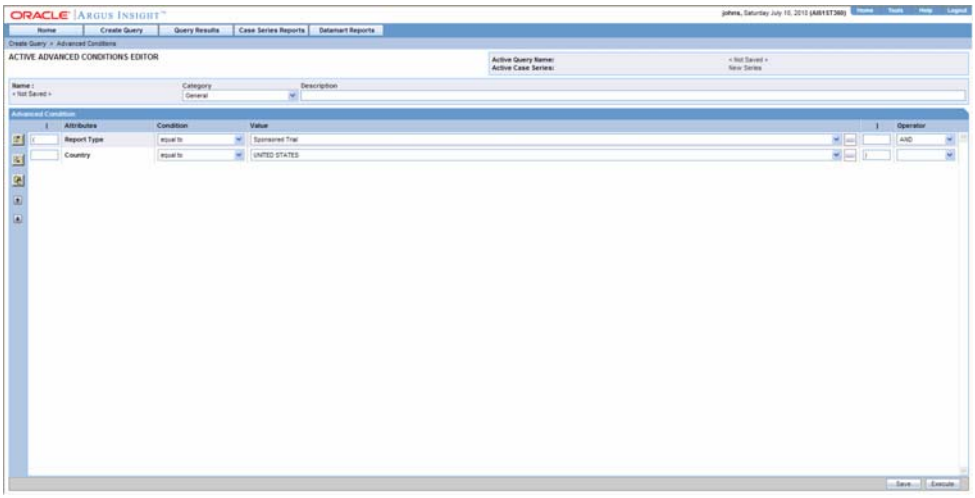
- Converting a QBE to an Advanced Condition
- Integrating a QBE with an Advanced Condition

Converting a QBE to an Advanced Condition

A QBE can be used to start an Advanced Condition that employs Set or Boolean 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 in the **Active Advanced Conditions Editor** page as Advanced Condition attributes.

Use the following procedure to convert a QBE to 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 the **Convert to Advanced Condition** button. The **Active Advanced Condition Editor** page appears; all the fields in which you specified values in the QBE form are listed as Advanced Condition attributes.



4. In the Advanced Condition editor, you can 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 Set and Boolean operators to join the various attributes

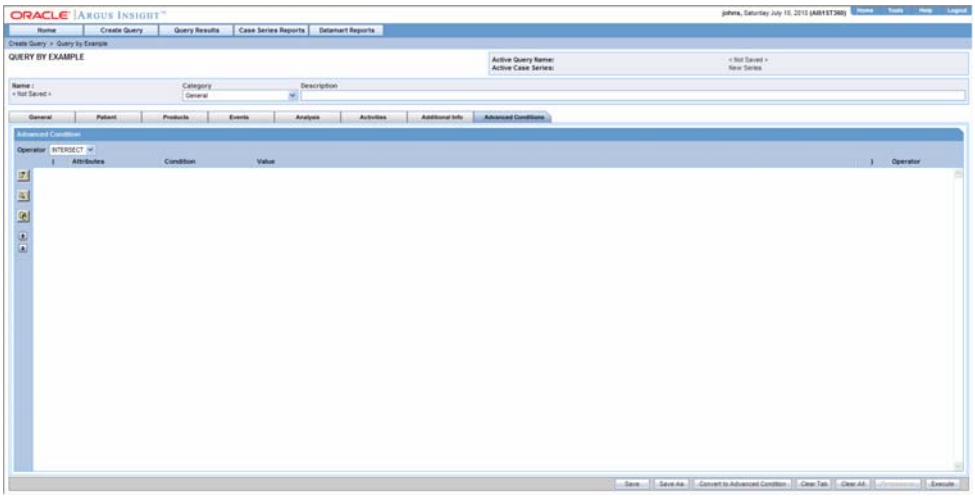
See the Advanced Conditionschapter for detailed information on building Advanced Conditions by using the options in the Advanced Condition editor.

Integrating a QBE with an Advanced Condition

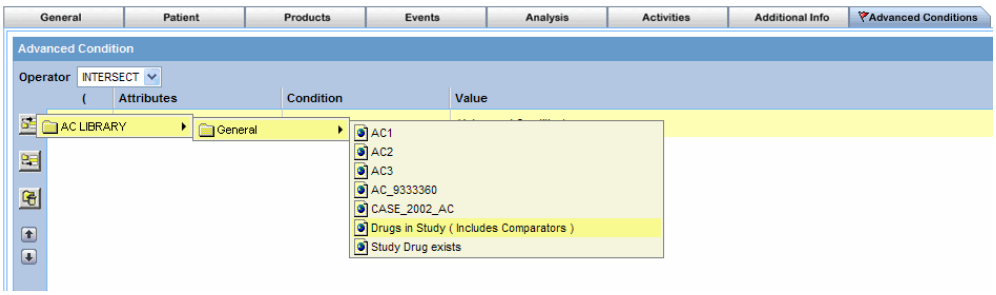
Argus Insight lets you integrate a new, active, or saved QBE with an existing Advanced Condition through these Set operators: Intersect, Minus, or Union. If required, you can integrate your QBE with multiple Advanced Conditions. The multiple Advanced Conditions can have Set or Boolean operations between them.

Use the following procedure to integrate a QBE with existing Advanced Conditions:

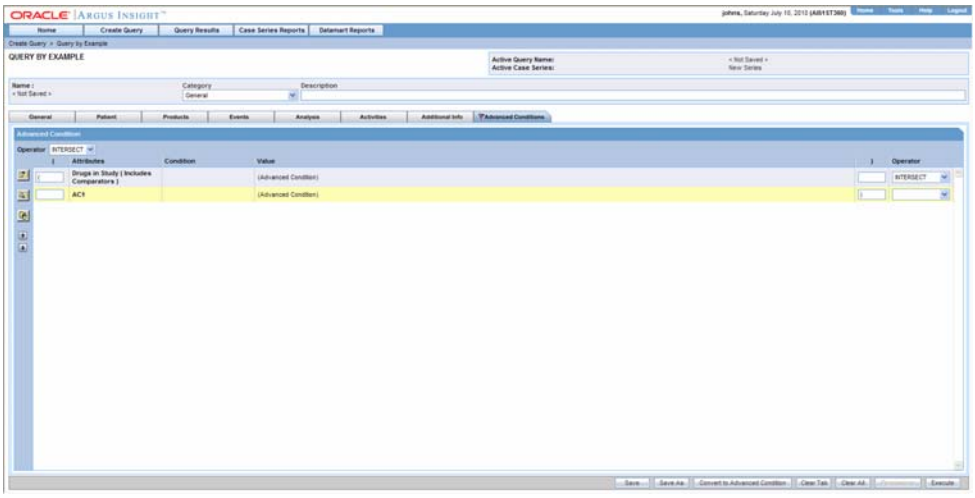
1. Open a QBE *form* bystarting a new QBE, opening the Active QBE, or opening a saved QBE.
2. Verify the *field* values you specified in the various tab pages in the QBE form.
3. Click the **Advanced Conditions** tab in the QBE form. The **Advanced Condition** tab page displays the Advanced Condition editor.



4. Use the **Operator** list box to specify the Set operator you want to use to integrate the QBE and the Advanced Condition. You can select one of these options: **Intersect**, **Minus**, **Union**.
5. Select the Advance Condition you want to integrate with the QBE.
6. Click the icon on the left bar. A context menu appears. In the context menu, all the Advanced Conditions which are stored in the system and are accessible to the user are organized by categories.



7. In the context menu, browse to the appropriate category and select the required Advanced Condition. The selected Advanced Condition appears as a row in the Advanced Condition editor.



8. If required, add other Advanced Conditions. Click the icons on the left bar to insert another Advanced Condition above or below the existing Advanced Condition.

   Tip: You can change the structure of the*query* by changing order of rows in the editor. Use the following procedure to To do this, select a row and click the Up or Down buttons to move the row upwards or downwards.

9. Type parentheses in the **(** and **)** columns to determine the order of execution for the selected Advanced Conditions.

10. Use the list box in the **Operator** column to specify the operators between the selected Advanced Conditions. You can select from these options: **AND**, **OR**, **Intersect**, **Minus**, and **Union**.

    Note: See the Advanced Conditions chapter for detailed information on creating Advanced Conditions by using the options in the Advanced Condition editor.

11. Save the integrated query by clicking **Save As**.

    Note: You can convert the integrated QBE and Advanced Condition into a single Advanced Condition by clicking **Convert to Advanced Condition**. See Converting a QBE to an Advanced Condition for details.

12. Click **Execute** to run the integrated QBE and generate the Case Series. The **Active Case Series** page appears; the Case Series is displayed. See the Case Series chapter for more information on working with Case Series.

Filters

WhileQBElets you create queries by specifying unique *field* values in the various tab pages of the QBE *form*, Filters let you create queries by specifying multiple 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.

Argus Insight provides five predefined Filters. Each predefined *Filter* comprises of a set of specific datamart fields called filter elements. The following table lists the five predefined Filters and the elements associated with them.

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

Predefined Filter Name	Associated Elements (Fields)		
Compliance	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	Advanced Conditions
Configuration	Country of Incidence	Product	Project/Study/Center
	Advanced Conditions		
Management	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
	Advanced Conditions		
Pharmacovigilance	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	Advanced Condition

Predefined Filter Name	Associated Elements (Fields)		
Workflow	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	Advanced Conditions

Argus Insight also lets you define custom Filters by letting you select a set of elements (datamart fields) and saving the selection as your own Filter.

To create a filter using queries, select a predefined or custom Filter and specify values (multiple or range) in the desired filter elements associated with the Filter. You can then execute this query (Value Set)to generate a Case Series.

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

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

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

The topics that follow explain how to work with 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

Using Predefined Filters

This topic explains how to:

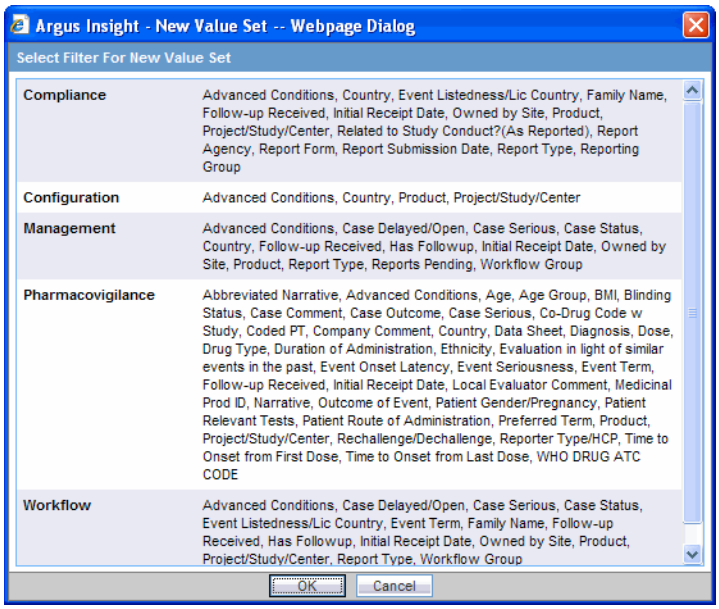
- Select a predefined *Filter*
- Create a Value Set for the predefined Filter by entering values in the associated elements

- Generate a Case Series by executing the Value Set

Selecting a Predefined Filter

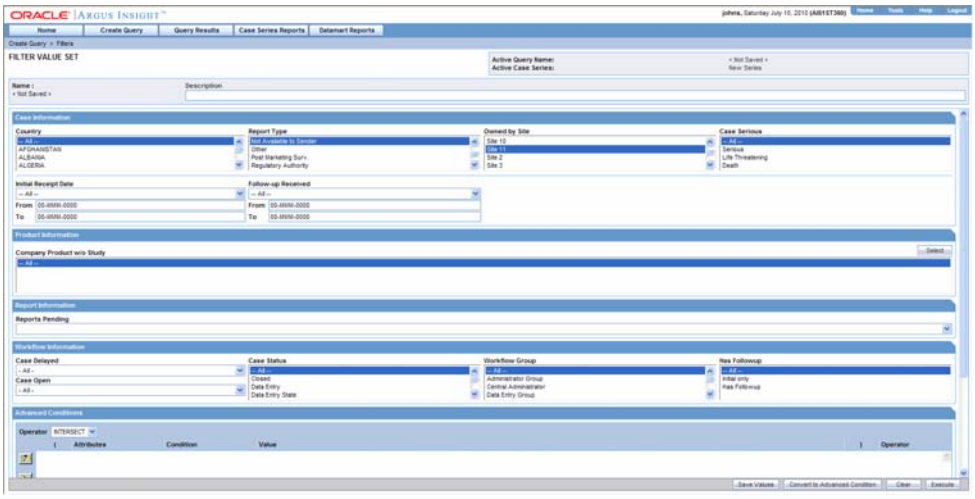
Use the following procedure to select a predefined filter.

1. Select Create *Query* > Filters > New Value Set. The Select Filter for New Value Set dialog box appears.



> **Note:** The **Select Filter for New Value Set** dialog box displays a list of all the predefined as well ascustom Filters and their associated elements. You need to scroll down the dialog box to view all the Filters.

2. Select a predefined Filter (**Compliance**, **Configuration**, **Management**, **Pharmacovigilance**, and **Workflow)** depending on your reporting needs. For example, select **Compliance**. If there are any custom Filters saved to the system, you can select one of those as well
3. Click **OK**. The **Filter Value Set** page appears.



Note: In the Filter Value Set page, all the elements associated with the Filter are organized in sections. You need to scroll down 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 theIntegrating a Value Set with an Advanced Condition topic for details. You can also convert the entire Value Set to an Advance Condition. The Converting a Value Set to an Advanced Condition topic explains how to do this.

Create a Value Set

Use the following procedure to create a value set.

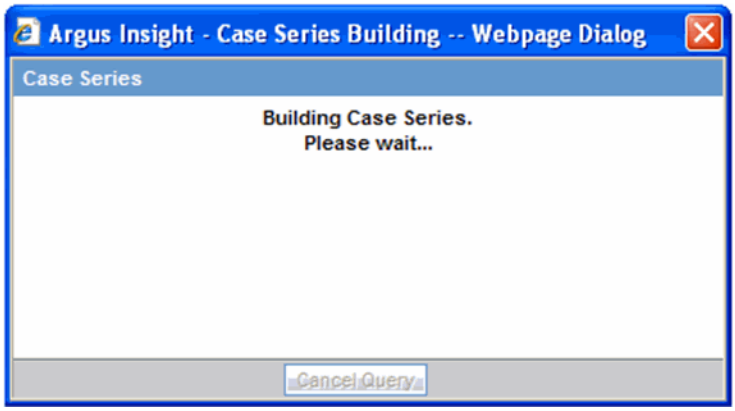
1. Specify values for the Filter elements in the various sections. Depending on the Filter you selected, the **Filter Value Set** page may contain these sections:

Sections in the New Value Set Page	Associated Elements (Fields)		
Case Information	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*
Patient Information	Patient Age Group	Patient Age (In Years)	BMI
	Patient Gender/Pregnancy	Patient Ethnicity	
Product Information	Regimen Daily Dose	Total Regimen Dosage	Product
	Drug Primary Indication Code	*Rechallenge/Dechallenge*	Total Drug Dosage
	ATC Code		

Sections in the New Value Set Page	Associated Elements (Fields)		
Event Information	Event Seriousness	Event Term	Onset Latency (minutes)
	Outcome of Event	Event Listedness/Lic Country	Related to Study Conduct? (As Reported)
Workflow Information	Workflow Group	Has Followup	Case Status
	Case Delayed/Open		
Miscellaneous Information	Lab Test/Assessment	Lab Results	
Report Information	Reports Pending	Report Agency	Report Submission Date
	Reporting Group	Report *Form*	

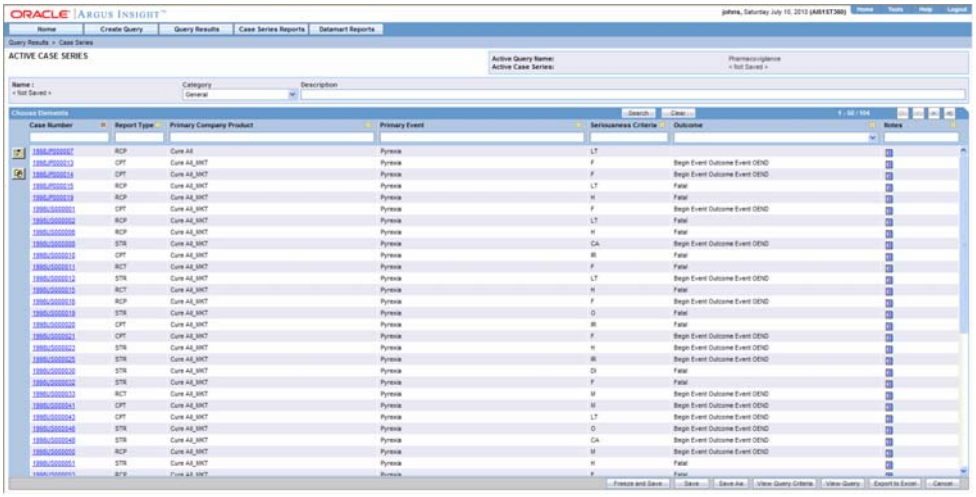
Note: The MedDRA browser can be accessed from the Create Query > Filters New Value Set > Pharmacovigilance | Workflow categories. The MedDRA browser for Pharmacovigilance | Workflow filter categories supports the following options specific to Filters: All hierarchy radio-button Use this option to enable 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 radio-button Use this option to select multiple terms within a specific AE term. Click on the term(s) you want to include in your search criteria. These terms are highlighted in yellow. The output based on the term(s) selected in the MedDRA browser, is populated in the relevant section of the Filter.

2. Examine the Value Set result.
3. Click **Execute**.
4. While the system searches for matching cases, the following dialog box is displayed.

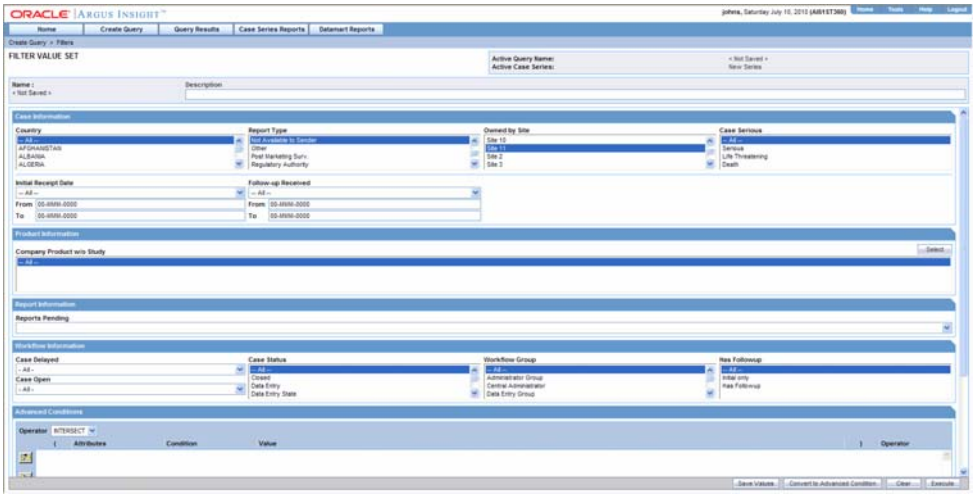


Tip: You may cancel the query execution at this point and return to the **Filter Value Set** page by clicking **Cancel Query** in the dialog box above.

If the system finds cases that match the query criteria, a list of such cases is displayed in the **Active Case Series** page.



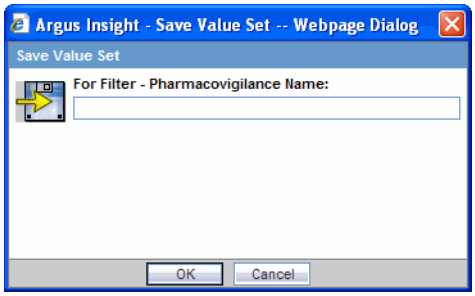
5. Examine the Case Series. If the Case Series is too large, you may want to modify the Value Set to narrow down the Case Series. Alternatively, if you find the Case Series to be appropriate, you can save the Value Set to the system.
6. To return to the **Filter Value Set** page, click **View Query** in the **Active Case Series** page. The **Filter Value Set** page appears.



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.

7. If required, modify the Value Set and examine the result again or proceed to save the Value Set.

8. Save the Value Set to the system.
9. Type a description of the Value Set in the **Description** text box. For example, you can describe the type of cases the Value Set retrieves.
10. Click **Save Values**. The **Save Value Set** dialog box appears.



11. Type the name of the Value Set in the **Name** text box.
12. Click **OK**. The system refreshes the **Filter Value Set** page. Note that the following new elements appear on the page.
    - The Name label displays the name of the Value Set page you specified
    - Two new buttons appear at the bottom of the page: Save Values As and Permissions.

    Note: All the Value Sets you save to the system are listed in the **Filter Library** page. The topicWorking with Saved Filters and Value Sets explains how to work with saved Value Sets.

    Tip: If you make modifications to the*field* values after you have saved the Values Set to the system, use the **Save Values** button to save the changed field values. To save the Value Set by another name, use the **Save Values As** button. To clear all the field values in the **Filter Value Set** page, click **Clear**.
13. Assign group-level permissions on the saved Value Set.
14. Click the **Permissions** button. The **Permissions** dialog box appears. A list in this dialog box displays the names of all the groups (except the **Administrator** group) that the system administrator has created.

15. Use the list box 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
No Access (Default)	No group members will be able to access the Value Set
R	Group members will only be able to view the Value Set
R/W	Group members will be able to view and modify the Value Set
R/W/D	Group members will be able to view, modify, and delete the Value Set
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the Value Set

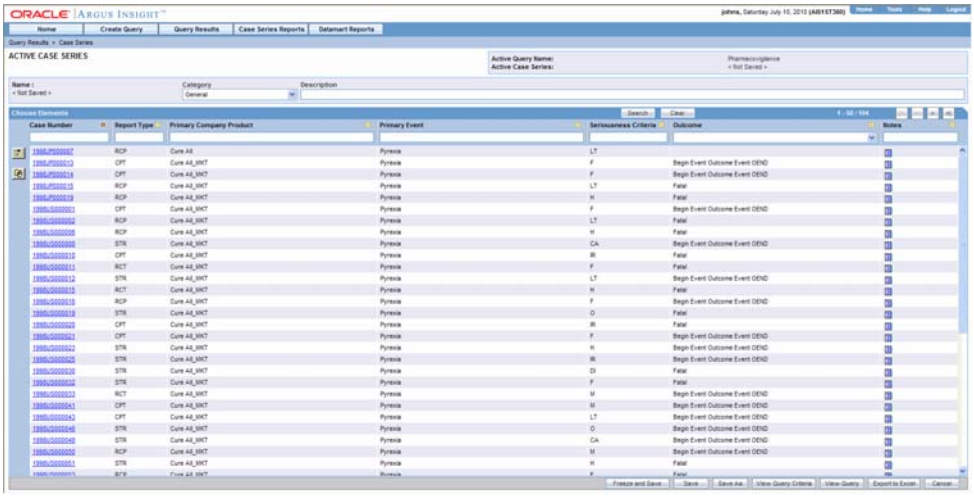
Note: The author of the Value Set always has the highest level of permission (R/W/D/P) on it. For example, you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a Value Set that you create. In this case, while you will continue to have the highest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

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

Executing a Value Set

Use the following procedure to execute a Value Set.

1. Click **Execute**.
2. The system retrieves the list of cases that match the Value Set criteria and displays it in the **Active Case Series** page.



3. After generating the Case Series, you can manually modify it or save it. See the Case Serieschapter for more information on working with Case Series.

Creating Custom Filters

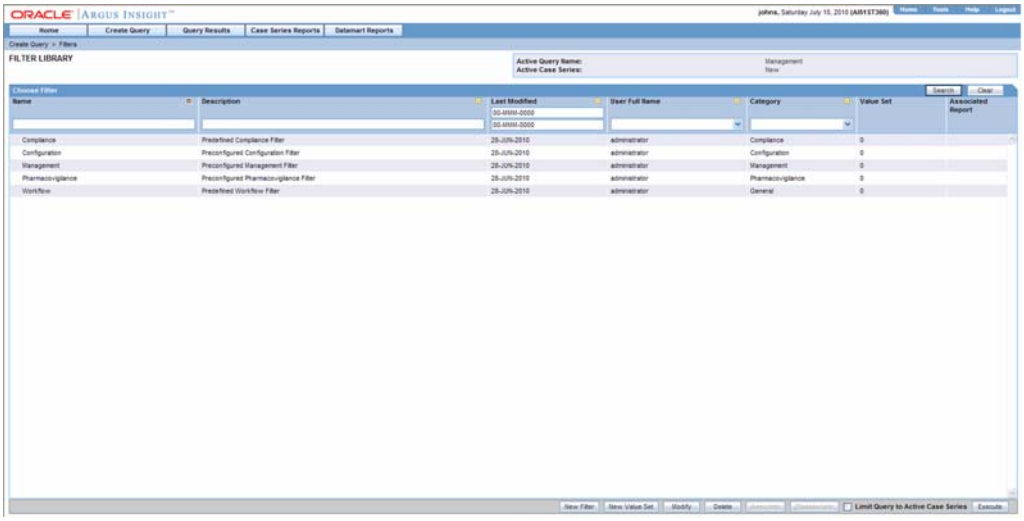
This topic explains how to:

- Create a custom *Filter*
- Create a Value Set for the custom Filter
- Generate a Case Series by executing the custom Value Set

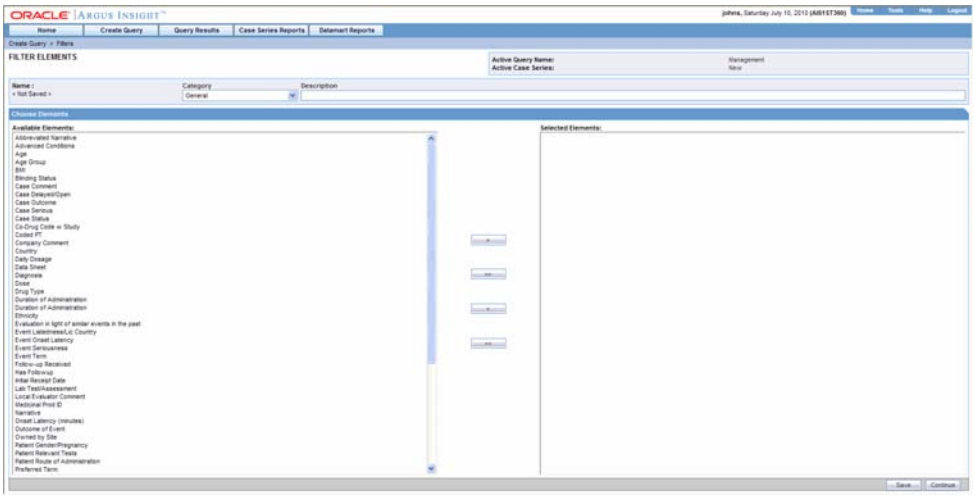
Creating a Custom Filter

Use the following procedure to create a custom filter.

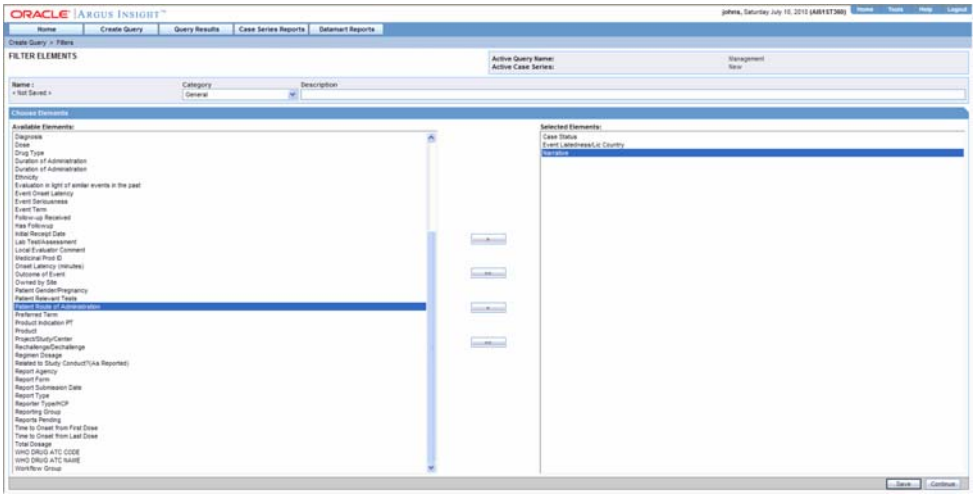
1. Select **Create Query > Filters > Library**. The **Filter Library** page appears. This page lists the predefined as well as custom Filters and their values sets in a control tree format.



2. Click the **New Filter** button. The **Filter Elements** page appears.



3. From the **Available Elements** list, select an element you want to associate with the custom Filter.
4. Click the **>** button to associate the selected element with the custom Filter. The selected element appears in the **Selected Elements** list.



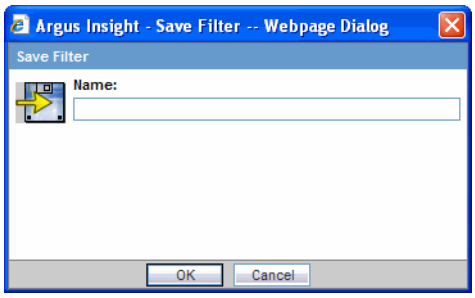
Tip: To add all the elements in **Available Elements** list to the **Selected Elements** list, click the >> button.

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** list box 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** text box.

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



9. Enter the custom Filter name in the **Name** text box.
10. Click **OK**. The system saves the custom Filter; the **Filter Elements** page refreshes. Note that the following new elements appear on the page.
11. The **Name** label displays the name of the saved filter.
12. The **Active Query Name** label in the upper-right corner of the page now displays the name of the Filter you specified.
13. Two new buttons appear at the bottom of the page: **Save As** and **Permissions**.

> **Note:** If you make modifications to the Filter elements after you have saved the Filter to the system, use the **Save** button to save the changes. To save the Filter by another name, use the **Save As** button.

14. Assign group-level permissions on the Filter.
15. Click the **Permissions** button. The **Permissions** dialog box appears. A list in this dialog box displays the names of all the groups (except the **Administrator** group) that the system administrator has created.

16. Use the list box next to a group name to assign permissions to the group members on the Filter you created. You can select from these options:

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

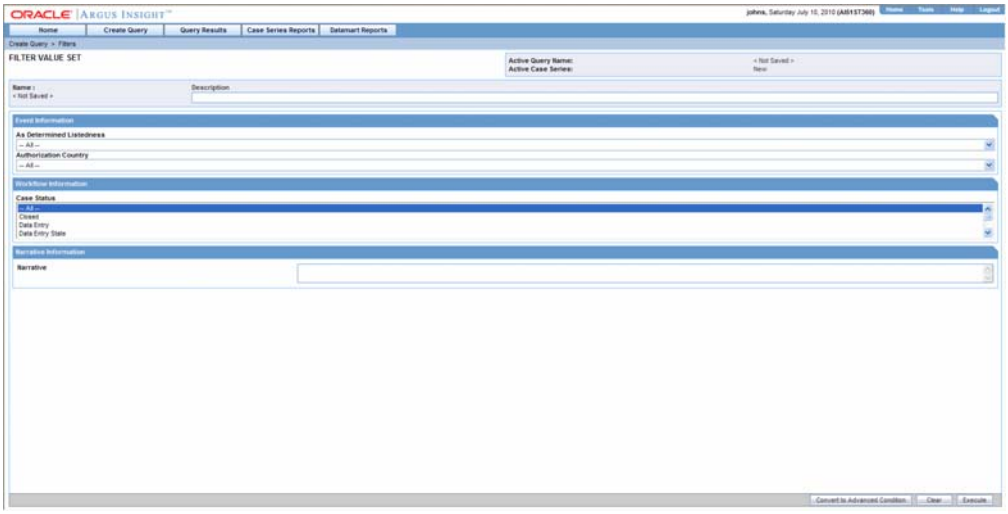
Note: The author of the Filter always has the highest level of permission (R/W/D/P) on the Filter. For example, you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a Filter that you create. In this case, while you will continue to have the highest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

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

Creating a Value Set for a Custom Filter

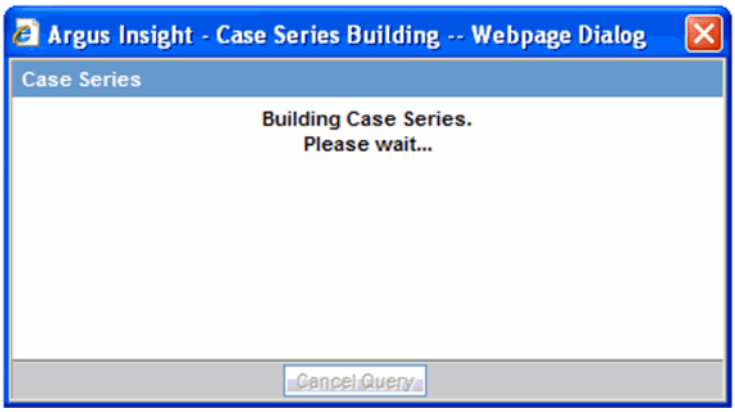
Use the following procedure to create a value set for a custom filter.

1. Click **Continue** in the Filter Elements page. The Filter Value Set page appears.



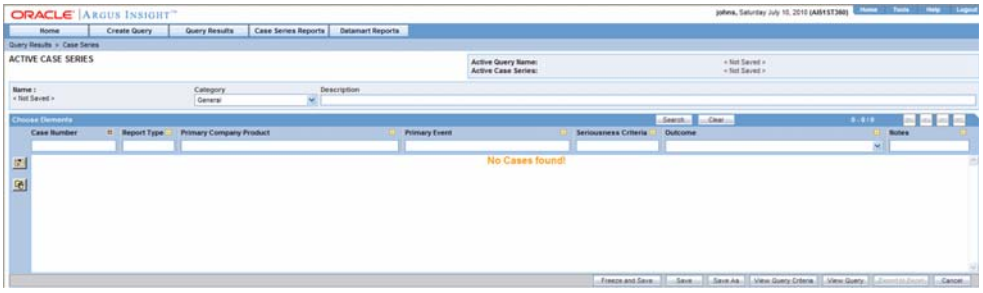
Note: In the **Filter Value Set** page, all the elements associated with the Filter are organized in sections. You need to scroll down the page to view all the sections. If you included the **Advanced Condition** element while creating your Filter in step 2, the **Filter Value Set** page displays an additional section **Advanced Condition**. You can use the options in this section to create an Advanced Condition and integrate your Value Set with it. See theIntegrating a Value Set with an Advanced Condition topic for details. You can also convert the entire Value Set to an Advance Condition. The Converting a Value Set to an Advanced Condition topic explains how to do this.

2. Specify values for the Filter elements. See step 2 in the Using Predefined Filters topic for details.
3. Examine the Value Set result.
4. Click **Execute**. While the system searches for matching cases, the following dialog box is displayed.

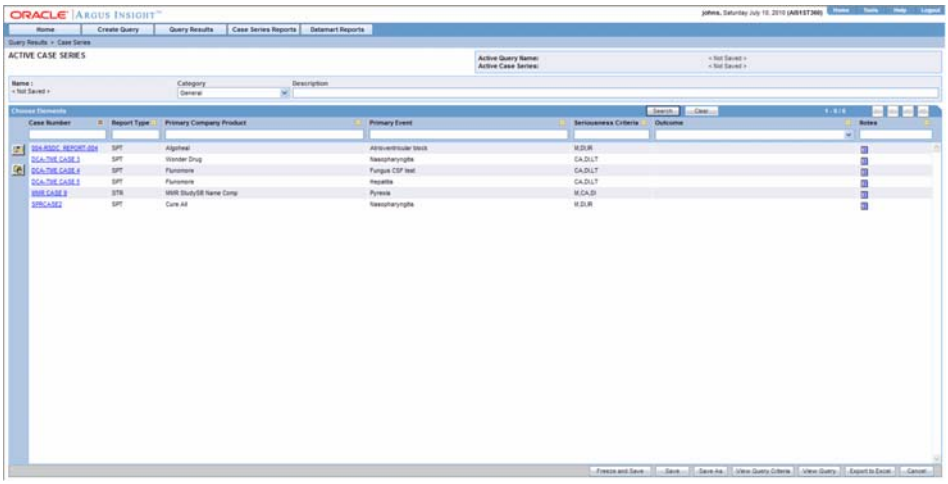


Note: You may cancel the query execution at this point and return to the **Filter Value Set** page by clicking **Cancel Query** in the dialog box above.

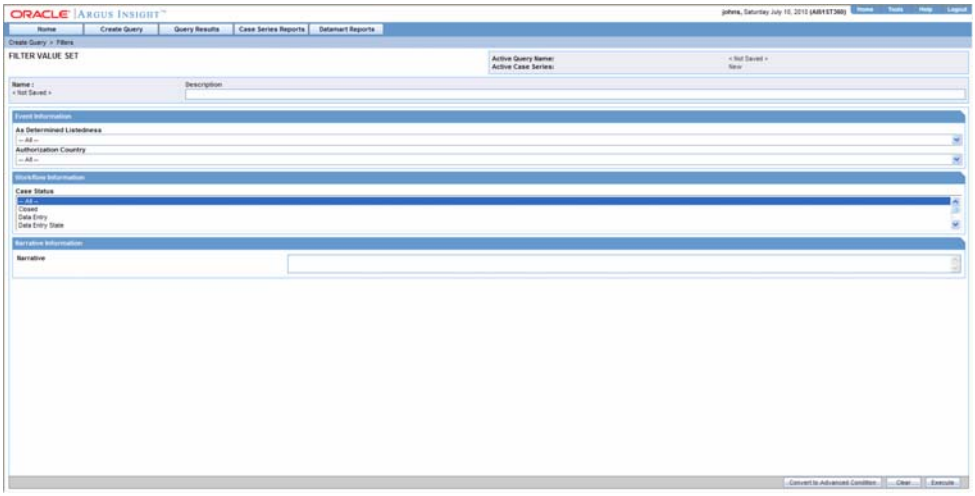
5. If the system does not find any cases that match the querying criteria, the following dialog box is displayed. Click **OK** in this dialog box to return to the Value Set *form*, modify the criteria, and execute the Value Set again.



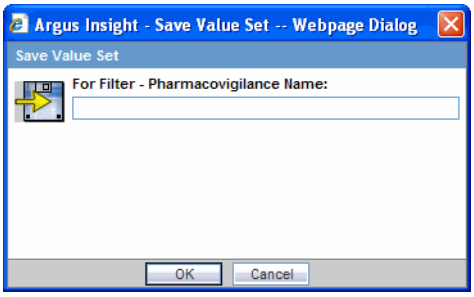
6. If the system finds cases that match the query criteria, a list of such cases is displayed in the **Active Case Series** page.



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. To return to the **Filter Value Set** page, click **View Query** in the **Active Case Series** page. The **Filter Value Set** page appears.



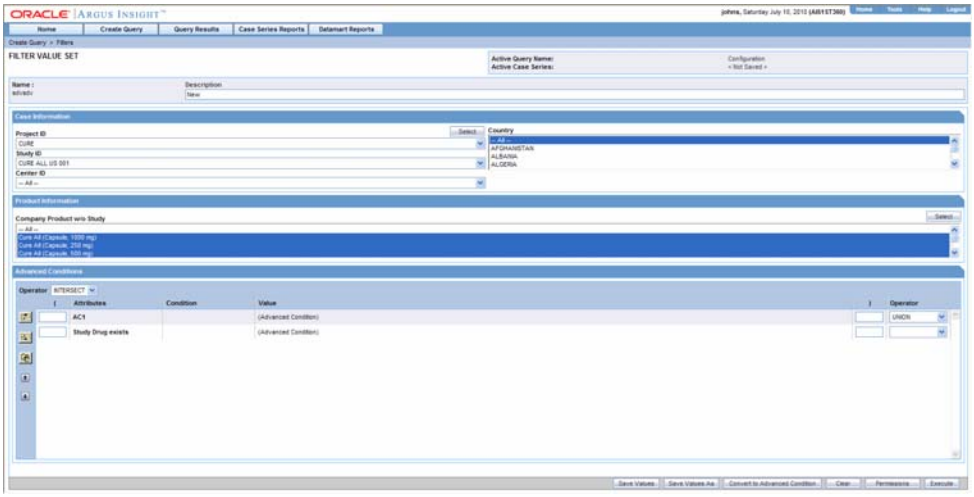
9. If required, modify the Value Set and examine the result again or proceed to save the Value Set.
10. Save the Value Set to the system.
11. Type a description of the Value Set in the **Description** text box. For example, you can describe the type of cases the Value Set retrieves.
12. Click **Save Values**. The **Save Value Set** dialog box appears.



13. Type the name of the Value Set in the **Name** text box.

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

14. Click **OK**. The system refreshes the **Filter Value Set** page. Two new buttons appear at the bottom of the page: **Save Values As** and **Permissions**.



> **Note:** The **Filter Library** page displays the custom as well as predefined Filters and their Values Sets in a control tree format. From this page you can select a Value Set and directly execute it. See theWorking with Saved Filters and Value Sets topic for more information on the **Filter Library** page. 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 the Using Predefined Filters topic for more information.

> **Tip:** If you make modifications to the field values after you have saved the Values Set to the system, use the Save Values button to save the changed field values. To save the Value Set by another name, use the Save Values As button.To clear all the field values in the Filter Value Set page, click Clear.

15. Assign group-level permissions on the saved Value Set.

16. Click the **Permissions** button. The **Permissions** dialog box appears. A list in this dialog box displays the names of all the groups (except the **Administrator** group) that the system administrator has created.

17. Use the list box 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
No Access (Default)	No group members will be able to access the Value Set
R	Group members will be able to only view the Value Set
R/W	Group members will be able to view and modify the Value Set
R/W/D	Group members will be able to view, modify, and delete the Value Set
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the Value Set

> **Note:** The author of the Value Set always has the highest level of permission (R/W/D/P) on it.

18. Click **OK**. The system saves the permission settings.
19. Click **Execute**. The system retrieves the list of cases that match the Value Set criteria and displays it in the **Active Case Series** page. After generating the Case Series, you can manually modify it or save it. See theCase Serieschapter for more information on working with Case Series.

Working with the Last Modified or Executed Value Set

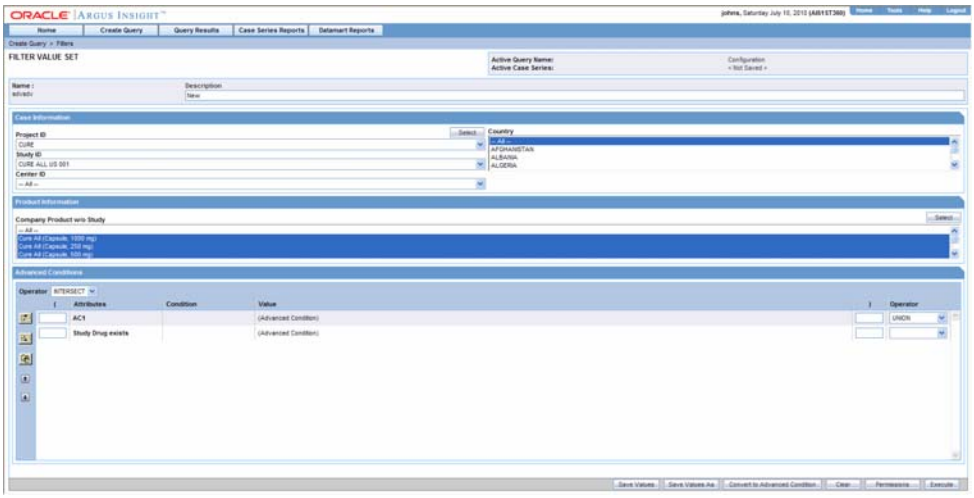
This topic explains how to view the Value Set you last modified or executed.

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.

Use the following procedure to view an Active Value Set,

1. Select **Create Query > Filters > Active**. The **Filter Value Set** page displays the Value Set you executed or modified last**.**



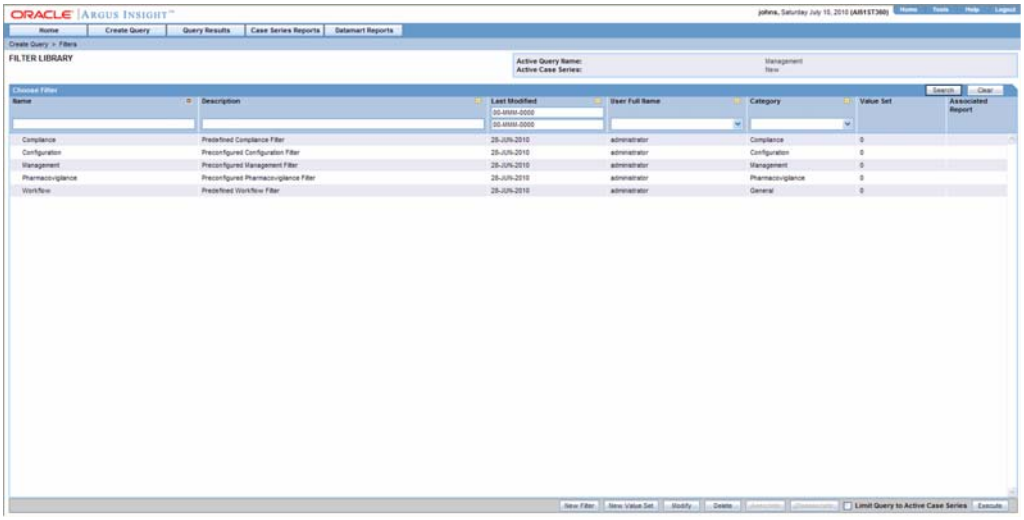
2. If the Value Set was saved to the system before executing, the name of the Value Set appears next to **Name** label. In addition, the name of the Filter appears next to the **Active Query Name** label.
3. However, if the Value Set was not saved to the system before executing, the text <Not Saved>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

Task	Description
Modify the Active Value Set	If required, you can modify the Value Set by changing the *field* values. While entering field values, if you wish to clear all the values you entered, click the **Clear** button. Use the **Save Values** button to save the changed field values. This button is only available for a saved Value Set.
Save the Active Values Set by another name	Click **Save Values As** to save the Active Value Set by a different name. The Value Sets you save to the system are listed in the **Filters Library** page. TheWorking with Saved Value Setstopic explains how to work with saved Value Sets.
Convert Active Value Set to Advanced Condition	Click **Convert to Advanced Condition** to convert the Active Values Set to an Advanced Condition. TheConverting a Value Set to an Advanced Conditiontopic explains how to do this.
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** text box. 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 Values 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, select **Create Query > Filters > Library**.



To view the Values 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 theAssociating a Value Set with a Reportsection below for more information

Searching Saved Filters and Value Sets

Use the following procedure 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 also 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** list box.
- To search for a Filter by its category, select the category from the **Category** list box.

2. Click **Search**. Based on your search criteria, the system displays the search result in a list.
3. You can sort the search result list by clicking the sort icon next to the column headers in the list.

Creating a New Filter

Click the **New Filter** button in the **Filter Library** page. See theCreating Custom Filterstopic for details.

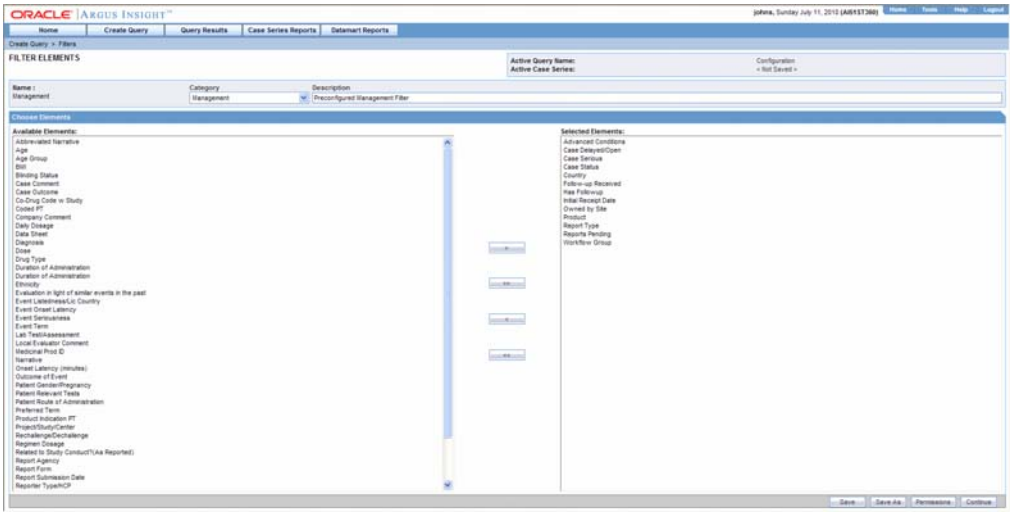
Creating a New Value Set

Instead of selecting **Create Query > Filters > New Values Set** to create a new Value Set, you can click the **New Value Set** button in the **Filter Library** page. You can create Value Sets for predefined as well as custom Filters by using this method. See theUsing Predefined Filterstopic for details.

Modifying a Filter or Value Set

Use the following procedure 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 appears. If you selected a Value Set, the **Filter Value Set** page appears.



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.

Use the following procedure to delete a Value Set or a custom Filter.

1. Select the Value Set or the custom Filter from the list in the **Filter Library** page.
2. Click **Delete**. The delete confirmation dialog box appears.
3. Click **OK**. The system deletes the selected Filter/Value Set; the **Filter Library** page appears.

Associating a Value Set with a Report

Argus Insight lets you associate a Value Set to a particular Standard Report and schedule a time when the report needs to be generated and sent to another user through email. This is helpful in situations when you need to generate the latest Case Series and run a report on it each time the datamart is refreshed. Instead of manually executing the Value Set to generate the latest Case Series and running the report, you can use the report association functionality of Argus Insight.

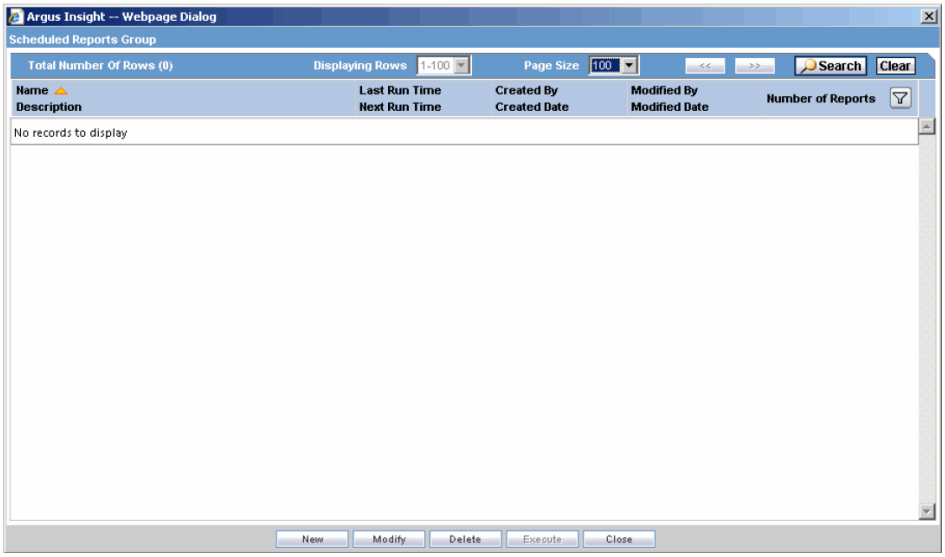
> **Note:** The user who is scheduling reports should have an enterprise login configured in Cognos to schedule the report.

Use the following procedure to associate a Value Set with a Standard Report:

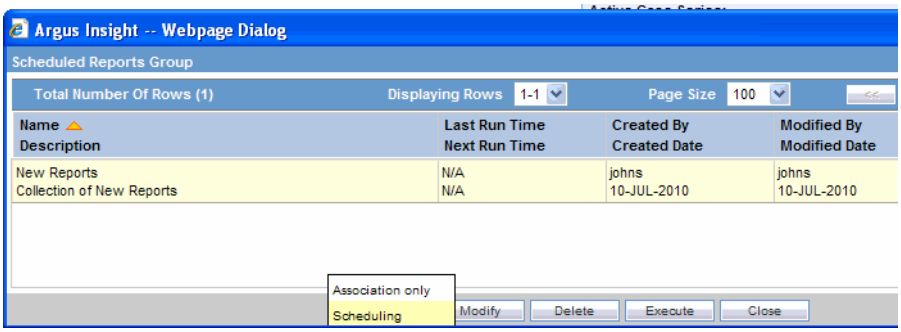
1. In the **Filter Library** page, select the Value Set that you wish to associate with a Standard Report.

   Associate the Value Set with a Standard Report.

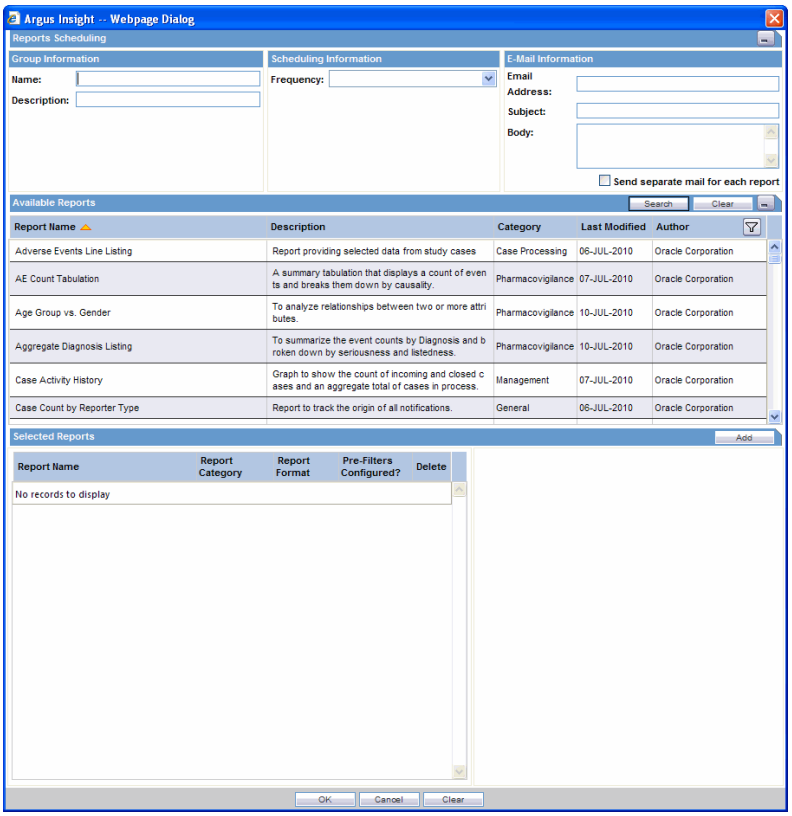
2. Click **Associate**. The **Scheduled Reports Group** dialog box appears. This page displays a list of all groups of reports which were scheduled or associated with the query.



3. Click **New** and a context menu appears. Select **Scheduling**.



4. The **Reports Scheduling** window appears.

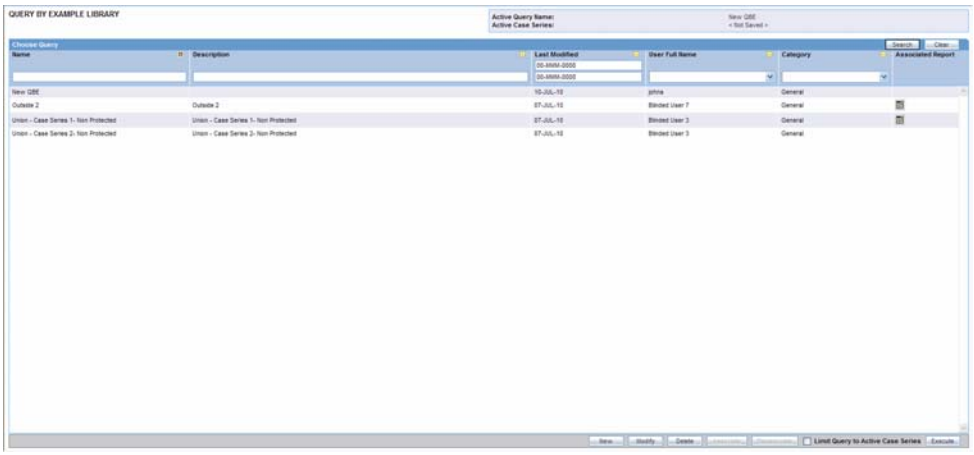


5. On this window, you can schedule multiple reports at once.
6. Schedule the report.
7. This window has 3 main sections:
   - **Scheduling Information** - The Schedule timing and E-Mail information.
   - **Available Reports** - All the available reports in the system that can be scheduled.
   - **Selected Reports** - These reports are scheduled.
8. Provide a Name for your reports group along with description.
9. Use the **Frequency** list box to specify how often you wish to have the system run the selected QBE and generate the selected report. The options available are: **Once**, **Daily**, **Weekly**, **Monthly**, **Quarterly**, and **Yearly**.

10. Specify the schedule time in the **Time** field.
11. Based on the option you selected in the step above, specify the instant when you want the report generated as described in the table below.

Frequency Option Selected	Additional Scheduling Information to Specify
Once	In the **Date** text box that appears, enter the date when you want to have the report generated.
Daily	In the **Time** text box that appears, enter the time when you want to have the report generated. The time must be entered in the HH:MM AM/PM format. Hours should be between 1 and 12.
Weekly	From the **Day of Week** option button group that appears, select the day of week on which you want to have the report generated. Also, specify the time in the **Time** text box.
Monthly	Use the **Day** list box to select the day of the month on which you want to have the report generated. Also, specify the time in the **Time** text box.
Quarterly	Quarterly reports are generated on the first day of the quarter. In the **Time** text box, enter the time when you want to have the report generated on the first day of the quarter.
Yearly	In the **Date** and **Time** text boxes, specify the date and time when you want to have the yearly report generated.

12. Specify the email recipients of the report you scheduled.
13. In the **Email Address** text box, type the email address of the report recipient. If there are multiple recipients, use a semicolon to separate their email addresses.
14. Type the subject line in the **Subject** text box.
15. Type the email body text in the **Body** text box.
16. If you want all the reports in a single mail, leave the **Send separate mail for each report** checkbox unchecked. If you check this checkbox, each report is delivered in a separate mail to the user.
17. From the Available reports grid, select a report and click **Add** button. The report will be selected and will appear in the **Selected Reports** section.
18. To remove a report from **Selected Reports**, click the X button against the report. When you click the selected report(s) in this section, its corresponding prompts are loaded in the right pane.
19. Enter the sub-title for the report pre-filter in the right pane and click **OK**.
20. Click **OK** in the Reports Scheduling window.
21. Click **OK**. The system associates the Value Set with the selected report and saves the scheduling information; the **FilterLibrary** page appears. The icon displayed in the **Associated Report** column indicates that the Value Set is associated with a report.

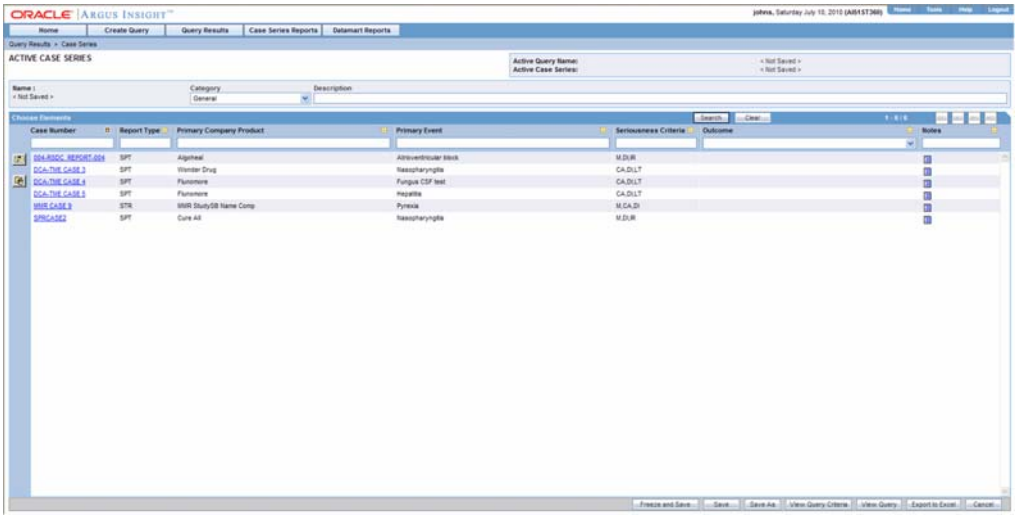


Note: Refer to the Associated Library and Query Library sections in the Library chapter, to view the steps on how to disassociate reports in those libraries.

Executing a Value Set

Use the following procedure to execute a Value Set.

1. Select a Value Set from the list in the **Filter Library** page.
2. Click **Execute**. The system executes the Value Set; the **Active Case Series** page appears.



3. 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.
4. Enter the prompts value in the **Pre Filter** page.
5. Click on the **Execute** button to generate the report.

   After generating the Case Series, you can manually modify it or save it. See the Case Series chapter for more information on working with Case Series.

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.

Use the following procedure to narrow down the list of cases in the Active Case Series, you may want to run a Value Set on an Active Case Series.

1. Generate the Case Series on which you wish 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 wish to run another Value Set is already saved in the system, select **Query Results > Case Series > Case Series Library**. In the **Case Series Library** page that appears, select the Case Series title and click **Make Active**.
2. Select Create Query > Filters > Library. The Filter Library page appears.
3. Select the Value Set you want to run on the Active Case Series you generated in step 1.
4. Check the Limit Query to Active Case Series checkbox.
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. In Argus Insight, Advanced Conditions are created 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).

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

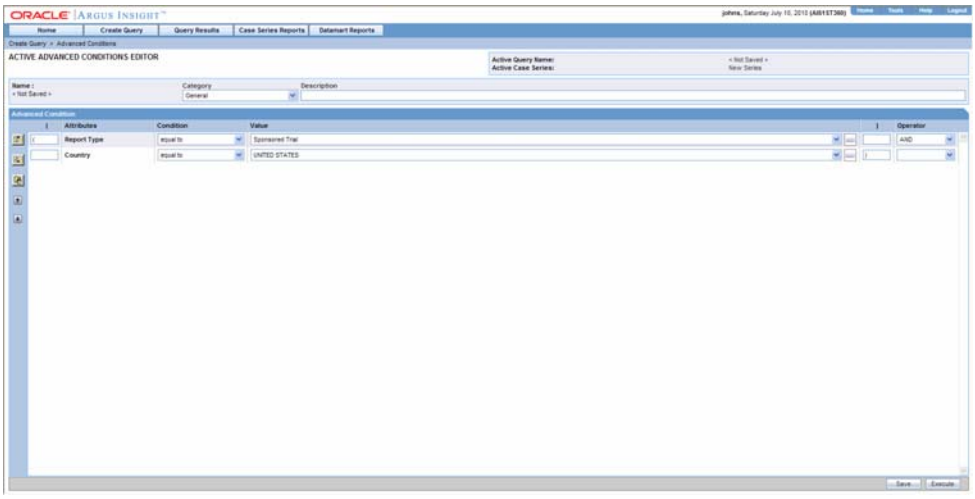
Converting a Value Set to an Advanced Condition

A *Filter* Value Set can be used to start an Advanced Condition that employs Set or Boolean operations between elements that have multiple values. When you convert a Value Set to an Advanced Condition, al its fields are listed in the **Active Advanced Conditions Editor** page as Advanced Condition attributes.

Use the following procedure 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 **Filters Library** page (seeWorking with Saved Value Sets).
2. Verify the *field* values you specified in the various fields in the Value Set.
3. Click the **Convert to Advanced Condition** button. The **Active Advanced Condition Editor** page appears; all the fields in which you specified values in the

QBE *form* are listed as Advanced Condition attributes. The fields in which you selected multiple values are repeated.



In the Advanced Condition editor, you can 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 Set and Boolean operators to join the various attributes

See theAdvanced Conditionssection for detailed information on building Advanced Conditions by using the options in the Advanced Condition editor.

Integrating a Value Set with an Advanced Condition

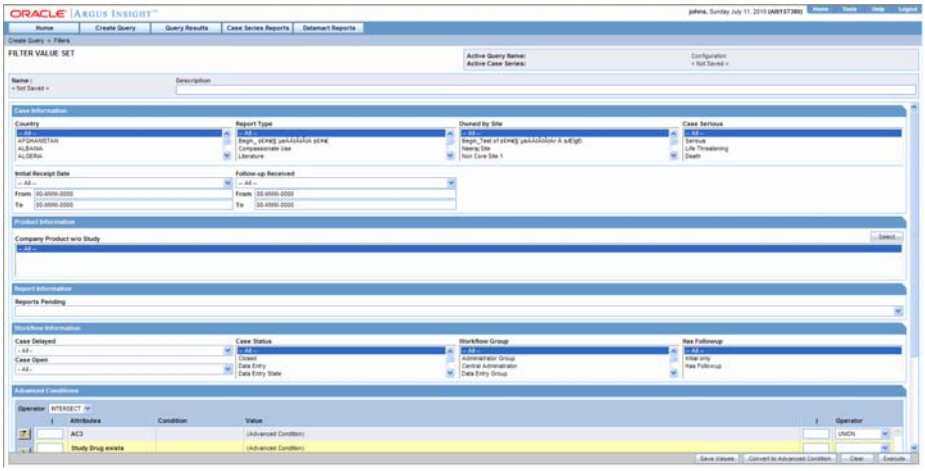
Argus Insight lets you integrate a Value Set with an existing Advanced Condition through these Set operators: Intersect, Minus, or Union. If required, you can integrate a Value Set with multiple Advanced Conditions. The multiple Advanced Conditions can have Set or Boolean operations between them.

> **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 wish to convert a custom*Filter* Value Set to an Advanced Condition, make sure you select the **Advanced Condition** element while creating the custom Filter.

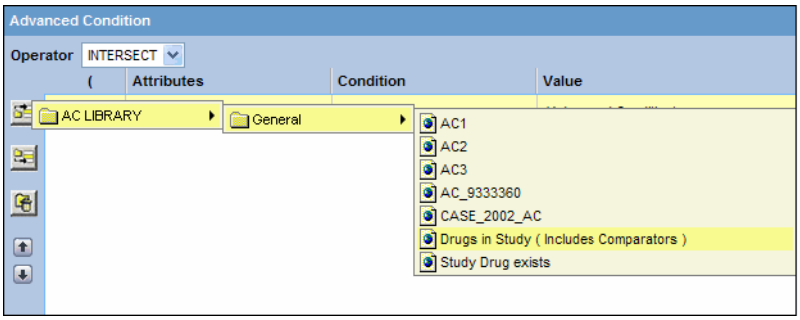
Use the following procedure to integrate a Value Set with existing Advanced Conditions.

1. Create a new Value Set by eitherUsing Predefined FiltersorCreating Custom Filters. Alternatively, open a saved Value Set from the **Filters Library** page (seeWorking with Saved Value Sets). If you create a custom Value Set, make sure you include the Advance Condition element.

2. In the **Filter Value Set** page, verify the *field* values you specified you specified for the Value Set.
3. Scroll down to the **Advanced Condition** section in the **Filter Value Set** page.



4. Use the **Operator** list box to specify the Set operator you want to use to integrate the Values Set and the Advanced Condition. You can select one of these options: **Intersect**, **Minus**, **Union**.
5. Select the Advance Condition you want to integrate with the QBE.
6. Click the context menu icon. A context menu appears. In the context menu, all the Advanced Conditions stored in the system are organized by categories.



7. In the context menu, browse to the appropriate category and select the required Advanced Condition. The selected Advanced Condition appears as a row in the Advanced Condition editor.
8. If required, add other Advanced Conditions. Click the icon to insert another Advanced Condition above the existing Advanced Condition. Click the icon to insert another Advanced Condition below the existing Advanced Condition.

   Tip: You can change the structure of the*query* by changing order of rows in the editor. To do this, select a row and click the arrow button to move the row up or down.

9. Type parentheses in the **(** and **)** columns to determine the order of execution for the selected Advanced Conditions.

10. Use the list box in the **Operator** column to specify the operators between the selected Advanced Conditions. You can select from these options: **AND**, **OR**, **Intersect**, **Minus**, and **Union**.

> **Note:** See theAdvanced Conditions chapter for detailed information on creating Advanced Conditions by using the options in the Advanced Condition editor.

11. Save the integrated query by clicking **Save As**.

> **Note:** You can convert the integrated Value Set and Advanced Condition into a single Advanced Condition by clicking **Convert to AdvancedCondition**. SeeConverting a Value Set to an Advanced Condition for details.

12. Click **Execute** to run the integrated Value Set and generate the Case Series. The **Active Case Series** page appears; the Case Series is displayed. See theCase Serieschapter for more information on working with Case Series.

Advanced Conditions

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

> **Note:** The Advanced Conditions field labels are displayed as per the field labels configured in Argus.

In Argus Insight, Advanced Conditions are created 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).

Refer to the following topics for more information on working with Advanced Conditions.

- Creating a New Advanced Condition
- Working with the Last Modified or Saved Advanced Condition
- Working with Saved Advanced Conditions

Creating a New Advanced Condition

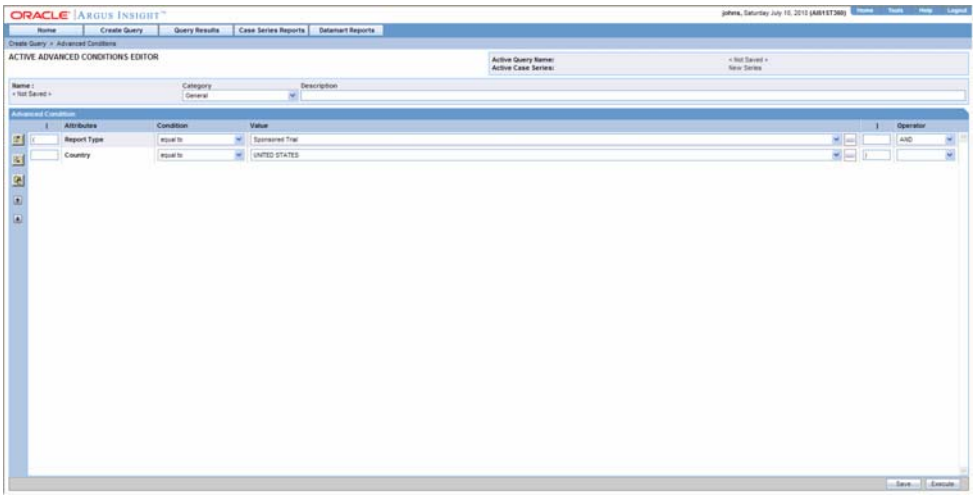
This topic explains how to:

- Start a new Advanced Condition
- Use the Advanced Condition Editor options to build your Advanced Condition
- Generate a Case Series by executing the Advanced Condition

Starting a New Advanced Condition

Use the following procedure to start a new advanced condition.

1. Start the new Advanced Condition. Select Create Query > Advanced Conditions > New. The Advanced Conditions Editor page appears.



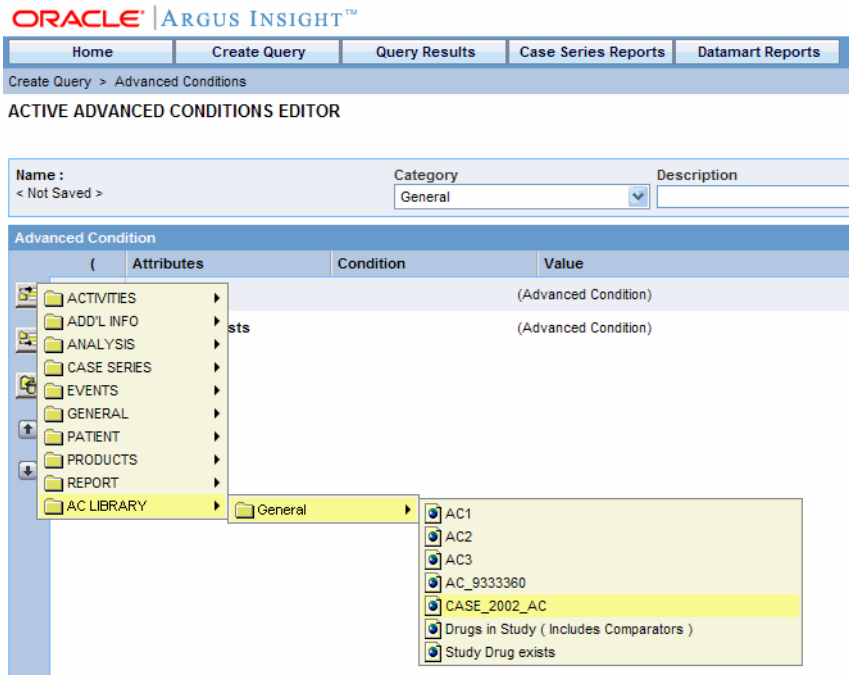
Note: You can also start an Advanced Condition by converting a Advanced Condition or a *Filter* Value Set to Advanced Condition. See these topics for details: Converting a Advanced Condition to an Advanced Condition and Converting a Value Set to an Advanced Condition.

2. Enter the Advanced Condition attributes (fields and values)

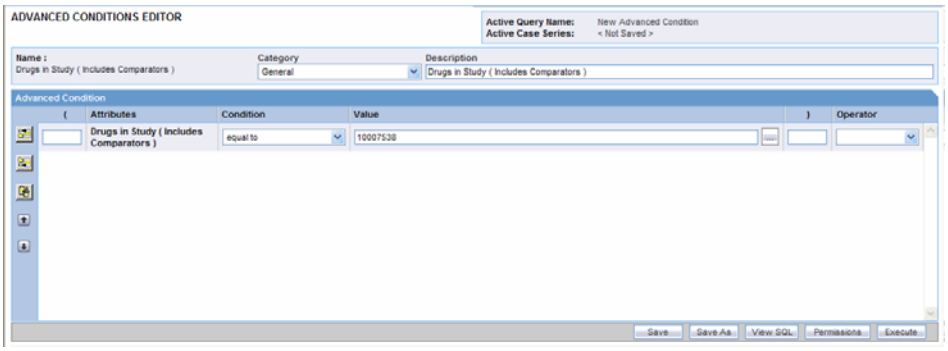
3. Click the context menu icon. A context menu appears. In the context menu, the first seven categories (**Activities**, **Additional Info**, **Analysis**, **Events**, **General**, **Patients**, and **Products**) represent the Argus case form tabs. In these categories, the various datamart fields that pertain to case information are organized in this hierarchy: Argus case form tab > sections within the tab page > Fields within the section. You can browse through the appropriate hierarchy and select the required *field* as an Advanced Condition attribute.

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

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



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



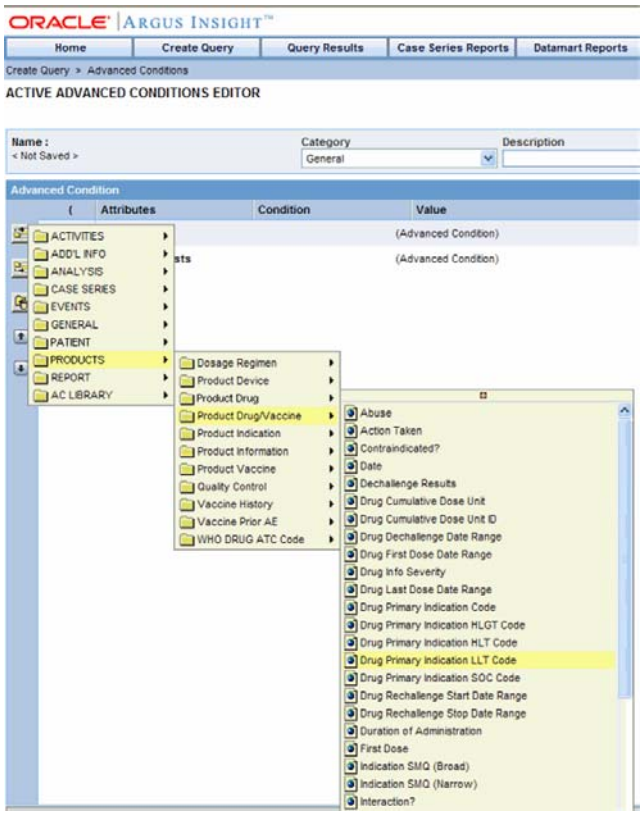
> **Note:** The user defined fields in Argus which have been converted as a look up are also available as attributes for the advanced condition search.

5. In the **Value** field, enter the value for the selected attribute. Depending on the type of attribute you selected, the system lets you populate the **Value** field by using a:
   - List box 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.

- Use the following procedure to use a Browser to populate the **Value** field, click the ellipsis button next to the **Value** field; in the context menu that appears, select the option corresponding to the browser name to launch the browser.

Note: The MedDRA browser for **Create Query > Advanced Conditions** tab, can be called for search criteria based on specific terms. The search criteria can be based on the specific term codes or descriptions depending on your requirement. Refer to the following**example** for more information.

1. Select the **Attribute** from the **Advanced Condition** *form*.
2. The Attribute chosen in the sample example is **Product > Product Drug > Product Indication PT.**The PT description of the **Product Indication** is returned to the Advanced Condition Page.



3. Select the **Condition**, **Value** and **Operator** depending on your search-criteria.
4. Click **Execute** to run the Advanced Condition *query*.

---

6. Specify the condition for the attribute value. Use the **Conditions** list box to specify a condition as explained below:

equal to - select this option if you want to retrieve cases where the selected attribute's value is equal to what the **Value** field specifies	**not equal to** - select this option if you want to retrieve cases where the selected attribute's value is not equal to what the **Value** field specifies

greater than - select this option if you want to retrieve cases where the selected attribute's value is greater than what the **Value** field specifies	**greater than or equal to -** select this option if you want to retrieve cases where the selected attribute's value is greater than or equal to what the **Value** field specifies
less than - select this option if you want to retrieve cases where the selected attribute's value is less than what the **Value** field specifies	**ess than or equal to** - select this option if you want to retrieve cases where the selected attribute's value is less than or equal to the **Value** that the field specifies
missing - select this option if you want to retrieve cases where the selected attribute's value has not been specified	**exists -** select this option if you want to retrieve cases where the selected attribute has any value
begins with - select this option if you want to retrieve cases where the selected attribute's value begins with what the **Value** field specifies	**contains** - select this option if you want to retrieve cases where the selected attribute's value contains what the **Value** field specifies
does not contain - select this option if you want to retrieve cases where the selected attribute's value does not contain what the **Value** field specifies	**in** - select this option if you want to retrieve cases where the selected attribute's value exists in what the Value field specifies
not in - select this option if you want to retrieve cases where the selected attribute's value does not exist in what the Value field specifies	Specify the operator. Use the **Operator** list box to specify the Boolean or Set operator through which you want to join the attribute with another attribute.
Add more attributes. Follow steps 2 through 4 to add more attributes to your Advanced Condition. Click the icons on the left bar to insert another attribute above or below the existing attribute.	

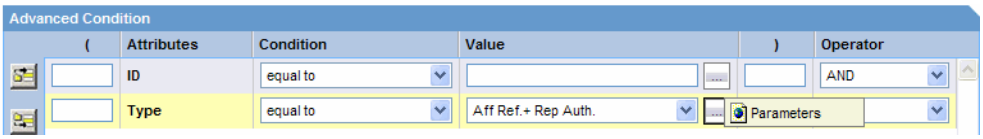
Tip: You can change the structure of the **Advanced Condition** query by changing the order of attribute rows in the editor. Use the following procedure to do this, select a row and click the Up or Down arrow buttons to move the row up or down. To delete a row from the editor, select the row and click the Delete icon.

7. Specify runtime parameters, as appropriate.

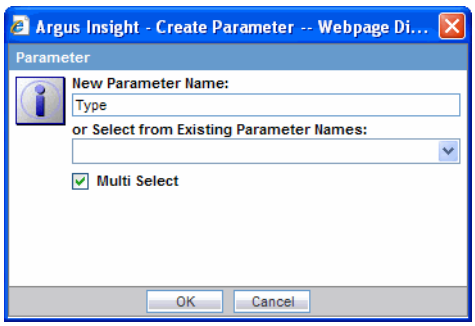
Note: Argus Insight lets you create Advanced Conditions which when executed, ask for user-specified values for certain attributes to generate the Case Series. For example, you may create an Advanced Condition in which the Case Number or the Product name may be specified only at the time of execution.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

8. Identify the attribute row where you want to specify runtime parameters.
9. Click the ellipsis button next to the **Value** field. A context menu appears.
10. Select the **Parameters** option.



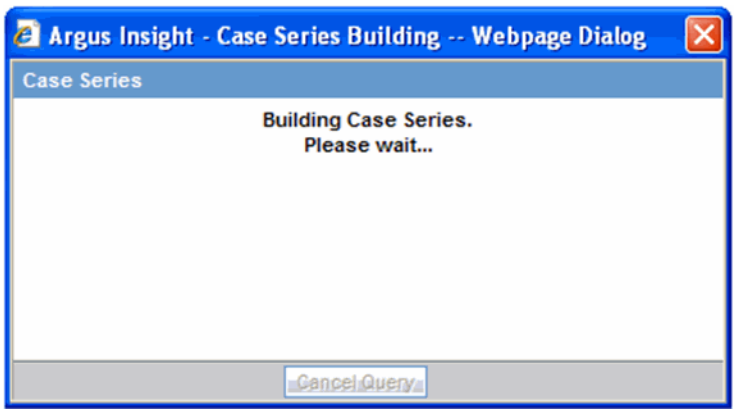
11. Click **Parameter**. The following dialog box appears.



12. Check the **Multi Select** checkbox 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.
13. Click **OK**. The field you configured as a runtime parameter is displayed in the **Value** text box enclosed within % symbol. For example, %Product Type% If you configured the field to accept multiple runtime parameters, the field name appears in the **Value** text box enclosed within %% symbol. For example, %%Product Type%%.
14. Type parentheses in the **(** and **)** columns to determine the order of execution for the selected Advanced Conditions, as appropriate.

> **Note:** Refer the **Advanced Condition Creation Process** section for further details on creating an **Advanced Condition**.

15. Examine the Advanced Condition result.
16. Click **Execute**. While the system searches for matching cases, the following dialog box is displayed.



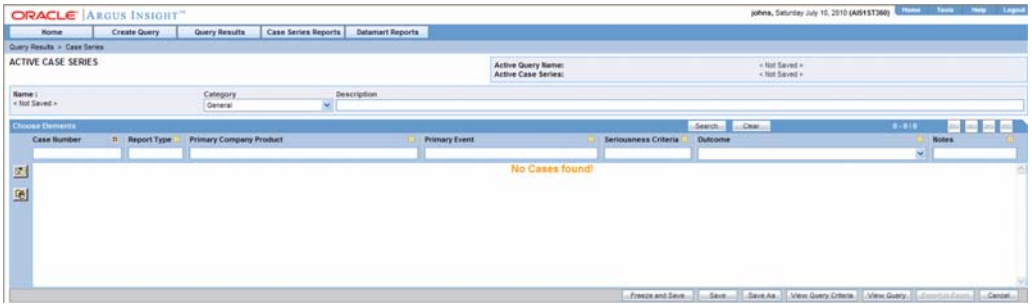
Tip: You may cancel the query execution at this point and return to the Advanced Condition Editor by clicking **Cancel Query** in the dialog box above.

- If you configured any runtime parameters, the **Parameters** dialog box appears. Specify the parameter values by using the options in the dialog box. Next, click **Execute**; the system retrieves the matching cases from the datamart and displays them in the **Active Case Series** page.

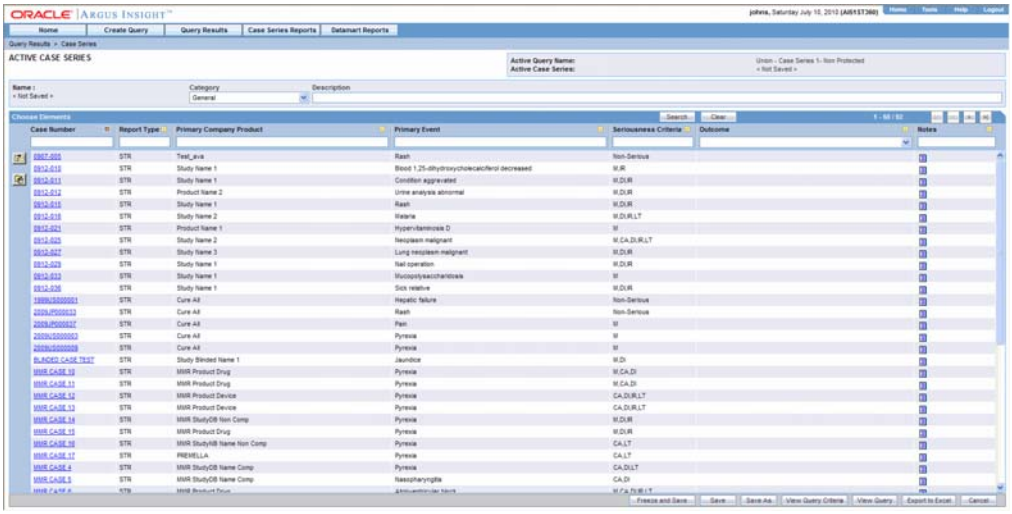
  Tip: If you select one run-time parameter and execute the search, you must enter a field.

  If you select multiple run-time parameters and execute the search, you have the option to ignore the run-time 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 Condition Editor, modify the criteria and execute again.



- If the system finds cases that match the query criteria, a list of such cases is displayed in the **Active Case Series** page.



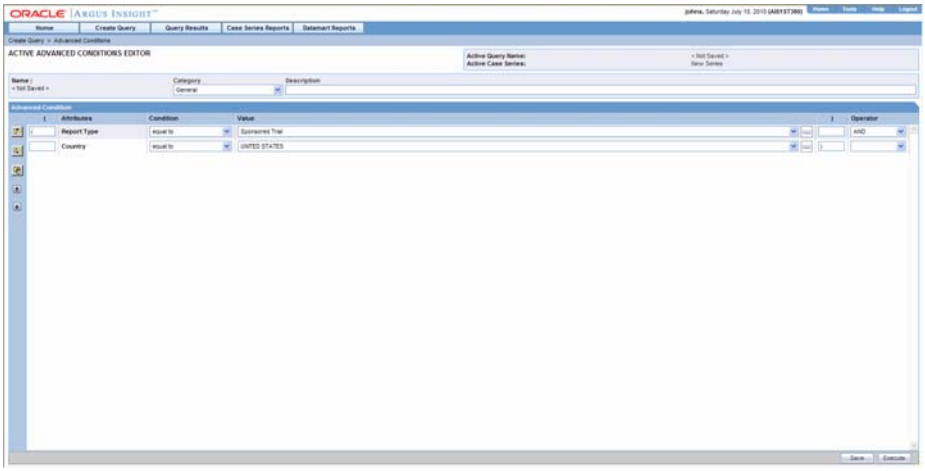
17. Examine the Case Series. If the Case Series is too large, you may want to modify the Advanced Condition by specifying additional attributes or changing values. Alternatively, if you find the Case Series to be appropriate, you can save the Advanced Condition to the system.

    The system retrieves the matching cases from the datamart and displays them in the **Active Case Series** page.

Returning the to Advanced Condition Editor

Use the following procedure to return to the Advanced Condition Editor.

1. Click **View Query** in the **Active Case Series** page. The **Active Advanced Condition Editor** page appears.



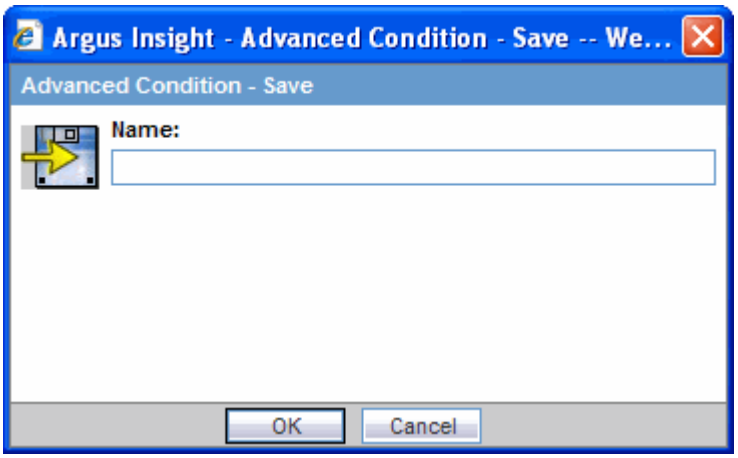
> **Note:** When you save the modifications to an Advanced Condition or execute it, the system assigns the Active status to the Advanced Condition. Therefore, when you return to the editor after executing the Advanced Condition, the page title changes to **ActiveAdvanced Condition Editor**. The field values you specified in the editor before executing are retained. See theWorking with the Last Modified or Saved Advanced Condition topic for details on Active Advanced Conditions.

2. If required, modify the Advanced Condition and examine the result again or proceed to save the Advanced Condition.
3. Save the Advanced Condition.

Assigning a Category to an Advanced Condition

Use the **Category** list box to assign a category to the Advanced Condition. A category indicates the reporting aspect to which your Advanced Condition pertains: **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** text box. For example, you can describe the type of cases the Advanced Condition retrieves.
2. Click **Save** in the Active Advanced Condition Editor page. The Save Advanced Condition dialog box appears.



3. Type the name of the Advanced Condition in the **Name** text box.
4. Click **OK**. The system refreshes the Active **Advanced Condition Editor** page. Note that the following new elements appear on the page.
5. 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.
6. Three new buttons appear at the bottom of the page: **Save As**, **View SQL** and **Permissions**.

Note: All the Advanced Conditions that you save to the system are listed in the **Advanced Condition Library** page. TheWorking with Saved Advanced Conditions topic explains how to work with saved Advanced Conditions

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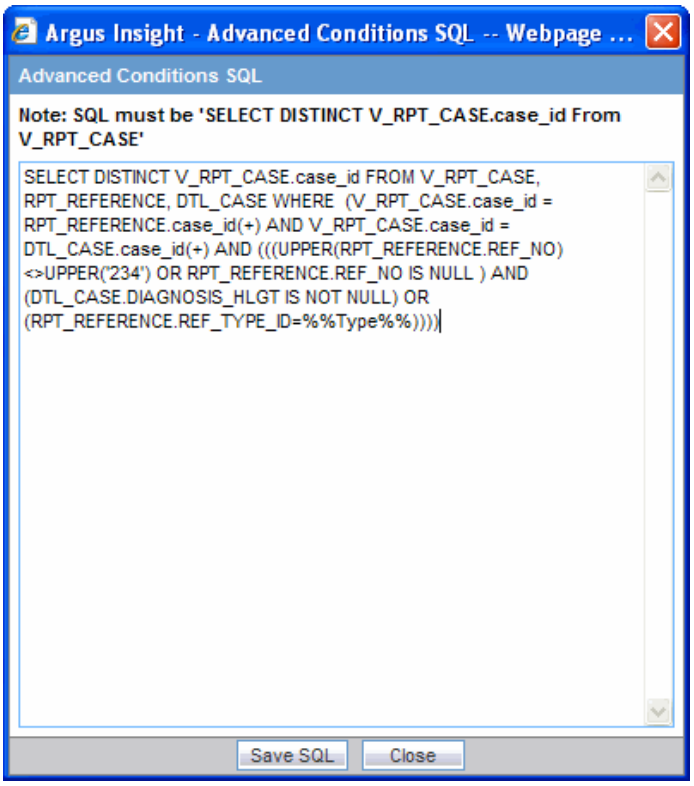
Tip: If you modify the field values after saving the Advanced Condition to the system, use the **Save** button to save the changed field values.

7. Click **View SQL** to view the underlying SQL query for the Advanced Condition.

   View SQL helps you to view and edit the underlying SQL for the Advanced Condition created.



- Click Save SQL after editing the query.

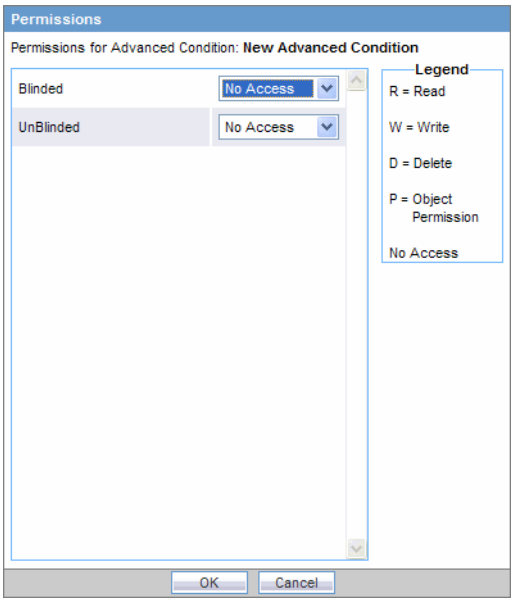
Note: When using this Save SQL functionality the Advanced Condition can be executed only from the Advanced Conditions library and the Query Library page.

The View SQL textbox can have a maximum of 4000 characters.

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

- Click Close.

8. Assign group-level permissions on the saved Advanced Condition.
9. Click the **Permissions** button. The **Permissions** dialog box appears. A list in this dialog box displays the names of all the groups (except the **Administrator** group) that the system administrator has created.



10. Use the list box 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
No Access (Default)	No group members will be able to access the Advanced Condition
R	Group members will be able to only view the Advanced Condition
R/W	Group members will be able to view and modify the Advanced Condition
R/W/D	Group members will be able to view, modify, and delete the Advanced Condition
R/W/D/P	Group members will be able to view, modify, delete, and assign permission on the Advanced Condition

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

11. Click **OK**. The system saves the permission settings.
12. Click **Execute** to generate the Case Series.
    - The system retrieves the matching cases from the datamart and displays them in the **Active Case Series** page.
    - If you configured any runtime parameters, the **Parameters** dialog box appears. Specify the parameter values by using the options in the dialog box. Next, click **Execute**; the system retrieves the matching cases from the datamart and displays them in the **Active Case Series** page. See the Case Series chapter for more information on working with Case Series.

Creating an Advanced Condition

Use the following Order of precedence for the various operators selected when creating an Advance Condition.

Order	Operator	Use
1	And	Use with all fields available in Advanced Condition.
2	Or	Use with all fields available in 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.

PL/SQL syntax should be kept in mind while creating an Advanced Condition.

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

Now 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 wants to intersect the results of this Advanced Condition with the existing Advanced Condition

Where country = "United States" or country = "Australia"

Then you should create the Advanced Condition as shown in the screen shot below.

The user needs not to take care of parenthesis if the PL/SQL syntax and the order and precedence of operators are taken care off.

The following SQL will get generated in this case.

SELECT DISTINCTv_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)

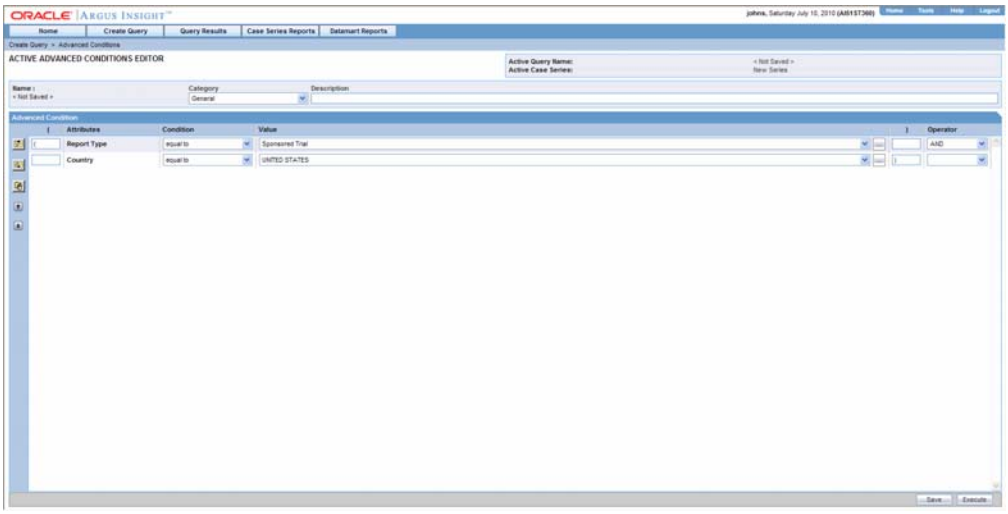
OR (v_rpt_case.country_id = 223))

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.

Use the following procedure to view an active Advanced Condition,

1. Select Create *Query* > Advanced Condition > Active. The **Active Advanced Conditions Editor** page displays the Advanced Condition you executed or modified last.



2. If the Active Advanced Condition was saved to the system before executing, the name of the Advanced Condition appears next to the **Active Query Name** and **Name** label. However, if the Active Advanced Condition was not saved to the system before executing, the text **<Not Saved>** is displayed next to the **Active Query Name** label.

   From the **Active** Advanced Condition page, you can per*form* the following tasks:

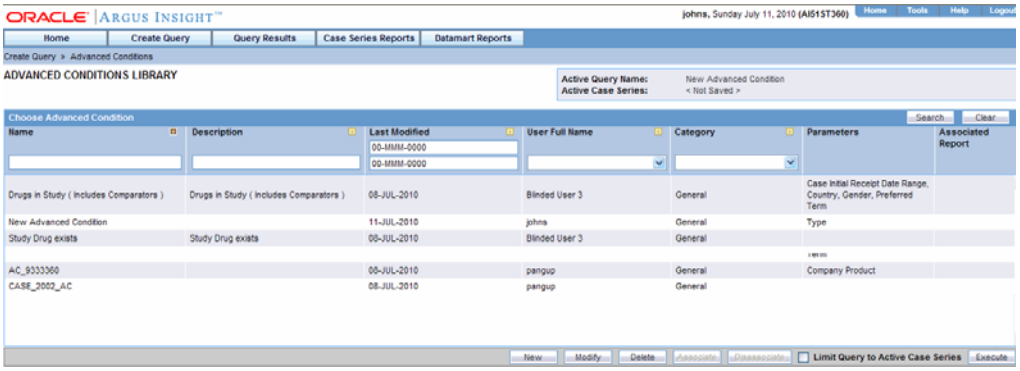
Task	Description
Modify the attributes in the Advanced Condition editor	If required, you can modify the attributes (fields and values) in the Advanced Condition editor. See theCreating a New Advanced Conditiontopic for information on working with the Advanced Condition editor. Use the **Save** button to save the changed *field* values. This button is only available for a saved Active Advanced Condition.
Save Active Advanced Condition with another name	Click **Save As** to save the Active Advanced Condition by a different name. The Advanced Conditions that you save to the system are listed in the **Advanced Condition Library** page. TheWorking with Saved Advanced Conditionstopic explains how to work with saved Advanced Conditions.
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 theCreating a New Advanced Conditiontopic for information on setting permissions. 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** text box. 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 Condition 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 Condition editor and execute the Advanced Condition without saving the modifications.

Working with Saved Advanced Conditions

The **Advanced ConditionsLibrary** page lists all of the Advanced Conditions saved to the system. To access this page, select **Create Query > Advanced Conditions > Library.**



The **Advanced Condition Library** page displays a list of the saved Advanced Conditions in a grid format. The descriptions of the grid columns follow.

Column	Description
Name	Displays the name of the Advanced Condition
Description	Displays the Advanced Condition description
Last Modified	Displays the date when the Advanced Condition was last modified
User Full Name	Displays the name of the user who created the Advanced Condition
Category	Displays the category assigned to the Advanced Condition
Parameters	Displays the name of fields for which a runtime parameters need to be specified while executing the Advanced Condition
Report	The icon indicates that a report is associated with the Advanced Condition See theAssociating an Advanced Condition with a Reportsection below for more information.

Searching Saved Advanced Conditions

Use the following procedure 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 also 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** list box.
- To search for an Advanced Condition by its category, select the category from the **Category** list box.

2. Click **Search**.
3. Based on your search criteria, the system displays the search result in a list.
4. You can sort the search result list by clicking the sort icon next to the column headers in the list.
5. To clear the search result and display all the Advanced Conditions in the list, click the **Clear** button.

Creating a New Advanced Condition

Use the following procedure to create a new Advanced Condition.

1. Click the **New** button in the **Advanced Condition Library** page.

See theCreating a New Advanced Condition topic for details.

Modifying an Advanced Condition

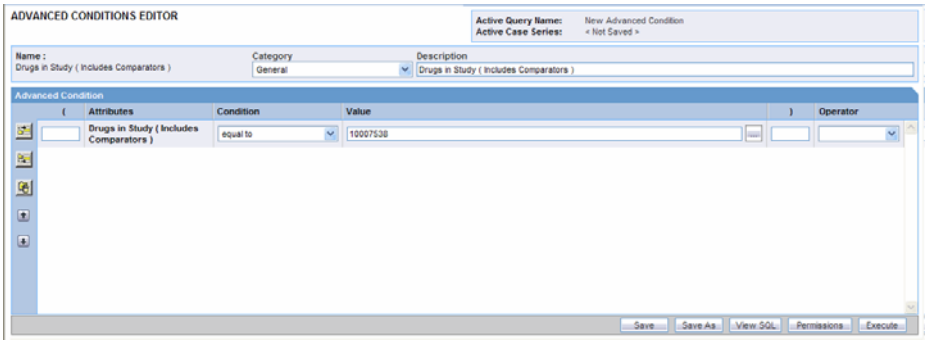
Use the following procedure to modify an Advanced Condition:

1. Select the Advanced Condition from the list in the **Advanced Condition Library** page.
2. Click **Modify**. The Advanced Condition editor appears
3. Make your modifications to the Advanced Condition, as appropriate.
4. Click **Save** to save the modifications you made. Alternatively, click **Save As** to save the modified Advanced Condition by another name.

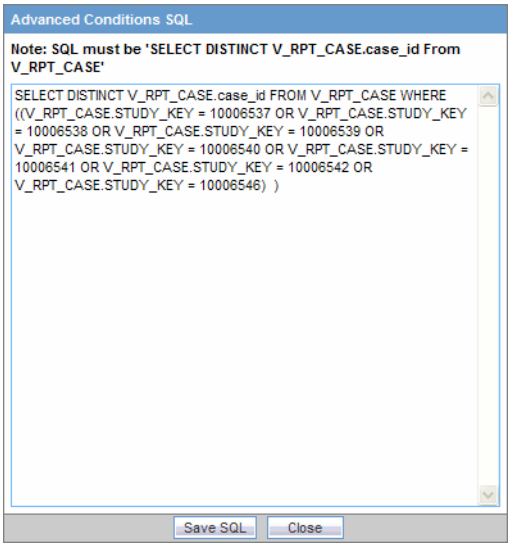
Modifying the SQL of an Advanced Condition

Use the following procedure to modify the SQL of an Advanced Condition:

1. Go to the Advanced Conditions Library page.
2. Select a particular Advanced Condition and click **Modify**. **The Active Advanced Conditions Editor** screen appears.



3. Click View SQL. The **Advanced Conditions SQL** dialog appears.



4. Modify the SQL as per your requirement and click Save SQL. The SQL is saved and the **Advanced Conditions SQL** dialog appears.
5. Click Close. The **Advanced Conditions Library** page appears.
6. Select the modified Advanced Condition and click Execute. You will get the results as per modified SQL.

> **Note:** You can not modify an Advanced Condition once you have added user defined SQL in that, you can modify SQL but can not add new items in Advanced Condition.
>
> If you want to add new items, you have to revert the SQL to original by clicking on the Revert to Original button.

Deleting an Advanced Condition

Use the following procedure to delete an Advanced Condition

1. Select the Advanced Condition from the list in the **Advanced Condition Library** page.
2. Click **Delete**. The delete confirmation dialog box appears.
3. Click **OK**. The system deletes the selected Advanced Condition; the **Advanced Condition Library** page appears.

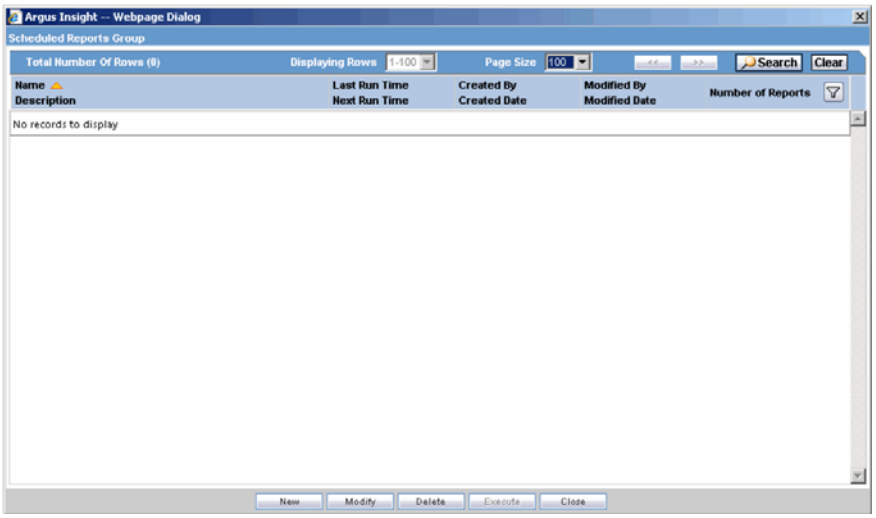
Associating an Advanced Condition with a Report

Argus Insight lets you associate an Advanced Condition to a particular Standard Report and schedule a time when the report needs to be generated and sent to another user through email. This is helpful in situations when you need generate the latest Case Series and run a report on it each time the datamart is refreshed. Instead of manually executing the Advanced Condition to generate the latest Case Series and running the report, you can use the report association functionality of Argus Insight.

> **Note:** The user who is scheduling reports should have an enterprise login configured in Cognos to schedule the report.

Use the following procedure to associate an Advanced Condition with a Standard Report:

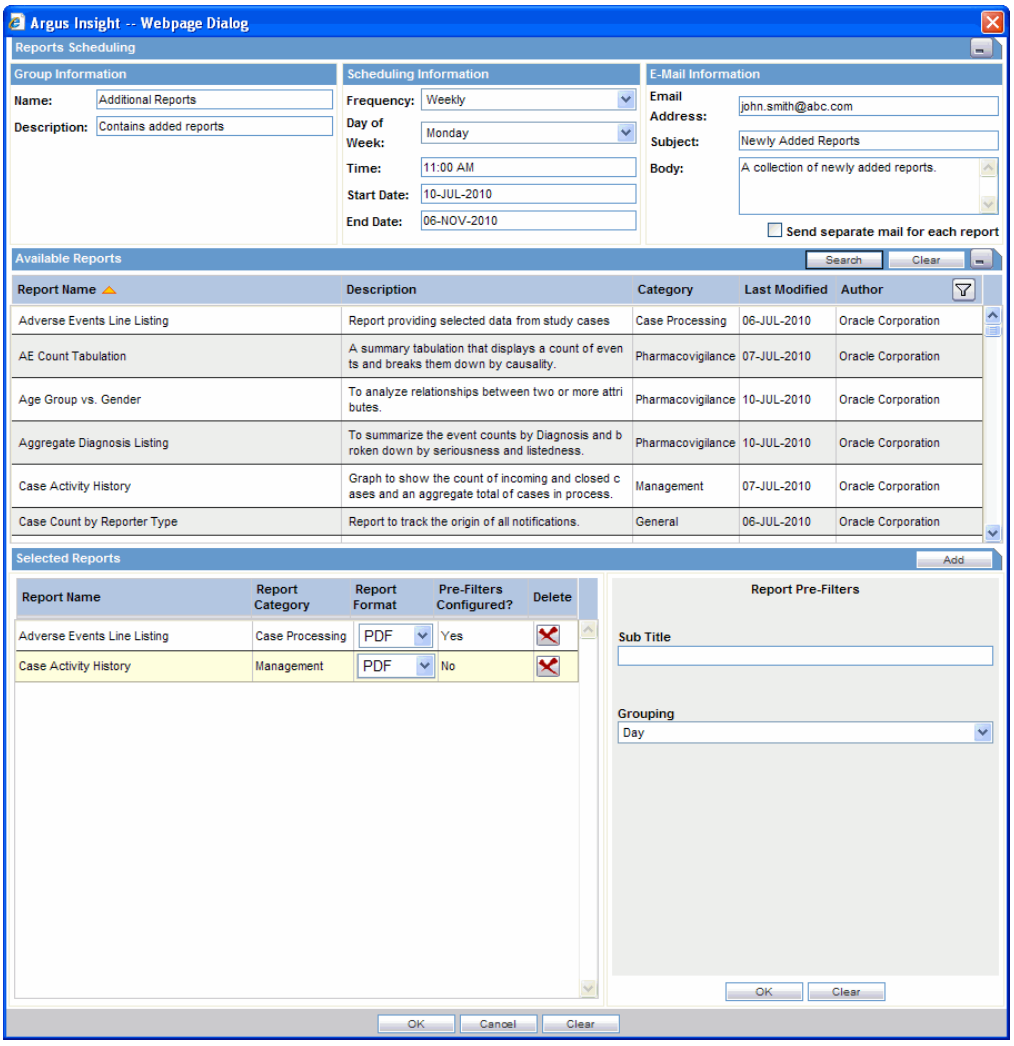
1. On the **Advanced Condition Library** page, select the Advanced Condition that you wish to associate with a Standard Report.
2. Associate the Advanced Condition with a Standard Report.
3. Click **Associate**. The **Scheduled Reports Group** dialog box appears. This page displays a list of all groups of reports which were scheduled or associated with the query.



4. Click **New** and a context menu will appear. Select **Scheduling** option.
5. The **Reports Scheduling** window will appear.
6. On this window, you can schedule multiple reports at once.
7. Schedule the report.

   This window has 3 main sections:

   - **Scheduling Information** - The Schedule timing and E-Mail information
   - **Available Reports** - All the available reports in the system that can be scheduled.
   - **Selected Reports** - These reports will be scheduled.

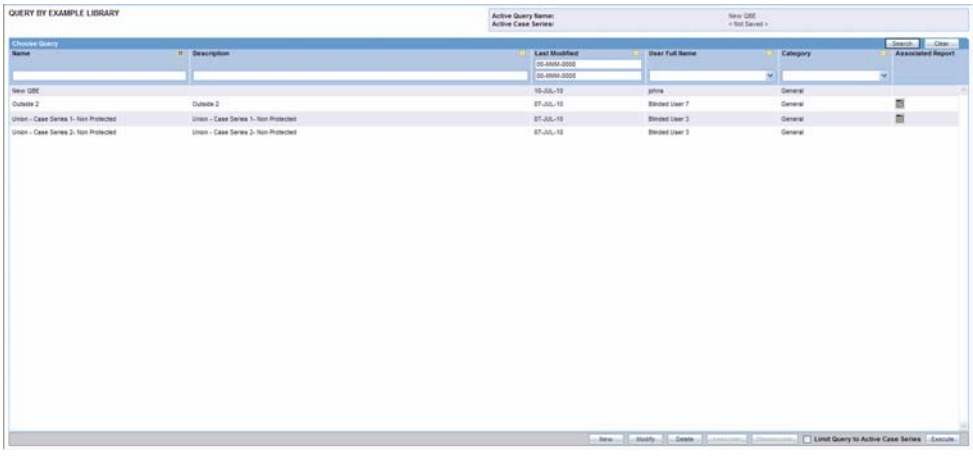


8. Provide a Name for your reports group along with description.
9. Use the **Frequency** list box to specify how often you wish to have the system run the selected QBE and generate the selected report. The options available are: **Once**, **Daily**, **Weekly**, **Monthly**, **Quarterly**, and **Yearly**.
10. Specify the schedule time in the **Time** field.
11. Based on the option you selected in the step above, specify the instant when you want the report generated as described in the table below.

Frequency Option Selected	Additional Scheduling Information to Specify
Once	In the **Date** text box that appears, enter the date when you want to have the report generated.
Daily	In the **Time** text box that appears, enter the time when you want to have the report generated. The time must be entered in the HH:MM AM/PM format. Hours should be between 1 and 12.
Weekly	From the **Day of Week** option button group that appears, select the day of week on which you want to have the report generated. Also, specify the time in the **Time** text box.

Frequency Option Selected	Additional Scheduling Information to Specify
Monthly	Use the **Day** list box to select the day of the month on which you want to have the report generated. Also, specify the time in the **Time** text box.
Quarterly	Quarterly reports are generated on the first day of the quarter. In the **Time** text box, enter the time when you want to have the report generated on the first day of the quarter.
Yearly	In the **Date** and **Time** text boxes, specify the date and time when you want to have the yearly report generated.

12. Specify the email recipients of the report you scheduled.
13. In the **Email Address** text box, type the email address of the report recipient. If there are multiple recipients, use a semicolon to separate their email addresses.
14. Type the subject line in the **Subject** text box.
15. Type the email body text in the **Body** text box.
16. If you want all the reports in a single mail, leave the **Send separate mail for each report** checkbox unchecked. If you check this checkbox, each report will be delivered in a separate mail to the user.
17. From the Available reports grid, select a report and click **Add** button. The report will be selected and will appear in the **Selected Reports** section.
18. To remove a report from **Selected Reports**, click the X button against the report.
19. For each selected report, you must fill the Pre-filters associated with each report. To do this, click on any report in the **Selected Reports** grid and the pre-filters will appear beside it. Fill them and click the **OK** button of Report Pre-Filters section.
20. Click **OK**. The system associates the Advanced Condition with the selected report and saves the scheduling information; the **Advanced Condition Library** page appears. The icon displayed in the **Report** column indicates that the Value Set is associated with a report.

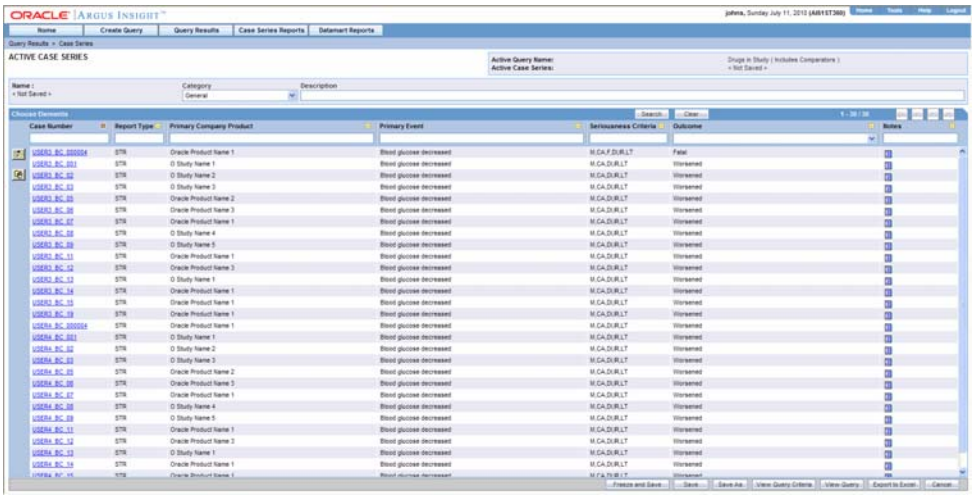


Refer to the Associated Library and Query Library sections in the Library chapter, to view the steps on how to disassociate reports in those libraries.

Executing an Advanced Condition

Use the following procedure to execute an Advanced Condition:

1. Select an Advanced Condition from the list in the **Advanced Condition Library** page.
2. Click **Execute**. The system executes the Advanced Condition; the **Active Case Series** page appears.



3. If a **report** is associated with the saved Advanced Condition, click on **Execute** button. The **Active Case Series** page and **Pre Filter** page of the associated report is displayed.
4. Enter the prompts value in the Pre Filter page.
5. Click on the Execute button to generate the report.

After generating the Case Series, you can manually modify it or save it. See the Case Series chapter for more information on working with Case Series.

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.

Use the following procedure to narrow down the list of cases in the Active Case Series, you may want to run an Advanced Condition on an Active Case Series.

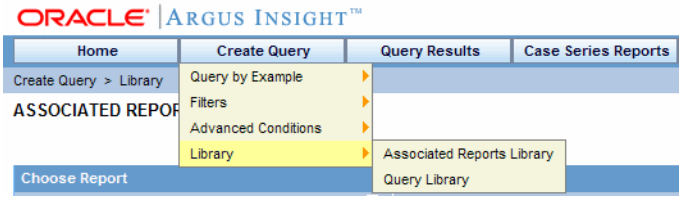
1. Generate the Case Series on which you wish to run another Value Set:
   - You can generate the Case Series by either using QBE, Filters, or Advanced Conditions. This Case Series automatically becomes the Active Case Series and remains so until you execute another query to generate a different Case Series.
   - Alternatively, if the Case Series on which you wish to run another Value Set is already saved in the system, select **Query Results > Case Series > Case Series Library**. In the **Case Series Library** page that appears, select the Case Series title and click **Make Active**.
2. Select Create Query > Advanced Conditions > Library. The Advanced Condition Library page appears.
3. Select the Advanced Condition you want to run on the Active Case Series you generated in step 1.
4. Check the Limit Query to Active Case Series checkbox.

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.

Library

Argus Insight provides a library that serves as a repository for all queries. This library comprises all the query searches performed for QBE, Filters, and Advanced Conditions. In addition, the Associated Library feature enables you to search for those queries, which have a report associated with them.

Go to **Create Query>Library** to view the components of the **Library** menu.



This chapter discusses the following components that comprise the Library menu in Argus Insight:

- Associated Reports Library
- Query Library

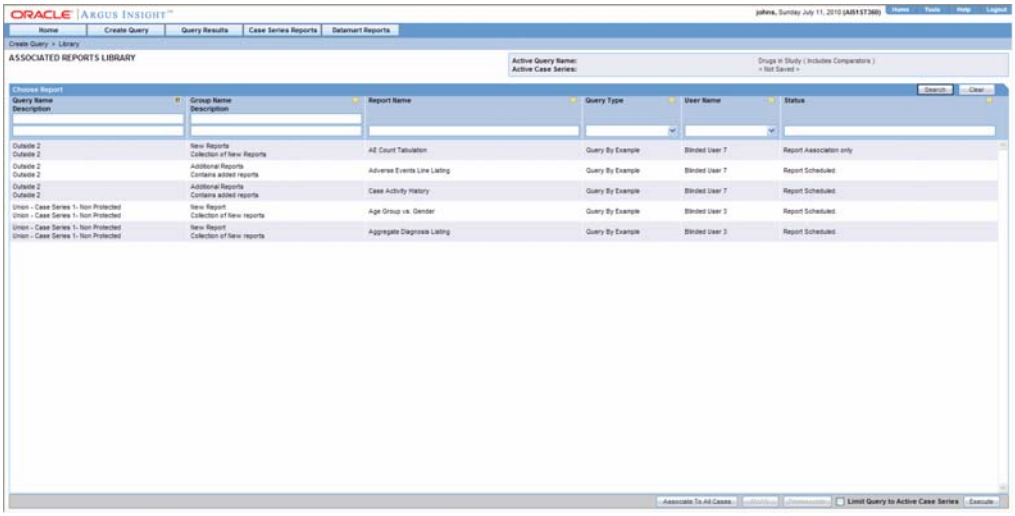
> **Note:** To use LDAP configuration in Argus Insight, your Cognos administrator must configure LDAP on the Cognos Server.

Associated Reports Library

The Associated Library feature enables you to view all the reports associated with a query.

1. Open **Create Query>Library>Associated Reports Library** to view a list of all the reports that are associated with a query.

   The following screen is displayed:



The following table describes the columns in this page:

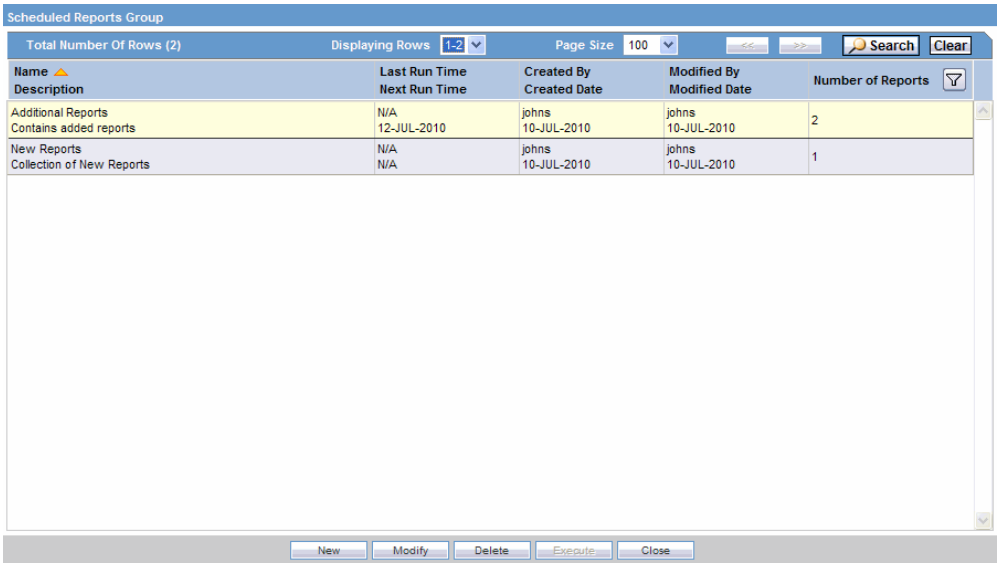
Column	Description
Name	Displays the name of the query that is associated with the report.
Description	Displays the description of the query associated with the report.
Last Modified	Displays the date when the query was last modified.
Query Type	Displays the type of query associated with the report.
User Full Name	Displays the name of the author of the query.
Category	Displays the category where the query is saved.
Report Name	Displays the name of the report associated with the query.
Limit Query to Active Case Series	Enables you to limit the query to the active case series.

Modifying a Query in the Associated Reports Library

Use the following procedure to modify a query in the associated library:

1. Select the query from the list in the **Associated Reports Library** page.
2. Click **Modify**.

   This displays the **Scheduled Reports Group** page.



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

Deleting a Query in the Associated Reports Library

Use the following procedure to delete a query from the associated library.

1. Select the query from the list in the Associated Reports Library page.
2. Click **Delete**.

3. The **Delete Confirmation** dialog appears.
4. Click **OK**.

Disassociating a Report in the Associated Reports Library

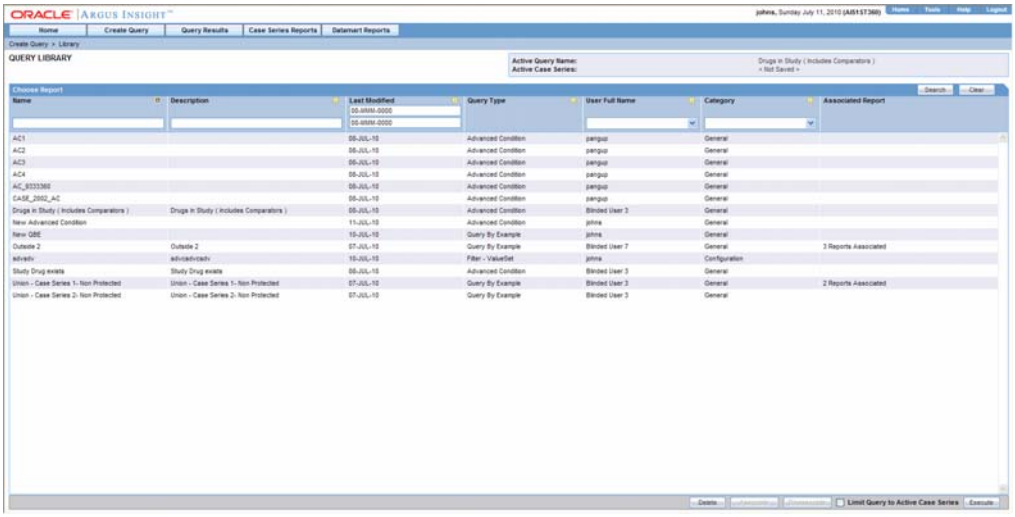
Use the following procedure to disassociate a report from the associated report library:

1. Select the report from the list in the **Associated Reports Library** page.
2. Click **Disassociate**.
3. The **Disassociate Report** dialog appears.
4. Click **OK**.

Query Library

The **Query Library** feature enables you to view all the queries. Select **Create Query>Library>Query Library** to view a list of all the queries.

The following screen is displayed:



The following table lists the descriptions of the columns in this page:

Column	Description
Name	Displays the name of the query.
Description	Displays the description of the query.
Last Modified	Displays the date when the query was last modified.
Query Type	Displays the type of query.
User Full Name	Displays the name of the author of the query.
Category	Displays the category where the query is saved.
Report Name	Displays the name of the report associated with the query.
Limit Query to Active Case Series	Enables you to limit the query to the active case series.

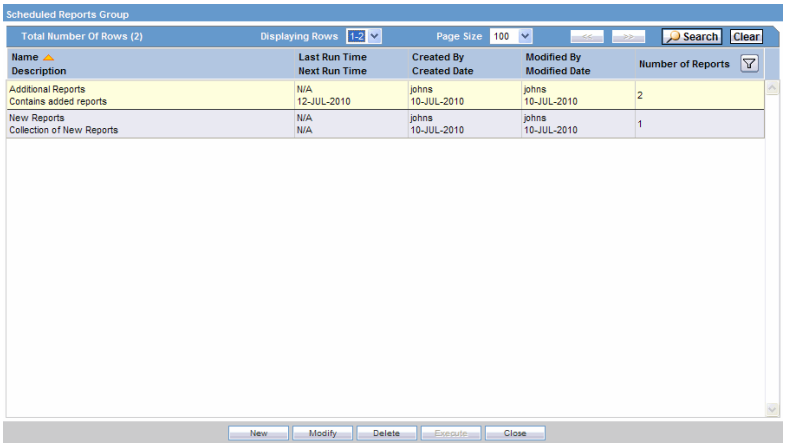
Associating a Query in the Query Library

Use the following procedure to modify a query in the query library:

1. Select the query from the list in the **Query Library** page.

2. Click **Associate**.

   This displays the **Scheduled Reports Group** page.



3. Select any report group and click **Modify**.
4. Make the necessary modifications and click **OK**.
5. Click **Execute** to execute a report. The **Execute** button will be available only if a group has just 1 report in it.

Deleting a Query in the Query Library

Use the following procedure to delete a query from the query library:

1. Select the query from the list in the **Query Library** page.
2. Click **Delete**.
3. The **Delete Confirmation** dialog appears.
4. Click **OK**.

Disassociating a Report in the Query Library

Use the following procedure to disassociate a report from the query library:

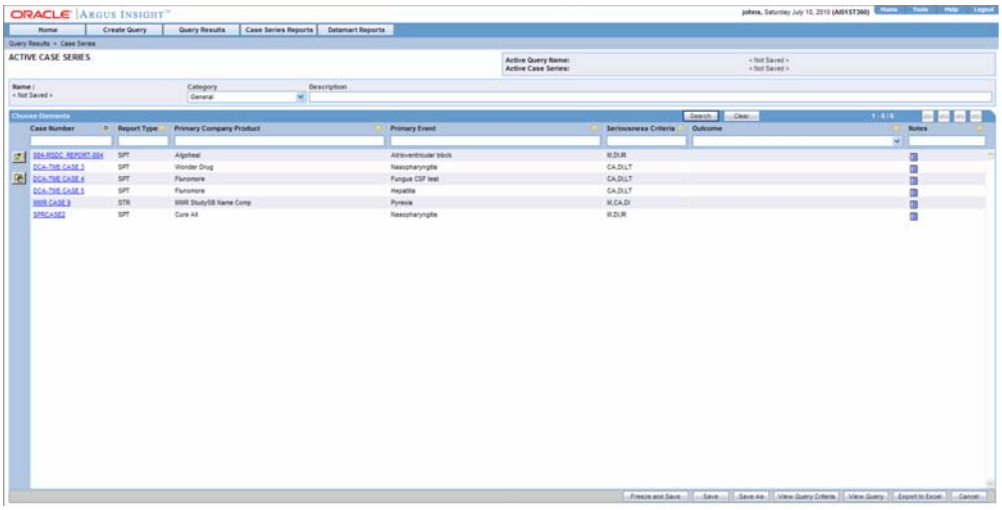
1. Select the report from the list in the **Query Library** page.
2. Click **Disassociate**.
3. The **Disassociate Report** dialog appears.
4. Click **OK**.

5

Working with Case Series

Working with Case Series

When you execute a QBE, *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. The Case Series output is displayed in a listing format in 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.

In addition to letting you generate a Case Series by using a *query*, Argus Insight enables you to:

- Save the Case Series with a name and description for future reference.
- Search the saved Case Series by their name, description, category, source, date of modification, and author.
- Assign group level access permissions on the Case Series.
- Combine two Case Series through Union, Intersect, or Minus set operators.
- Import a Case Series from external sources such as TXT, XLS, or CSV files.
- Manually modify the Case Series after it has been generated.

Note: The Case Series might become obsolete each time the datamart is refreshed by running an ETL. This is because new cases with similar attributes might get added to the datamart.

General Usage Information

Before working with Case Series, you should be aware of information about the following:

- Case Series Hyperlink to Medical Review
- Freezing Case Series Data

Case Series Hyperlink to Medical Review

Be aware of the following:

- The case series dialog enables the user to open the Medical Review dialog in Read Only mode from the Active case Series dialog.
- All of the reports that can be executed from Medical Review are available to the user.
- Even if a Single Sign On user has no protection in Argus Safety and Blinded Protection is applied in Argus Insight, the user can still view the Medical Review screen. The Medical Review screen can display all the products of the Blinded security-enabled case.
- If the user does not have access to the case from an Argus Safety perspective, the system presents the following message:

  " <user> does not have access to the case in Argus Safety".
- If the case the user is trying to access has been deleted since the last ETL, the system presents the following message:

  "This case has been deleted in Argus Safety since the last ETL".
- If the user has logged into Insight without logging through Argus, the system presents the following message:

  "<user> is not logged into Argus."

Freezing Case Series Data

Business Context

Once the alerts are configured, customers are interested in analyzing the case series that is generated by the alert. The system does the following as part of the analysis:

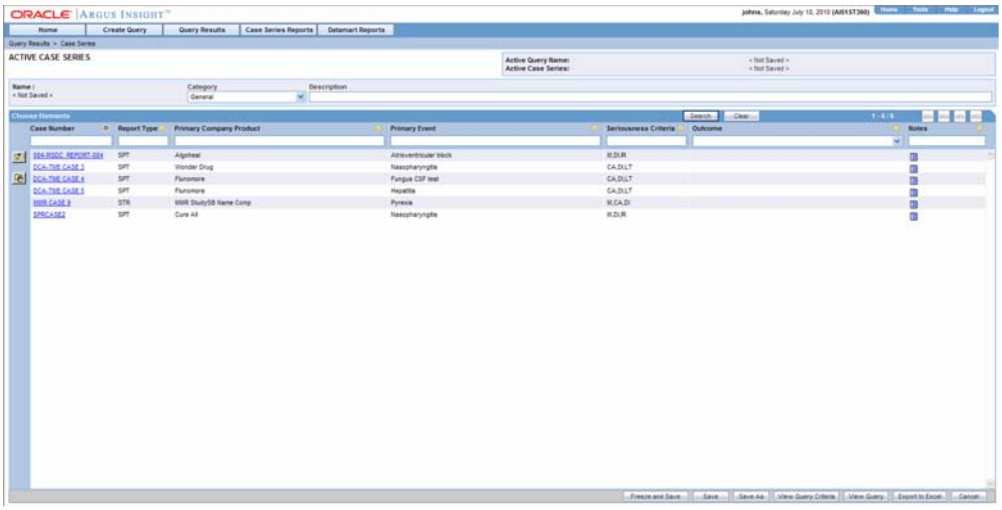
- Freezes the Case Series data that needs to be analyzed
- Displays case details using either the standard reports or the CIOMS II line listing (available in Insight) after the regular queries, case series, and their subsets are completed.

Feature Details

Be aware of the following:

- The system allows the use to freeze a case series as follows:
  - The user can freeze a custom case series when editing the case series from the Case Series Library page.
  - The user can freeze any system-generated case series (active or inactive) (e.g., Using Insight queries, filters and advanced conditions) by clicking the "Freeze and Save" button.

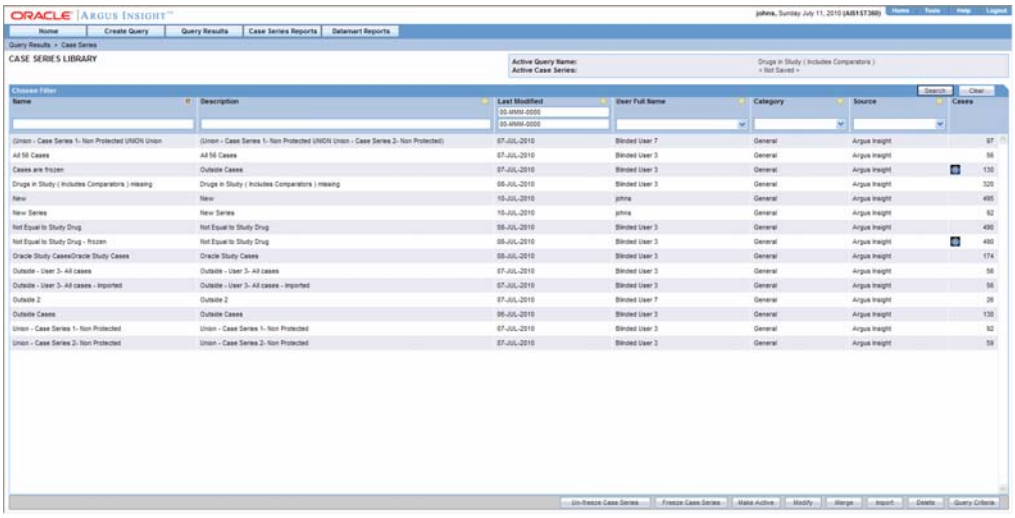
    The system freezes the case series and presents the user with the standard Case Series Save dialog. The user must enter the name of the saved case series.



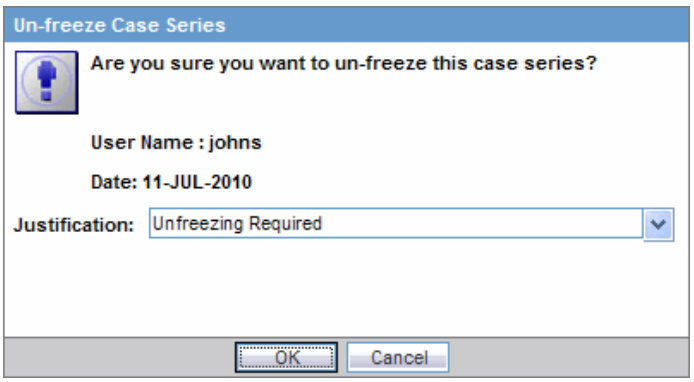
- If the user has not yet saved the case series from the active case series screen and clicks the Freeze and Save button, the system saves only one copy of the frozen case in the library. The frozen case series should then be the active case series.
- In the Case Series Library the User can view a frozen case series by clicking the icon next to the case number.

  Hovering over this icon shows the Date the user froze the case series.
- The system enables the user to freeze existing cases in the case series by clicking the "Freeze Case Series button."
  - When the user clicks this button, the system prompts the user to provide and additional name for the frozen case series.
  - The Frozen Case Series has icon beside case number to identify it as frozen.

- When the user clicks "Un-freeze Case Series," the system removes the icon beside the case number and fetches the latest information for the cases.



  - The user must provide a justification when unfreezing a case series.
  - The user adds the justification to the Case Series Criteria.
    * The user types a new justification when the case series is unfrozen or can user a pre-configured justification.



    * A list maintenance item, "Case Series Un-freezing Justification," enables the user to configure justifications for use when unfreezing a case series.
    * The Add, Modify and Delete functionality is the same as that of the Case Series Modification Justification UI.
  - The administrator can configure the freeze case series function so that it reflects Insight security settings
  - The user has the option of freezing and unfreezing case series by clicking the appropriate check boxes on the Access Right tab.
  - The user **cannot** insert cases into a frozen case series.
  - The user can delete cases from the frozen case series.
  - When an Advanced Condition or query is run against a frozen case series, frozen data is used.
  - By default, the Report Writer displays all the versions (both frozen and current) for a case.

        * Use the "Display Latest Data" filter if the report needs to contain only the current case version.
        * If user selects the Active Case Series filter, then report contains only the Frozen case data if 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 next to the case series name:

      "The data in this report was frozen as of <particular date and time>".

      Time is the database system time with the GMT offset.
- Reports run on normal case series data, show the follow message next to the case series name: should
- "The case series was last modified on <Case series modification date and time>".
- List Maintenance items are not frozen. Therefore, some reports will have a mismatch of LM Items and the frozen case series data.
- The derivation rules operate against current case data if the LM Rules are being 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 LM records related to the derivation rule will not be deleted in cases used in the frozen case data table.
- The hyperlink for the medical review access, links to the latest data for the case.
- Frozen case series **are not** available to Perceptive.
- Frozen case series **cannot** be shared with Argus Safety.
- The following portions of the Argus Insight application **do not** all case data to be frozen:
    - Dashboard
    - Copy Configuration Utility
    - BO and CO standard cubes
    - Standard Cubes Drill Through reports
    - Report scheduling
    - Derivation Rules

Working with the Last Generated Case Series

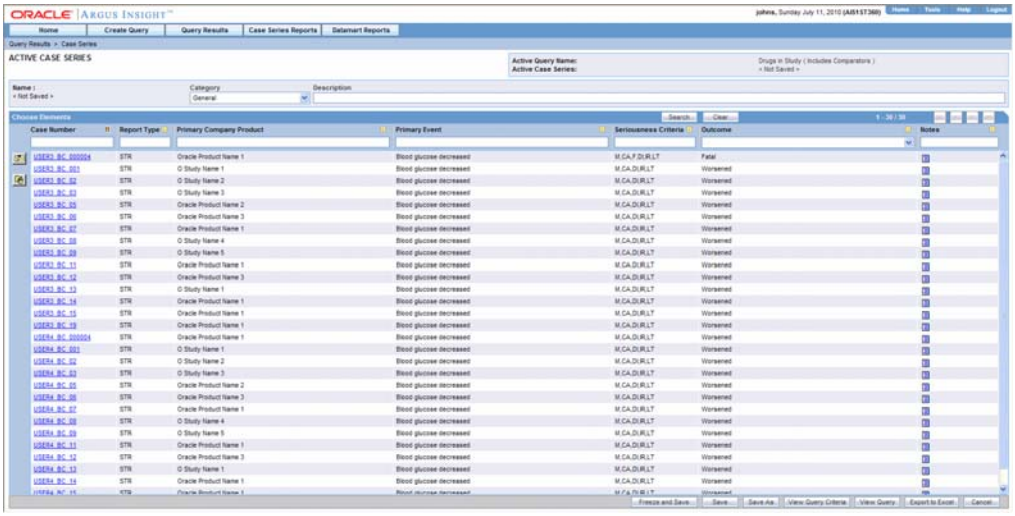
This section provides information for working with the last generate case series and includes discussions of the following:

- Saving a Case Series
- Viewing Case Series Generation Criteria within the Query Interface
- Modifying the Case Series
- Deleting a Case from a Case Series

The system assigns the Active status to a Case Series that you generated last by executing a *query*. Only one Case Series can remain active at a time. Unless you generate another Case Series or save modifications to one, the last Case Series you generated remains active.

> **Note:** You can also make a Case Series active by manually assigning it the Active status. This option works only for Case Series you have saved to the system. See theMaking a Case Series Active topic for details.

To view an Active Case Series, select **Query Results > Case Series > Active**. The **Active Case Series** page displays the Case Series you executed, modified, or manually made active last.

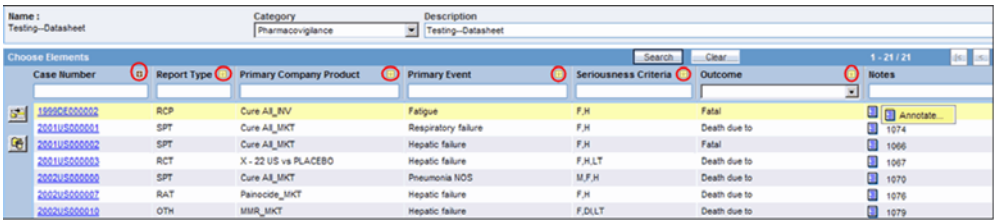


In the **Active Case Series** page, the **Active Query Name** label displays the name of the saved query (QBE, *Filter*, or Advanced Condition) that generated the Case Series. If the query was not saved, the label displays the text **<Not Saved>**.

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

If the active Case Series has more than 50 cases, they are displayed in multiple pages. Use the arrows in the button group to navigate the Case Series pages.

The column headers in the Case Series grid can also be sorted, as shown by the circled icons in the following image.



You can sort the column data by clicking on the arrows displayed in the image. The sorted grid retains its sorting and filtering order even after being exported to Excel. To filter for any column, such as the Seriousness Criteria column, enter the filtering criteria in the textbox under the column header. The grid also supports context menus.

Saving the Case Series

If you have not saved the active Case Series to the system yet, click either the **Save** or **SaveAs** buttons to save the Case Series to the system by assigning a name to it. You need to enter the Case Series description in the **Description** text box before saving the Case Series.

If you are modifying a Case Series that is already saved, click the **Save** button to save the modification or click **Save As** to save the Case Series by another name.

Viewing Case Series Generation Criteria within the Query Interface

Click the **View Query** button to the see the querying criteria in the query tool interface (QBE *form*, Values Set page, or Advanced Condition Editor) that was used to generate the Case Series.

This button is only available for an Active Case Series that is not saved to the system.

If you have saved your Active Case Series, then refer to the section on**Viewing the Case Series Generation Criteria in a Single Page**

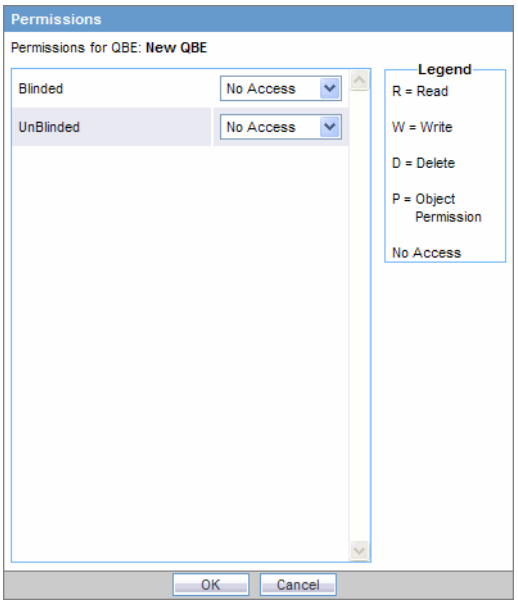
Setting Access Permissions

You can set group-level access permissions for the Case Series. This determines which user groups will be able to view, modify, or delete a Case Series.

Note: You can set permissions only on Case Series you have saved to the system.

Use the following procedure to set Case Series permissions.

1. In the **Active Case Series** page, click the **Permissions** button. The **Permissions** dialog box appears. A list in this dialog box displays the names of all the groups (except the **Administrator** group) that the system administrator has created.



2. You can set permissions only on Case Series you have saved to the system.

   Use the list box next to a group name to assign permissions to the group members on the Case Series you have generated. You can select from these options:

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

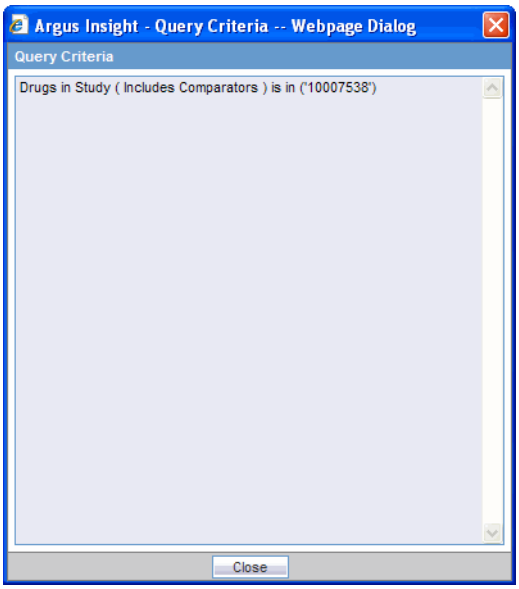
> **Note:** The author of the Case Series always has the highest level of permission (R/W/D/P). For example, you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a Case Series that you generate. In this case, while you will continue to have the highest level of permission on your Case Series, other members in your group will not be able to access your Case Series.

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

Viewing the Case Series Generation Criteria in a Single Page

Use the following procedure to view the case series generation criteria.

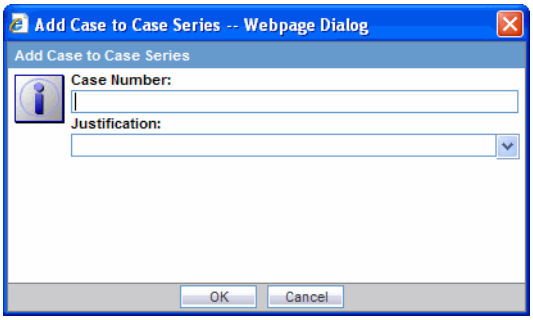
1. Click the **View Query Criteria** button to view the Case Series Generation criteria in a statement format within a dialog box.



Modifying the Case Series

If required, you can modify the Case series by deleting or adding cases manually. Use the following procedure to add a case to the Case Series:

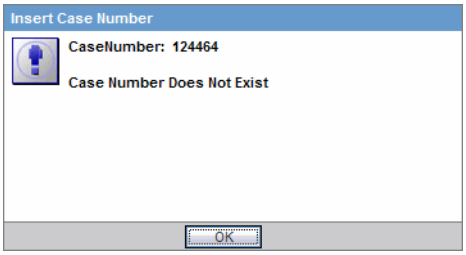
1. Click the icon on the left bar in the **Active Case Series** page. The **Add Case to Case Series** dialog box appears.



2. In the Case Number text box, type the case number you want to add to the Case Series.
3. Use the **Justification** list box to specify a justification for modifying the Case Series.

> **Note:** You can also type your own justification text for modifying the case series.

4. Click **OK**. If the Case number you specified exists in the datamart, the system adds the case to the Case Series and save the changes. If the Case number you specified does not exist in the datamart, a message appears. Click **OK** to continue.

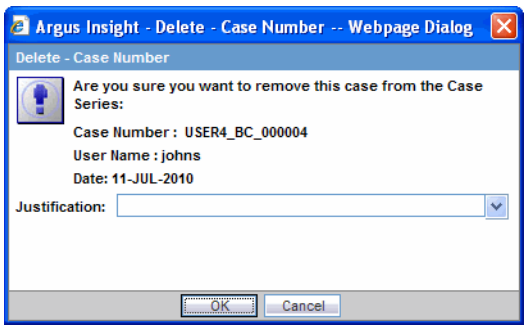


5. Click **Save As** to save the modified Case Series by another name. Note that if you have not yet saved the Case Series to the system, clicking either the **Save** or **Save As** buttons will prompt you to save the Case Series to the system by assigning a name to it.

Deleting a Case from a Case Series

Use the following procedure to delete a case from the Case Series.

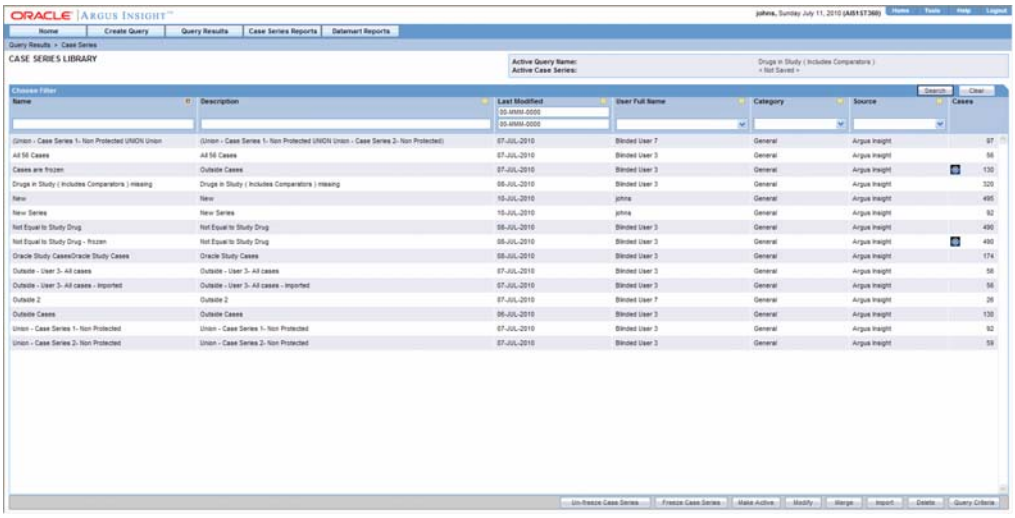
1. In the **Active Case Series** page, select the case you want to delete.
2. Click the icon on the left bar in the **Active Case Series** page. The **Delete Case Number** dialog box appears.



3. Use the **Justification** list box to specify a justification for deleting the case.
4. Click **OK**. The system deletes the case from the Case Series and save the changes.

Working with Saved Case Series

The **Case Series Library** page lists all of the Case Series saved to the system. Select *Query* Results > Case Series > Library to access the Case Series Library page.



The **Case Series Library** page displays a list of the saved Case Series in a grid format. The descriptions of the grid columns follow.

Column	Description
Name	Displays the name of the Case Series
Description	Displays the Case Series description
Last Modified	Displays the date when the Case Series was last modified
User Full Name	Displays the name of the user who generated the Case Series
Category	Displays the category assigned to the Case Series
Source	Displays the source of the Case Series as: ■ **Internal** - generated by using Argus Insight querying tools are called Internal ■ **External** - imported into Argus Insight from sources, such as TXT, CSV, or XLS files
Cases	Displays the number of cases in the Case Series

Searching for a Saved Case Series

Use the following procedure to search for a saved Case Series.

1. Specify the search criteria, as appropriate:
   - To search for a Case Series by its name, type the Case Series name in the **Name** text box.
   - To search for a Case Series 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 Case Series descriptions.
   - To search for a Case Series 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 Case Series by its author, select the author name from the **User Full Name** list box.
   - To search for a Case Series by its category, select the category from the **Category** list box.

2. Click **Search**. Based on your search criteria, the system displays the search result in a list.
3. You can sort the search result list by clicking the sort icon next to the column headers in the list.
4. To clear the search result and display all the saved Case Series in the list, click the **Clear** button.

Making a Case Series Active

Use the following procedure to make a case series active.

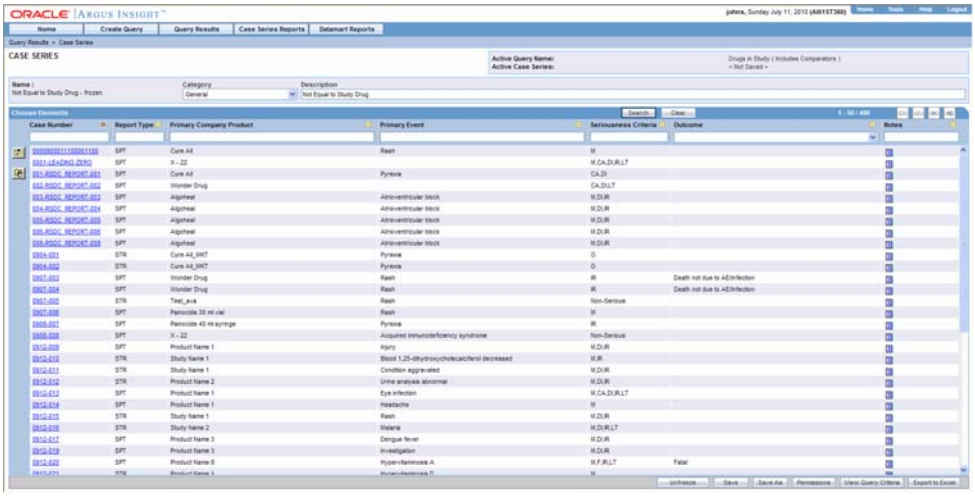
1. In the Case **Series Library** page, select the Case Series you want to make Active.
2. Click **Make Active**. The **Active Case Series** label in the upper-right corner of the **Case Series Library** page displays the name of the Case Series you made Active.

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.

Use the following procedure to modify a Case Series.

1. In the **Case Series Library** page, select the Case Series you want to modify.
2. Click **Modify**. The Case Series is displayed in the **Active Case Series** page. See the Working with the Last Generated Case Series for detailed information about making modifications to the Case Series and setting permission.



Merging Case Series

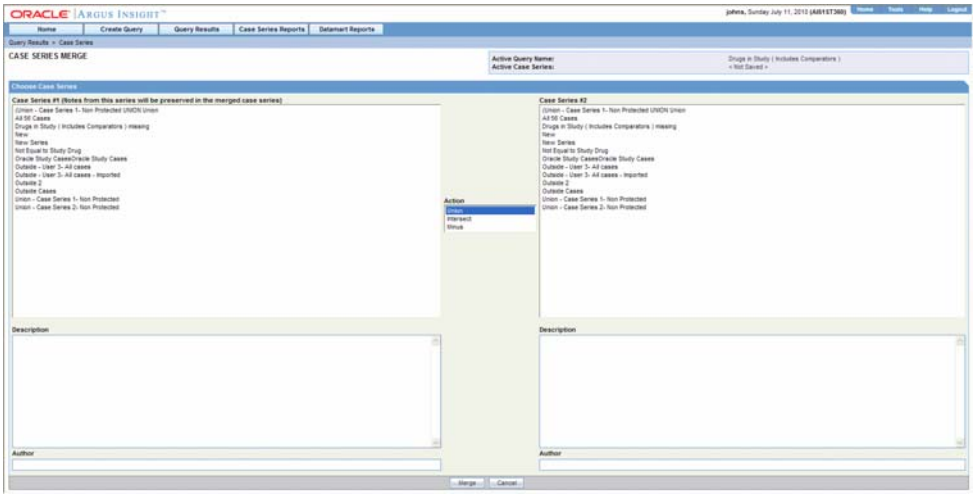
Argus Insight allows creating a new Case Series by merging two Case Series through a Set operator. The Set operator you select works on the Case numbers. The case numbers included in the merged Case Series depend on the type of Set operator you use:

- Union - creates a new Case Series that consists of all the cases in both Case Series; common case numbers are included, and are listed only once
- Intersect - creates a new Case Series that consists of only those case numbers that exist in both Case Series

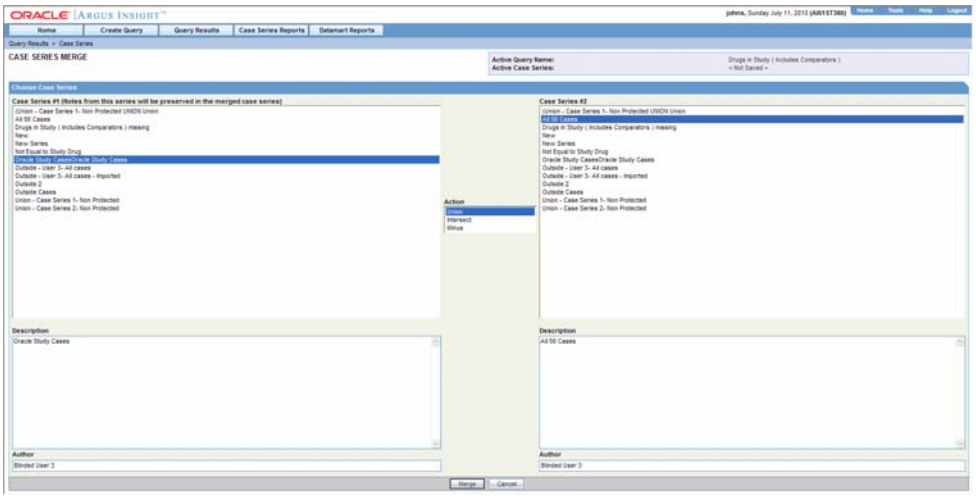
- Minus - creates a new Case Series that contains only those case numbers that are present in the first Case Series, but are not present in the second Case Series.

Use the following procedure to generate a merged Case Series:

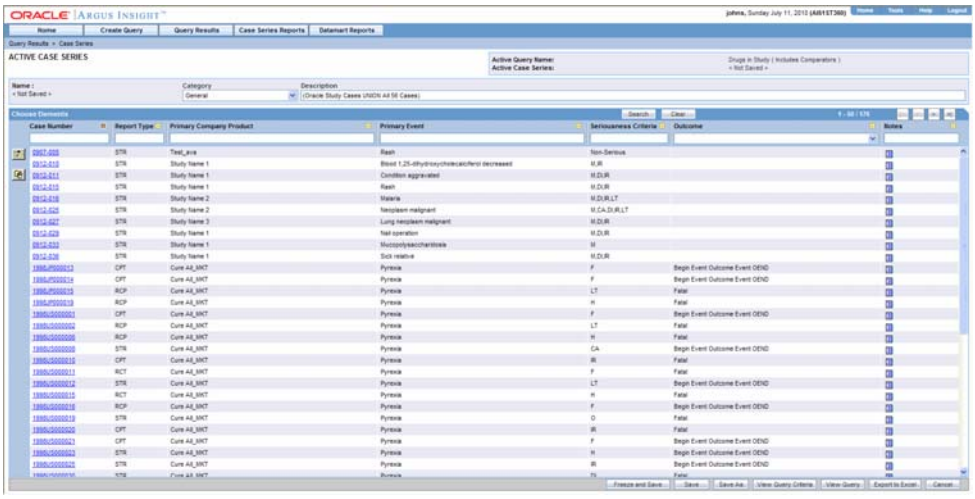
1. In the Case Series Library page, click **Merge**. The Case Series Merge page appears.



2. Select the two Case Series you wish to merge.
3. Select the first Case Series from the **Case Series # 1** list.
4. Select the second Case Series from the **Case Series # 2** list.
5. From the **Action** list, select the Set operator you wish to use to merge the two selected Case Series you selected. The two Case Series and the operator are selected.



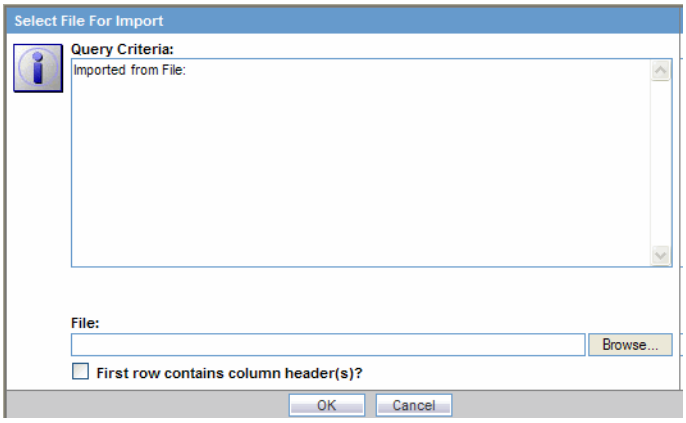
6. Click **Merge**. The system merges the selected Case Series and displays the resultant Case Series in the **Active Case Series** page.



Importing a Case Series from an External Source

Use the following procedure to import a Case Series from anexternal sources, such as TXT or CSV, into Argus Insight.

1. In the **Case Series Library** page, click **Import**. The **Select File for Import** dialog box appears.



2. Click **Browse** to locate the external Case Series source file. Alternatively, type the file name with complete system path. Each case number in the file must be on a new line.
3. If the first row in your TXT or CSV is the column-header row, check the **First row contains column header(s)** checkbox.
4. Click **OK**.
5. The **Import Case Series** dialog box displays the status of the import operation.

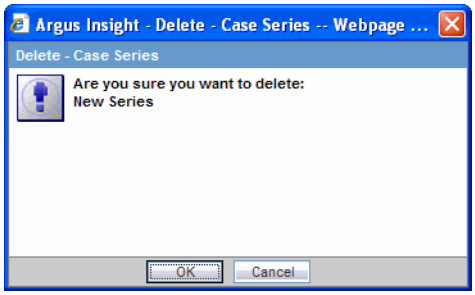
> **Note:** You can view the import operation log by clicking the **View Log** button.

6. Click **OK** to view the imported Case Series in the **Active Case Series** page.

Deleting a Case Series

Use the following procedure to delete an existing Case Series.

1. In the **Case Series Library** page, select the Case Series you wish to delete.
2. Click **Delete**. A confirmation dialog box appears.

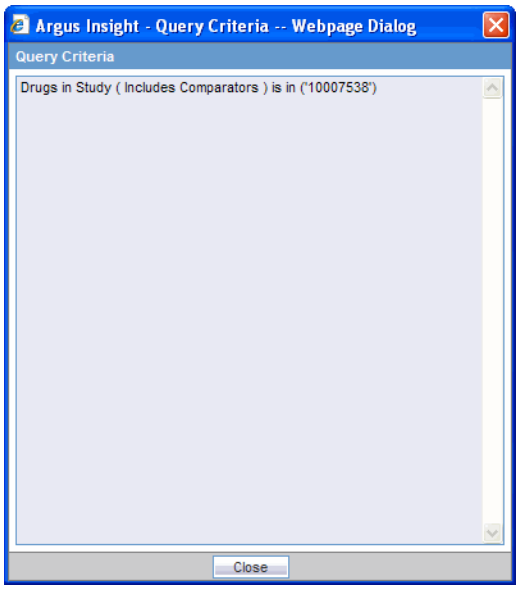


3. Click **OK**. The system deletes the selected Case Series; the **Case Series Library** page appears.

Viewing the Details of the Query that Generated the Case Series

Use the following procedure to view the details of the query that generated a Case Series:.

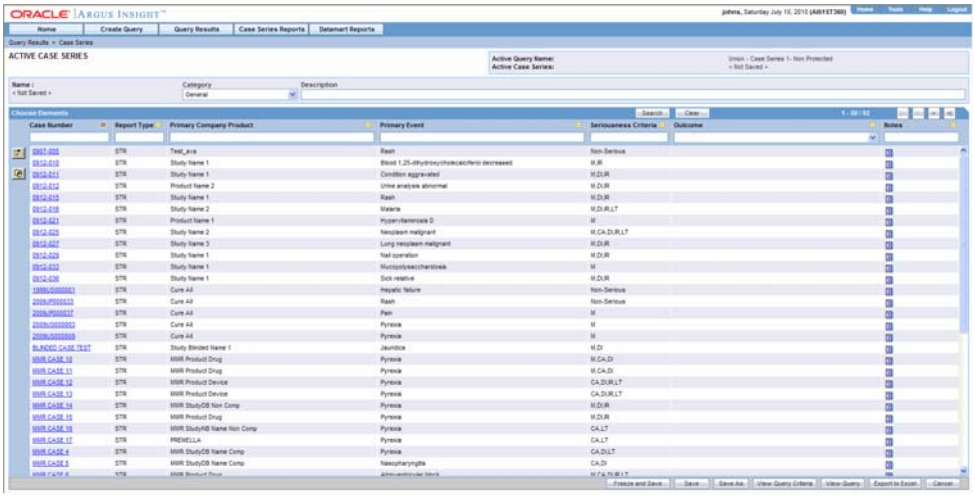
1. In the **Case Series Library** page, select a Case Series.
2. Click **Query Criteria**. The **Query Criteria** dialog box displays the criteria.



Note: For a saved Case Series, the system displays the query details only in an SQL-statement format within 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 (QBE*form*, Values Set page, or Advanced Condition Editor) as well as in the SQL-statement format.

Sharing Case Series with Argus Safety Web

The system enables you to share cases between Argus Safety Web and Argus Insight using **Query Results > Make Active from Argus**.



Use the following procedure to share cases between Argus Insight and Argus Safety Web.

1. Login to Argus Insight with your user id and password.

   Note: You need a common user id and password for Argus Safety Web and Argus Insight to enable case sharing between the two applications.

   An error message stating "Your user id is not present in Argus" appears if you do not have a valid user id in Argus Safety Web

2. Select **Query Results > Case Series > Make Active From Argus** to view the Active Cases in the Argus Safety Web application. The Active Case Series of Argus appear on the screen. The Active Case Series present in Argus are now the active case series in Argus Insight.

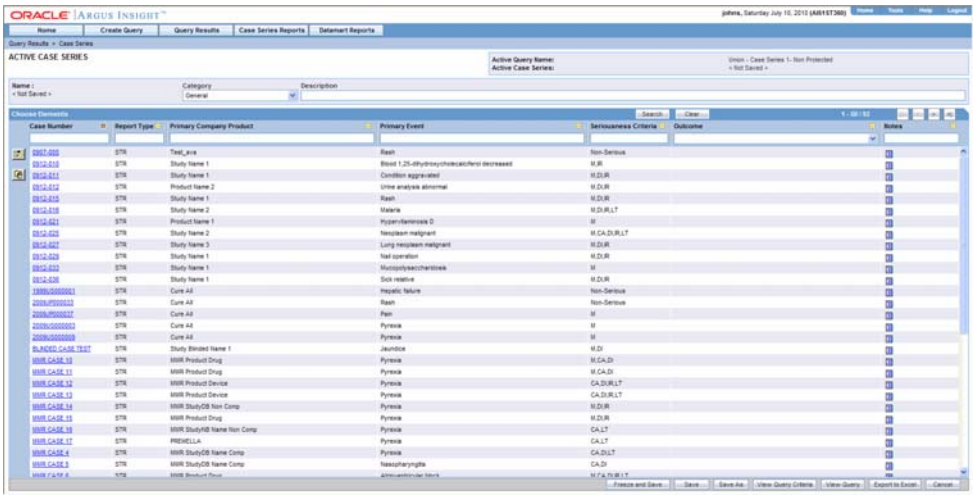
   Note: If there are no cases present in the active series of Argus, an error message appears indicating the same.

3. Save the case series using the **Save** or **Save As** feature.

Exporting Case Series to Excel

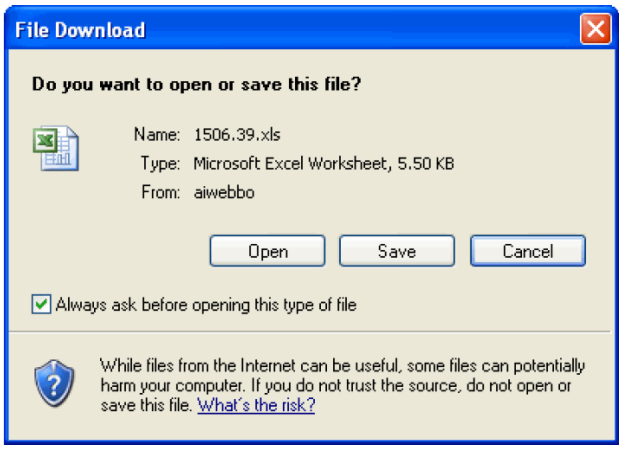
Use the following procedure to export a case series to an Excel file.

1. Create a new query from Query By Example, Filter or an Advanced Condition, or open a saved query from the Library of Query By Example, Filter or an Advanced Condition.
2. Click **Execute** to open the Case Series page with the list of cases.



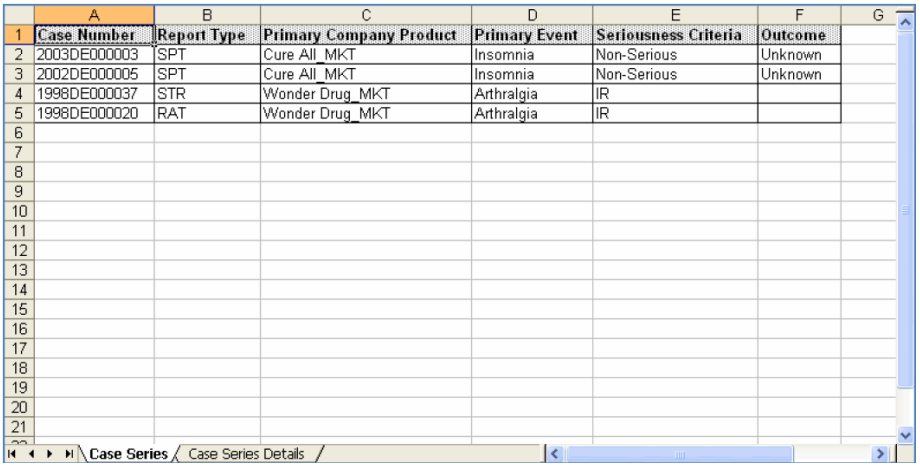
3. Now, click **Export to Excel** at the lower right end of the web page.

   A dialog box displays for saving or opening an excel file.



4. Click Open to open the excel file and view the Case Series results in excel. Click Save to save the excel file in your system for future reference.

   In the excel file you can see the case Series results in Case Series tab and Case Series details, i.e., Name, Case Count, Description and Criteria in Case Series Details tab.



	A	B	C	D	E	F	G
1	Case Number	Report Type	Primary Company Product	Primary Event	Seriousness Criteria	Outcome	
2	2003DE000003	SPT	Cure All_MKT	Insomnia	Non-Serious	Unknown	
3	2002DE000005	SPT	Cure All_MKT	Insomnia	Non-Serious	Unknown	
4	1998DE000037	STR	Wonder Drug_MKT	Arthralgia	IR		
5	1998DE000020	RAT	Wonder Drug_MKT	Arthralgia	IR		
6							
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21							

Case Series | Case Series Details

6

Generating Standard Reports

General Report Usage Information

Argus Insight provides built-in Standard Reports which can be run on Active Case Series to analyze your company's safety, workflow, and product data.

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 type of cases. Pre-filters let you narrow down the Case Series further so that the system runs the report only on those cases that confirm to the pre-filter criteria. For example, your Case Series might consist of cases that were reported in all the countries for a particular product.

However, you may only wish to see information about those cases in your report that were reported in the United States. In this case, you can specify a pre-filter to have the system display only those cases in the report output that were reported in the United States.

Note: Since a Case Series might become obsolete each time the datamart 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 Case Series. See the Associating a QBE with a Report, Associating a Value Set with a Report, and Associating an Advanced Condition with a Report topics for details.

Before using Argus Insight to generate the Standard Reports, configure the browser as defined in the Argus Insight Installation Guide.

Using Reports

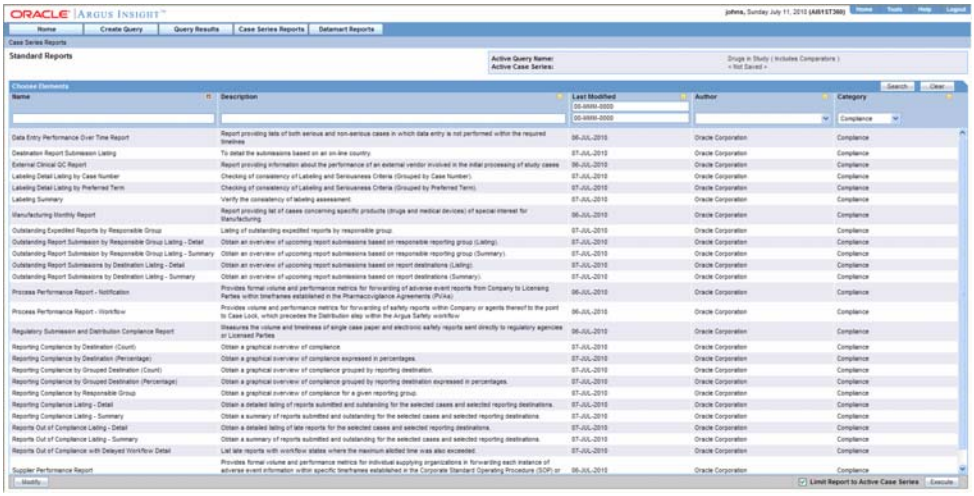
Before generating reports, you should be aware of information regarding the following:

- Event Level Reporting
- Report Scheduling

Executing Reports

Use the following procedure to access the Reports page for any category. For instance, if you select Compliance Reports, execute the following steps:

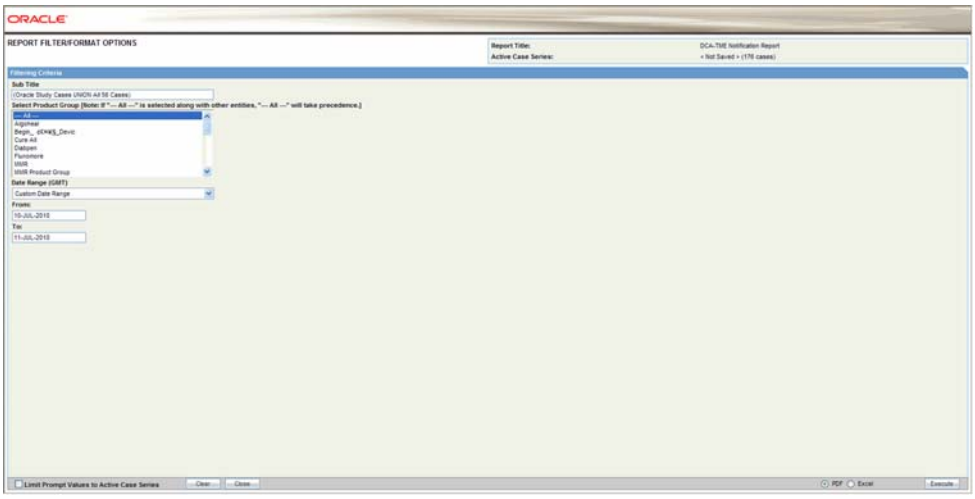
1. Select the **Case Series Reports > Standard Reports >Compliance**. The **Standard Reports** page displays a list of all the standard Compliance reports. The description of a report is displayed next to its name.



2. Select the report that you want to generate.
3. Select the **Limit to Active Case Series** checkbox to generate the report on the Active Case Series.

> **Note:** Select the **Limit to Active Case Series** checkbox before generating the report. This prevents the report from querying the entire datamart and slowing down the report output generation. Use the following procedure to view the **Active Case Series**, select **Query Results > Case Series > Active** in Argus Insight. If you want to make another Case Series active, select **Query Results > Case Series > Library** in Argus Insight. In the **Case Series Library** page that appears, check the Case Series you want to make active and click **Make Active**.

4. Click **Execute** to generate the report. A new browser window displays the pre-filter options in the Report *Filter* page. The following pre-filter elements may be available depending on the type of information the report displays.



- List box - this element lets you filter the report output by specifying a single value from the list; for example, the country of incidence, a regulatory authority, or a pre-defined date range. List boxes may also contain options for grouping the report output; for example, grouping by age group or product name
- Multiple selection lists - this element lets you filter the report output by multiple values you select from the list; for example, license countries or report types.

Note: If **All** is selected along with other entities for a category, then all the items under that category are searched.

- Text boxes - this element lets you filter the report output by specifying a numerical value for timelines or dates for date ranges. All the report pre-filter pages contain a text box for specifying a sub-title for the report
- The Pre-filter page can display values in Prompts. By default, prompts on the Pre-filter page display values from LM tables.
- By default, a checkbox called Limit Prompts Values to Active Case Series is displayed on the Pre-filter page. You can check this checkbox to generate pre-filter prompts and view values limited to the cases in the case series. This impacts only those prompts which are populated from case tables and corresponding LM tables exist for that prompt.
- Custom prompts created by the user for ad-hoc reporting do not have the option of displaying values in prompts from LM tables. Custom prompts always display data as per the conditions (SQL) that were defined during the creation of the prompts.

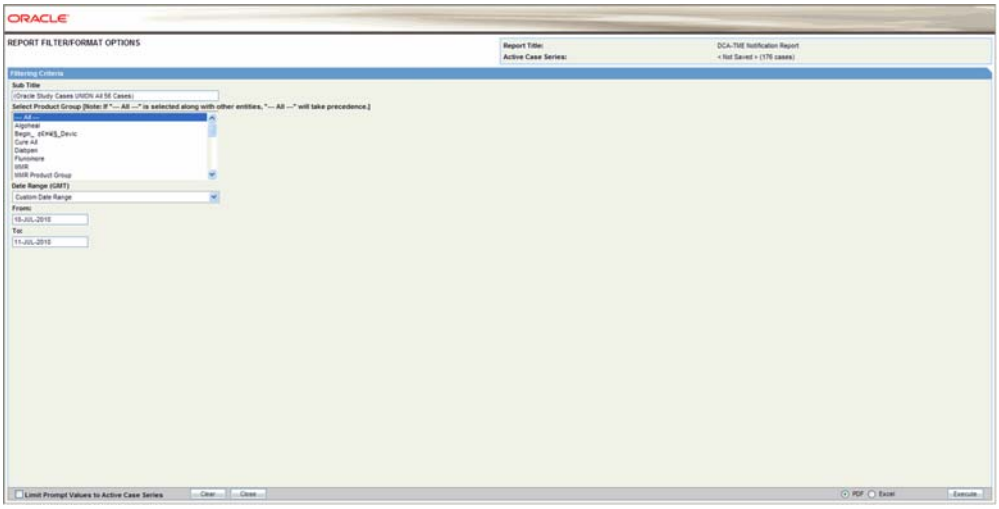
5. Specify the pre-filter options, as appropriate.
6. Select the **PDF** or **Excel** option button to specify the report output format.
7. Click **Execute** in the **Report Filter** page. The system generates the report output and displays it in the selected format. You can print this report or save it to the system drive, if required.
8. Close the new browser window to return to the **Standard Reports** page.

Event-Level Reporting

Currently, Insight Reports are focused on cases. This permits event level report in Insight Report output.

Feature Details

Extended reporting in the standard reports enables the user to produce event-level reports. To produce an event-level report, the user must click the "Limit to events within Query Criteria" checkbox shown in the following illustration.



- The event group information is populated from the Event Groups configured in the Perceptive application.
- The user can select multiple Event Groups.
- If the user selects the Event groups, the system limits the output to only the Events selected in the Event Group definition.
- If the user clicks "Limit to Events within the Query Criteria," the system limits report output to the Events chosen in the report output query criteria.
  - This applies to all queries executed from QBE, Filters, or Advanced Conditions
  - This applies for Event Terms for the entire hierarchy (i.e., SOC, HLGT, HLT, PT, LLT for the MedDRA Coded events only).
  - This cannot be executed with hard-coded SQL queries.
  - This feature **cannot** be used with a case series from Safety.
  - This feature **cannot** be used with an imported case series.
- If the user uses a power query to generate a case series, the following terms are respected as the event query in the reports:
  - From QBE - Events tab - Event Coding
    * System Organ Class (SOC)
    * High Level Group Term
    * High Level Term
    * Preferred Term
    * Lower Level Term

- From Filters - Event Information
  - Event Term -
    i. SOC
    ii. HLGT
    iii. HLT
    iv. PT
    v. LLT
  - Preferred Term
- From Advanced Conditions -
  - EVENTS:Event Information Event Body System Code
  - EVENTS:Event Information System Organ Class (SOC)
  - EVENTS:Event Information Event High Level Group Term Code
  - EVENTS:Event Information High Level Group Term
  - EVENTS:Event Information Event High Level Term Code
  - EVENTS:Event Information High Level Term
  - EVENTS:Event Information Preferred Term
  - EVENTS:Event Information Preferred Term Code
  - EVENTS:Event Information Event Low Level Term
  - EVENTS:Event Information Lower Level Term
  - EVENTS:Event Information Event Included Term Code
  - EVENTS:Event Information Event SMQ (Broad)
  - EVENTS:Event Information Event SMQ (Narrow)
  - EVENTS:Primary Event Event SMQ (Broad)
  - EVENTS:Primary Event Event SMQ (Broad)
- This feature is available in the following reports:
  - Event term frequency listing by HLGT
  - Event term frequency listing by HLT
  - Event term frequency listing by PT
  - Event term frequency listing by SOC
  - AE count tabulation (case causality)

Report Scheduling

Report Scheduling comprises the following:

- Scheduling Multiple Reports Against a Single Query
- Scheduling a Report without a Query

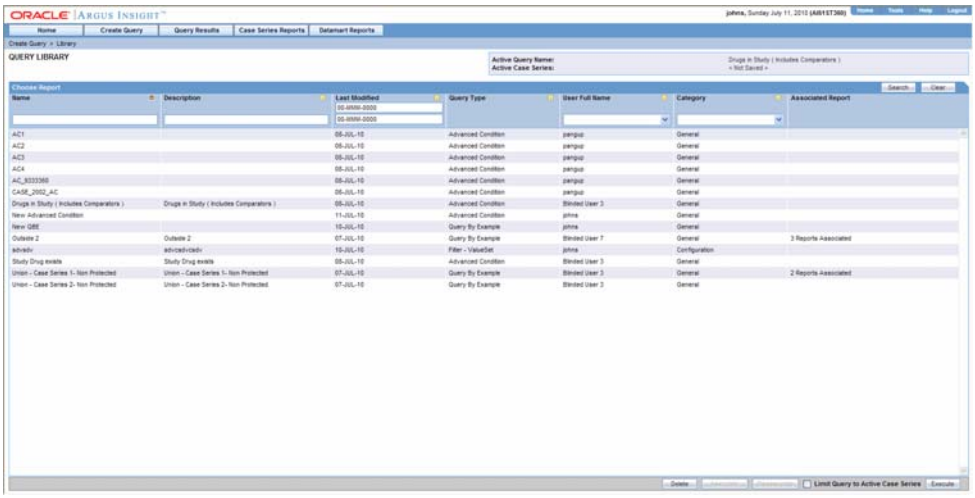
Scheduling Multiple Reports Against a Single Query

The system enables users to schedule multiple reports in a single query. A set of

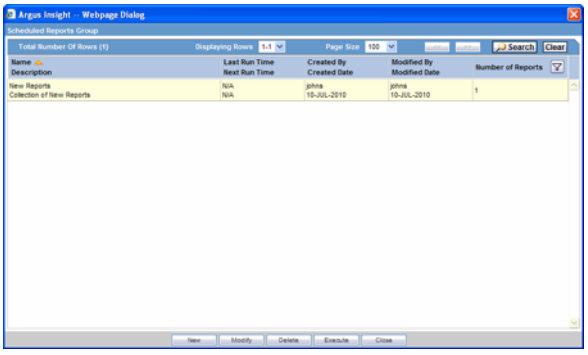
reports run on a weekly or periodic basis can be scheduled with the same report and run as a package.

On clicking the Associate button from the query library, only one report is selected. If a different report is chosen for the query, the system prompts the user is to change. The system permits the user to associate many reports with a single query.

- The user can select any query from any library (QBE/Filters/AC) and click Associate.
- The user can use the Query Library and the Associated Query Library to schedule an association.
- Since multiple reports can be associated with a single query on these Query pages, the Execute button does not open any pre-filters page after generating the case series.



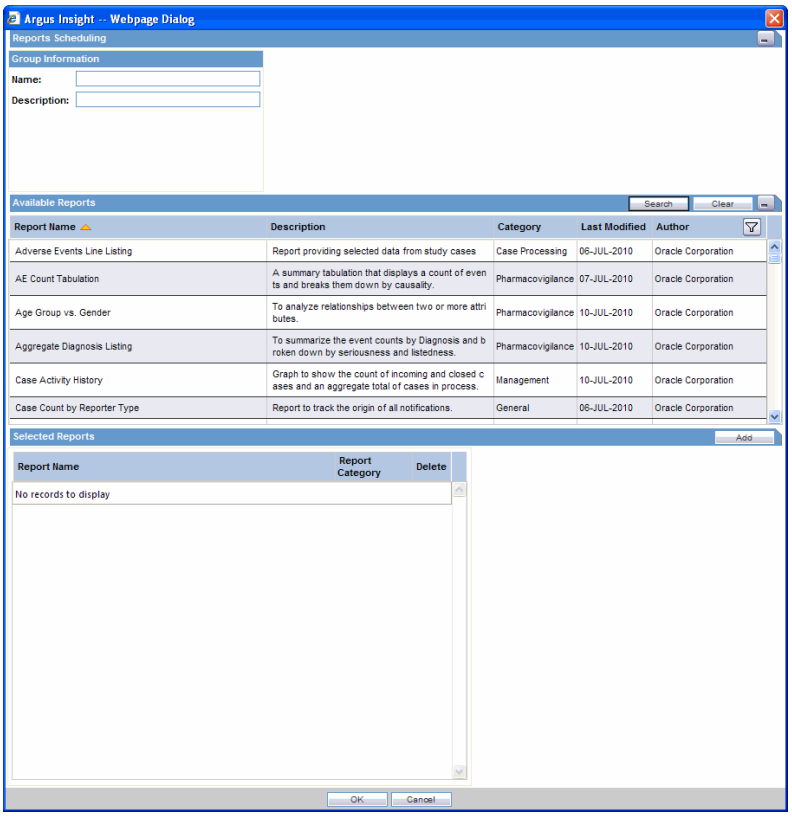
When you select a query and click Associate, the *Scheduled Report Groups* window is displayed.



This window includes the following features:

- This window displays information about all the report groups scheduled by the logged-in user.
- Sorting and Search functionality is available for all columns.
- Pagination is also available.
- Each group can contain one or more reports. "Group" means that all the reports are scheduled at the same time.

- This window has the following buttons:
  - **New:** Redirects the user to the *Report Scheduling* page with blank values. The system presents the context menu to enable the user to choose Report Association Only or for Scheduling.
  - **Modify:** Redirects the user to the *Report Scheduling* page and enables the user to modify an existing *scheduled report group*.
  - **Delete:** Deletes a selected *scheduled report group*.
  - **Execute:** Closes the window and executes the query in parent window to show case series and launch pre-filter for the selected report on this page. This button is enabled on if the *scheduled report group* has a single report.
  - **Close:** Closes the window without any other action.
- The system opens the Schedule Information page when the user selects Association Only from the drop-down list.



- This the main scheduling page in Insight. On this page, user can select any number of reports for scheduling.
- The *Reports Scheduling* page has four (4) sections as follows:
  - **Group Information:** The user provides the group name and description.
  - **Schedule Information:** The user provides the scheduling frequency.
  - **Email Information:** The user provides e-mail information for the receivers.
  - **Available Reports:** The user selects the reports to schedule. Select any report and click Add to add the report to Selected reports. The user can select multiple reports and add them at the same time.

- **Selected Reports:** Reports associate with the query (as per the selection by the user from Available Reports section) are listed in this field.
  - User can remove a selected report by clicking the **X** button against report's row in the grid from the Selected Reports section.
  - Sorting and Search functionality is available for all the columns in the Available Reports Section.
  - Pagination is also available on the Available Reports Section.
- The system does not permit the user to save a schedule without entering the pre-filter information for each report. The system uses the value in the Pre-Filters Configured? Column in the Selected Reports section to detect whether the pre-filter configuration is complete.
- The user can enter pre-filter information by selecting any report in the Selected Reports section. When the user selects the report, the system loads the pre-filter information for the report in the sidebar and enables the user to enter the information.
- Side bar has OK and Cancel buttons
  - **OK:** Save the pre-filter information for the selected report.
  - **Clear:** Reset the pre-filter page to blank values after confirming with user.
- The *Schedule Information* page has the following buttons:
  - **OK:** Saves the scheduling information to the database and returns to the *Scheduled Report Groups* page.
  - **Cancel:** Returns to the *Scheduled Report Groups* page without making any changes.
  - **Clear:** Resets the *Schedule Information* page to blank values after confirming with user

Scheduling a Report without a Query ■

Reports can be scheduled without a query from the Associated Library Page.

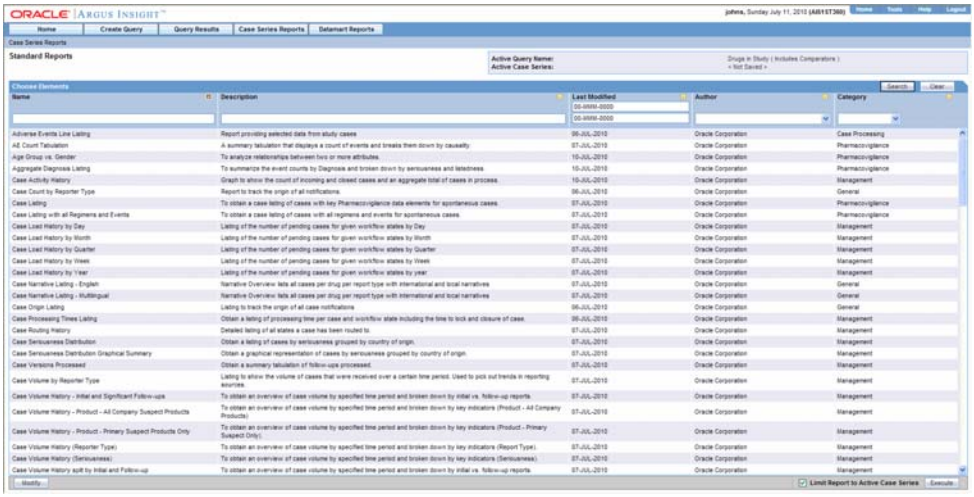
- This page has a button named "Associate to <All Cases>."

- The user can configure Text All Cases can from the List Maintenance items.
  - The system appends configured text to "Associate to <LM Text>". For example, if we configure All System Cases in the LM item, the text of this button would be "Associate to All System Cases".
- The default value is All Cases.
- The name of the LM Item is "All Cases Query Name".
- When the user clicks this button, the system opens the *Scheduled Report Groups* window and behaves exactly the same way as described in the section, "Multiple Reports on a Single Query".
- The Associated Reports Library page includes the following features:
  - This page is the main status page for all scheduled reports.
  - The user can see all reports in different/same groups at the same time. For example, if a user has 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.

- This page has the following buttons:
  * **Modify:** Enables the user to modify a selected association. This opens the *Scheduled Report Groups* page to query of the selected association. The system highlights the current group of the selected association.
  * **Execute:** Executes the selected query to get the case series and opens the Pre-Filter page for the associated report.

Standard Reports

The **Standard Reports** page displays a list of all the Standard Reports built into Argus Insight. Select **Case Series Reports > Standard Reports > All** to display the **Standard Reports** page. This page displays a list of the saved Standard Reports in a grid format. You can search for specific types of reports by specifying values for any of the columns as the search criteria and clicking **Search**.



The descriptions of the grid columns follow.

Column	Description
Name	Displays the name of the Standard Report
Description	Displays the Standard Report description
Last Modified	Displays the date when the Standard Report was last modified
Author	Displays the name of the Standard Report author
Category	Displays the Standard Report Category

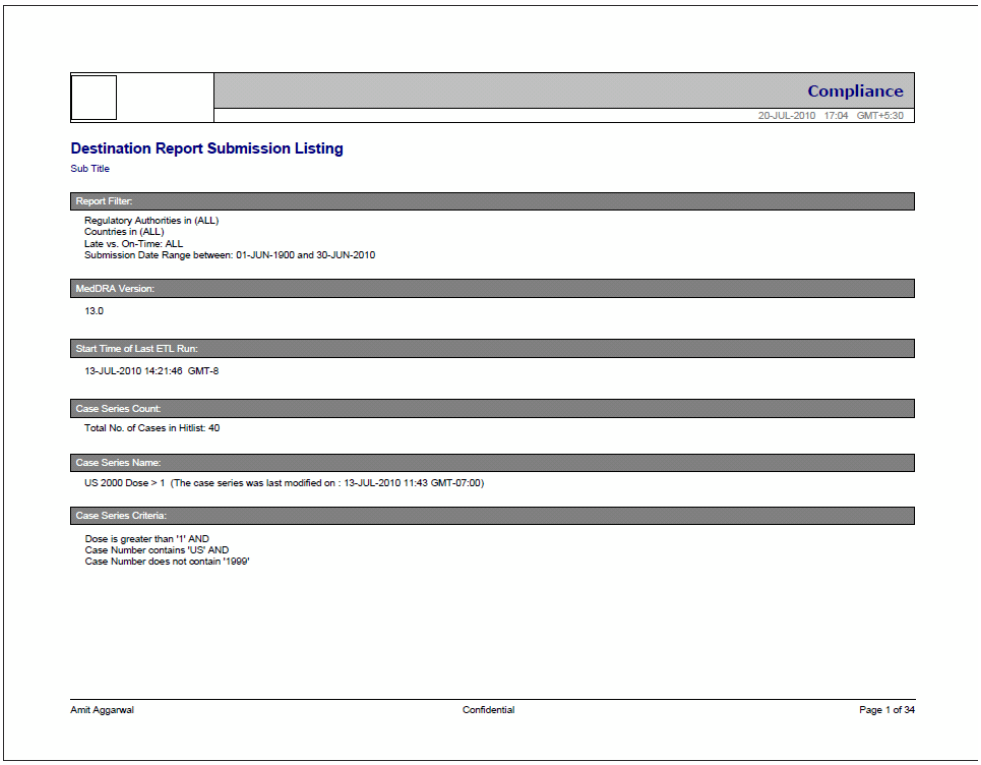
Standard Reports are grouped into six categories and can be accessed from the Argus Insight folder in the Installation CD. The following topics explain the various standard reports.

- Case Processing Reports
- Compliance Reports
- Configuration Reports
- General Reports
- Management Reports

- Pharmacovigilance Reports

Reports - Cover Page

The following image displays the Cover page of the report when it is generated in PDF format.



The following table describes each component of the cover page shown in the above image.

Cover Page Component	*Description*
Company logo (upper-left box)	Placeholder for a configurable logo. The image of the logo can be configured in the whitespace.
Report Category (upper-right box)	The name of the category to which the selected report belongs.
Report Execution Date (under 'Report Category')	Report Execution Time (in GMT).
Report Title (under the Heading of the Report)	Title of the selected report, such as Serious Adverse Events Report.
Report Sub-Title (under 'Report Title')	Configurable Sub-title of the selected report. You can enter a sub-title to further define the report. Example: 01-JAN-1900 to 31-DEC-2007.
Report Filter	A selected value from the Report Prompt.
MedDRA Version	The MedDRA Version for the selected report.
Start Time of Last ETL Run	Start time of the last successful ETL run (in GMT).

Case Series Count	A count of the total number of unique cases in the case series.
Case Series Name	The name of the saved case series on which the report has been executed. Reports that are run on frozen case series data indicate on the report next to the case series name that "The data in this report was frozen as of <particular date and time>". Time is the database system time with the GMT offset. Reports that are run on normal case series data indicate on the report next to the case series name that "The case series was last modified on <Case series modification date and time>".
Case Series Criteria	Query criteria to get case series on which the report has been executed.
User Name (bottom-left)	The name of the user who executed the report.
Confidential (bottom-centre)	Configurable Confidential text.
Page x of y (bottom-right)	Page Number (in Current Page number of Total Pages in the Report format).
Footer logo (bottom-right box)	Placeholder for a configurable logo. The image of the logo can be configured in the whitespace. This component may not appear in every report.

Case Processing Reports

The following table describes each Case Processing Report.

Report Title	Description
Adverse Events Line Listing	This report provides a tabular report containing data of selected fields.
DCA-TME Notification Report	This report provides a list of cases in which an event of special interest is associated with a specific product.
Serious Adverse Events Report	This report displays a case-wise compilation of selected data, including the narrative.

Compliance Reports

The following table describes each Compliance Report.

Report Title	Description
Destination Report Submission Listing	Use this report to view the submission details based on an on-line country.
Labeling Detail Listing by Case Number	Use this report to check for consistency between Labeling and Seriousness Criteria. The report is a listing of cases with events and their labeledness for the licenses of selected countries. Only the first company suspect product is included in the report; however, all events are listed. This report is grouped by case numbers.
Labeling Detail Listing by Preferred Term	Use this report to check for consistency between Labeling and Seriousness Criteria. This report is a listing of cases with events and their labeledness for the licenses of the selected countries selected. Only the first company suspect product is included in the report; however, all events are listed This report is grouped by Preferred Term.

Report Title	Description
Labeling Summary	Use this report to verify the consistency of labeling assessment. This report is a summary tabulation of labeling for events based on the countries selected.
Outstanding Expedited Reports by Responsible Group	Use this report to view a listing of cases for which expedited reports are outstanding. The listing is grouped by the responsible group.
Outstanding Report Submission by Responsible Group Listing - Detail	Use this report to view a detailed listing of cases for which report submissions are coming up. The listing is grouped by responsible group and again sub-grouped by agency. The listing is sorted in descending order of due-date.
Outstanding Report Submission by Responsible Group Listing - Summary	Use this report to view the outstanding report count for each reporting destination. Against each destination, the outstanding reported count is further broken up in these groups: ■ Due in greater than seven days ■ Due in 3-7 Days ■ Due in 0-2 days ■ Past the due date
Outstanding Report Submissions by Destination Listing - Detail	Use this report to obtain a detailed listing of upcoming report submissions based on report destinations.
Outstanding Report Submissions by Destination Listing - Summary	Use this report to obtain a summary listing of upcoming report submissions based on report destinations (Summary).
Reporting Compliance by Destination (Count)	Use this report to obtain a graphical overview of reporting compliance.
Reporting Compliance by Destination (Percentage)	Use this report to obtain a graphical overview of compliance expressed in percentages.
Reporting Compliance by Grouped Destination (Count)	Use this report to obtain a graphical overview of compliance grouped by reporting destination.
Reporting Compliance by Grouped Destination (Percentage)	Use this report to obtain a graphical overview of compliance grouped by reporting destination expressed in percentages.
Reporting compliance by Responsible Group	Use this report to obtain a graphical overview of compliance for a given reporting group. This report shows how many reports were assigned to a particular reporting group, that were submitted before the due date/ on the due date/ after the due date.
Reporting Compliance Listing - Detail	Use this report to view a detailed listing of submitted as well as outstanding reports for the selected cases and reporting destinations. The listing is grouped by destination; subtotals and compliance % are provided for each destination along with an overall total and total compliance %.
Reporting Compliance Listing - Summary	Use this report to view a summary listing of submitted as well as outstanding reports for the selected cases and reporting destinations. The listing is grouped by destination; subtotals are provided for each destination along with compliance percentage.

Report Title	Description
Reports Out of Compliance Listing - Detail	Use this report to view a detailed listing of all reports that were past the due date for the selected cases and reporting destinations. The listing is grouped by reporting destination; subtotals are provided for each destination apart from the overall total.
Reports Out of Compliance Listing - Summary	Use this report to view a summary listing of all reports that were past the due date for specific destinations. The listing is grouped by reporting destination; subtotals are provided for each destination apart from the overall total.
Reports Out of Compliance with Delayed Workflow Detail	Use this report to view a listing of late reports along with the details of the workflow states where they exceeded the maximum allotted time.

Configuration Reports

The following table describes each Configuration Report.

Report Title	Description
ETL Log Argus to Staging Incremental	Displays the ETL Log for the latest Argus to Staging ETL Incremental Process.
ETL Log Staging to Mart Incremental	Displays the ETL Log for the latest Staging to Data Mart ETL Incremental Process.
ETL Log Summary	Displays the ETL Summary for all the ETL Processes.
Listing of Licenses by Family and Product	Obtain an overview of defined licenses grouped by families.
Listing of Product by Family and Licenses	Obtain an overview of defined products grouped by families.
*Study*Configuration	Obtain a listing of configured Studies.
Workflow Configuration by State	Obtain a listing grouping the workflow states listing the incoming and outgoing states.
Workflow Configuration by Transition	Obtain a listing of the configured transitions sorted by From and Use the following procedure to states.
Reporting Rules Configuration	Obtain a listing of configured Reporting Rules.

General Reports

The following table describes each General Report.

Report Title	Description
Case Count By Reporter Type	This is a report for tracking the origin of all notifications.
Case Narrative Listing -English	This report is a narrative overview list of all cases per drug per report type with international and local narratives
Case Narrative Listing -Multilingual	This report is a narrative overview list of all the cases per drug per report type with international and local narratives
Case Origin Listing	This report is a listing to track the origin of all case notifications.
CIOMS II Line Listing	This report prints the standard CIOMS II Listing report for all cases of the case series.
CIOMS Report	This report prints the standard CIOMS I report for all cases of the case series.

Report Title	Description
Clinical Medical Review List	This report provides a listing of serious clinical trial events grouped by study ID.
Downgraded Reports Listing	This report obtains a listing of downgraded reports.
Literature Listing	This report provides an overview including case number with literature reference and case details.
Lot Number Listing - Detail	Use the following procedure to investigate a correlation of events for a certain lot number (Listing).
Lot Number Listing - Summary	Use the following procedure to investigate a correlation of events for a certain lot number (Summary).
Relevant Medical History listing	This report is a listing of all relevant histories for the selected cases.
Study Reconciliation Report	This report provides a data-set to enable reconciliation between Argus and the company clinical database.
US FDA MedWatch 3500A	Prints the standard US FDA MedWatch 3500A report for all cases of the case series.

Management Reports

The following table describes each Management Report.

Report Title	Description
Case Activity History	Graph to show the count of incoming and closed cases and an aggregate total of cases in process
Case Load History by Day	Listing of the number of pending cases for given workflow states by Day
Case Load History by Month	Listing of the number of pending cases for given workflow states by Month
Case Load History by Quarter	Listing of the number of pending cases for given workflow states by Quarter
Case Load History by Week	Listing of the number of pending cases for given workflow states by Week
Case Load History By Year	Listing of the number of pending cases for given workflow states by year
Case Processing Times Listing	Obtain a listing of processing time per case and workflow state including the time to lock and closure of case.
Case Routing History	Detailed listing of all states a case has been routed to.
Case Seriousness Distribution	Obtain a listing of cases by seriousness grouped by country of origin.
Case Seriousness Distribution Graphical Summary	Obtain a graphical representation of cases by seriousness grouped by country of origin.
Case Versions Processed	Obtain a summary tabulation of follow-ups processed.
Case Volume by Reporter Type	Listing to show the volume of cases that were received over a certain time period. Used to pick out trends in reporting sources.

Report Title	Description
Case Volume History - Initial and Significant Follow-ups	Obtains an overview of case volume by specified time period and broken down by initial vs. follow-up reports.
Case Volume History - Product - All Company Suspect Products	Obtains an overview of case volume by specified time period and broken down by key indicators (Product - All Company Products)
Case Volume History - Product - Primary Suspect Products Only	Obtains an overview of case volume by specified time period and broken down by key indicators (Product - Primary Suspect Only).
Case Volume History (Reporter Type)	Obtains an overview of case volume by specified time period and broken down by key indicators (Report Type).
Case Volume History (Seriousness)	Obtains an overview of case volume by specified time period and broken down by key indicators (Seriousness).
Case Volume History split by Initial and Follow-up	Obtains an overview of case volume by specified time period and broken down by initial vs. follow-up reports.
Case-Load	Obtain a graphical representation of cases in each workflow state.
Case-Load Listing	Obtain a listing of the number of cases received and processed per workflow state for a given time period.
Cases by Reporter Type Listing	To compare the number of cases from each reporter type and the associated case details.
Cases by Reporter Type Tabulation	Compares the number of cases from each reporter type.
Delayed Workflow Listing by Case	Obtains a list of cases where the max time has been exceeded.
Delayed Workflow Listing by Workflow State	Obtains a list of cases where the max time has been exceeded.
Event Comparison of Two Periods	Review events (diagnoses) over two time periods and compare these different time periods in one document including labeledness.
First and Last Reporter Contact	Obtain a listing of case details including first and last contact from the reporter (Initial receipt and most recent follow-up date) for each case.
Follow-up Status Listing	Obtain a listing of cases requiring follow-up and the status of those cases.
Listing of Cases due for Lock	Obtain a listing of cases that due for lock
Listing of Cases Late for Lock	Obtain a listing that displays case work state milestones and lead times for workflow as well as minimal case information.
Open Action Items Listing	Obtain a list of cases with open action items by responsible group.
Product Tabulation by Site and Case Source	Obtain a summary that lists the number of cases by site and product (Ingredient) by Report Type with totals.
Receipt Latency of Cases by Site - Initial and All Follow-ups	Obtain a listing of latency from initial receipt date to central received date for initial and follow-up reports.

Report Title	Description
Receipt Latency of Cases by Site - Initial and Significant Follow-ups	Obtain a listing of latency from initial receipt date to central received date for initial and follow-up reports.
Receipt Latency of Cases by Site and Country of Origin	Obtain a listing of latency from initial receipt date to central received date for initial and follow-ups, broken down by country of origin.
Received AE Reports by Protocol	Obtain a line Listing of all cases received grouped by Protocol Number (Study ID).
Report Volume History	Listing to show the volume of reports that were submitted over a certain time period broken down by reporting destination.
Total Case WorkLoad by Site	Obtain a listing of total number of cases in the system.
Total Case Workload by Site and COI - Init. and Sig. Follow-ups	Obtain a listing of total number of cases in the system grouped by site and country of origin.
Total Case Workload by Site and COI - Initial and All Follow-ups	Obtain a listing of total number of cases in the system grouped by site and country of origin.
Total Case Workload by Site Graphical Summary	Obtain a graphical overview of the total number of cases in the system broken down by seriousness.
Workflow Monitoring Report	Obtain a listing that displays case workflow milestones and lead times for workflow as well as minimal case information.
Workflow Report - 3 months	Counts based on Groups over 3 month periods, based on a selected date range.
Workflow Report - 4 quarters	Counts based on Groups over 4 quarters, based on a selected date range.

Pharmacovigilance Reports

The following table describes each Pharmacovigilance Report.

Report Title	Description
AE Count Tabulation	This report is a summary tabulation that displays a count of events and breaks them down by causality.
Age Group Vs. Gender	This report is an analysis of relationships between two or more attributes.
Aggregate Diagnosis Listing	This report is a summary of the event counts by Diagnosis and broken down by seriousness and listedness.
Case Listing	This report is a case listing of cases with key Pharmacovigilance data elements for spontaneous cases.
Case Listing with all Regimens and Events	This report is a case listing of cases with all regimens and events for spontaneous cases.
Clinical Case Listing	This report is a case listing for clinical cases
Clinical Trial Causality	This report captures the Table of event count grouped by selected MedDRA levels (SOC,HLGT,HLT,PT), administered drug, event causality to support medical investigation. Case counts for selected MedDRA levels and administered drug is also included

Report Title	Description
Clinical Trial Causality Tabulation	This report is required to tabulate the causality assessments for each occurring PT.
Count of Serious Related Cases by Product	This report provides an overview of serious related cases over a given time period.
Data Quality Indicator (Alphabetically by Quality Indicator)	This report provides a graphical summary of case data quality for the following key data elements
Data Quality Indicator Listing	This report provides a list that contains the cases that contributed to the data value as the graphical report
Data Quality Indicator (Ascending Order of Count)	This report provides a graphical summary of case data quality for the following key data elements.
Dechallenge and Rechallenge Listing	This report provides the Line Listing for Dechallenge and rechallenge information
Dosage Frequency Tabulation	This report captures the frequency of dosing for a particular product to see if there is an increase in frequency of various AEs.
Dose Formulation Product Relationship	This report captures the relationship between dosage formulation and events for a given suspect drug.
Event (PT) Vs Age Group	This report is required to analyze relationships between two or more attributes.
Event (PT) Vs Daily Dose	This report is required to analyze relationships between two or more attributes.
Event (PT) Vs Duration of Treatment Until Event	This report is required to analyze relationships between two or more attributes.
Event (PT) Vs Gender	This report is required to analyze relationships between two or more attributes.
Event (PT) Vs Report Type	This report is required to analyze relationships between two or more attributes.
Event Term Frequency Listing by HLGT	This report is required o identify the frequency of events in descending order, grouped by SOC, HLGT, HLT, or PT.
Event Term Frequency Listing by HLT	This report is required to identify the frequency of events in descending order, grouped by SOC, HLGT, HLT, or PT.
Event Term Frequency Listing by PT	This report is required to identify the frequency of events in descending order, grouped by SOC, HLGT, HLT, or PT.
Event Term Frequency Listing by SOC	This report is required to identify the frequency of events in descending order, grouped by SOC, HLGT, HLT, or PT.
Event Vs Daily Dose	This report is required to analyze relationships between two or more attributes.
Event Vs Report Type	This report is required to analyze relationships between two or more attributes.
Event Vs. Age Group	This report is required to analyze relationships between two or more attributes.
Event Vs. Duration of Treatment Until Event	This report is required to analyze relationships between two or more attributes.

Report Title	Description
Event Vs. Gender	This report is required to analyze relationships between two or more attributes.
Fatal Case Listing	This report is required to obtain a listing of cases with fatal seriousness criteria.
Fatal/Life-Threatening Cases Listing	This report is required to obtain a listing of cases with fatal or life-threatening seriousness criteria.
Frequency Listing of Events	This report is a table of event counts - sorted by descending event count frequency to help support labeling or package insert review.
Product and Disease Listing	This report captures the concomitant medications and underlying disease
Product Interaction Tabulation	This report is a summary tabulation that displays a count of the incidence of other products involved in cases.
Quick Signal	This report captures the event-reporting rates that might suggest a possible change in the safety profile of a product.
Seriousness Case Listing	This report provides a listing of cases by grouped by seriousness criteria.
SOC/PT Tabulation (Event Count)	This report compares events based on report type.
Temporal Relationships	This report captures a graphical overview of the temporal relationships of the dates recorded in the case.
Top 10 Substances	This report captures a listing of the top 10 frequent substances occurring in cases for the specified time period.

7

Custom Reports

Creating Custom Reports

In addition to the preformatted Standard Reports, Argus Insight provides Report Writer, Cubes, and Dashboard Indicators tools that let you create custom reports for ad hoc/special reporting requirements.

Report Writer is used to create a custom report by directly selecting datamart 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.

A Cube is a data model that contains multiple dimensions (key reporting elements). You can observe and analyze the interactions between reporting elements by performing operations such as nesting, drill, sort, count, and total. Argus Insight provides six built in Cubes pertaining to varied reporting aspects.

Dashboard Indicator reports are configured by the administrator and made available to users based on their profile. These reports pull the latest data from the datamart and provide information on key product performance and workflow efficiency parameters.

The following topics explain how to use the custom report tools.

- Using Report Writer
- Using AdHoc Reports

Using Report Writer

In this version of Argus Insight, Report Writer utilizes the features of Business Objects® XI™ Java Report Panel to let you create custom reports by directly selecting datamart fields and viewing the customized result (report output). The Report Writer interface provides a list of database fields organised 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.

The following topics explain how to use Report writer for creating and managing custom reports.

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

- Saving and Accessing Reports
- Using SMQs in Report Writer
- Using Case Annotations

Creating a New Report

This topic explains how to start Report Writer and create a new report. Use the following procedure to create a new report..

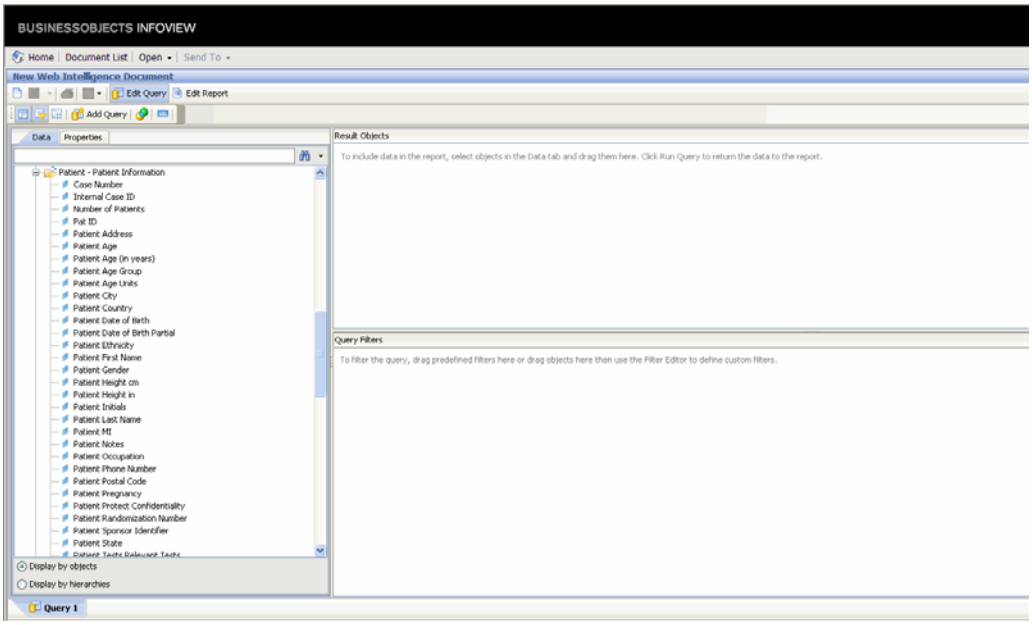
1. In Argus Insight, select **Case Series Reports > Report Writer > New**. The Business Objects® XI™ Java Report Panel appears. In the left frame, the **Report Writer** panel contains all the fields (i.e. classes and dimensions). These are used as the filtering criterion for data analysis.

> **Note:** The fields that you select here are displayed as columns in your report output.

2. Select the Active Case Series Filter.

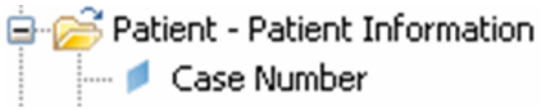
> **Note:** We recommend selecting the **Active Case Series Filter** before selecting the datamart fields for your report. This prevents Report Writer from querying the entire datamart and slowing down the report output generation. To view the Active Case Series, select **Query Results > Case Series > Active** in Argus Insight. If you want to make another Case Series active, select **Query Results > Case Series > Library** in Argus Insight. In the **Case Series Library** page that appears, check the Case Series you want to make active and click **Make Active**.

3. In the left frame, expand the class folders under **Report Writer**.The dimensions for the class category are displayed.


BUSINESSOBJECTS INFOVIEW
Home
Document List
Open
Send To
New Web Intelligence Document
Edit Query
Edit Report
Add Query
Data
Properties
Result Objects
To include data in the report, select objects in the Data tab and drag them here. Click Run Query to return the data to the report.
Patient - Patient Information
Case Number
Internal Case ID
Number of Patients
Pat ID
Patient Address
Patient Age
Patient Age (in years)
Patient Age Group
Patient Age Units
Patient City
Patient Country
Patient Date of Birth
Patient Date of Birth Partial
Patient Ethnicity
Patient First Name
Patient Gender
Patient Height cm
Patient Height in
Patient Initials
Patient Last Name
Patient MI
Patient Notes
Patient Occupation
Patient Phone Number
Patient Postal Code
Patient Pregnancy
Patient Protect Confidentiality
Patient Randomization Number
Patient Sponsor Identifier
Patient State
Query Filters
To filter the query, drag predefined filters here or drag objects here then use the Filter Editor to define custom filters.
Display by objects
Display by hierarchies
Query 1

Tip: Classes and Dimensions

In this example, we will discuss a class and its dimension.



In the illustration displayed above, **Patient- Patient Information** is a class and **Case Number** is a dimension.

When you expand the **Patient- Patient Information** class, you can see all the associated dimensions of this class.

For instance, the dimension **Case Number** captures the Case Number for all the reported cases.

You can use any combination of dimensions as filtering criterion. Each dimension you include in your query, appears as a column in the report output section.

Using the required combination of dimensions you can collate data to analyze your information better.

Filtering

In this example, we will discuss the concept of filtering.

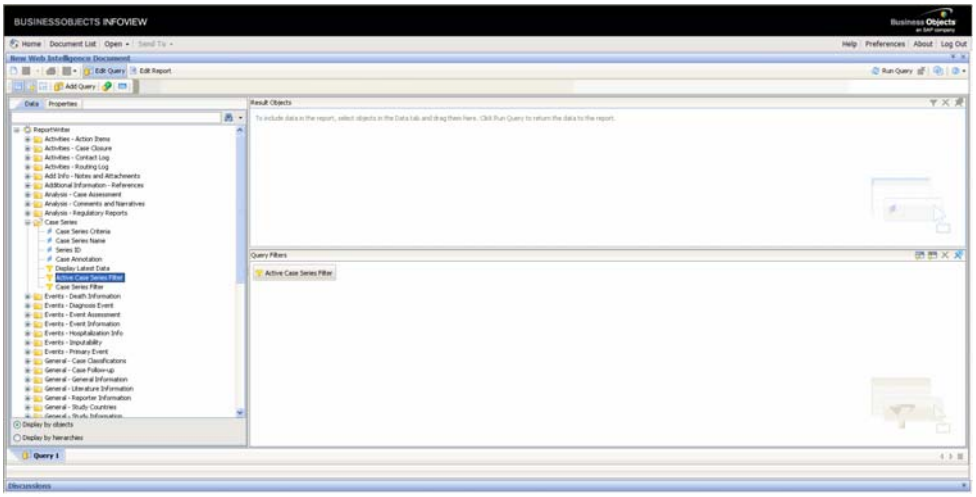
An example of filtering is, when you want to list case numbers, where female patients, were associated with an overdose of drug.

In this scenario, **Case Number** and **Dug Overdose** are the two dimensions which will appear in the report output. To ensure that only female patient cases are listed, use the panel to define the exact filtering requirements.

To ensure that only female patient cases are listed, use the **Query Filters** panel to define the exact filtering requirements.

When you execute this query, the report output section displays the tabulated data for female patients, with **Case Number** and **Dug Overdose** data displayed in columns.

4. Scroll down the list of views so that the **Active Case Series Filter** folder is visible.
5. Expand the **Filters** folder. The built in **Active Case Series Filter** is displayed.

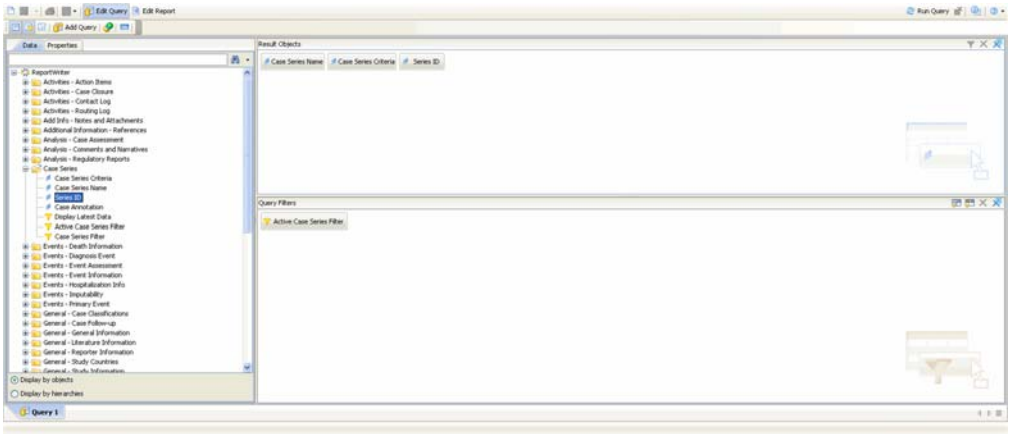


6. Select the Filter.
7. Drag and drop the filter into the **Query Filters** panel. The selected filter appears in the right frame.
8. Select the datamart fields to include in your report.
9. In the left frame, expand the dimensions under **Report Writer**. The dimensions are displayed.

10. Select the fields (dimensions), 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.**

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



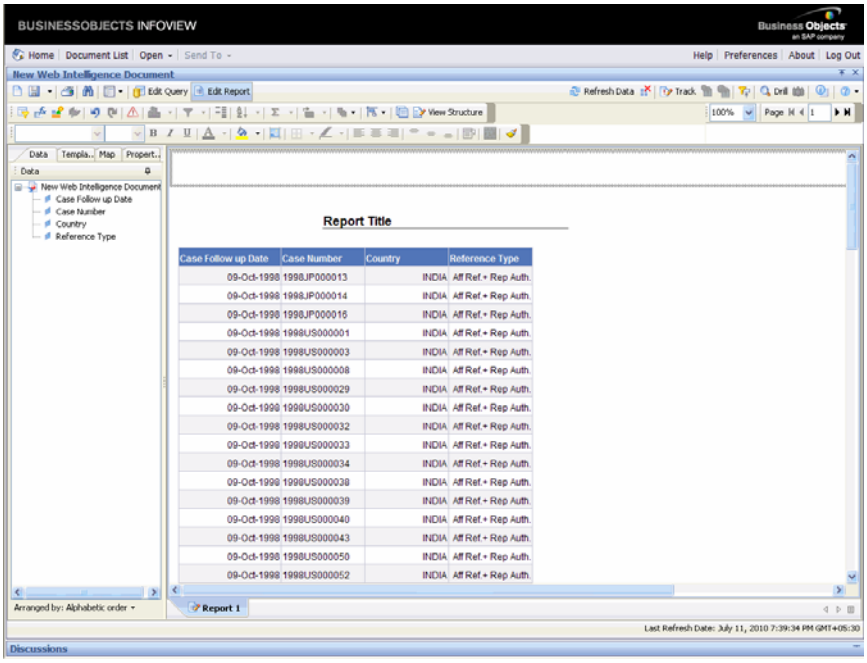
Tip: To select multiple fields, hold down the **CTRL** key and select the fields. Then drag the field entities to the report output area (in the right panel).

If you wish to delete a *column* from the report output, select the column, right click to access the Remove button from the context menu.

You can revert any action you perform in the **Java Report Panel** by clicking the **Undo** toolbar button, respectively.

12. Execute the query. Click the **Run Query** toolbar button in the BOXI web browser to execute the query.

The Report Writer queries the datamart, 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. The **Report** section appears.



The example in the illustration captures the cases (limited to the active case series) listed by their case numbers and the associated overdose information (as yes, no or unknown).

Using Case Series Criteria and Case Series Name in new Report

Use the following procedure to generate a report for displaying all the **Case Series Criteria** and **Case Series Name**.

1. Drag and drop the **Case Series Criteria** and **Case Series Name** objects from the **Case Series** class into the Results pane.
2. Click the Run Query toolbar button in the BOXI web browser to execute the query.
3. The Report Writer queries the datamart, to get all the **Case Series Criteria** and **Case Series Name**.

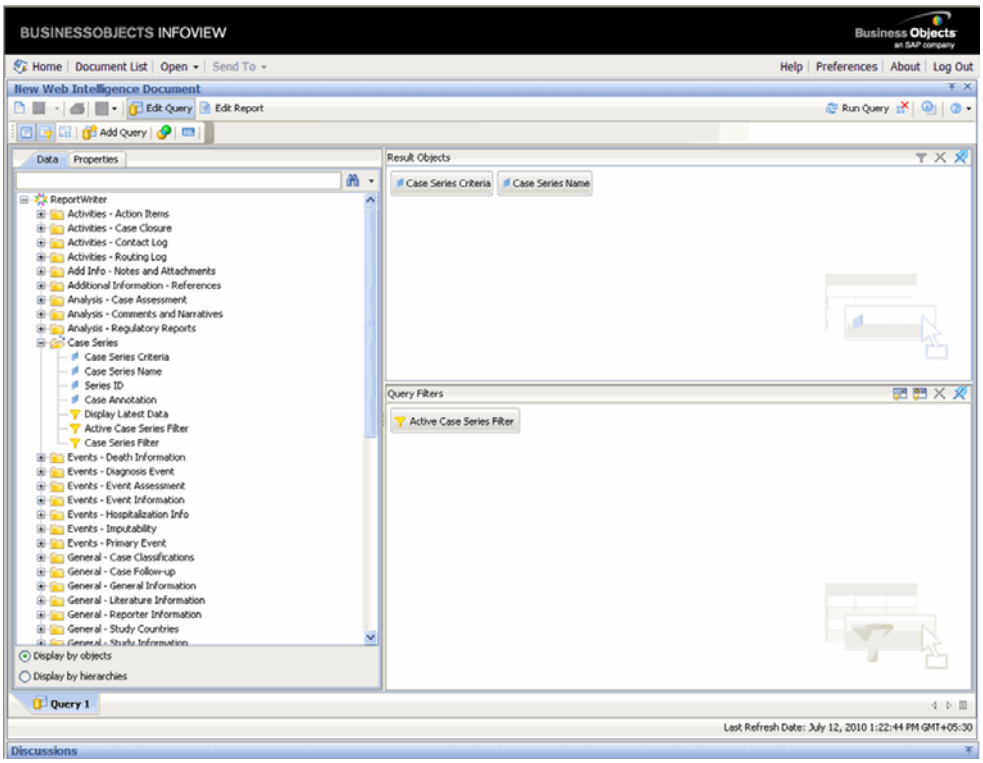
Note: The system does not display Temporary Case Series Criteria or Case Series names.

Using Case Series Criteria and Case Series Name with Other Objects

Use the following procedure to use case series criteria and the case series name with other objects.

1. In the left frame, expand the class folders under Report Writer. The dimensions for the class category are displayed.

2. Scroll down the list of views so that the **Case Series** folder is visible.
3. Expand the **Case Series** folder. The built-in **Active Case Series Filter** is displayed.
4. Drag and drop the Active Case Series Filter into the Query Filters panel. The selected filter appears in the right frame.
5. Drag and drop the Case Series Criteria and Case Series Name in the Results pane with other objects on which you want to create the report.



6. Click Run Query to run the query.

Note: Always use Active Case Series Filter while using Case Series Criteria and Case Series Name with other objects.

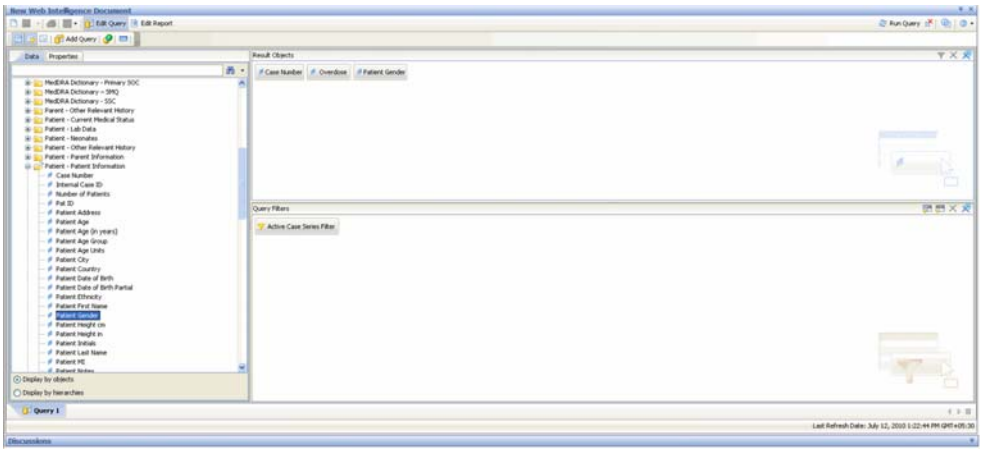
To view the Active Case Series, select Query Results > Case Series > Active in Argus Insight. If you want to make another Case Series active, select Query Results > Case Series > Library in Argus Insight. In the Case Series Library page that appears, check the Case Series you want to make active and click Make Active.

Tip: If you wish to rename the report, click on the existing report title to select it. If the report title is not visible in the formula toolbar, then click the Formula Toolbar icon to view the toolbar. Edit the Report name as required and click Enter. The new report title is displayed in the Report Section.

After selecting the required datamart fields and generating the output, use use the various Java Report Panel options to edit the report, change the report layout, and save the report.

Editing Reports

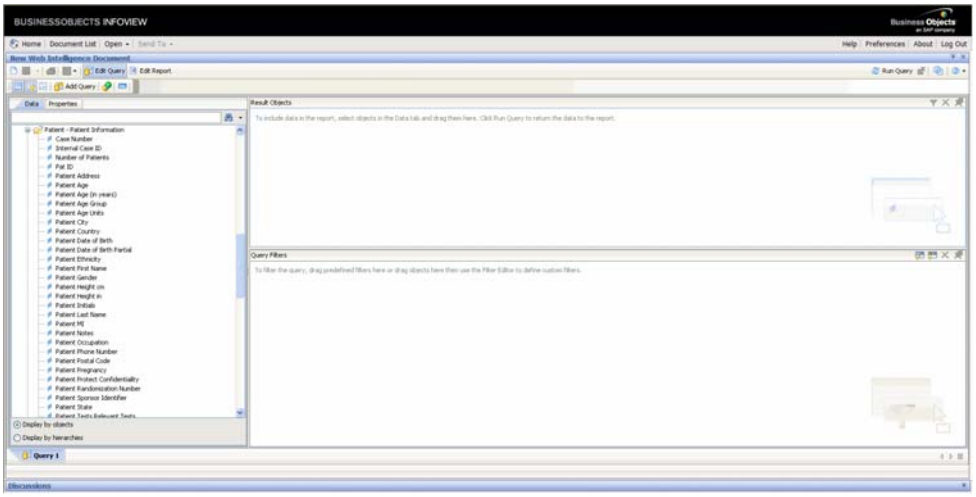
You can access Business Objects® XI™ Java Report Panel's report editing options by selecting the **Edit Query** menu option**.** The report querying options let you control the data that appears in your report as well as how it is formatted, calculated, and sorted. None of the edit operations you perform are stored in the database.



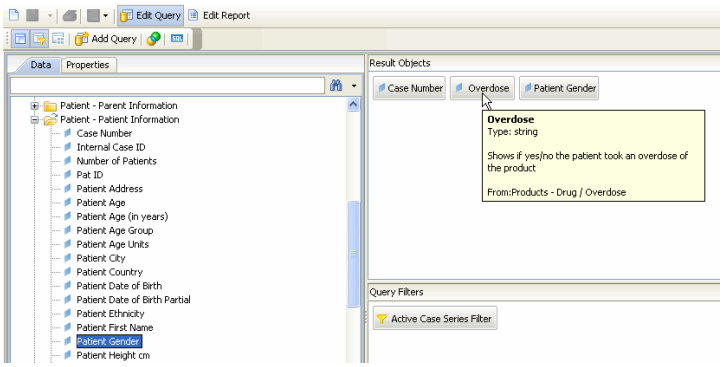
Filtering Data

You can use the filtering option to select data fields with specific filtering criterion for your report.

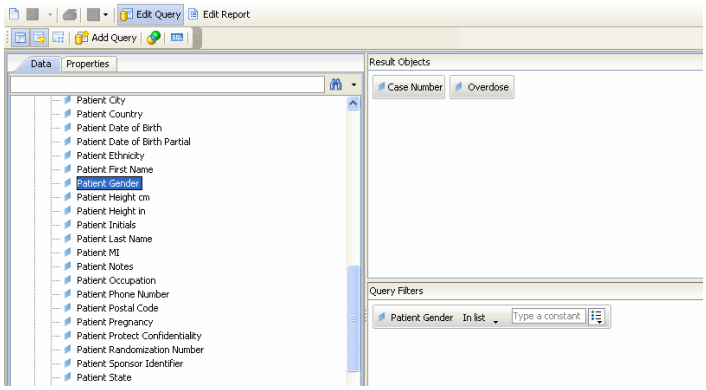
1. In the toolbar menu, click **Edit Query** to view the **Data** (objects) and the **Result Objects** panes.
2. In the left frame, expand the dimensions under **Report Writer**.The dimensions are displayed.



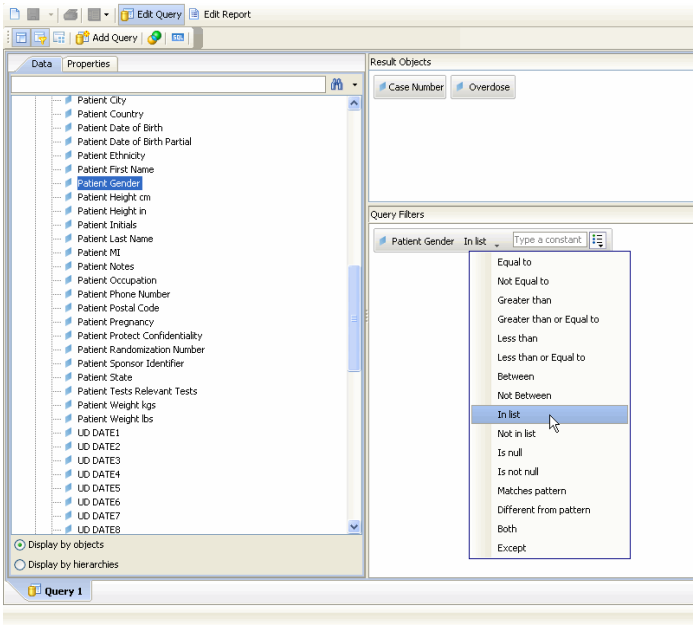
3. From the **Data** (objects) panel, drag and drop the data fields into the **Result Objects** panel. The objects are placed in the **Result Objects** panel.



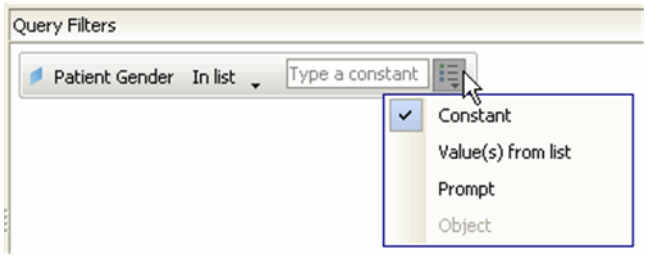
4. From the **Data** (objects) panel, drag and drop the filter criterion into the **Query Filters** panel.The selected filter appears in the right frame.

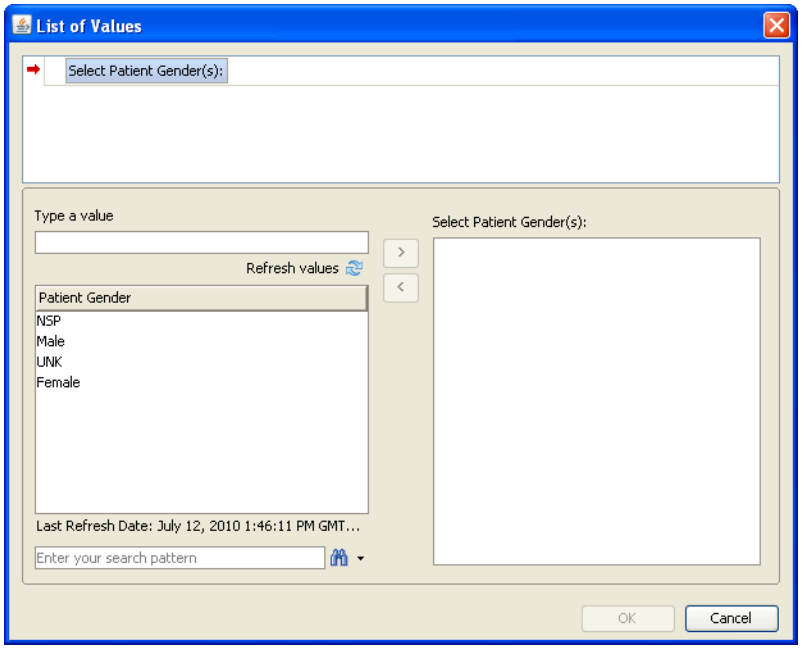


5. Select the **operator type** from a drop-down list by clicking the drop-down icon. The operator selected in the illustration is the **In list** operator. Using this operator, the filter is limited to any one or all of the values defined in the list.

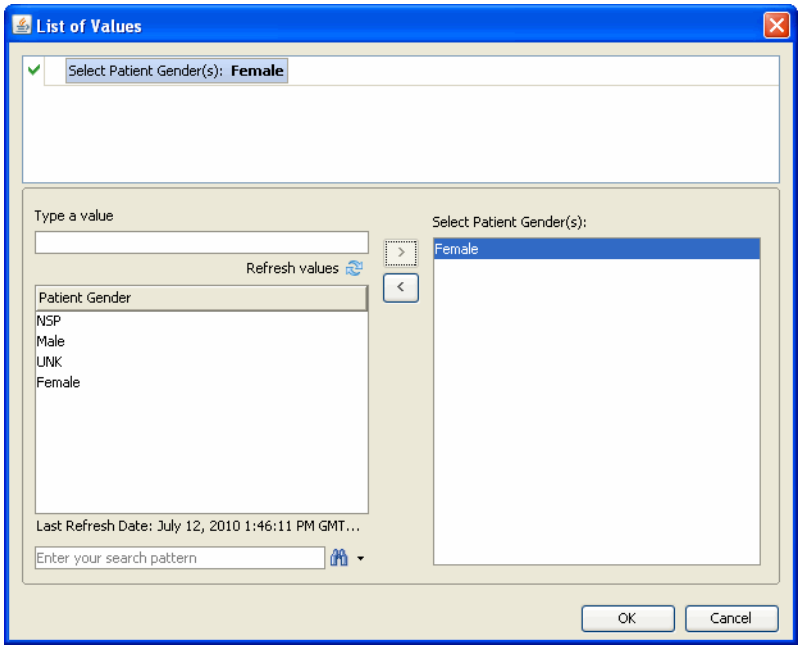


6. To select the value(s) associated with the operator, click the icon next to the text field, as shown below. The value is defined using the **Value(s) from list** option

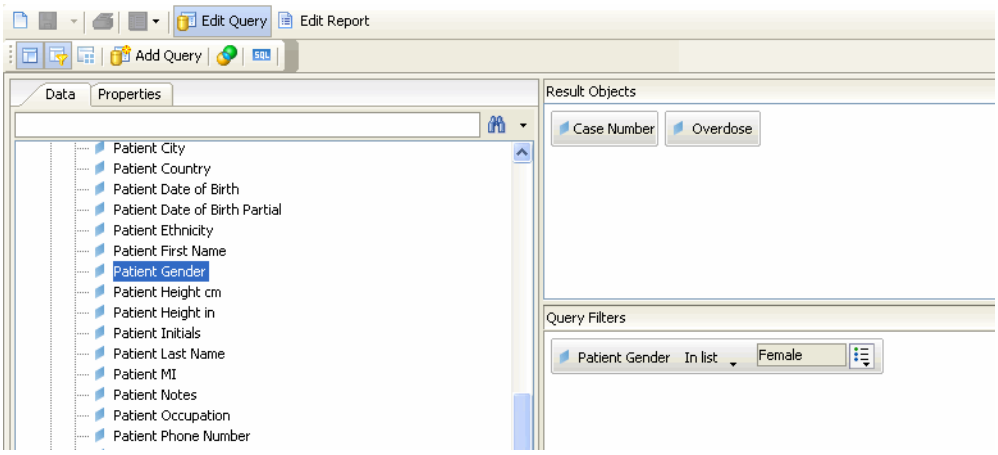




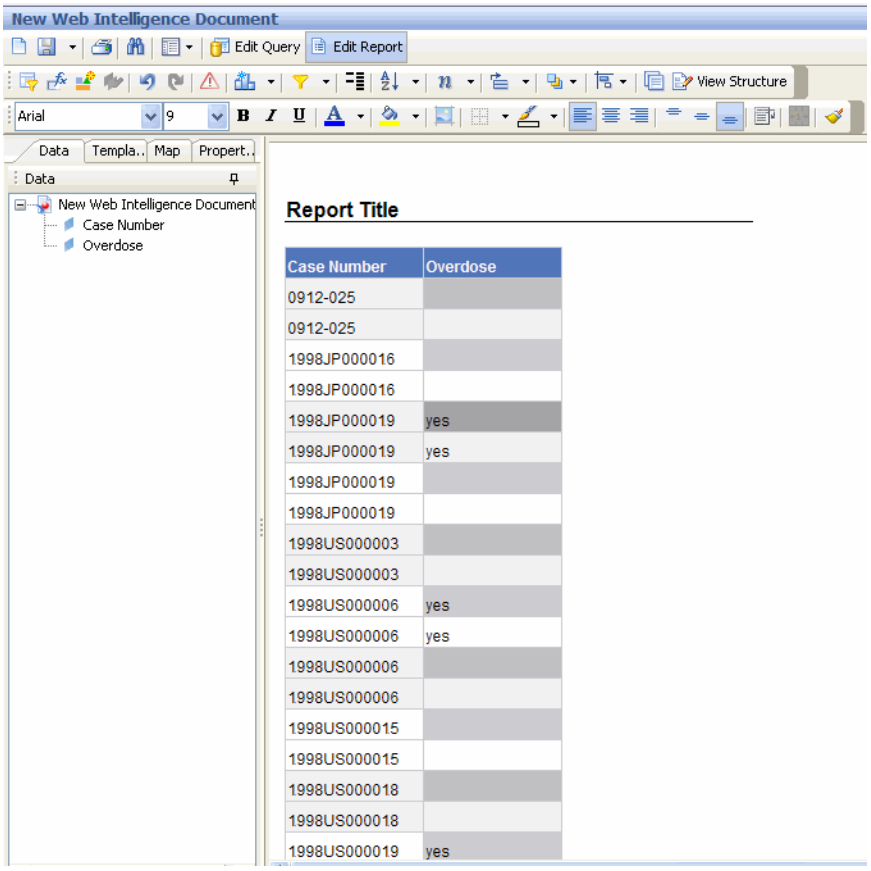
7. Define the value by selecting the term/word to be used as a filtering criterion. Click **OK** to confirm the action.



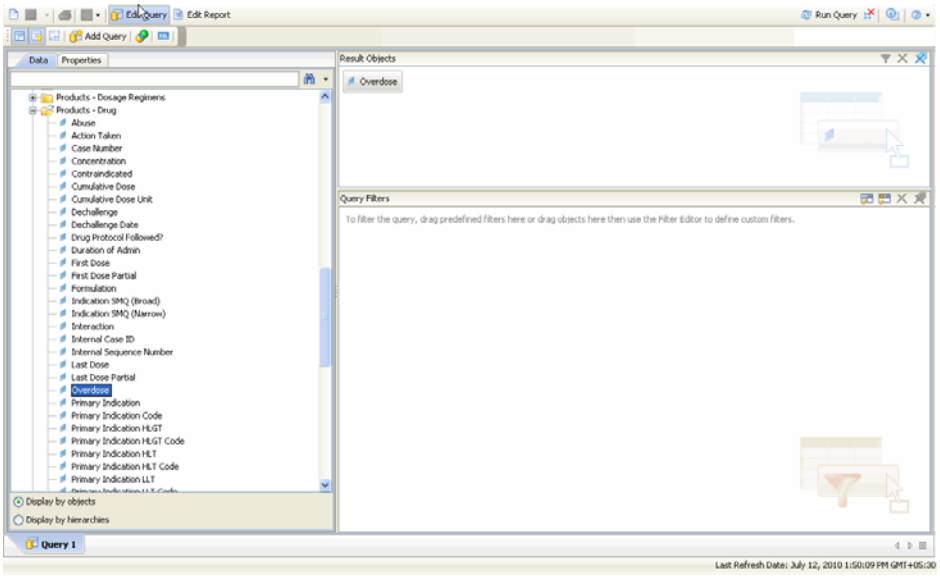
8. The **Query Filters** panel refreshes automatically to display the complete filtering criterion.



9. Click the Run Query toolbar option in the BOXI web browser, to execute the query. The **Report** section appears in the right frame. The example in the illustration captures the cases that have been filtered and limited to female patients. For each female patient, the case number and the associated overdose information (as yes, no or unknown) is displayed.



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

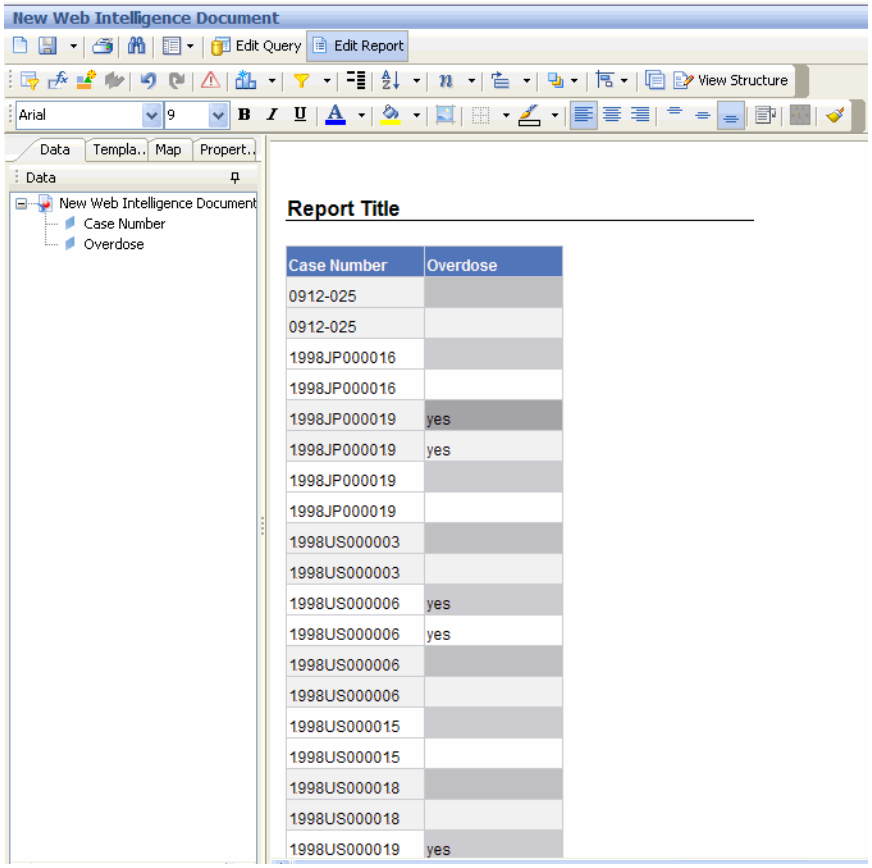


11. Repeat steps 1 to 5 to add new dimensions as filtering criterion and execute the query.

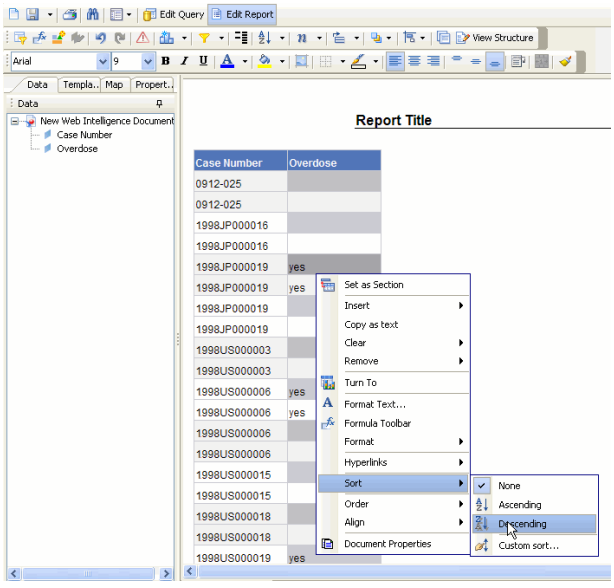
Sorting Data

You can use the sorting option to change the order in which data appears in your report. Use the following procedure to sort data in your report.

1. In the **Report** section, select (or click) the column values that you wish to sort for the report output. The selected column is highlighted.



2. Right-click on the selected column within the data-cell.The context menu for **Sort** appears.

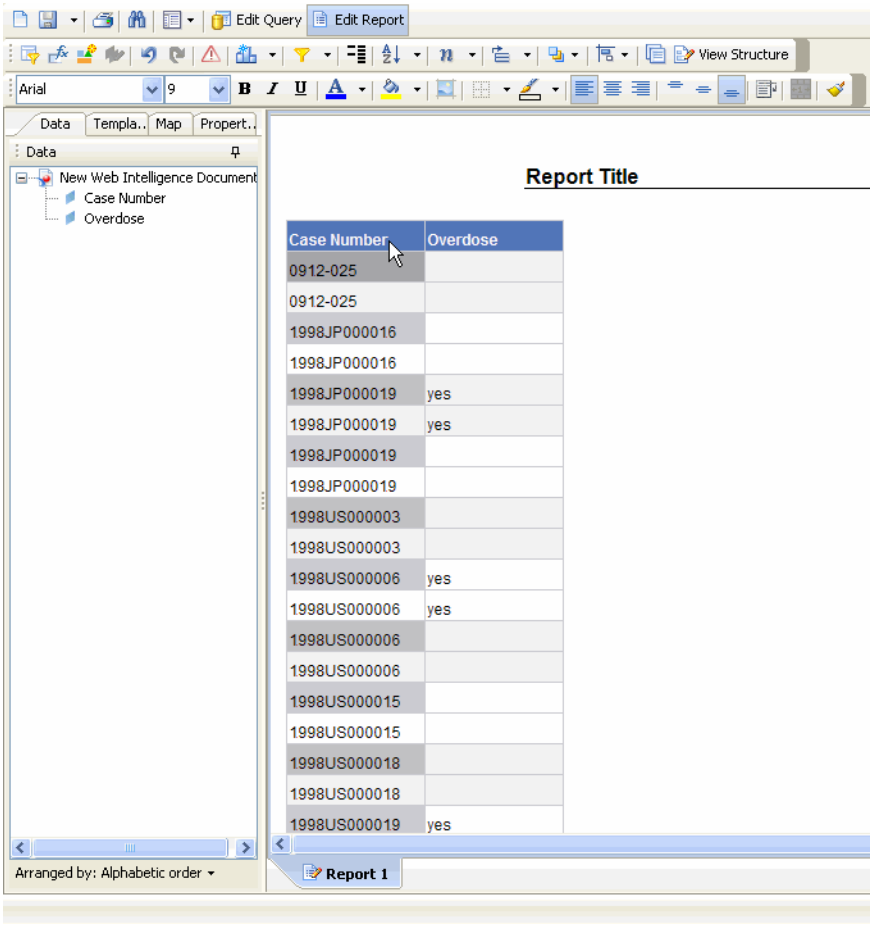


3. Select the required sorting option by using the **Sort** option provided in the context menu.The system refreshes the report and displays the sorted output.

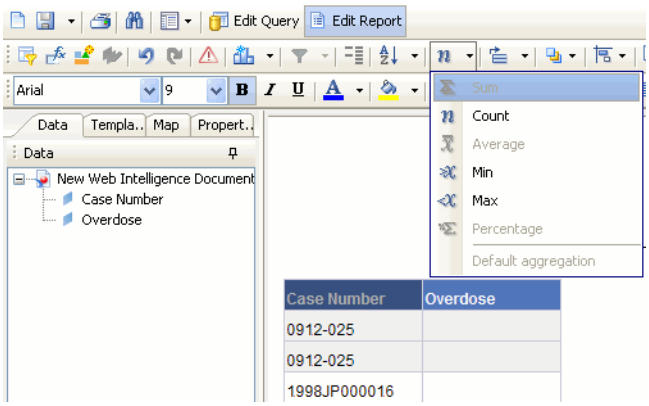
Summarizing Data

You can 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 wish 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.

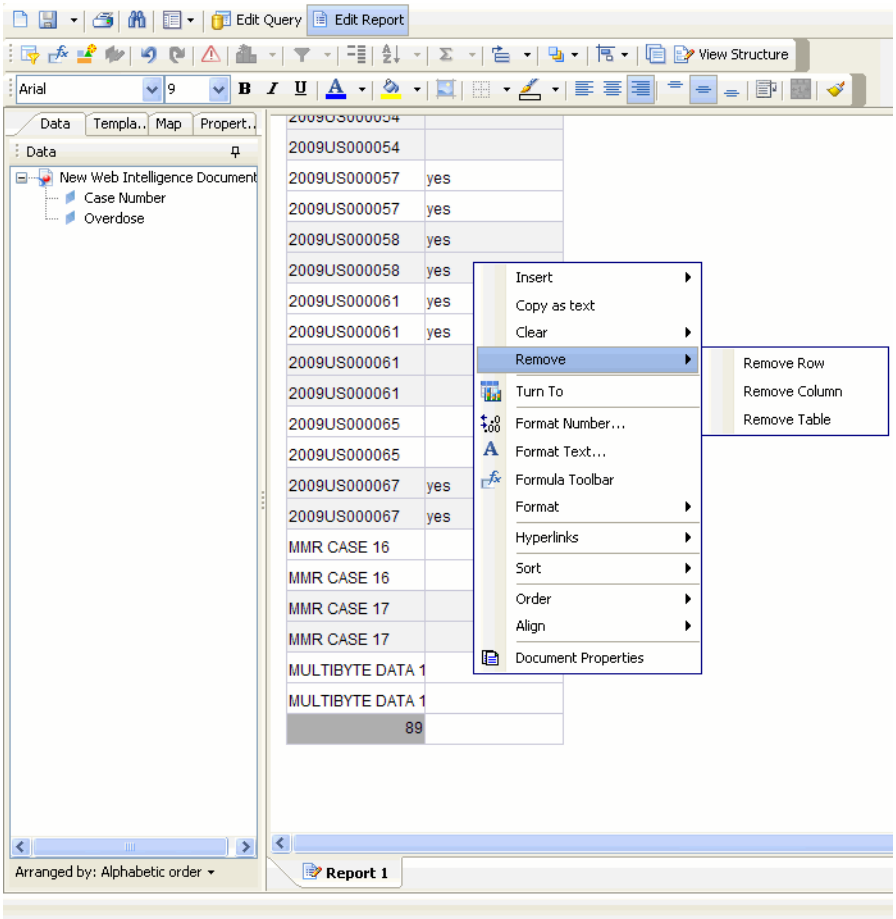
1. In the **Report Title** section, click on the column that you wish to summarize.The selected column is highlighted.



2. Select **Insert Sum** from the menu options in the top frame.The **Insert Sum** appears as a drop down context menu in the top frame.



3. From the **Insert Sum** drop down context menu, select the required summary option. The options available depend on the type of values the select column contains.
4. The report output displays the column summary at the bottom of the report.
5. To remove summary information, select the relevant column and right click to view the context menu. Click **Remove** to clear the contents of the cell



Formatting Data in Cells

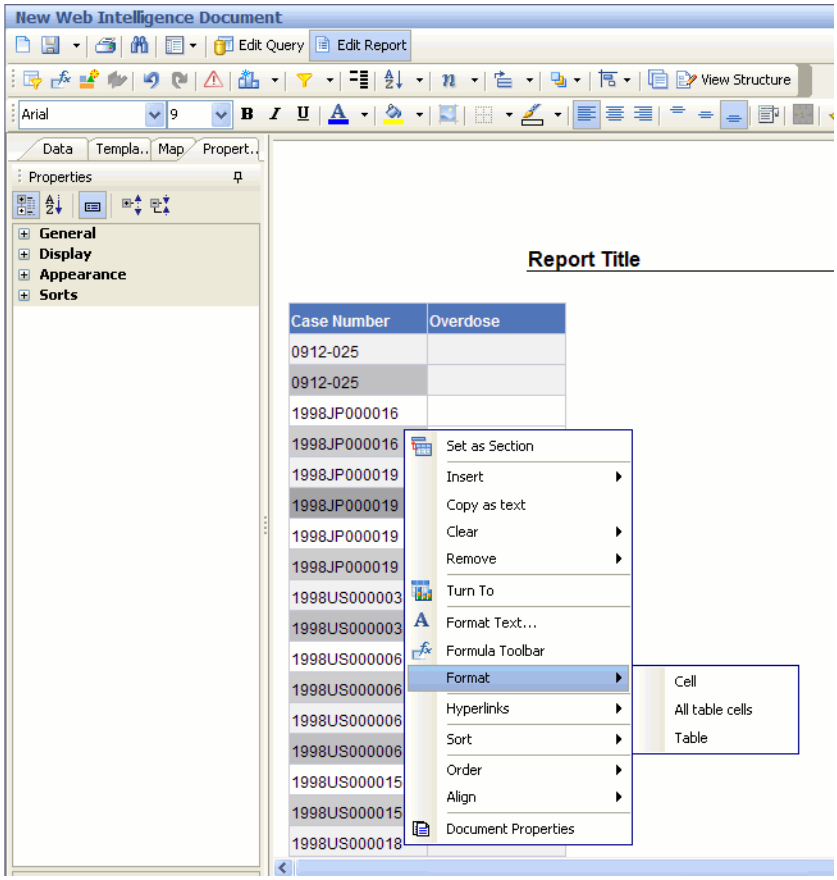
You can use predefined formats to change the appearance of numbers, dates, and

times in your report. Formatting does not change the underlying data. The following table describes the various formatting options available.

Format	Description
Default	The default format is the format of the report item before any formatting is applied in Java Report Panel. 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. You can also 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.

Use the following procedure to format data.

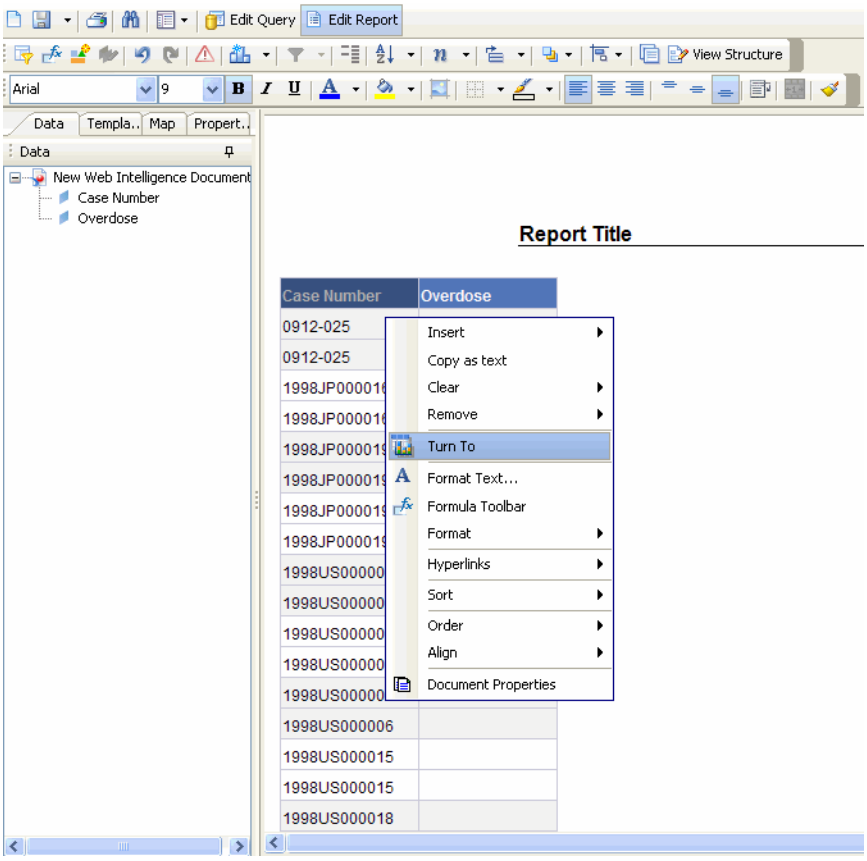
1. In the report output area, click within the column that you wish to format. The selected column is highlighted.
2. Right-click on the highlighted column and select **Format** from the drop-down menu.



3. Set the data format properties from the **Properties** pane (displayed on the left), as appropriate.
4. Click **OK**. The report output is refreshed and displays the formatted data.

Changing the Report Layout

You can access Business Objects® XI™ Java Report Panel's report layout options by selecting 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. You can also group your report by a specific column, swap rows and columns, or create sections within your report.

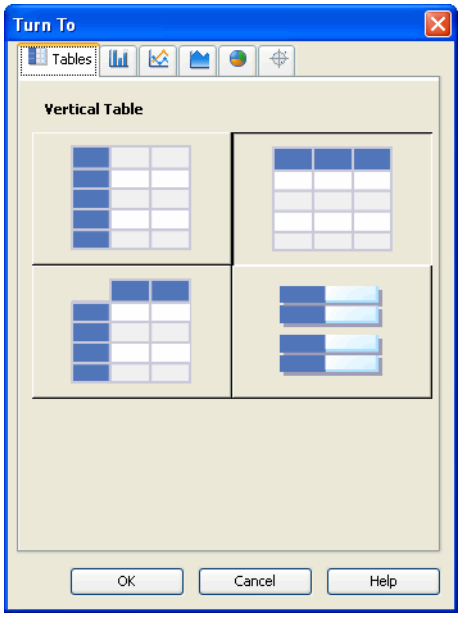


The sections explain how to use the various report layout options. This topic describes the basic layout operations in the Java Report Panel. For detailed information, refer to the documentation supplied with the BOXI products.

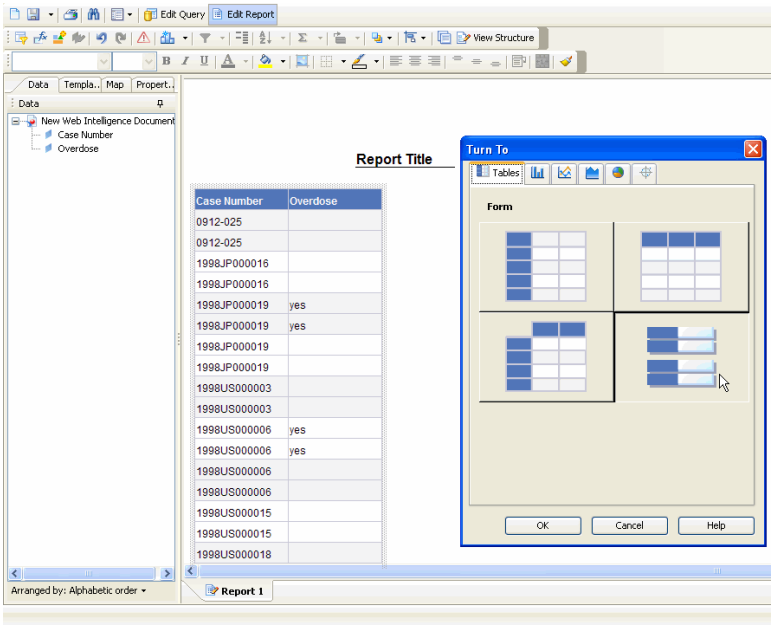
Creating a Table

Use the **Turn to > Table** option to tabulate data. Use the following procedure to create a table from a report.

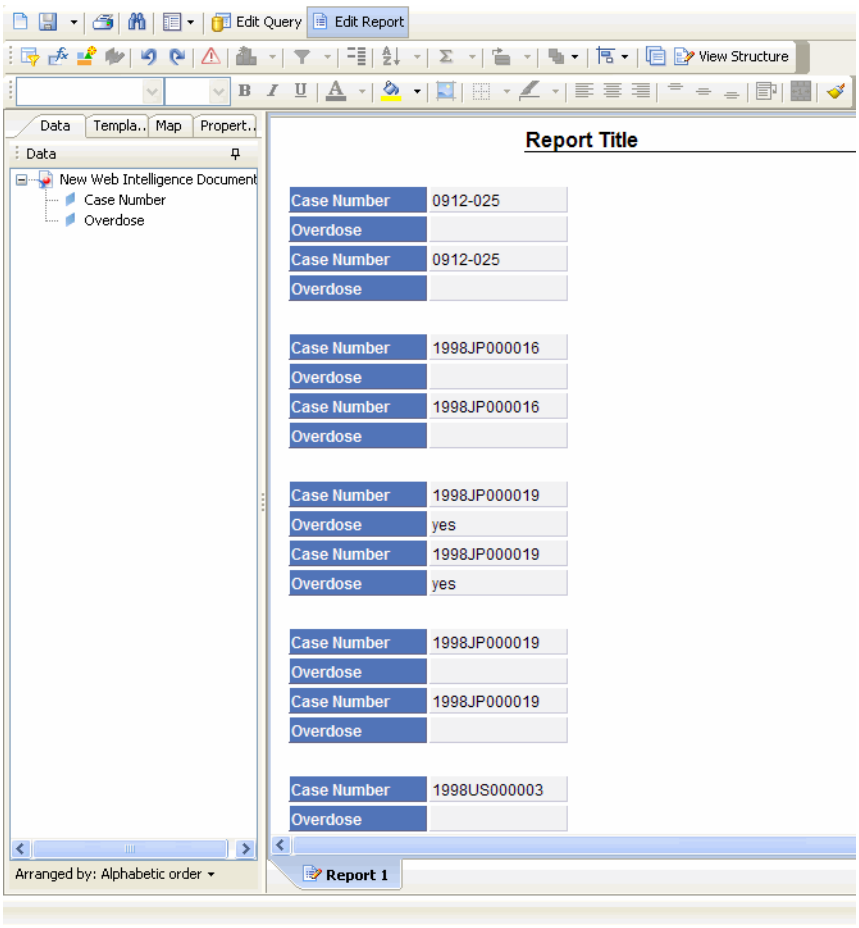
1. While your report is displayed, select the **Table** tab from the **Turn To** context menu option. The **Turn to** > **Table** options appear in the report output section in the right frame.



2. Select the required table format. For example, vertical, horizontal, crosstab or form.



3. Click **OK**. The report output refreshes. The table is displayed in the selected format



Creating a Bar Chart

Use the **Turn to > Bar** option to display data as a bar-chart. Use the following procedure to create a bar chart from a report.

1. While your report is displayed, select the **Bar** tab from the **Turn To** context menu option.The **Turn to** > **Bar** options appear in the report output section in the right frame.
2. Select the required bar format.
3. Click **OK**. The report output refreshes to display the selected format.

Creating a Line Chart

Use the **Turn to > Line** option to display data as a line-chart. Use the following procedure to create a line chart from a report.

1. While your report is displayed, select the **Line** tab from the **Turn To** context menu option.The **Turn to** > **Line** options appear in the report output section in the right frame.
2. Select the required line format.
3. Click **OK**. The report output refreshes to display the selected format.

Creating an Area Chart

Use the **Turn to > Area** option to display data as a area-chart. Use the following procedure to create an area chart from a report.

1. While your report is displayed, select the **Line** tab from the **Turn To** context menu option.The **Turn to** > **Area** options appear in the report output section in the right frame
2. Select the required area format.
3. Click **OK**. The report output refreshes to display the selected format.

Creating a Pie Chart

Use the **Turn to > Pie** option to display data as a pie-chart. Use the following procedure to create a pie chart from a report.

1. While your report is displayed, select the **Pie** tab from the **Turn To** context menu option. The **Turn to** > **Pie** options appear in the report output section in the right frame
2. Select the required pie format.
3. Click **OK**. The report output refreshes to display the selected format.

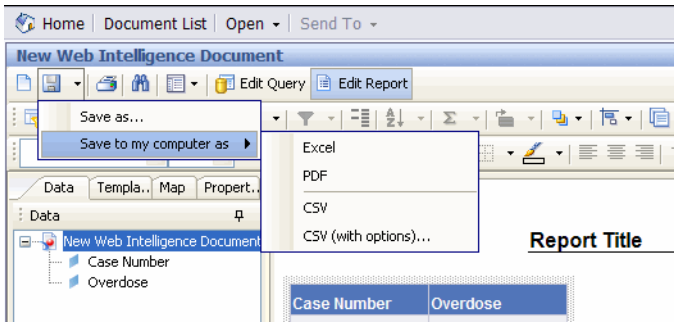
Creating a Radar Chart

Use the **Turn to > Radar** option to display data as a radar-chart. Use the following procedure to create a radar chart from a report.

1. While your report is displayed, select the **Radar** tab from the **Turn To** context menu option. The **Turn to** > **Radar** options appear in the report output section in the right frame.
2. Select the required radar format.
3. Click **OK**. The report output refreshes to display the selected format.

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 (datamart fields you select) for extracting data from the datamart 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 datamart as a result of the ETL process.

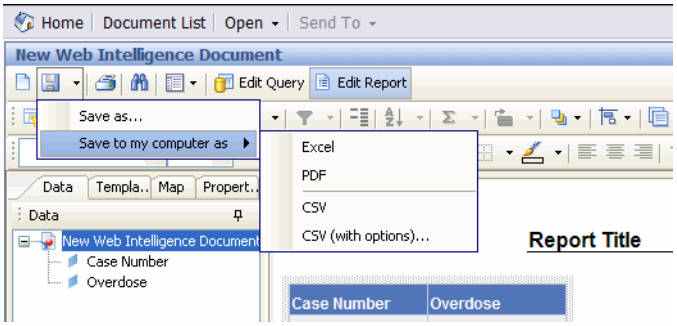


The following sections explain how to save reports and access saved reports.

Saving Reports

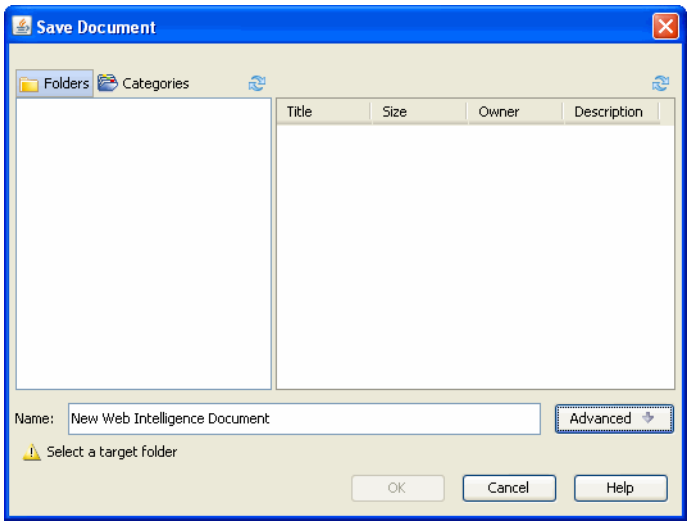
Use the following procedure to save a report.

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



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

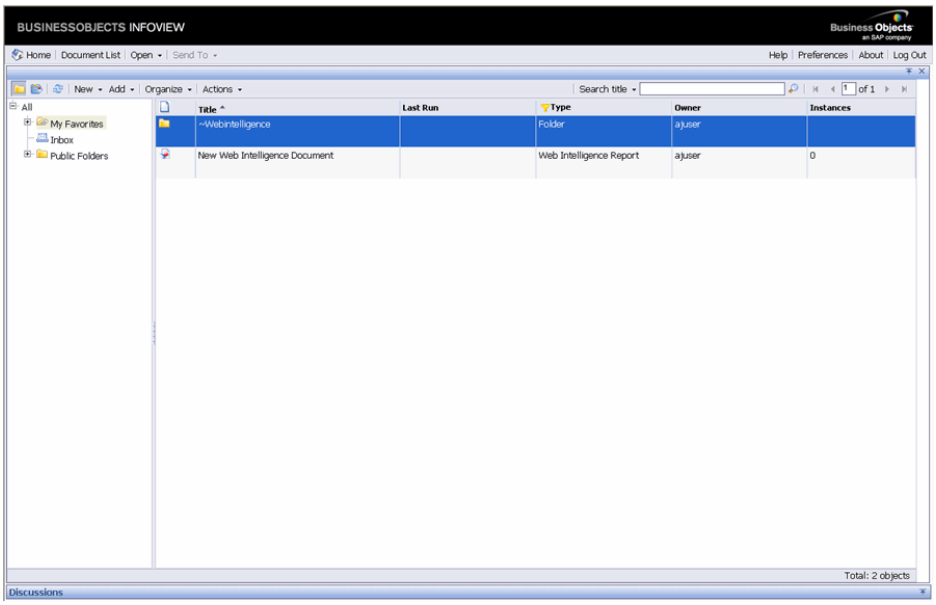
2. Click **Save As** to save the report on your system. The **Save Document** dialog box appears.



3. Enter the report name in the Title text box.
4. Enter the report description in the Description text area.
5. Select a Location folder 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 > Favourites** folder if you wish to save the report as a personal document.
6. Click **OK** to save the report in the location you specified.

Accessing the Report Writer Library

The reports you save in the **My Favourites** folder can be accessed from Case Series Reports > Report Writer > New > BO Infoview Home page > My Favorites. You can access the saved reports from the following screen.



Note: The **Case Series Reports > Report Writer > Library** menu is not available in Argus Insight anymore.

Right-click a report and select Modify to edit a saved report. The report opens in the BOXI 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.

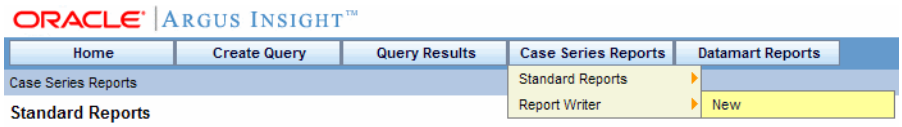
Using SMQs in Report Writer

If a user selects an SMQ, all the cases based on that SMQ are displayed. The following section explains how to use SMQs in report writer.

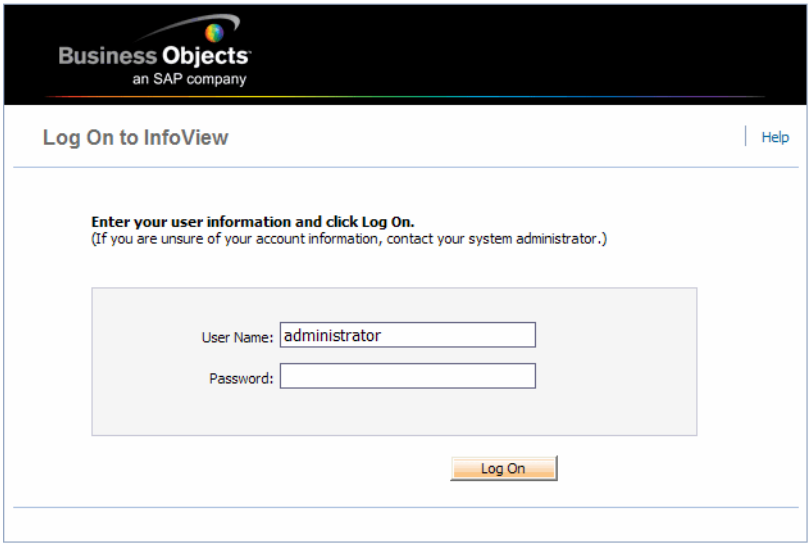
Using SMQs

Use the following procedure to use SMQs in report writer.

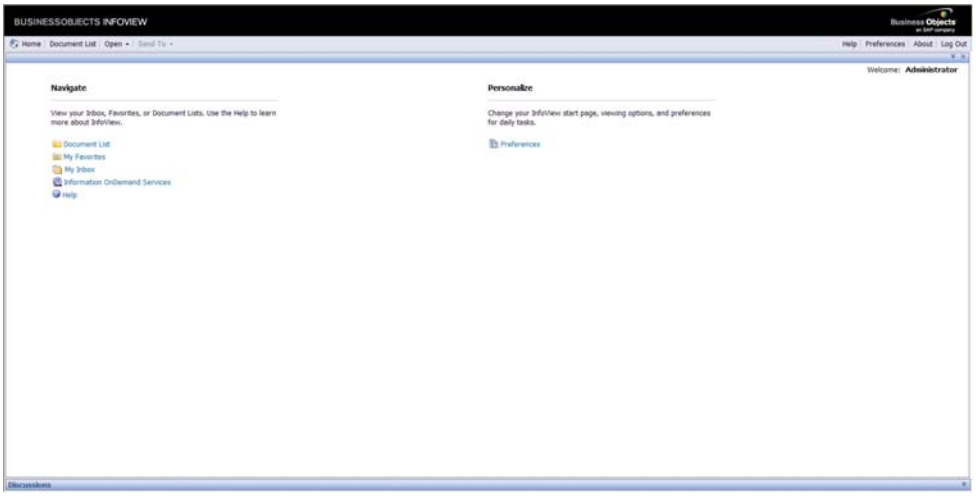
1. Go to **Case Series Reports > Report Writer > New**. The Business Objects (BO) Infoview window opens. Enter your login credentials.



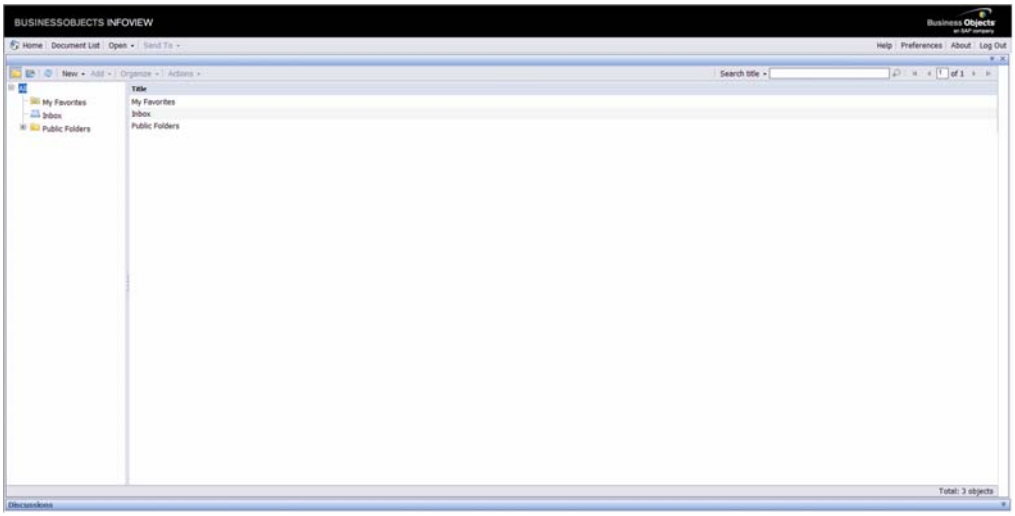
2. The Business Objects (BO) Infoview window opens. Enter your login credentials.



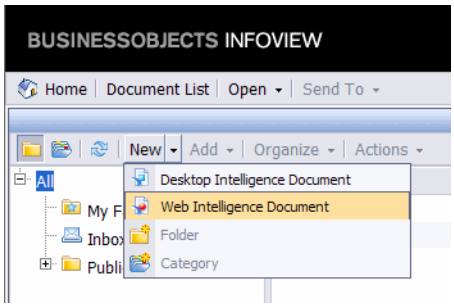
3. Click Log On. The Home page opens.



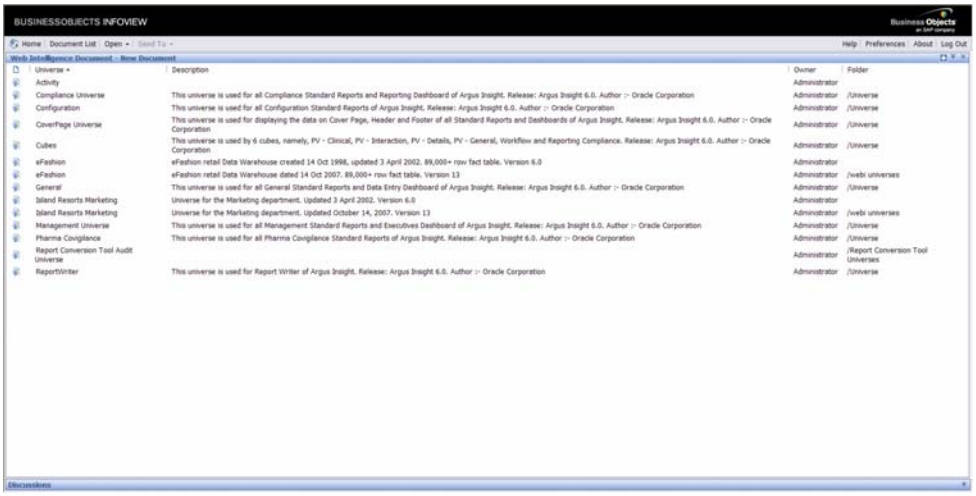
4. Click **Document List**. The following screen apeears.



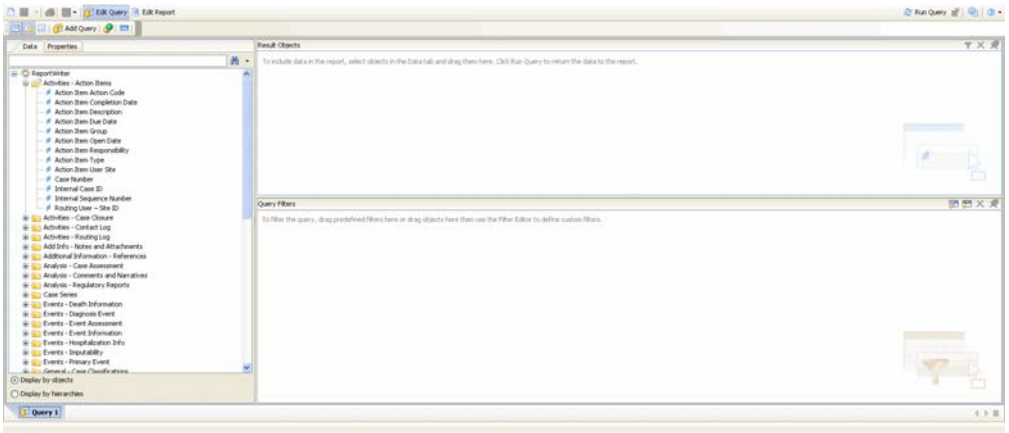
5. Go to **New > Web Intelligence Document**, as shown below.



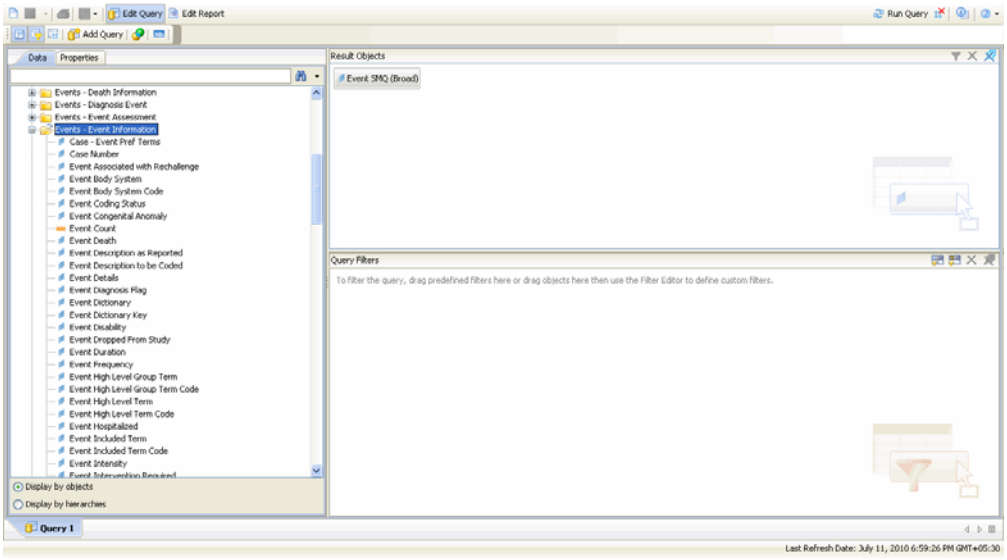
The following screen appears.



6. Click **Report Writer**. The following screen appears.



7. Under the **Data** tab, in **Events - Event Information**, either double-click **Event SMQ (Broad)** or drag-and-drop it to the **Results Object** pane, and click **Run Query**.

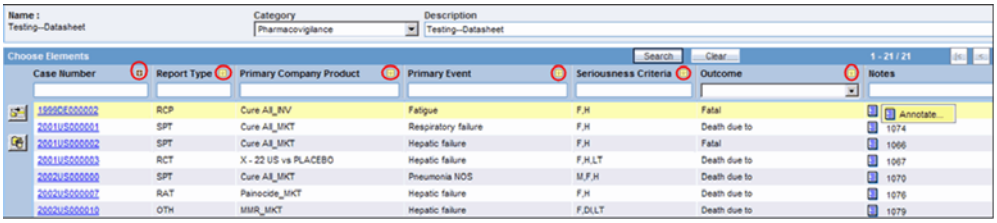


8. Click **Edit Query** to revert to the previous page. Perform a similar operation as shown in the above step for **Event SMQ (Narrow)**.
9. Under the **Data** tab, in **Events - Event Information**, either double-click **Case Number** or drag-and-drop it to the **Results Object** pane, and click **Run Query**. This displays all the case numbers that correspond to the selected SMQ.

Using Case Annotations

The term Case Annotation means the addition of notes to a case. An annotated case makes for better understanding about the case, due to the presence of notes added to describe anything relevant and important about the case.

Users can annotate cases within a case series as shown in the first row of the Notes column below.



The Annotate option for a case allows you to add a Note field for the respective case. This note is saved with the case series, and gets copied to a new case series if the case series where it was created is also copied.

While entering the notes, ensure that you do not exceed 200 characters. The note is then added through a context menu.

The created note remains with a case if the case series has been subsetted. Once entered, a note is saved for the case series. This means that you do not need to explicitly save a case series to save the note entered in it.

This note 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. This note also gets exported to Microsoft Excel when the Export to Excel functionality is used.

As shown in the following image, notes of a case series are retained when the case series merges with another case series. The text in the header "Notes from this series will be preserved in the merged case series" also displays the same.

A note can be frozen along with a frozen case series. Therefore, you cannot edit, add, or delete a note in a frozen case series. Similarly, if a user can access a case series, its corresponding notes can also be accessed and vice versa.

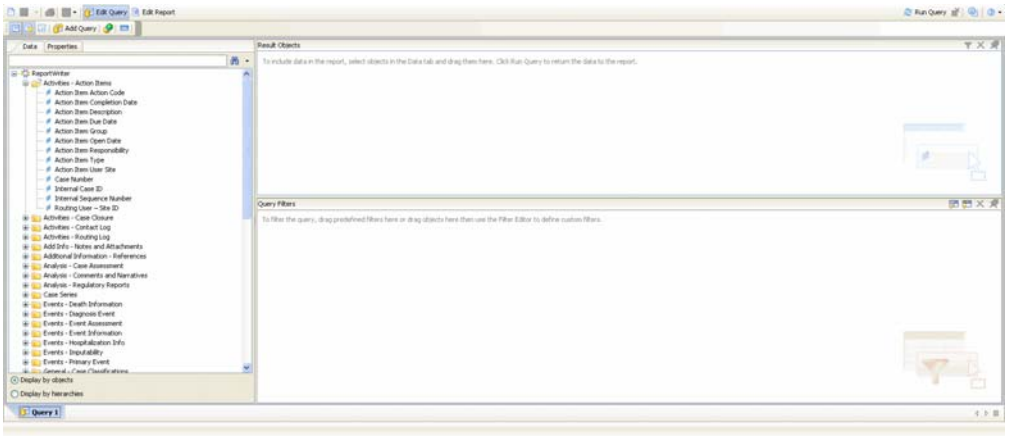
To use notes in Advanced Conditions, go to Case Series > Cases > Case Annotations. This field is a free hand text type field and supports single select only.

This Note is not available in Argus Safety and does not impact the case series there.

Using Case Annotations

Use the following procedure to use case annotations in report writer.

1. Click **Report Writer**. The following screen appears.



2. Either double-click **Event SMQ (Broad)** or drag-and-drop it to the **Results Object** pane, and click **Run Query**. This displays all the results that match the selected SMQ.

Using AdHoc Reports

AdHoc Reports is a repository where all the customized reports are saved. Argus Insight allows you to generate reports by using BO Infoview.

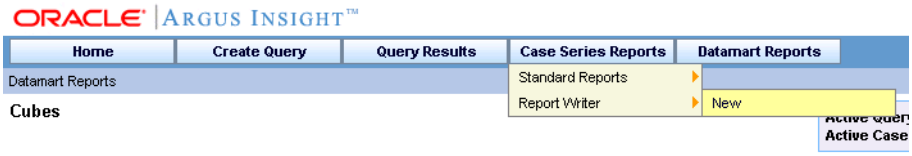
The biggest advantage of using BO Infoview is that it saves a lot of time, because the user does need to login each time. Additionally, the reports can also be shared among different users.

This section describes how to use BO Infoview and save the customized reports under the AdHoc Reports menu.

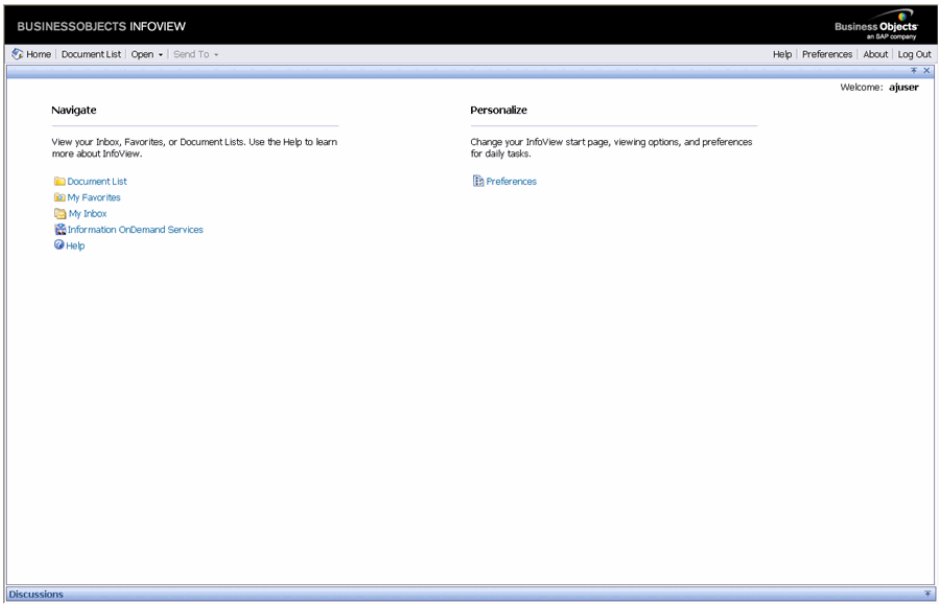
Using BO Infoview

Use the following procedure to create a report through BO Infoview

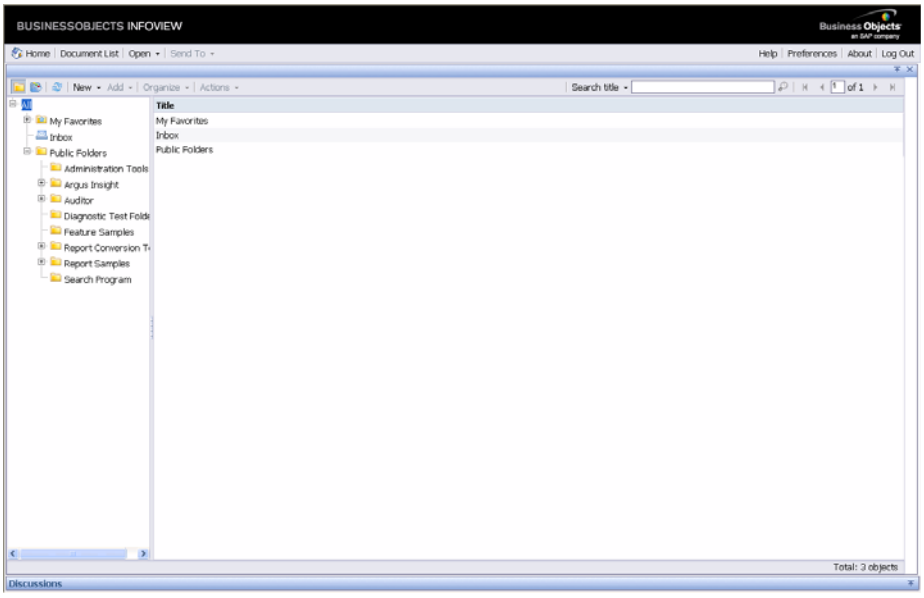
1. In Argus Insight, go to Case Series Reports > Report Writer > New.



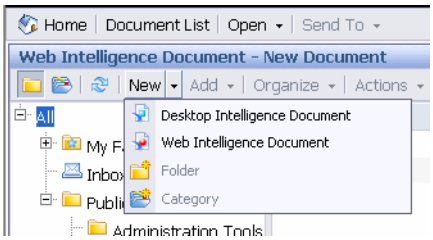
2. The BO Infoview Home page appears. Click Document List in the following screen.



3. The following screen appears. Click the down arrow under **New** and select the type of document to be created.



4. Click the down arrow under **New** and select the type of document to be created.



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

Note: It is essential to use BO Infoview to access the saved ad-hoc reports, created by using BO Infoview. This is because such reports cannot be accessed through Argus Insight anymore.

8

Using Cubes

Using Cubes to Generate Custom Reports

In addition to the pre-formatted Standard Reports, Argus Insight also provides Cubes, that let you create custom reports for ad hoc/special reporting requirements.

> **Note:** Make sure that when using Cubes, you have ENABLED the Interactive mode in BO Infoview. You can enable the Interactive mode by editing My Preferences for Web Intelligence.

A Cube is a data model that contains multiple dimensions (key reporting elements). You can observe and analyze the interactions between reporting elements by performing operations such as nesting, drill, sort, count, and total. Argus Insight provides six built in Cubes pertaining to varied reporting aspects.

> **Note:** Before using cubes, make sure to install FixPack 1.2 on top of the BOXI R3.1 release.

The following topic explains how to use the custom report tools by using cubes.

Using Cubes

A Cube is a data model that consists of dimensions and measures. The dimensions represent key reporting aspects in rows and columns headers of the data model. At the intersection of each row and *column* (a cell), the Cube shows a measure, such as case, *report*, or event count. In this version of Argus Insight, you access Cubes through the Business Objects® XI Web Explorer interface. The interface uses a *web browser* and provides access to available dimensions and measures.

Using Cubes, you can run complex queries by selecting various datamart fields as dimensions and display the output on the fly. You can also select the desired measures. To display the exact data you require, you can add filters, add calculations, drill down hierarchical dimensions, and statistically analyze the measures. Cubes also let you explore the interactions between different dimensions by letting you nest dimensions.

Argus Insight lets you create Demand Cubes (Cubes on the Fly) based on existing Standard Cubes in Argus Insight. The difference between the two types of cubes is-

Standard Cubes: These cubes are built-on the entire database.

Demand Cubes: These cubes are built on specific case series.

The structure of a Demand Cube is similar to the structure of the Standard Cube. This is because a Standard Cube acts as a base for creating Demand Cubes.

The following topics explain how to work with Cubes.

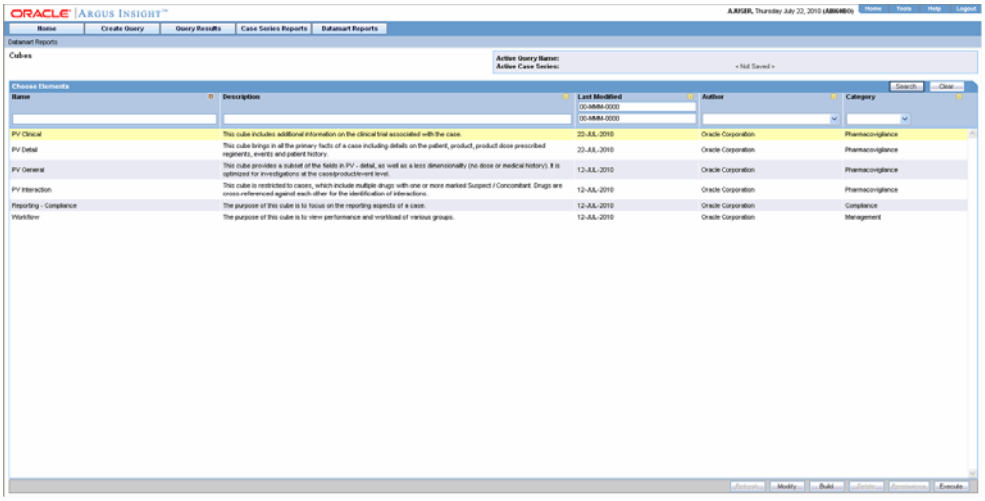
- Working with Cubes
- Cubes Available in Argus Insight
- Creating Demand Cubes
- Performing Drill-Through Operations
- Saving Cubes Views
- Refreshing Cubes

Working with Cubes

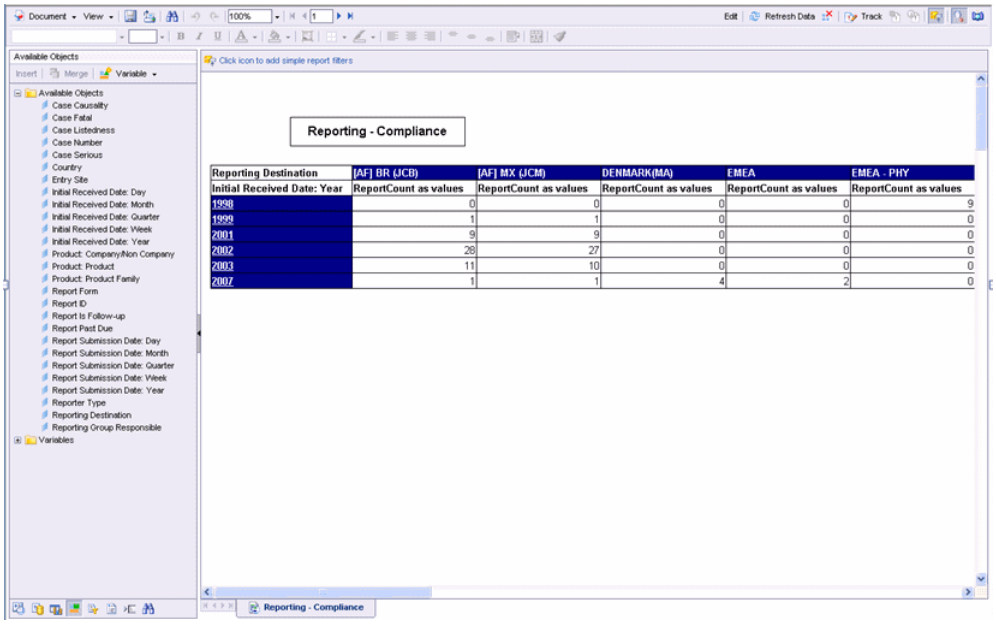
This topic explains how to execute and use Cubes.

Use the following procedure to execute a Cube

1. In Argus Insight, select **Datamart Reports >Cubes>All**.The **Cubes** page displays all the built-in Cubes in Argus Insight. To view Cubes in a specific category, first select **Datamart Reports > Cubes** and then select a category name: **Compliance**, **Management**, or **Pharmacovigilance**.



2. Select the Cube you wish to execute.
3. Click **Execute**. A separate BOXI Web Explorer window displays the Cube in the interface similar to the one shown in the following figure.



The left frame of the BOXI Web Explorer window displays the available dimension categories (reporting aspects) in a tree hierarchy. The **Variables** folder in the tree structure contains the available measures for the Cube. The *report* output area in the right frame displays the Cube structure, which is similar to a crosstab report. The dimensions from the first two categories appear as rows and columns in the Cube, respectively. To explore dimensions from other available categories, you can replace the existing dimensions in the Cube or nest other dimensions with the existing dimensions. You can also *filter* the output or drill down the dimensions in the Cube to display specific data.

4. Click **Edit** on the toolbar.

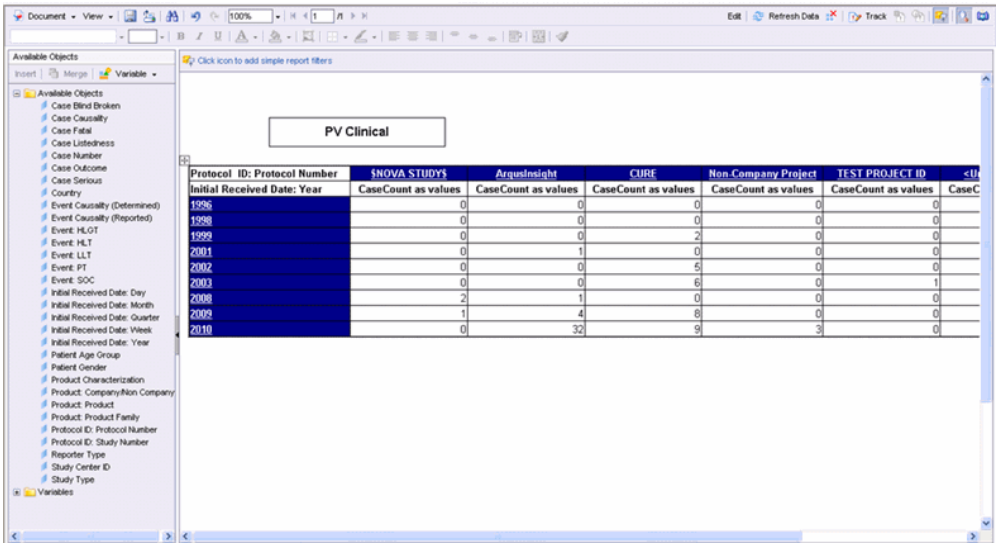
The following sections explain the basic BOXI Web Explorer options that let you work with Cubes.

Filtering Data

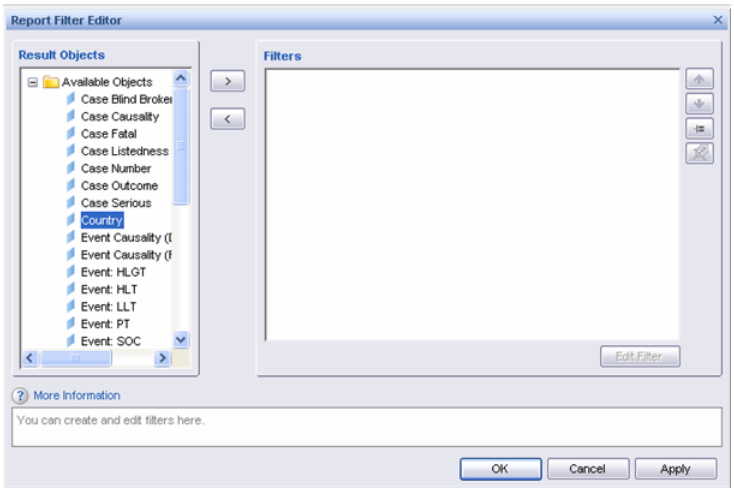
You can select a dimension to filter a Cube in order to reduce the data displayed in the Cube output. Unlike the drill operation, filtering does not change the existing Cube layout. Instead, it changes the measure values displayed in the Cube output according to the dimension you select as the filter. An example follows.

In the **PVClinical** Cube, the default row dimensions are from the **Protocol ID: Protocol Number** category and the default column dimensions are from the **Initial Received Date:Year** category. At the intersection of each row and column dimension the Cube displays the total Case Count. However, instead of viewing the total Case Count for the existing dimensions, you may wish to view the Case Counts for a specific country of incidence. Use the following procedure to view Case Counts for a specific country of incidence.

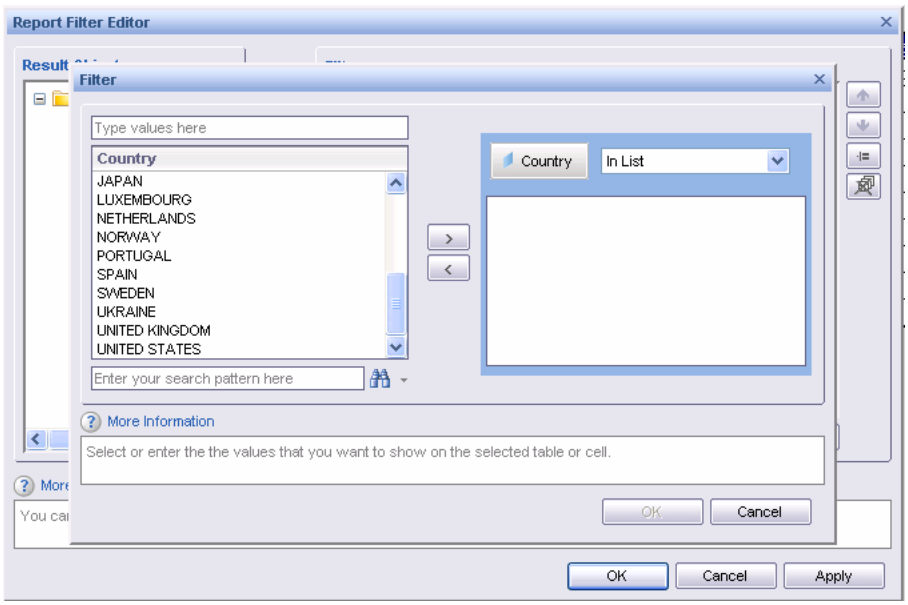
1. While the **PV Clinical** Cube is open, select **Available Objects** from the drop down box in the upper-left corner of the BOXI Web Explorer page.The left pane displays all the dimension categories available for the **PV Clinical** cube



2. In the right pane, right-click underneath the table to access the **Add Filter** icon from Filter text menu. The Report Filter Editor displays the various options you can use for filtering data.

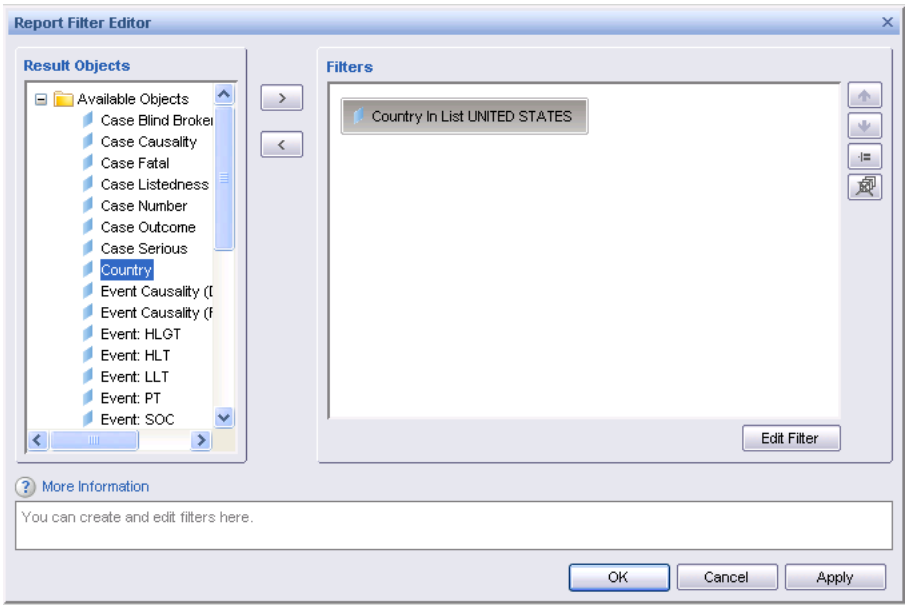


3. Select **Country** from the **Result Objects** pane and click >. The Filter dialog appears.

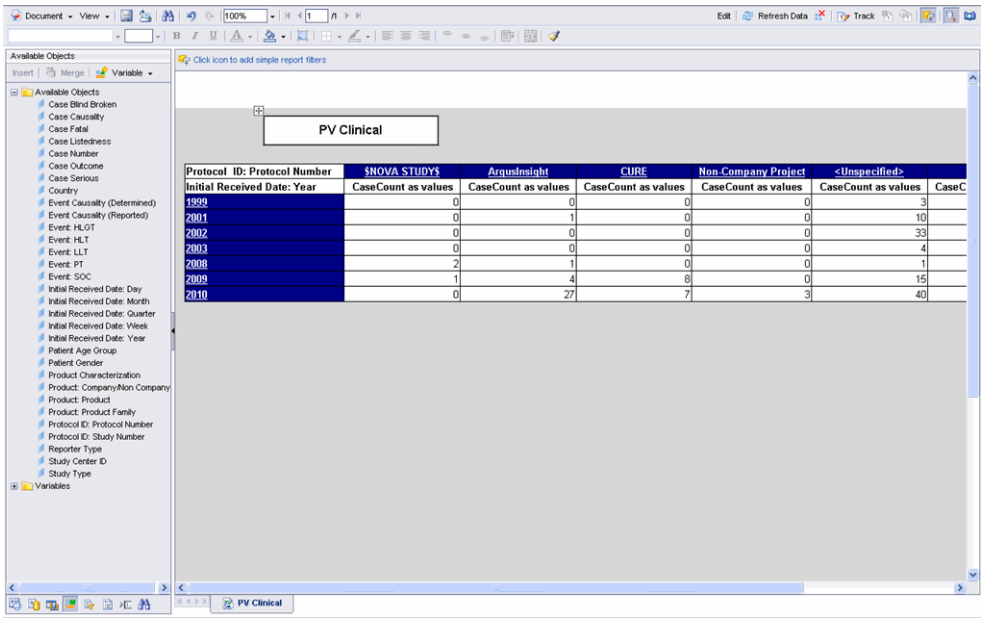


4. To define the country to be used as filter criteria, select the appropriate operator and value. In this example we have selected the **In List** operator to select from a list of countries.

5. Select the country to be used as a filtering criteria. In this example, we have selected **United States a**s the filtering criteria.



6. While the layout of the **PV Clinical** Cube remains the same, the data in the Cube output changes to display the measure values specific to the selected country.



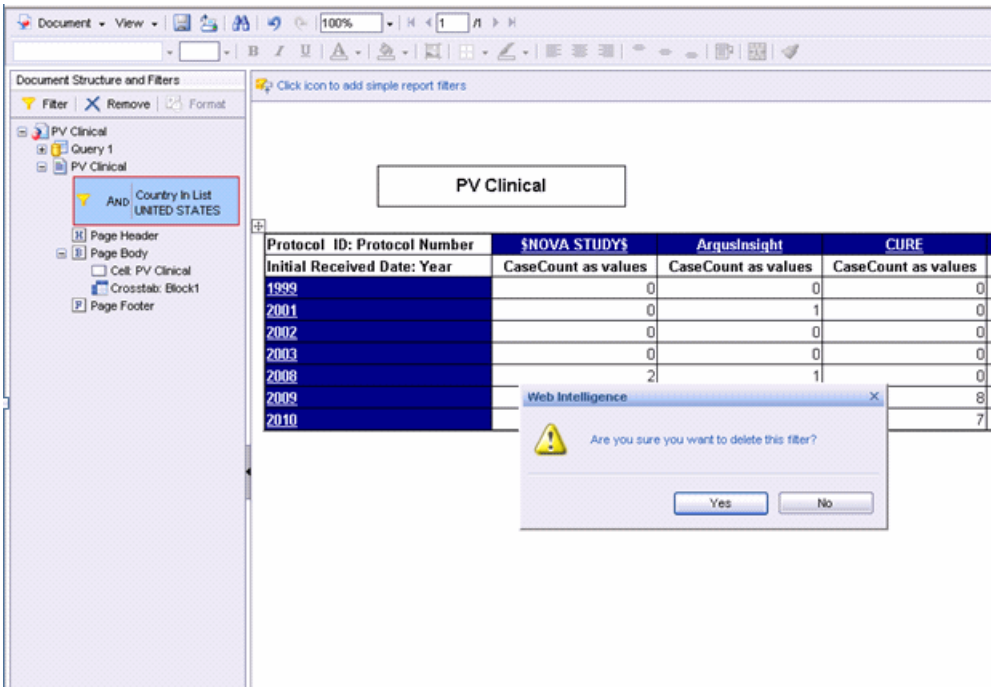
You can filter the output further by selecting another dimension as the filtering criterion.

> **Tip:** To filter a Cube based on the existing dimensions displayed in the Cube output, click a dimension within a dimension row or column. The Cube output is filtered to display the data for the selected dimension.

Use the following procedure to remove the filter.

1. Select the **Document Structures and Filters** from the drop-down box in the upper-left corner of the BOXI Web Explorer page
2. Select the filter to be removed.
3. Click **Remove**.

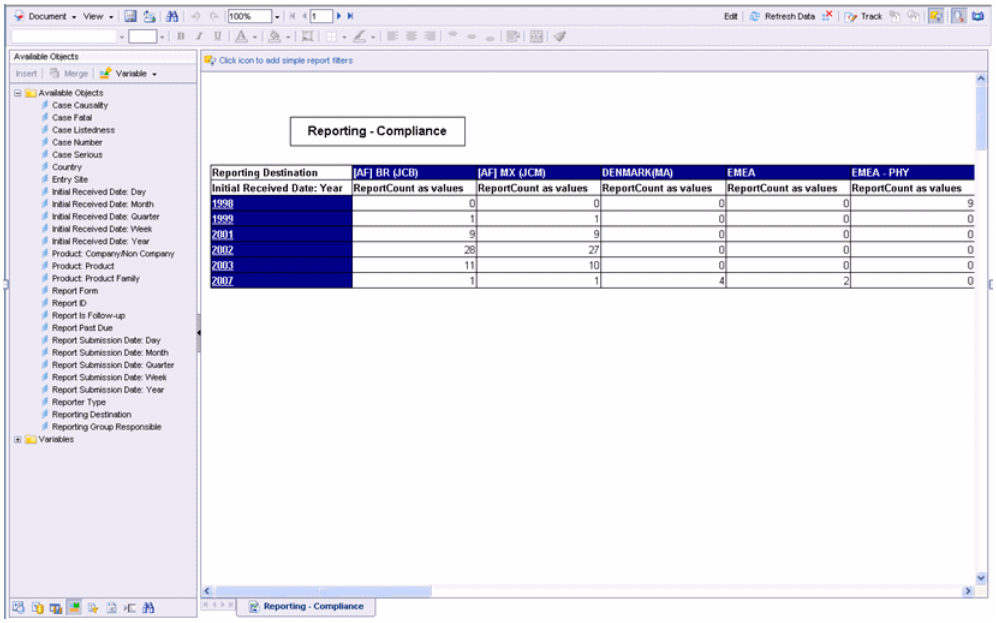
For example, to remove the **Country in List UNITED STATES** filter described in the example above, select in the categories filter, and click **Remove**.



Replacing Rows and Columns

You may want to replace the existing row or column dimensions with dimensions from another category to observe the interaction between dimensions from different categories. To do this, you can drag a category or a dimension from the left dimensions pane of the BOXI Web Explorer window into the middle of any cell of the column or row you want to replace. An example follows.

In the **PVClinical** Cube, the default row dimensions are from the **Protocol ID: Protocol Number** category and the default column dimensions are from the **Initial Received Date:Year** category.



Similarly you can replace the existing column dimensions with other dimensions. You can also replace the existing row/column dimensions with a single category from a

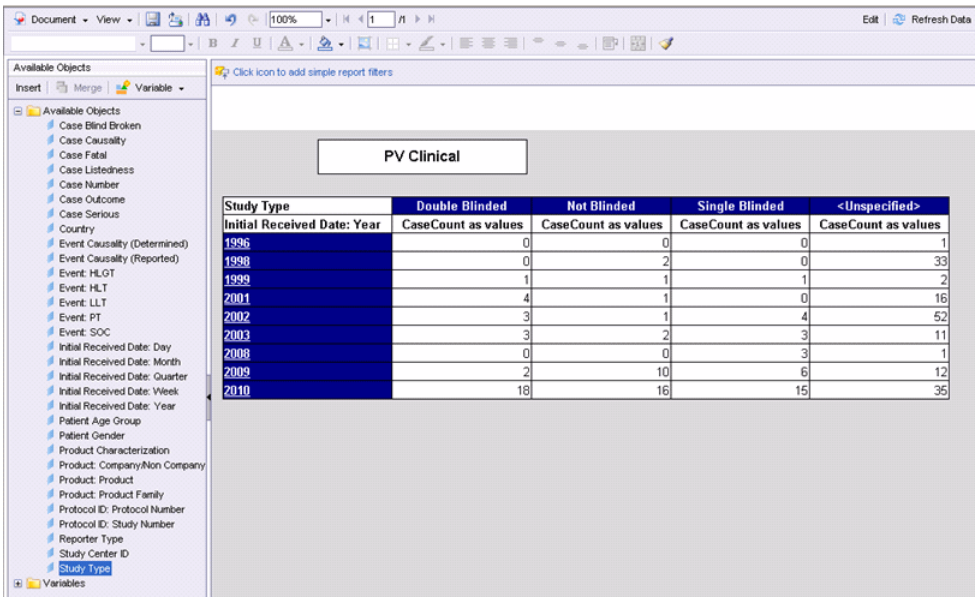
dimension by dragging the category from the left pane into the middle of a row/column cell.

Use the following procedure to replace existing row dimensions with Study Type dimensions.

1. Select the **Study Type** dimension from the left dimensions pane .and drag the dimension from the left frame to the middle of any row cell in the Cube.

> **Note:** Drag and drop the dimension(s) into the middle of the cell row/column.
>
> **Do not** drop the dimension(s) onto the row/column header.

2. The existing row dimensions in the Cube are replaced with the **Study Type** dimension.



Study Type	Double Blinded	Not Blinded	Single Blinded	<Unspecified>
Initial Received Date: Year	CaseCount as values	CaseCount as values	CaseCount as values	CaseCount as values
1996	0	0	0	1
1998	0	2	0	33
1999	1	1	1	2
2001	4	1	0	16
2002	3	1	4	52
2003	3	2	3	11
2008	0	0	3	1
2009	2	10	6	12
2010	18	16	15	35

Grouping Multiple Rows and Columns by a Dimension or Category

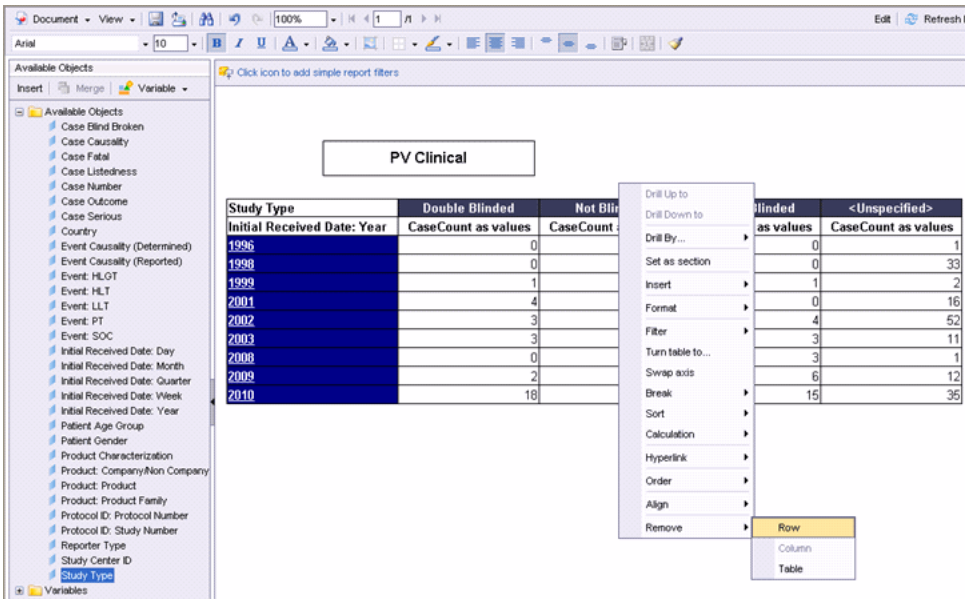
You can have multiple rows and columns in a Cube by dragging additional dimensions from the tree structure (left pane) into the Cube. When you add a new entity to a Cube, the output is automatically grouped to let you view data easily. Row grouping happens by the leftmost row entity and column grouping happens by the topmost column entity.

Groupings can be obtained as follows:

- To obtain a row grouping by a new entity, select an entity from the tree structure in the left frame of the BOXI Web Explorer window and drag it into the left or right edge of the row area within the Cube. The Cube output refreshes to show the grouping depending on the edge of the row area where you dragged the new entity.
- To obtain a column grouping by a new entity, select an entity from the tree structure in the left frame of the BOXI Web Explorer window and drag it into the upper or lower edge of the column area within the Cube. The Cube output refreshes to show the grouping depending on the edge of the column area where you dragged the new entity.

You can remove specific groupings from the Cube by deleting a dimension row or column from the Cube. The procedures follow.

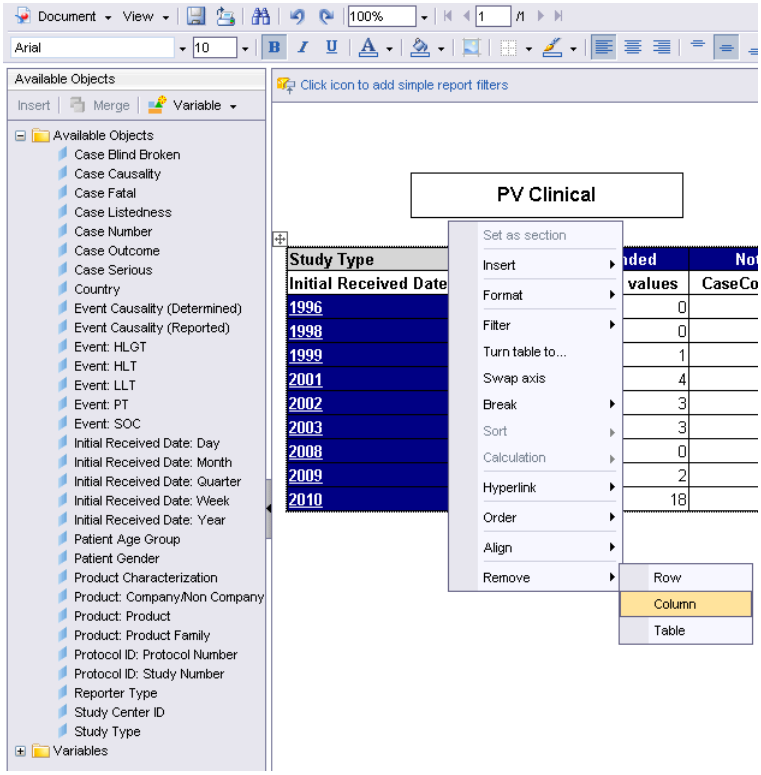
1. To remove a dimension row from the Cube, right click on the table as shown in the illustration.



2. In the context menu that appears, click **Remove > Row** to delete the dimension row.

Use the following procedure to remove a dimension column from a Cube.

1. To remove a dimension column from the Cube, right click on the table as shown in the illustration.

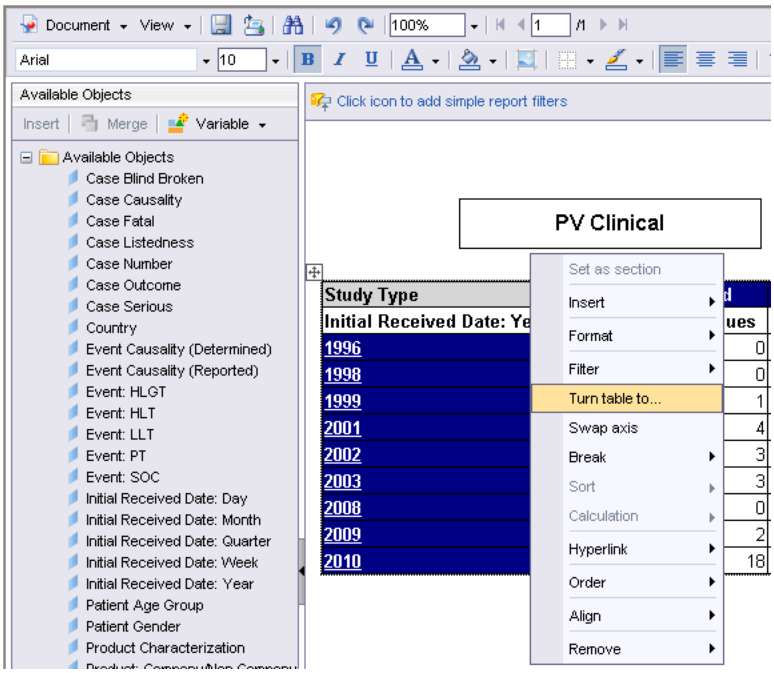


2. In the context menu that appears, click **Remove > Column** to delete the dimension column.

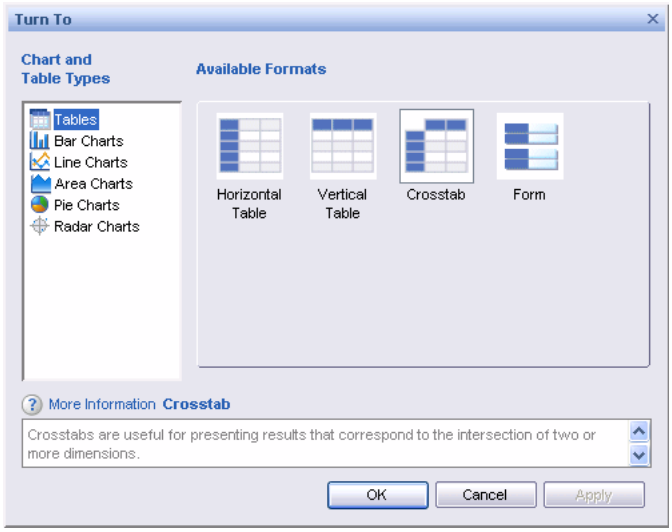
Creating Charts

You can display a Cube as a *chart* to graphically see patterns and trends in data.

1. Perform the necessary operations on the Cube to get the desired reporting focus.
2. Right click on the table, in the right panel of the BOXI web explorer. A context menu displays the **Turn table to** option.



3. Click the **Turn Table to** option. Select the required format from the **Turn Table to** dialog box.

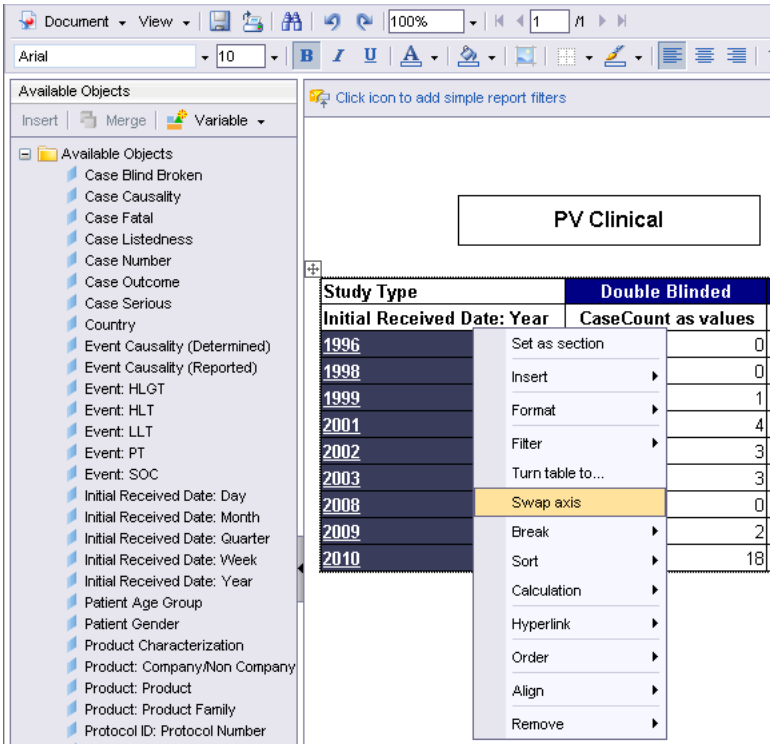


4. The cube data is displayed in the selected format.

Swapping Rows with Columns

You may want to swap the rows with columns in a Cube that has few rows and many columns. This improves the readability of the Cube output.

To interchange rows and columns in a Cube, right click on the table and select the **Swap axis** in the context menu that appears as shown in the illustration.



Tip: If there are multiple/grouped rows or columns in the Cube, the outermost rows become the outermost columns, and the outermost columns become the outermost rows.

Exporting the Cube Output to Specific Formats

You can export the Cube output to formats, such as PDF, EXCEL, and CSV, and save the file on the local machine.

1. Perform the necessary operations on the Cube to get the desired reporting focus.
2. If required, change the Cube layout to a crosstab or chart, as appropriate.
3. Click **Document > Save to my computer** on the BOXI Web Explorer toolbar. A context menu displays the available export options.
4. Select the desired export option (EXCEL, PDF or CSV)
5. Specify the file settings for the selected export option such as file location, to save the file onto your system.

Changing Measures

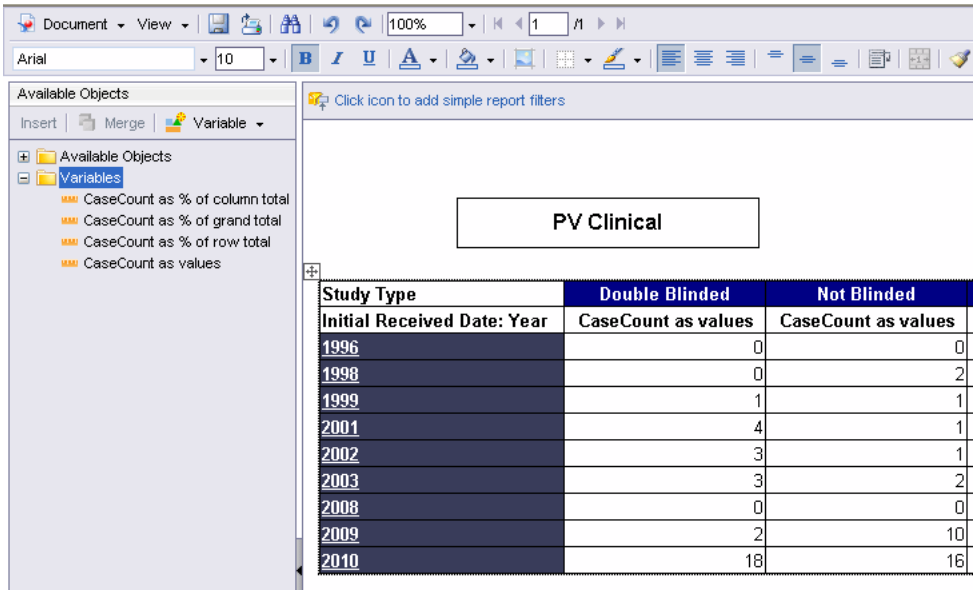
The reporting focus of Cubes that have multiple dimensions available can be changed by replacing an existing measure within the Cube with another measure. For example, Pharmacovigilance Cubes have Case Count (row,column, grand or values) as available measures. While the default measure displayed in these Cubes is Case Count, you can replace it with the percentage total of (row,column, grand or values) to change the reporting focus.

Use the following procedure to change the measures.

1. While the **PV Clinical** Cube is open, select **Available Objects** from the drop down box in the upper-left corner of the BOXI Web Explorer page. The left pane displays

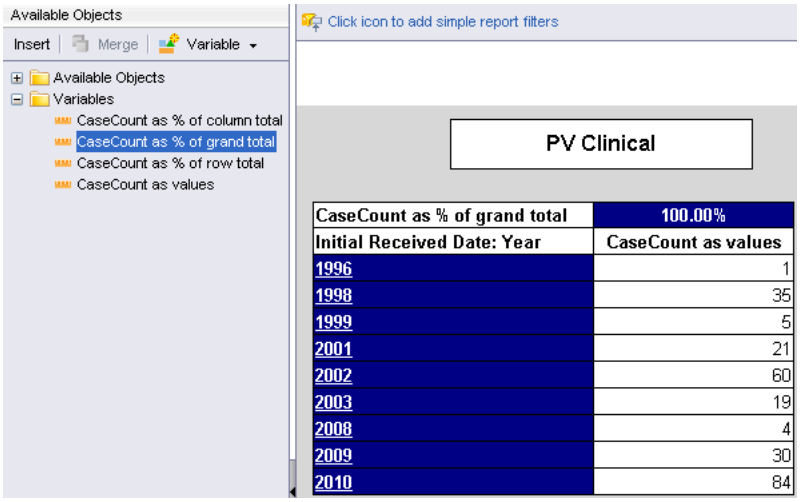
the **Variables** folder which consists of all the measure categories available for the **PV Clinical** cube.

2. Select **Variables**. The measures available for the Cube are displayed.



Study Type	Double Blinded	Not Blinded
Initial Received Date: Year	CaseCount as values	CaseCount as values
1996	0	0
1998	0	2
1999	1	1
2001	4	1
2002	3	1
2003	3	2
2008	0	0
2009	2	10
2010	18	16

3. Click and drag the measure required, onto the data cell**.** The crosstab output is refreshed; **Case Count as % of grand total** is the new measure added to the Cube.



CaseCount as % of grand total	100.00%
Initial Received Date: Year	CaseCount as values
1996	1
1998	35
1999	5
2001	21
2002	60
2003	19
2008	4
2009	30
2010	84

Tip: Drag the measure and place the cursor after the data in the cell, to display the original data of the cell and it's percentage as per the measure

If you simply drag the measure onto the cell data, the tabular data is displayed as per the measure percentage

The available measures for all the six cubes are:

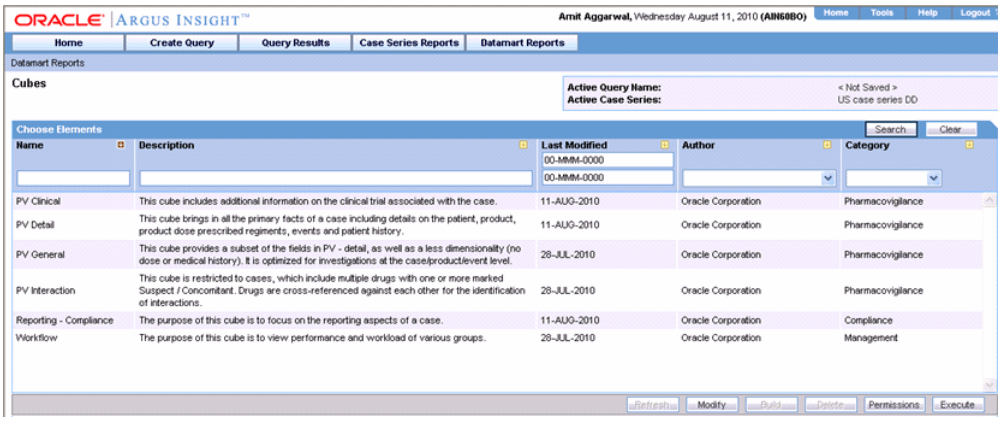
- CaseCount as % of column total
- CaseCount as % of grand total

- CaseCount as % of row total
- CaseCount as % of values

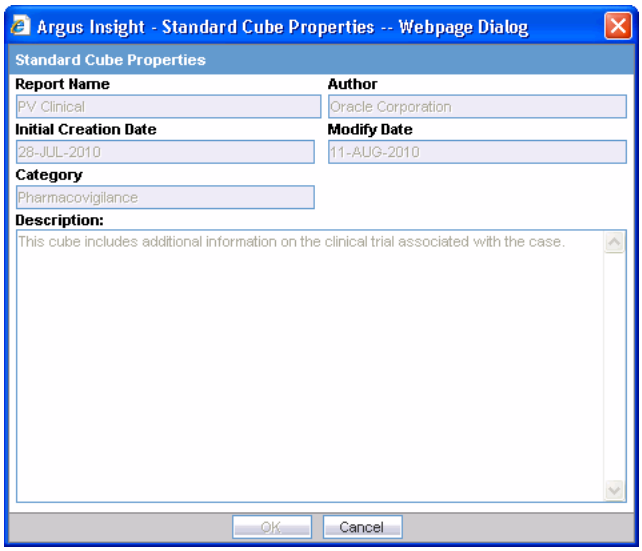
Modify/Delete

Use the following procedure to **modify** the Cube.

1. In Argus Insight, select **Datamart Reports>Cubes>All**. The **Cubes** page displays all the built-in Cubes in Argus Insight and the Demand Cubes which the group users have created.



2. Select the required Cube and click **Modify**.
3. The Modify cube interface appears. This interface helps you to capture information to modify the Cube.

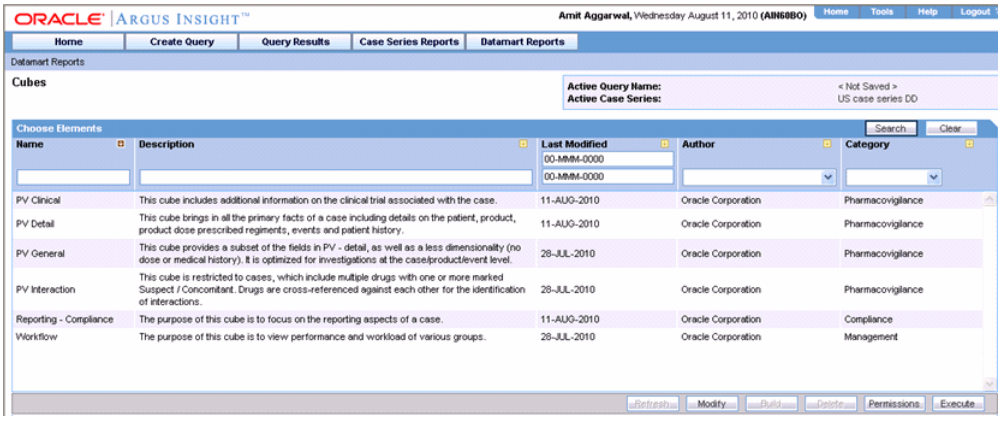


- **Expiration Date** informs you about the expiration date of the cube. You are notified when the expiry date is due and you can save or delete the existing cube as per preference. This field is visible only for Demand cubes.
- **Initial Creation Date** captures the date when the Cube was loaded in the repository for the first time.
- **Modify Date** captures the date when the Cube was last modified.

- **ETL Run** captures the date of ETL run on which the case data is based. This field is visible only for demand cubes. This field is visible only for Demand cubes.
- **Case Series** captures the name of the case series on which the cube was built. This field is visible only for Demand cubes.

To delete the Cube:

1. Use the following procedure to **delete** the Cube:
2. In Argus Insight, select **Datamart Reports >Cubes** > **All**. The **Cubes** page displays all the built-in Cubes in Argus Insight and the Demand Cubes which the group users have created.



> **Note:** You cannot modify or delete Standard Cubes.

3. Select the required Cube and click **Delete**.
4. The Delete cube confirmation dialog appears. Click **OK** to confirm the operation.

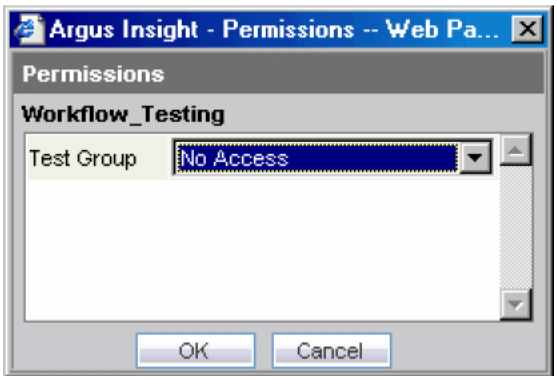
Setting Access Permissions

You can set group-level access permissions for the Demand Cubes. This determines which user groups can view, modify, or delete a Demand Cube.

> **Note:** You can set permissions only on Demand Cubes you have saved to the system.

Use the following procedure to set Demand Cube permissions.

1. In the Argus Insight page, select the **Datamart Reports > Cubes > All**.
2. Click **Permissions**. The **Permissions** dialog box appears. A list in this dialog box displays the names of all the groups (except the **Administrator** group) that the system administrator has created.



3. Use the list box next to a group name to assign permissions to the group members on the Demand Cube you have selected. You can select from these options:

Permission	Description
No Access (Default)	No group members can access the Case Series
Full Access	You can modify/delete/view the Cube

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

Cubes Available in Argus Insight

Argus Insight provides six different Standard Cubes grouped in categories to let you analyze your safety data from Compliance, Management and Pharmacovigilance perspectives.

Category	Cube Name
Compliance	Reporting Compliance
Management	Workflow
Pharmacovigilance	PV Clinical, PV Detail, PV General, PV Interaction

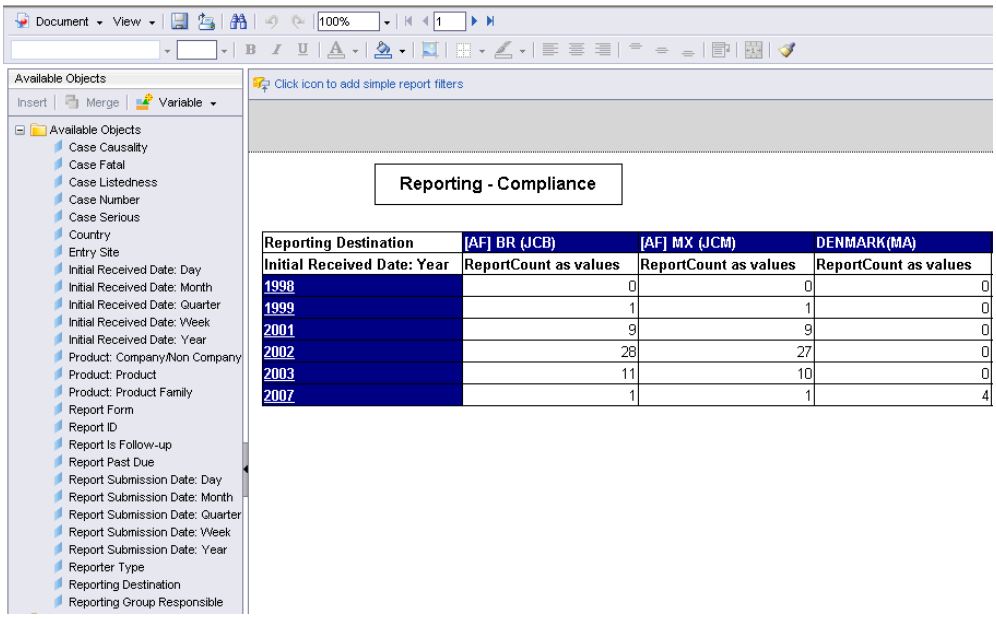
The dimensions available in a Cube depend on the type of analysis that the Cube lets you perform. The following types of measures are available.

Measures	Available in
Case Count	All Cubes in Pharmacovigilance, Management and Compliance categories.

The following sections describe the various Standard Cubes available in Argus Insight. For information on executing and working with Cubes, see the Working with Cubes topic.

Compliance Cubes

The Compliance category consists of the Reporting Compliance Cube

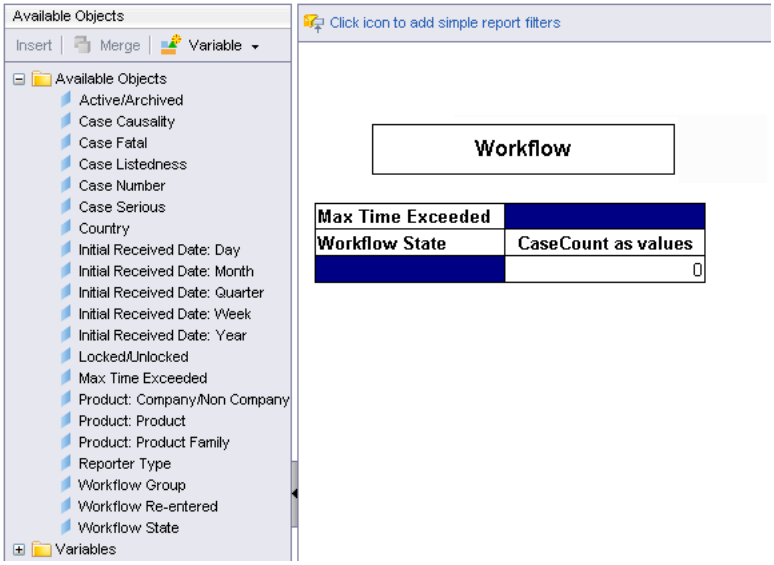


Reporting Destination	[AF] BR (JCB)	[AF] MX (JCM)	DENMARK(MA)
Initial Received Date: Year	ReportCount as values	ReportCount as values	ReportCount as values
1998	0	0	0
1999	1	1	0
2001	9	9	0
2002	28	27	0
2003	11	10	0
2007	1	1	4

The Reporting Compliance cube lets you explore the following dimensions:

Management Cubes

The Management category consists of the Workflow cube:



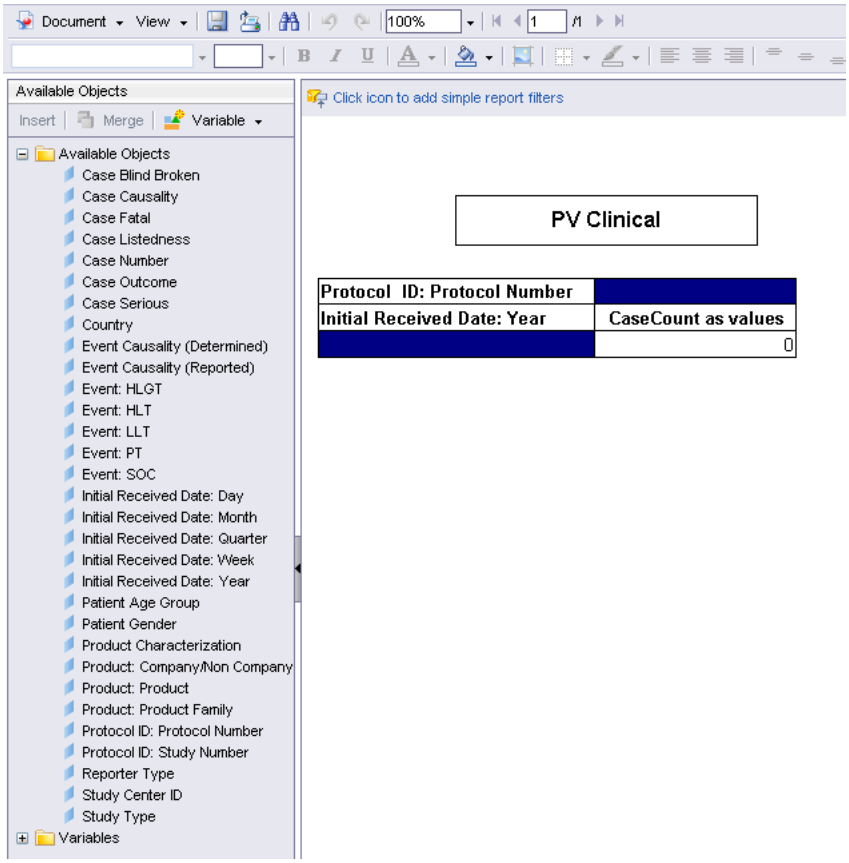
The Workflow cube lets you explore the following dimensions:

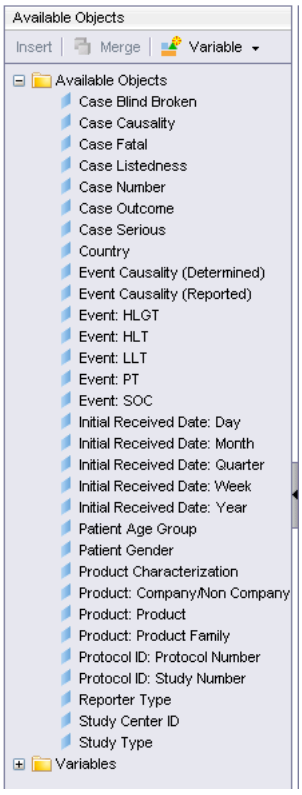
Pharmacovigilance Cubes

Pharmacovigilance (PV) Cubes let you perform *data mining* for cases based on events, medical history, cause of death, and other key indicators. The Pharmacovigilance category has four Cubes:

PV Clinical Cube

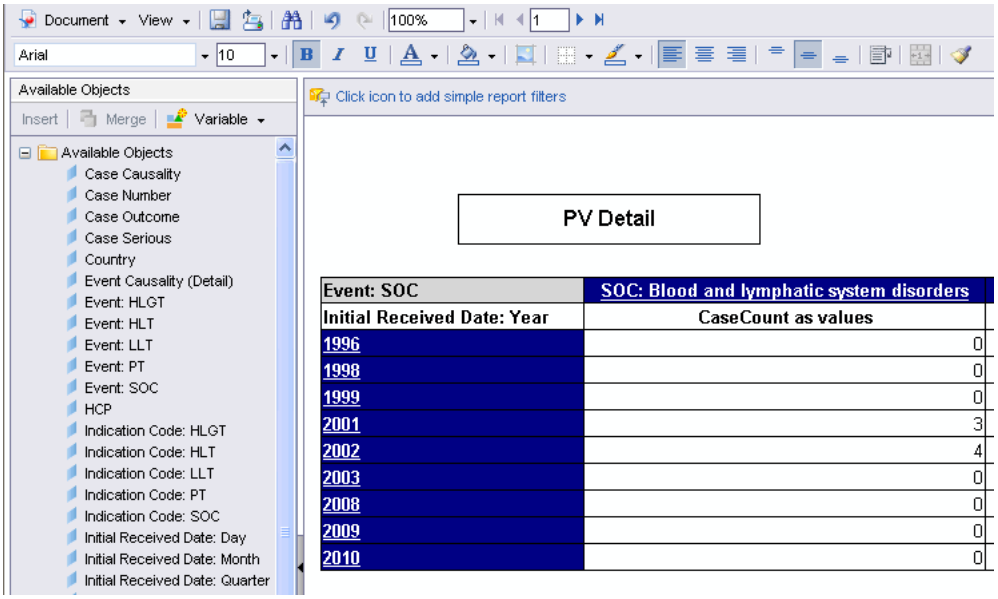
The PV Clinical Cube lets you explore the following dimensions

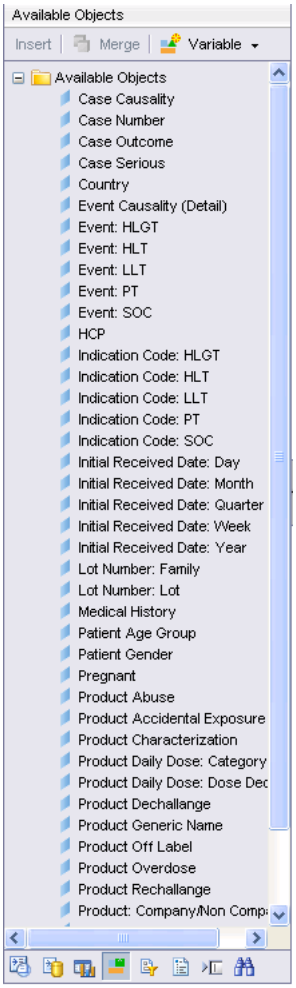

Document
View
100%
1
/1
Available Objects
Insert
Merge
Variable
Available Objects
Case Blind Broken
Case Causality
Case Fatal
Case Listedness
Case Number
Case Outcome
Case Serious
Country
Event Causality (Determined)
Event Causality (Reported)
Event: HLGT
Event: HLT
Event: LLT
Event: PT
Event: SOC
Initial Received Date: Day
Initial Received Date: Month
Initial Received Date: Quarter
Initial Received Date: Week
Initial Received Date: Year
Patient Age Group
Patient Gender
Product Characterization
Product: Company/Non Company
Product: Product
Product: Product Family
Protocol ID: Protocol Number
Protocol ID: Study Number
Reporter Type
Study Center ID
Study Type
Variables
Click icon to add simple report filters
PV Clinical
Protocol ID: Protocol Number
Initial Received Date: Year
CaseCount as values
0


Available Objects
Insert
Merge
Variable
Available Objects
Case Blind Broken
Case Causality
Case Fatal
Case Listedness
Case Number
Case Outcome
Case Serious
Country
Event Causality (Determined)
Event Causality (Reported)
Event: HLGT
Event: HLT
Event: LLT
Event: PT
Event: SOC
Initial Received Date: Day
Initial Received Date: Month
Initial Received Date: Quarter
Initial Received Date: Week
Initial Received Date: Year
Patient Age Group
Patient Gender
Product Characterization
Product: Company/Non Company
Product: Product
Product: Product Family
Protocol ID: Protocol Number
Protocol ID: Study Number
Reporter Type
Study Center ID
Study Type
Variables

PV Detail Cube

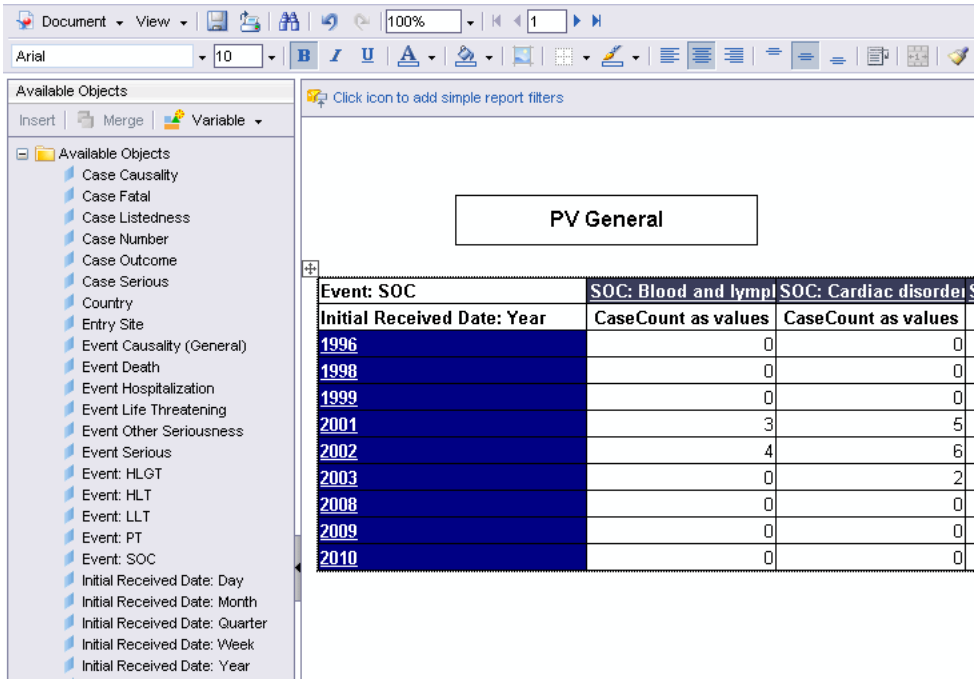
The PV Detail Cube lets you explore the following dimensions





PV General Cube

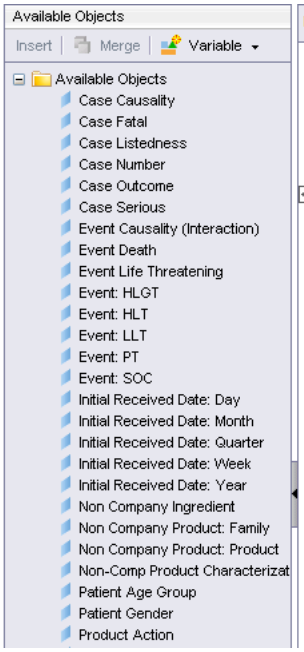
The PV General Cube lets you explore the following dimensions

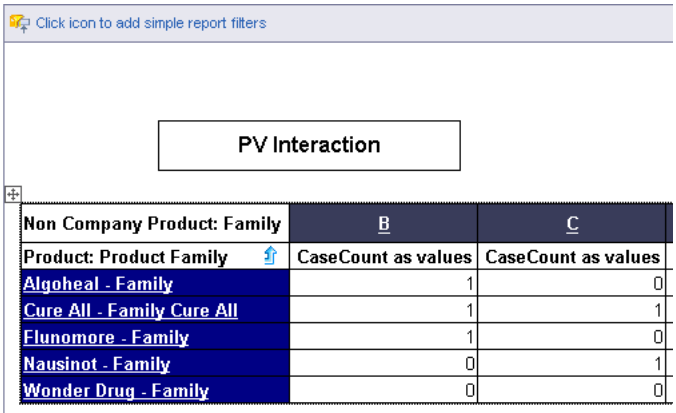


Event: SOC	SOC: Blood and lympl	SOC: Cardiac disorder
Initial Received Date: Year	CaseCount as values	CaseCount as values
1996	0	0
1998	0	0
1999	0	0
2001	3	5
2002	4	6
2003	0	2
2008	0	0
2009	0	0
2010	0	0

PV Interaction Cube

The PV Interaction Cube lets you explore the following dimensions





Non Company Product: Family	B	C
Product: Product Family	CaseCount as values	CaseCount as values
Algoheal - Family	1	0
Cure All - Family Cure All	1	1
Flunomore - Family	1	0
Nausinot - Family	0	1
Wonder Drug - Family	0	0

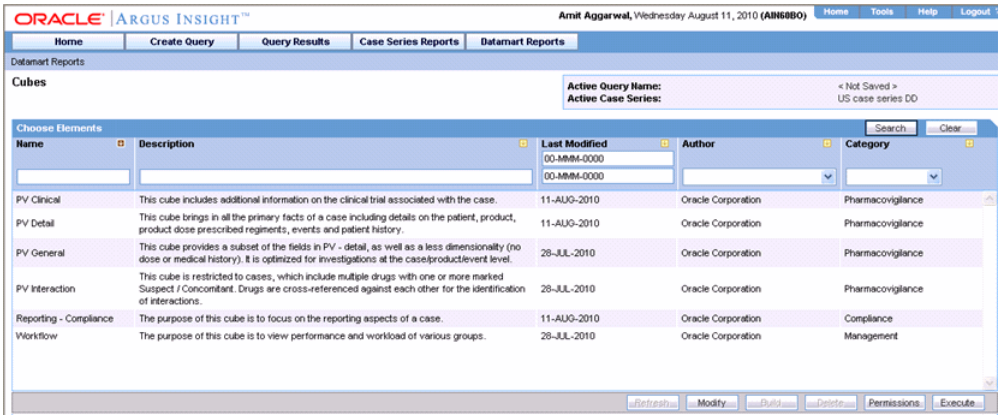
Creating Demand Cubes

Argus Insight lets you create demand Cubes based on existing standard Cubes in Argus Insight. The structure of a demand Cube is similar to the structure of the standard Cube you select to build the demand Cube. For more information on performing operations on Cubes refer to the section on Working with Cubes.

Demand Cubes are based on a specific Case Series instead of the entire datamart. Therefore, you can use demand Cubes to analyze a reduced data set based on a specific Case Series and quickly obtain the desired reporting focus without having to drill down or *filter* data. However, this feature makes the demand Cubes static, which means that each time the Case Series is modified, you need to delete the demand Cube and create a new one.

Use the following procedure to create a demand Cube.

1. In Argus Insight, select **Datamart Reports >Cubes>All**. The **Cubes** page displays all the built-in Cubes in Argus Insight.



2. Select the standard Cube using which you wish to create the demand Cube. The Cube name is highlighted; the **Build** button becomes active.
3. Click **Build**. The **Cube Properties** dialog box appears.

4. Enter the demand Cube name in the **Cube Name** text box.
5. Enter the demand Cube description in the **Description** text area.
6. Use the **Case Series** list box to select the Case Series on which you want to create the demand Cube. The description of the selected Case Series appears in the associated **Description** text area.
7. Click **Build Cube**. The **Cubes - Build** dialog box notifies you that the Cube has been scheduled for generation on the BOXI server.
8. Click **OK**. The **Cubes** page displays the demand Cube name in grey.
9. When the WebI server generates the demand Cube, the **Cubes Generated** dialog box notifies you. After the Cube is generated, you can execute it by selecting the Cube name and clicking **Execute**.

> **Note:** The maximum number of cases for creating **Demand Cubes** are configurable from the **List Maintenance** items.

Demand Cubes have a limited life span on the system. The system deletes the demand Cube after 14 days (default) from the date of creation.

When the demand Cube has reached the expiration date, the system notifies you through the following dialog box.

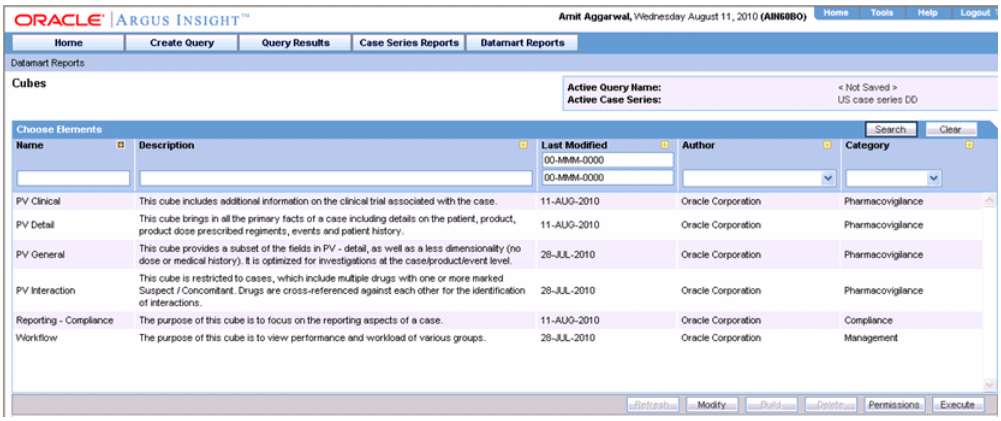
At this point, you can either delete the demand Cube or retain it for another 14 days (default).

Drill Through Cubes

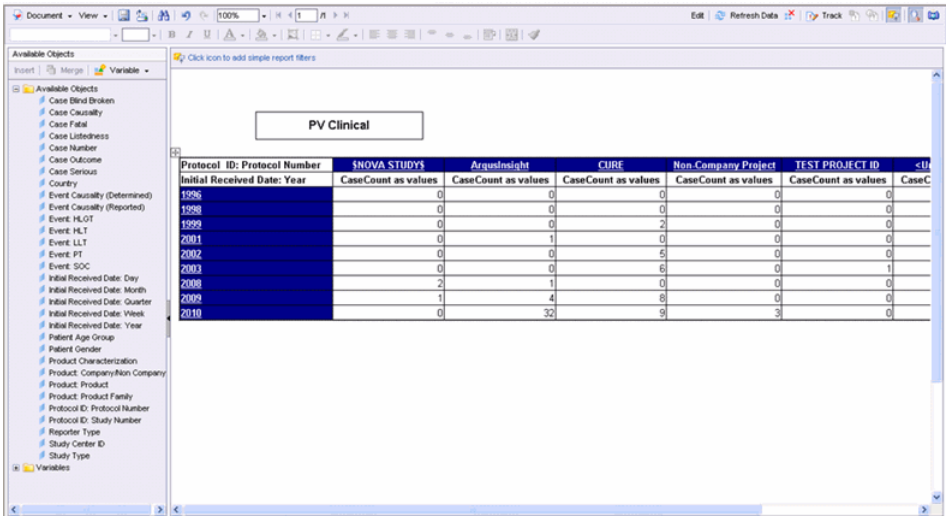
This section describes the procedure to drill through cubes for standard and demand cubes.

Use the following procedure to execute a Cube.

1. In Argus Insight, select **Datamart Reports >Cubes>All**.The **Cubes** page displays all the built-in Cubes in Argus Insight and the Demand Cubes which the group users have created.



2. Select the Cube you wish to execute.
3. Click **Execute**. A separate BOXI Web Explorer window displays the Cube in the interface similar to the one shown in the following figure.



Performing Drill Through Operations

You can drill-down and drill-up hierarchical dimensions to explore different aspects of your work and to move between levels of information. You can drill-down and drill-up multiple levels at a time. When you drill-down on a dimension that groups other dimensions in a row or *column*, some information may be removed from the Cube.

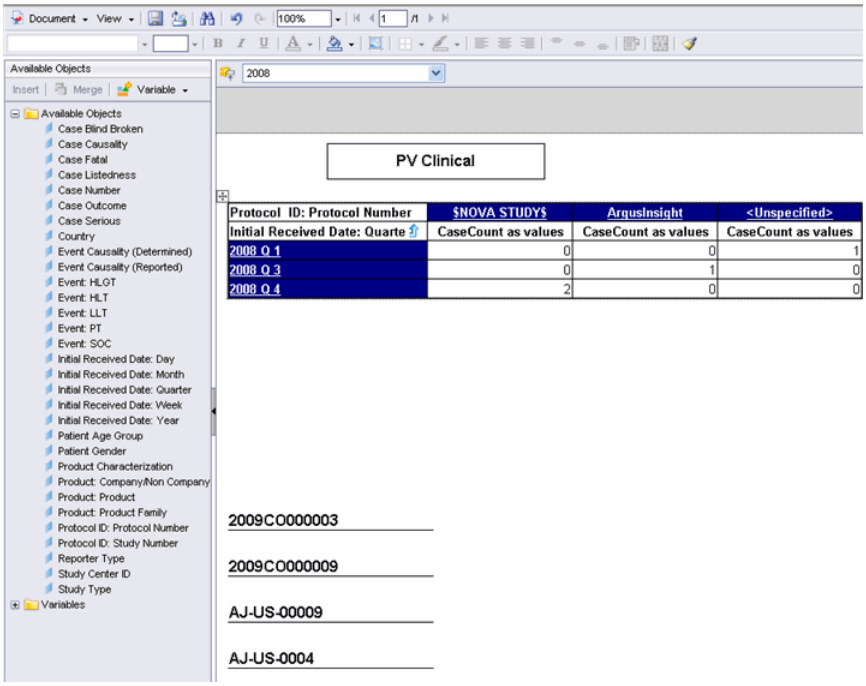
An example to demonstrate the drill functionality for listing Case Numbers associated with the initial received date (in years) follows.

Use the following procedure to drill down to the next level in a hierarchical dimension, such as a Case Series.

1. Drag and drop the **Case Number** dimension from the left pane into the right pane, underneath the table.

Tip: If you cannot see the dimension list in the left pane, select **Available Objects** from the drop down list in the left pane.

2. The Cube output changes to display the data for all the **Case Number** dimensions.



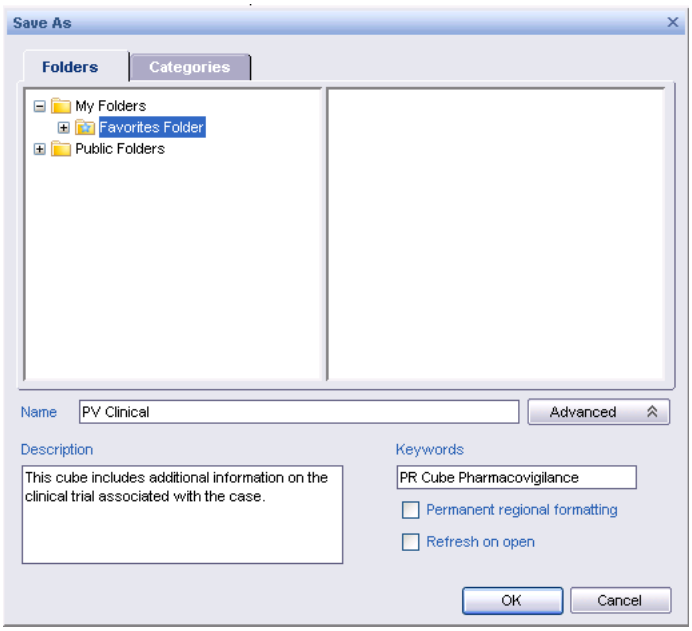
3. While the preceding steps let you display the data for all the lower levels for all the products, you may change the reporting focus by only displaying the lower-level data for a specific product. To do this, simply click on the dimension in the Cube output.

Saving Cubes Views

This section describes the procedure to save Cube views (based on the drilled-down data). You can access these saved cube views from **Datamart Reports > Cubes > Library**

Use the following procedure to save Cube views.

1. Click **Datamart Reports > Cubes All** to view all the cubes.
2. Select the Cube view that you want to save. The name of the cube is highlighted
3. Click **Execute**. BOXI web explorer is displayed
4. Perform the desired drill through operation. The cube view is displayed.
5. Click **Document > Save As** in the menu bar. The options for saving the report appear.



Tip: You can access **Document > Save to my computer as** to save the cube on your system in Excel, PDF or CSV (with options) format.

6. Enter and save the Title, Description and Keywords.
7. Select the location at which the cube view should be saved. Public Folder > Argus Insight > Standard Cube Category > Analysis

Note: You cannot save Cube views in the Demand Cubes folder. You must save the Cube view in the Analysis folder within any Standard Cube category.

8. Click **OK** to save the cube view.
9. To view the saved Cube view, click Datamart Reports > Cubes > Library. The Cube view name appears in the list of cubes saved in the library.

Note: **Standard Cubes:** If the *data mart* has been updated since the last saved view, the information displayed within the cube will reflect the updated data as the view of the Cube is saved.

Demand Cubes: If the data mart has been updated since the last saved view, the information displayed within the cube will remain static as it is based on static case series.

The Cube views can also be shared as viewswith other users.

Refreshing Cubes

Although the ETL process updates the datamart on a regular basis, you need to separately update each Cube after the incremental ETL process is completed. To do this, a batch process needs to be set up to update the Cubes installed as part of the Argus Insight application. The batch process performs the following task:

Updates Cube data - the data in the Cube is updated with the latest data from the datamart

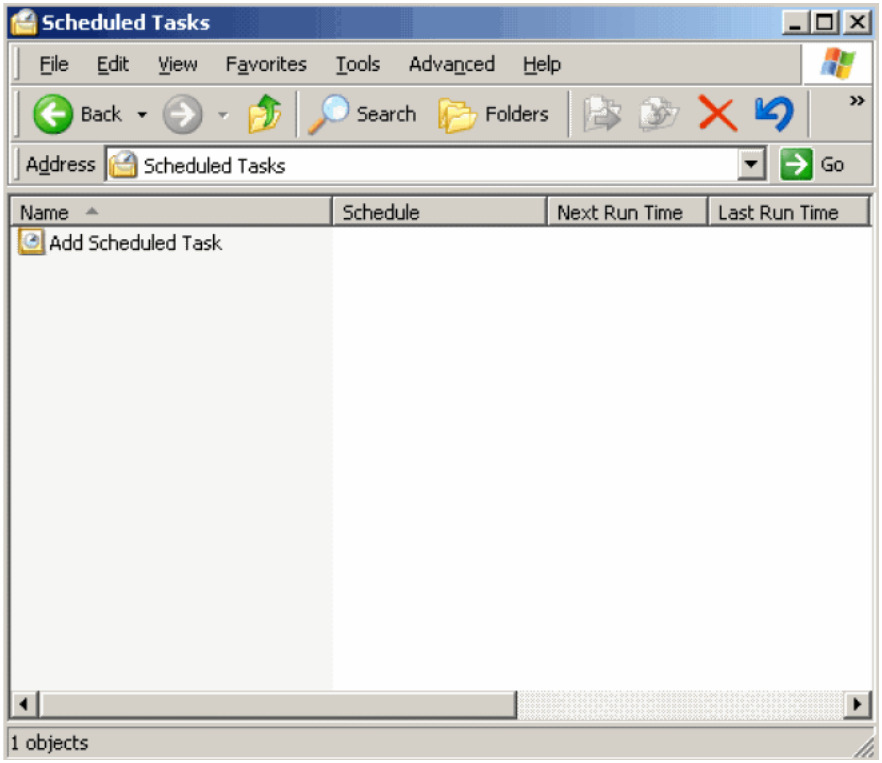
Individual tasks need to be scheduled to update each Cube. To improve the performance of the batch process, Verify that individual batch execution processes do not overlap with each other.

> **Note:** Demand Cubes are refreshed sequentially.

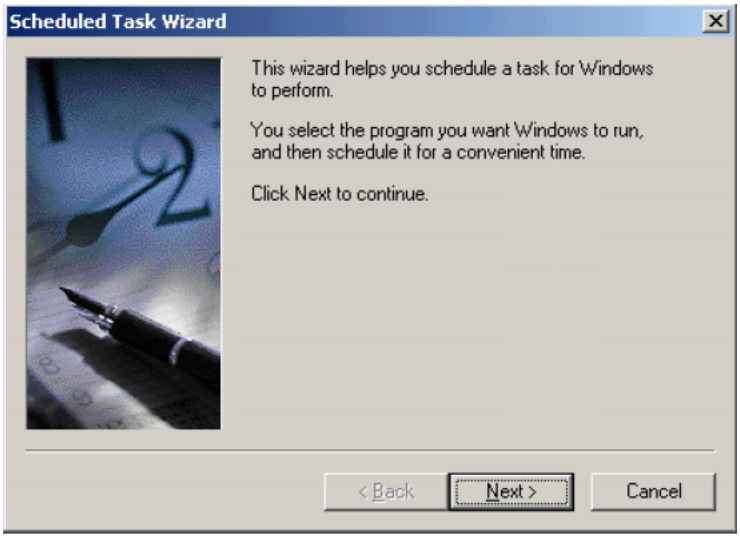
Setting up Batch Generation through Task Manager:

This section explains the procedure for scheduling batch generation by using Windows Task Manager. You need to perform this procedure for each of the six Cubes. The steps follow:

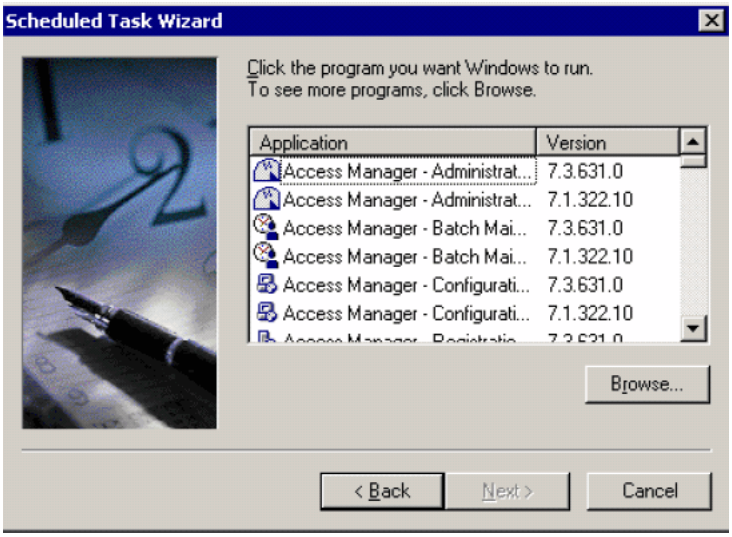
1. Select Start > Settings > Control Panel > Scheduled Tasks. Double-click the Add a Scheduled Task item.



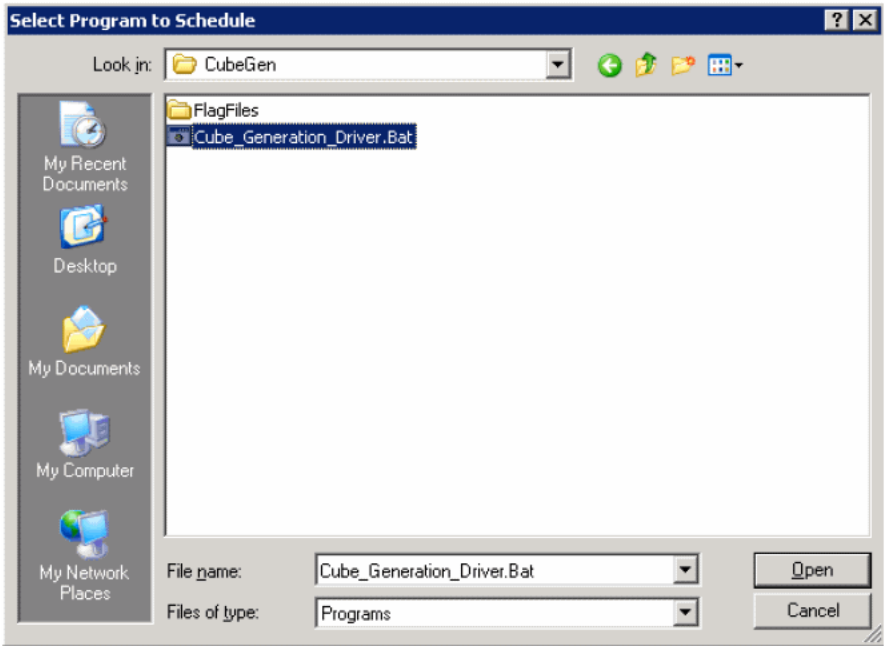
2. Click Next in the Schedule Task Wizard window.



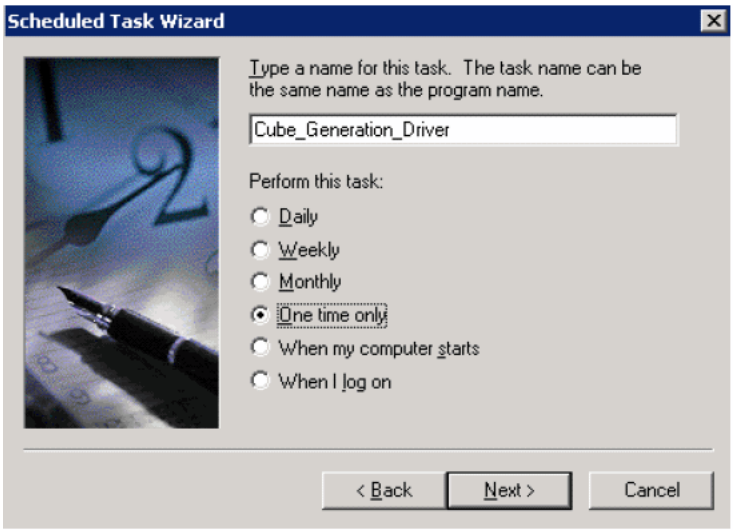
3. Click **Browse** to navigate to another folder location.



4. Navigate to the following location: **<Argus Insight Installation Folder>\PowerReports\CubeGen**This is the path of the folder where the Argus Insight application is installed on the system drive. For example D:\Relsys\PowerReports\CubeGen.
5. Select the Cube_Generation_Driver.bat file.
6. Click **Open** to select the Cube_Generation_Driver.bat file



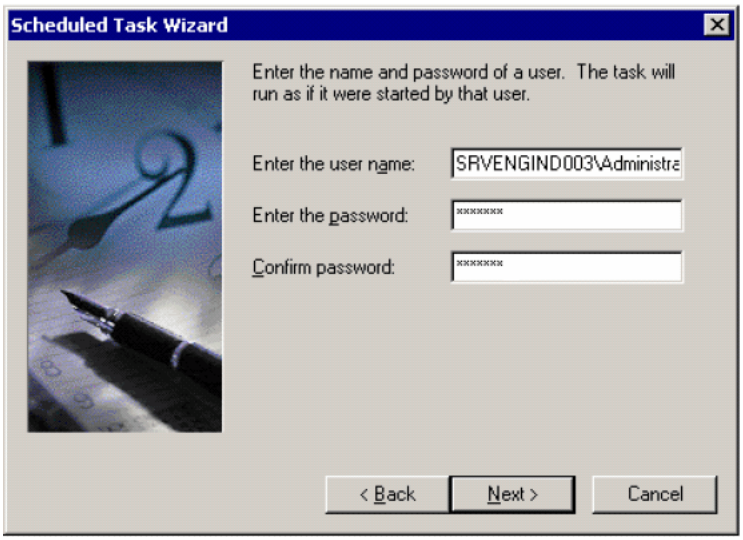
7. In the text box for entering the task name, type **Cube Generate 1**.The task name should be entered in the format **Cube Generate <Cube ID>**. The Cube IDs are listed in the table below.



Cube Name	Cube ID
PV Clinical	1
PV General	2
PV Interaction	3
PV Detail	4
Reporting Compliance	5
Workflow	6

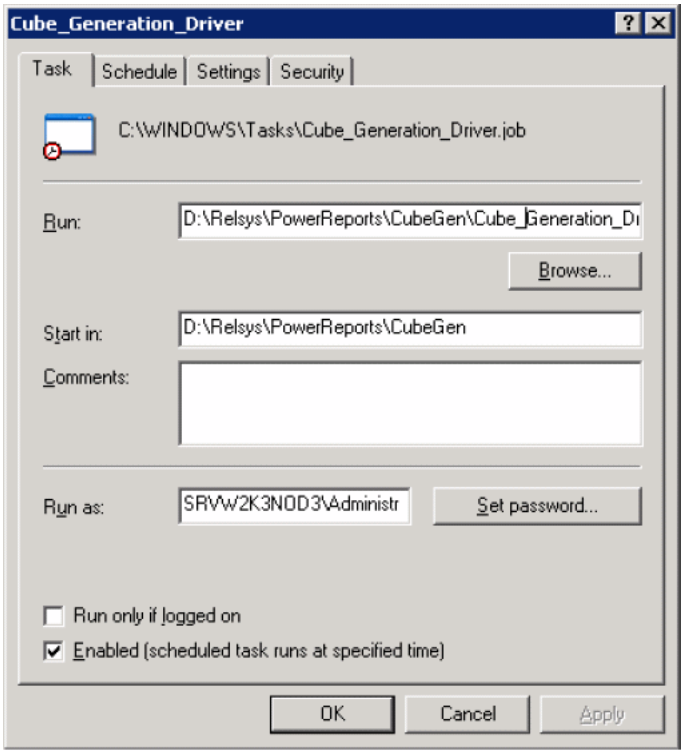
8. Use the **Perform this task** option button group to set the frequency of the task, as appropriate.
9. Click **Next** to proceed to the next step.
10. Set the Start Time and Start Date.

11. Click **Next** to proceed to the next step.
12. Enter the user name and password of the user authorized to run this task



13. Click **Next** to proceed to the next step.
14. Check the Open advanced properties for this task when I click finish checkbox

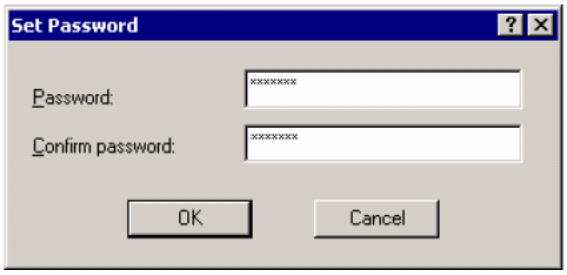
15. Click **Finish**. The dialog box for setting advanced properties for the task appears



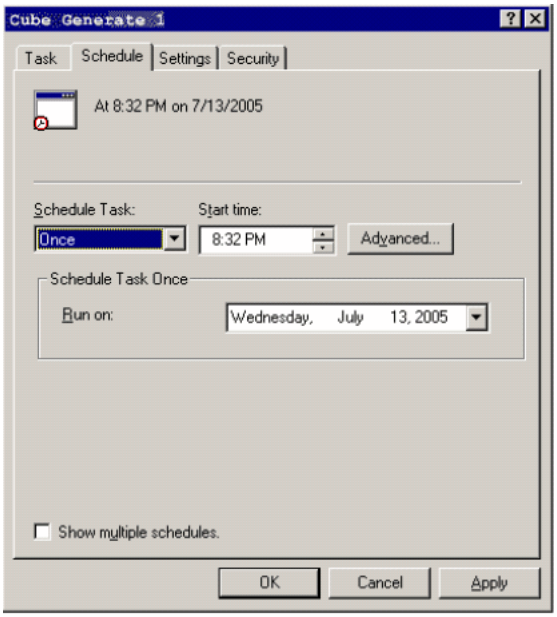
16. In the **Run** text box within the **Task** tab, enter the run-time parameter for this task in the following format:**<Argus Insight Installation Folder>\PowerReports\CubeGen\Cube_Generation_Driver.bat" <Cube ID>**where **CubeID** is the ID of the Cube for which you are scheduling the batch generation.Include the double quotation marks (" ") while entering the runtime parameter. The table below lists the Cube ID for each cube and provides examples of the run-time parameter to be entered.

Cube Name	Cube ID	Example Run-Time Parameter
PV Clinical	1	"D:\Relsys\ArgusInsight\CubeGen\Cube_Generation_Driver.bat" 1
PV General	2	"D:\Relsys\ArgusInsight\CubeGen\Cube_Generation_Driver.bat" 2
PV Interaction	3	"D:\Relsys\ArgusInsight\CubeGen\Cube_Generation_Driver.bat" 3
PV Detail	4	"D:\Relsys\ArgusInsight\CubeGen\Cube_Generation_Driver.bat" 4
Reporting Compliance	5	"D:\Relsys\ArgusInsight\CubeGen\Cube_Generation_Driver.bat" 5
Workflow	6	"D:\Relsys\ArgusInsight\CubeGen\Cube_Generation_Driver.bat" 6

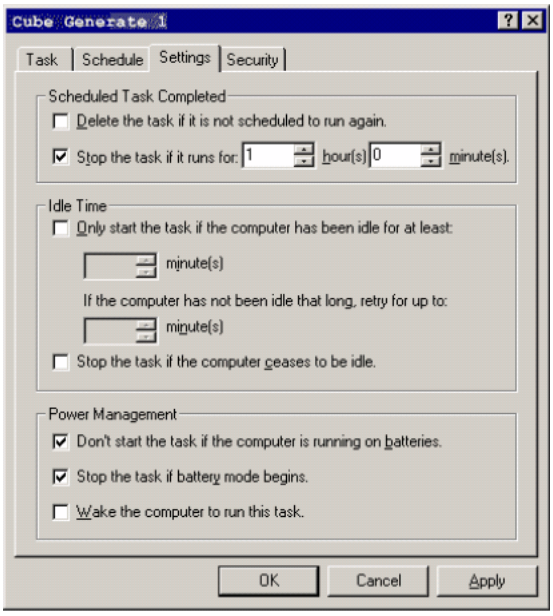
17. Click **Set Password** to set the password.
18. Enter the password for the BOXI Server admin user. Click **OK**.



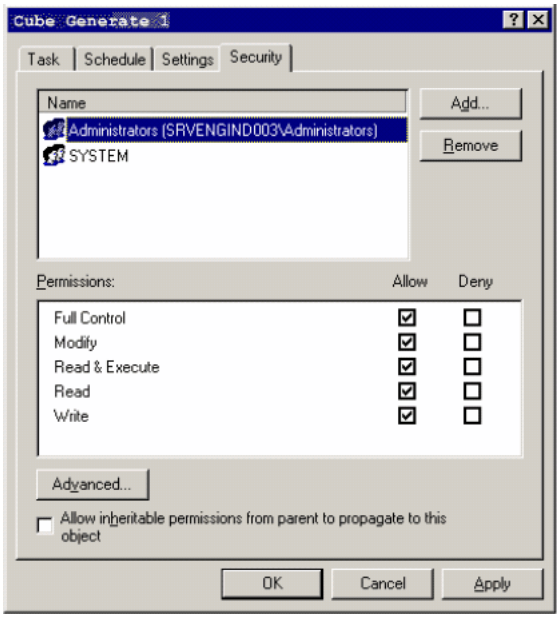
19. Select the **Schedule** tab to set the schedule options, as appropriate.



20. Select the **Settings** tab.



21. In the **Scheduled Task Completed** and **Power Management** sections, set the options as shown in the illustration above.
22. Select the **Security** tab to verify that the user has full permissions assigned.



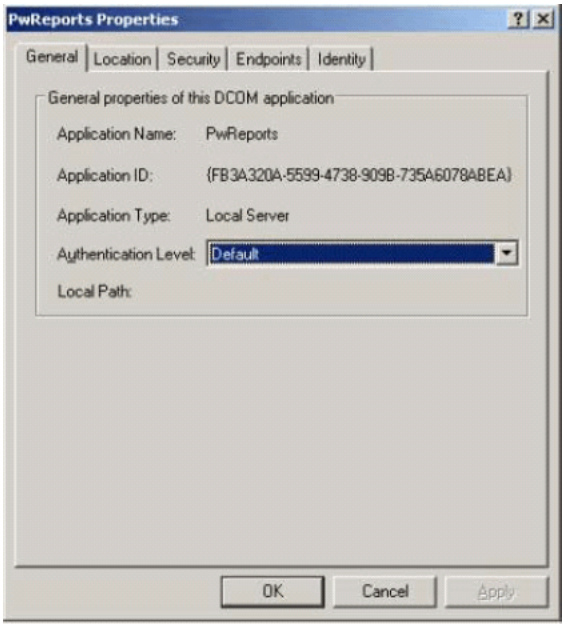
23. Click **OK**.The system creates the new scheduled task **Cube Generation 1**.Repeat the above steps to schedule batch generation for the remaining cubes.

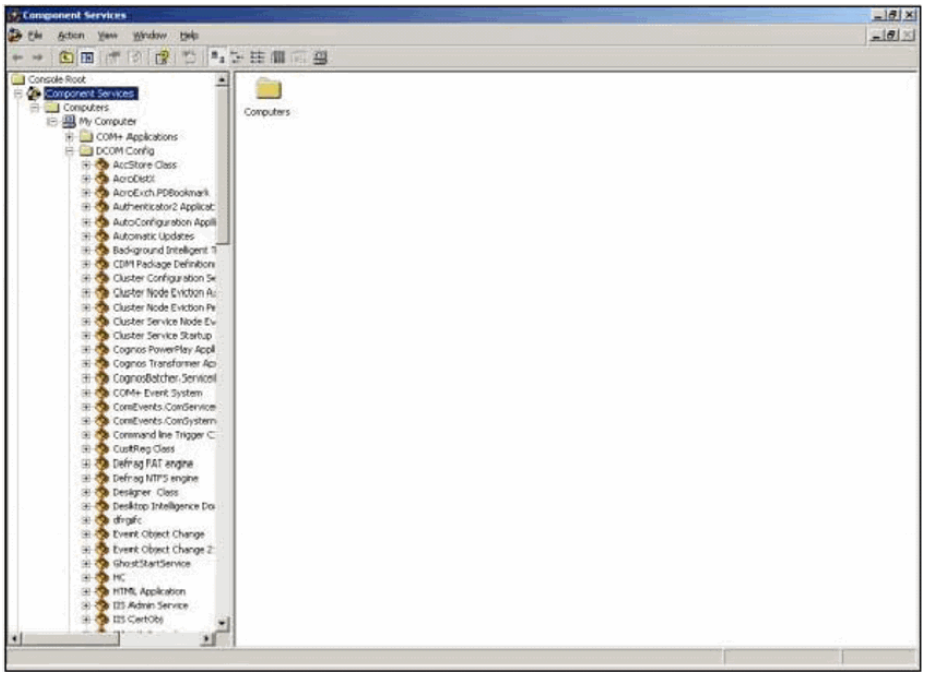
Configuring the CIOMS and MedWatch Reports

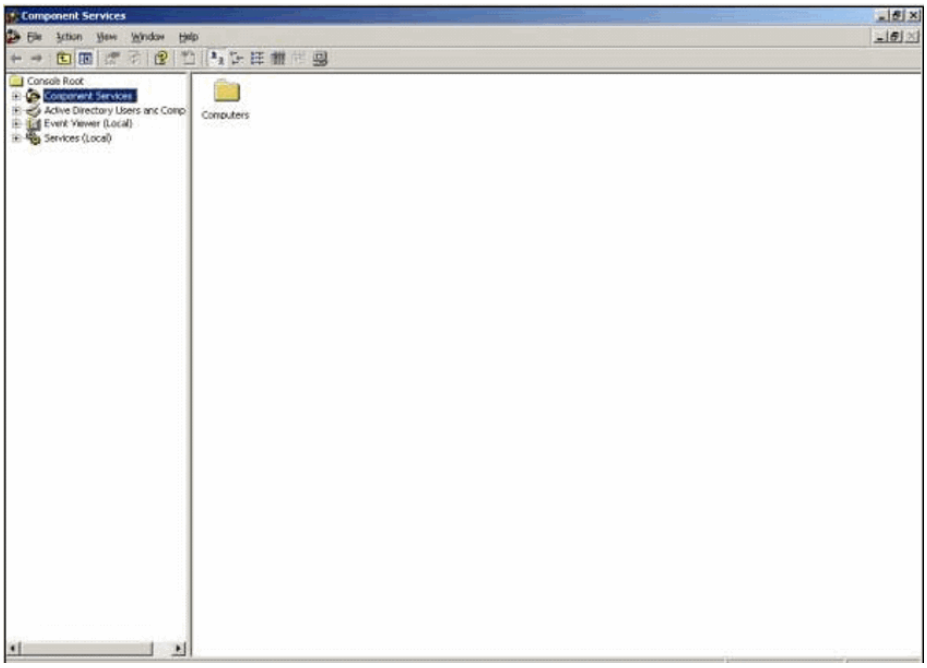
These settings are optional. Theses settings **are not** the recommended settings for running the Argus Insight and should only be configured if CIOMS and MedWatch **are not** running on the environment.

1. Go to **Start > Run** and type **dcomcnfg** and press Enter.

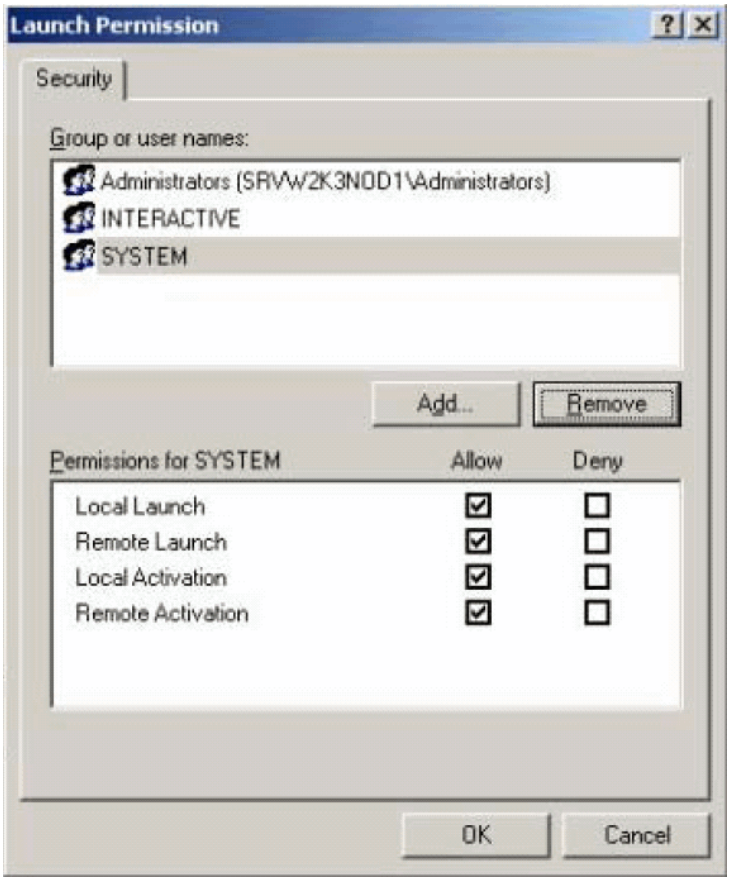
2. In the tree under **Console root > Component Services > Computer > My Computer > DCOM Config**.
3. Right click on the **PwReports** in the list and click **Properties**.



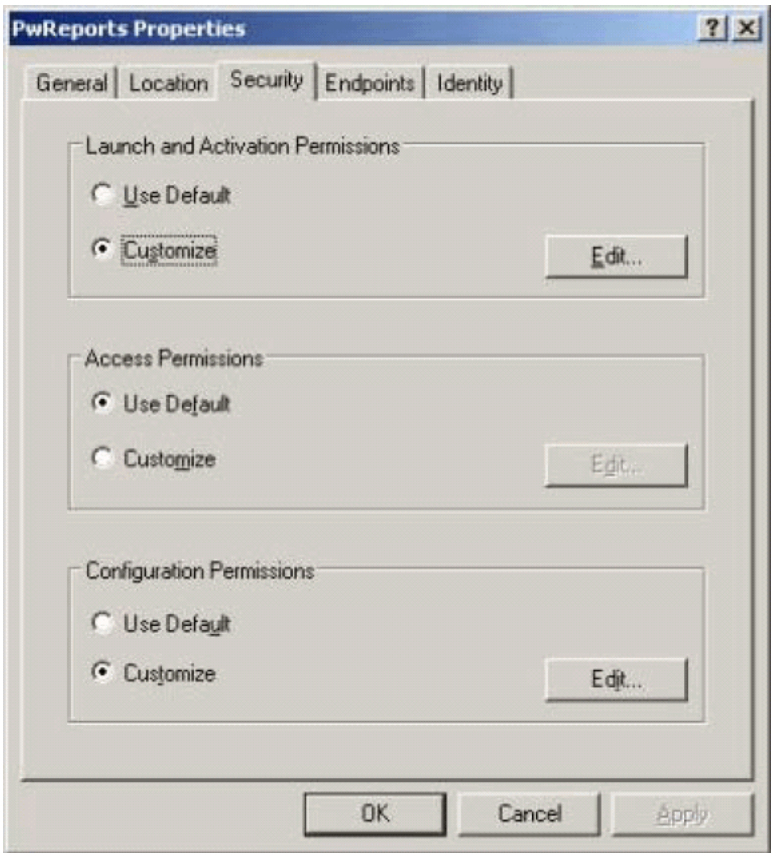




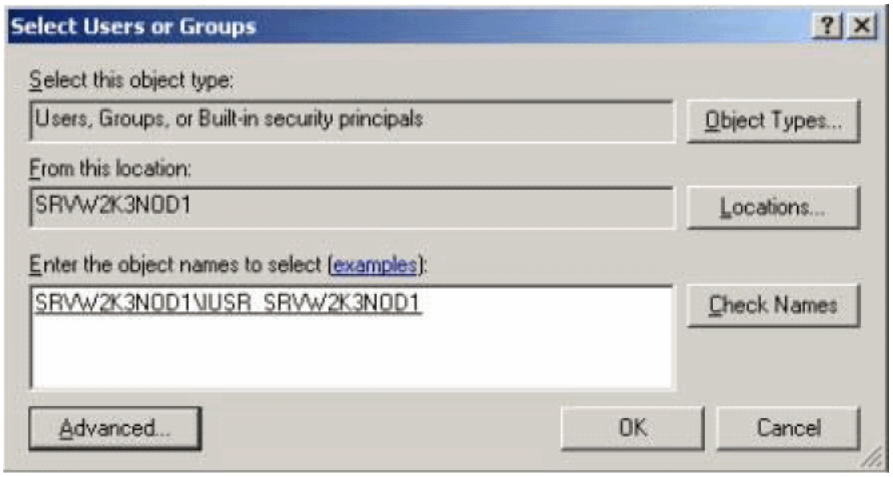
4. Click the Security tab.



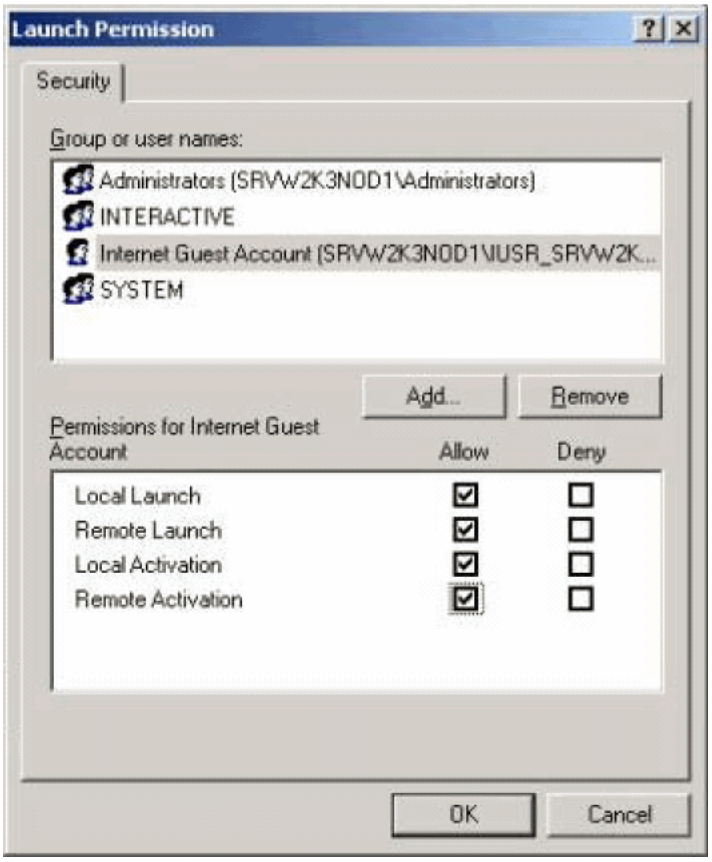
5. In the Launch and Activation Permissions Mark Customize and click Edit.



6. Click**Add.**



7. Under the **Enter the object names to select (examples)** add **<machine_name>/IUSR_<machine_name>** and click **OK**



8. Select the newly created **Internet Guest Account** and check all the permissions.
9. Click **Ok**.
10. Exit the Component Services program.

9

Viewing Dashboard Indicator Reports

Dashboard Indicator Reports

Dashboard Indicator reports are special reports that provide an insight into key parameters that let you monitor product performance and workflow efficiency. These reports are generated directly from the datamart so they display the latest data.

Argus Insight has three Dashboard Indicator reports: **Executives**, **Reporting**, and **Data Entry**. Each of these reports consist of a number of sub-reports, as the following table shows.

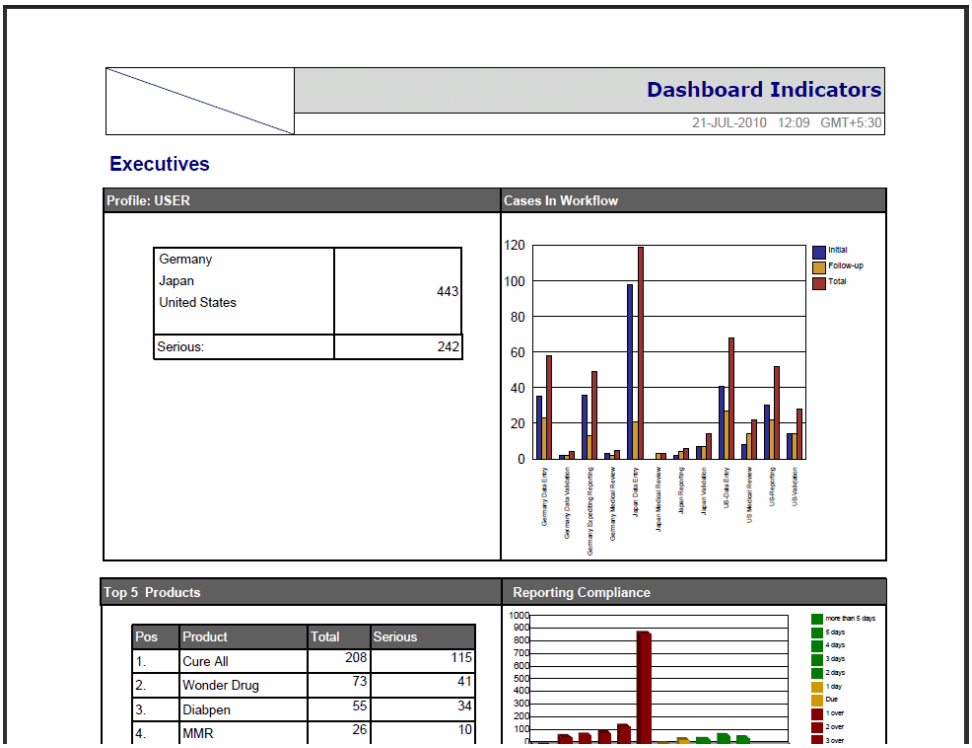
Dashboard Indicator ***Report***	**Sub Report**	
	Name	**Description**
Executives	Executives Profile	This report provides a tabulation of case count for each site. The total count of serious cases for all sites is also listed.
	Top 5 Products	This report is a listing of the top 5 products having the largest total case count sorted in descending order. The serious case count for each product is also listed.
	Cases in Workflow	This report is a graphical summary of the initial, follow up, and total case count in each workflow state.
	Late Reports	This report is a detailed listing of all cases for which reports are past the due date. Days past due are provided for each destination.
	Reporting Compliance	This report provides a graphical overview of reporting compliance count broken down by days remaining to due date and days past due date.
	Receipt Latency	This report provides a graphical overview of receipt latency (from initial receipt date to central received date) by country of origin.

Dashboard Indicator *Report*	Sub Report Name	Description
Reporting	Reporting Profile	This report is a summary of scheduled report and past due report count for all the reporting groups.
	Reporting Compliance (Count)	This report provides a graphical overview of reporting compliance count for each reporting destination. The counts are broken down by days remaining to due date and days past due date.
	Reporting Compliance (Percentage)	This report provides a graphical overview of reporting compliance percentage broken down by days remaining to due date and days past due date.
	Outstanding Submissions by Responsible Group (Summary)	For the selected reporting groups, this report shows the outstanding report count by reporting destinations. Against each destination, the outstanding reported count is further broken up in these groups: - Due in greater than seven days - Due in 3-7 Days - Due in 0-2 days - Past the due date
	Outstanding Submissions by Responsible Group (Listing)	This report provides a detailed listing of cases for which report submissions are coming up. The listing is grouped by the responsible group. Within each group, the listing is sorted in ascending order of days remaining for submission.
Data Entry	Data Entry Profile	This report provides a tabulation of case count for each site. The total count of serious cases for all sites is also listed.
	Receipt Latency	This report provides a graphical overview of receipt latency (from initial receipt date to central received date) by country of origin.
	Cases in Workflow	This report is a graphical summary of the initial, follow up, and total case count in each workflow state.
	Case Load	This report provides a tabulation of cases received, cases in processing, and pending case counts for each workflow state.
	Case Workload by Site and Country	This report provides a tabulation of serious, non-serious, and total case counts grouped by site. For each site, the counts are displayed for each country.

Depending on your profile and reporting requirements, the system administrator configures and assigns a specific Dashboard Indicator report to you.

To view the pre-configured Dashboard Indicator report assigned to you, select **Datamart Reports > Dashboard Indicator**. The report (PDF format) opens in a separate browser window. The samples for each report type are provided below:

- Executives



Dashboard Indicators

21-JUL-2010 12:09 GMT+5:30

Executives

Profile: USER

Germany Japan United States	443
Serious:	242

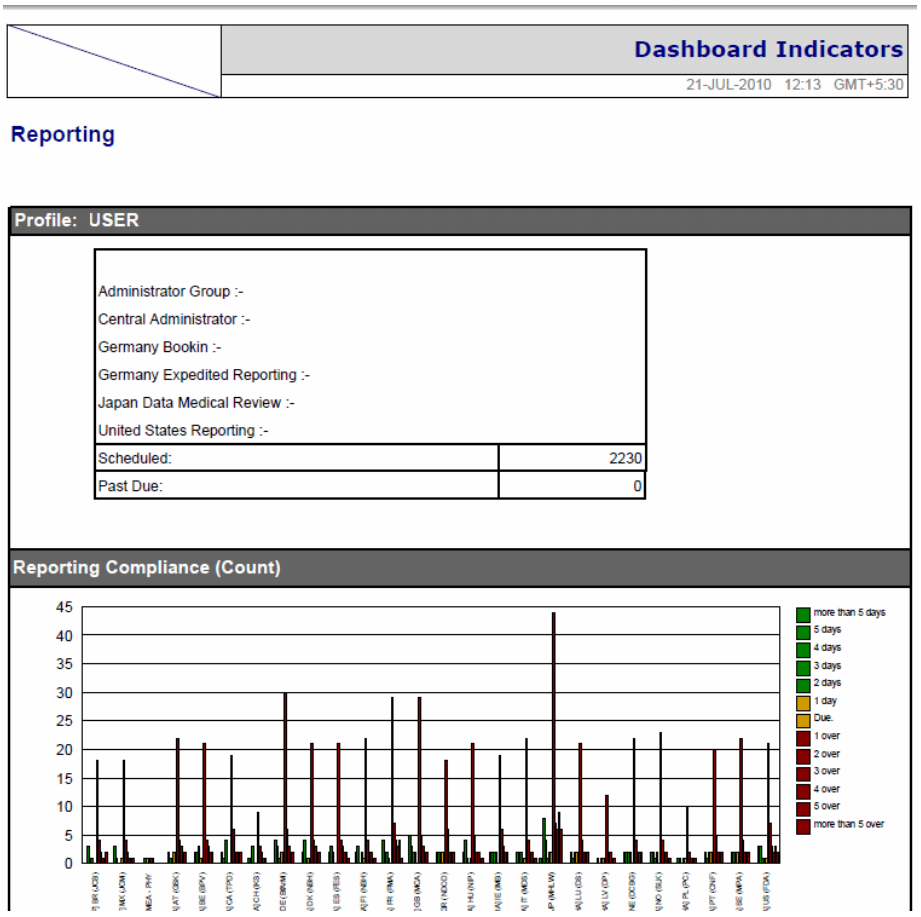
Cases In Workflow

Top 5 Products

Pos	Product	Total	Serious
1.	Cure All	208	115
2.	Wonder Drug	73	41
3.	Diabpen	55	34
4.	MMR	26	10

Reporting Compliance

- Reporting


Dashboard Indicators
21-JUL-2010 12:13 GMT+5:30
Reporting
Profile: USER
Administrator Group :-
Central Administrator :-
Germany Bookin :-
Germany Expedited Reporting :-
Japan Data Medical Review :-
United States Reporting :-
Scheduled: 2230
Past Due: 0
Reporting Compliance (Count)
45
40
35
30
25
20
15
10
5
0
more than 5 days
5 days
4 days
3 days
2 days
1 day
Due.
1 over
2 over
3 over
4 over
5 over
more than 5 over

- Data Entry

Dashboard Indicators

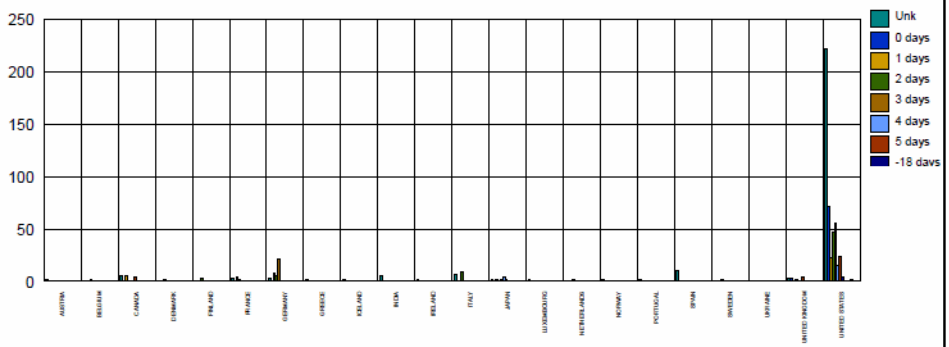
21-JUL-2010 12:18 GMT+5:30

Data Entry

Profile : USER

Germany Japan United States	256
Serious:	145

Receipt Latency



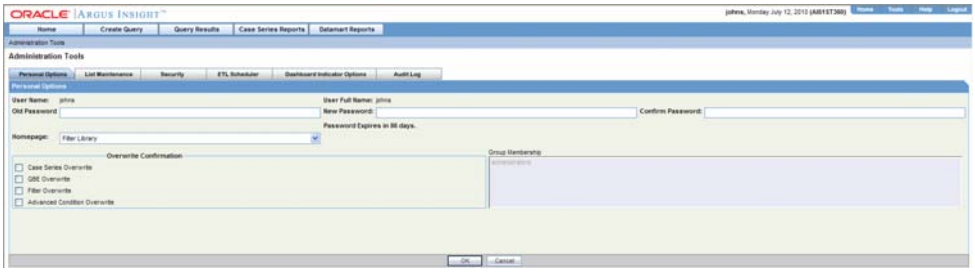
Cases in Workflow

10

Administration Tools

Administration Tools

This chapter explains how to use the Argus Insight administration tools. To access the administration tools, click the **Tools** button in the upper-right corner of the Argus Insight main page. The **Administration Tools** page appears.



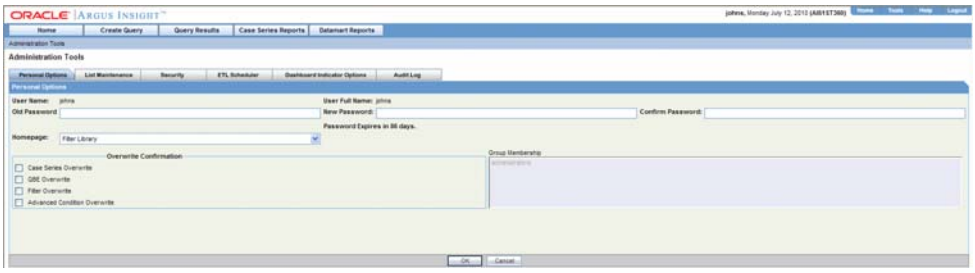
You can use the various tabs in the **Administration Tools** page to perform these tasks:

- Configuring Personal Options
- Maintaining Argus Insight Lists
- Configuring User Groups and Accounts
- Scheduling the ETL
- Configuring Dashboard Indicators
- Viewing the Audit Log

Configuring Personal Options

Use the **Personal Options** tab page to change the password for an account, change the *home page*, set overwrite confirmation, and view group membership.

The **Personal Options** tab page is the default page that appears when you access the **Administration Tools** page. This page is available to all users.



The description of tasks that you can perform from this tab page follows.

Task	Description
Changing the password for an account	1. In the **Old Password** text box, enter the existing password. 2. In the **New Password** text box, enter a new password. 3. Re-enter the new password in the **Confirm Password** text box. 4. Click **OK**. The system saves the new password. Passwords in Argus Insight are not case sensitive. Before verifying passwords, the system converts them to lower case.
Changing the Home Page	The default Argus Insight home page is the *Filter***Library** page. To change the default home page: 1. Select a page from the **Homepage** list box. 2. Click **OK**. The system changes the default home page.
Configuring overwrite confirmation	When you save any modifications you make to an existing Case Series, QBE, Filter, or Advanced Condition, Argus Insight saves the changes directly without prompting you to confirm whether you want to overwrite the existing one. You can have Argus Insight display an overwrite confirmation dialog box by checking these checkboxes, as appropriate: ■ Case Series Overwrite ■ QBE Overwrite ■ Filter Overwrite ■ Advanced Conditions Overwrite
Viewing group memberships	The **Group Membership** list shows the names of the groups to which the currently logged in user belongs. Group memberships can be managed from the Security tab page. Only an administrator can manage users and groups.

Maintaining Argus Insight Lists

Use the **List Maintenance** page to configure the various List Maintenance items and their attributes. The following topics describe the various List Maintenance items and explain how to configure them. Consult your company's policies and the terminology used before configuring Argus Insight lists.

Use the List Maintenance page for the following:

- Configuring Profile Switches
- Configuring EU Countries
- Configuring Workflow Management
- Configuring Categories
- Configuring Duration Value Bands
- Configuring Derivation Functions

- Configuring Case Series Modification Justification
- Configuring Cub-on-the-Fly Case Limit
- Configuring Holiday Schedule Management
- Configuring PDMECs
- Configuring Measurable Suppliers
- Configuring Report Pre-Filter Population

Configuring Profile Switches

The profile switches are used to control the behavior of the Argus Insight application. To configure profile switches, you specify a certain value for a switch. Depending on the type of profile switch, the values can either be pre-defined or based on user input. While certain profile switches can only be configured through direct SQL statements, many profile switches can be updated from the **List Maintenance** page. You can also add new profile switches to Argus Insight from the **List Maintenance** page.

This topic explains how to update profile switch values and describes the various profile switches, their possible values, and their use.

> **Note:** Refer to the **CMN_PROFILE** document for detailed information about all the profile switches. This document also has a sample SQL for inserting profile switches and updating their values in the database. All profile switch values are case sensitive.

The following table lists the profile switches included in the factory data:

Profile Switch	Description
ALPHANUMERIC PASSWORD	This value will force user to enter alphanumeric password. 1 - Alphanumeric and 0 - Non Alphanumeric.
ARGUS INSIGHT SERVER	Host Name or IP Address of Argus Insight Server. This is used for cube view save functionality with Cognos series 7. This value can be left blank if Cognos series 7 is not used for cubes.
BITOOL LDAP ENABLED	LDAP Enabled at BITool level. BITool could be Cognos or Business Objects. 1 - LDAP is enabled in Cognos or Business Objects, 0 - LDAP is not enabled in Cognos or Business Objects.
BO ADMIN AUTHENTICATION TYPE	BO Admin user authentication type. Following could be the possible values 1. SecLDAP 2. SecEnterprise
BO ADMIN PASSWORD	The BO Password for configured BO Admin User (BO_USER) stored encrypted in the Insight database. If it does not match the BO Password that was configured at the time of BO User creation then application access to BO will fail.
BO ADMIN USER	BO user having admin privileges to create, update and delete users in Business Objects Repository. This is a BO User name, potentially not an Insight user.
BO PORT NUMBER	BO PORT Number used by Infoview. The value should be a number with no. of digits between two and five (max value 65535). Access from Infoview will be denied if this value is incorrect. Default value - 8080.
BO REPORT FOLDER NAME	BO Reports root folder name, which will contain all the objects from Argus Insight. The length of folder name should not exceed 255 characters. If the folder name is incorrect, the list of reports will not function.

Profile Switch	Description
BO REPORT WRITER NAME	BO Report Writer Universe Name. If this value is incorrect, Report Writer functionality will not work. Default value - ReportWriter
BO SERVER	BO Server Host Name or IP Address. This is used to identify the BO server to be used. If BO clustering is used, please specify the primary cluster name.
BO USER GROUP NAME	BO Users group name under which all users will be created in Business Objects repository.
BO USER LICENSE	Type of the user created in BO by Argus Insight i.e. Named or Concurrent. Default value - Named
BO WEBI SERVER	BO WebI Server Name or IP Address. This is used while accessing ReportWriter and Infoview from Argus Insight.
BRING ARGUS USERS TO MART	Flag to bring User information (name, password) from Argus Safety if it does not exist in Argus Insight. Default value - 1
CASE REFERENCE TYPE ID	This key is used for populating RPT_CASE.FIRST_REF_NO column.
CAUSALITY ASSESSMENT.C	Used in Standard Reports for Company Defined Causality. Please refer cmn_profile document for the report list.
CAUSALITY ASSESSMENT.R	Used in Standard Reports for Reporter Defined Causality. Please refer cmn_profile document for the report list.
CAUSALITY ASSESSMENT.R+C	Used in Standard Reports for Reporter and Company Defined Causality. Please refer cmn_profile document for the report list.
CAUSALITY ASSESSMENT.UD *FIELD*	Used in Standard Reports for User Defined Field to determine Causality. Please refer cmn_profile document for the report list.
CIOMS MANUFACTURER	Allows the user to configure the Manufacturer information to be printed on the CIOMS Report.
COMPANY LOGO PATH	For Cognos - Logo File Name with full URL path of company logo on the local server. This will appear in header of reports. File types - .jpg, .gif, .bmp. For BO - Logo File Name with directory path of the images on the BO server. This will appear in header of reports. File types - .tiff, .bmp.
CONFIDENTIALITY TEXT	Confidential Text entry which will appear in the footer of reports. Default value - Confidential
CUBE-ON-THE-FLY-LIFESPAN	The default lifespan (in days) for the cubes created on the fly based on a case series.
CUSTOM HELP URL	Allows the user to configure the Custom Help URL. This must be a valid URL otherwise a 404 - Page Not Found error will be displayed to the user.
CUSTOM ROUTINE AFTER INCREMENTAL ETL	This is the full path of the custom routine (Oracle stored procedure) to be executed after Incremental ETL. If the routine fails or is not found, an email is sent to the administrator.
CUSTOM ROUTINE BEFORE INCREMENTAL ETL	This is 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 will not be run and an email will be sent to the administrator.
DATASHEET BPI	Allows the user to configure the user Defined fields for assessment of BPI Datasheet on the product tab. Please refer cmn_profile document for the report list.

Profile Switch	Description
DATASHEET EMEA	Allows the user to configure the user Defined fields for assessment of EMEA Datasheet on the product tab. Please refer cmn_profile document for the report list.
DATASHEET FLAG	Flag used during Incremental ETL for populating data based on four Datasheet Fields for all cases or modified cases. 0 - Modified cases 1 - ALL cases. Four Datasheet fields as defined in the LM (Datasheet BPI, Datasheet EMEA, Datasheet IB, Datasheet PI).
DATASHEET IB	Allows the user to configure the user Defined fields for assessment of IB Datasheet on the product tab. Please refer cmn_profile document for the report list.
DATASHEET PI	Allows the user to configure the user Defined fields for assessment of PI Datasheet on the product tab. Please refer cmn_profile document for the report list.
DATE DIFFERENCE BAND	Allows the user to configure the highest value of the Dimensions which are having Date Difference columns as data source in Administration Statistics and Submission Statistics Cube.
DAYS TO LOCK	Allows user to configure Days to Lock for a Case. Please refer cmn_profile document for the report list.
DELAY IDENTIFIER	Specify the delay text which will be used to extract routing comment. It is used by ETL to populate RPT_FOLLOWUP.CORE_DELAY_ROUTING_ COMMENT. This field is used in Supplier Performance Report and Process Performance - Workflow Report
DOSE CATEGORY UNITS	Dose units to be categorized separately in the Cubes, such as 'mg','ml'.
ENABLE COMPANY HOLIDAY	Company holiday calendar in due date calculation of Data Entry Performance Over Time Report (0 = Disable and 1 = Enable). A value of 1 will include COMPANY holidays in the calculations. A value of 0 will not include COMPANY holidays in calculations.
ETL DATA EXCLUSION	IGNORE - Continue the ETL but skip cases with erroneous data, ABORT - Abort the ETL if it encounters cases with erroneous data.
ETL EMAIL RECEIVER ADDRESS	If this field is left blank then an email will not be sent. Otherwise this field should contain the comma separated addresses of the administrators monitoring the ETL.
ETL EMAIL SENDER ADDRESS	If this field is left blank then email will not be sent. Otherwise it will contain the address on whose behalf the email should be sent.
ETL EMAIL SETUP	0 = Not Configured 1 = Send Email on Initial/Incremental ETL failure 2 = Send Email on Initial/Incremental ETL success 3 = Send Email on Initial/Incremental ETL Success or Failure.
FOLLOW-UP ACTION CODE	Allows user to configure Code considered for requiring a follow-up. Please refer cmn_profile document for the report list.
INVESTIGATIONAL DATASHEET	Allows the user to configure the Investigational Datasheet for the Event Listedness dimension in the Clinical Trial Analysis Cube.
LDAP ANONYMOUS	Set to 1 if Anonymous Bind is enabled on LDAP Server else 0. Default value - 1
LDAP AUTHENTICATION	System wide indicator for LDAP Authentication usage.
LDAP BASE DN	LDAP Distinguished Name

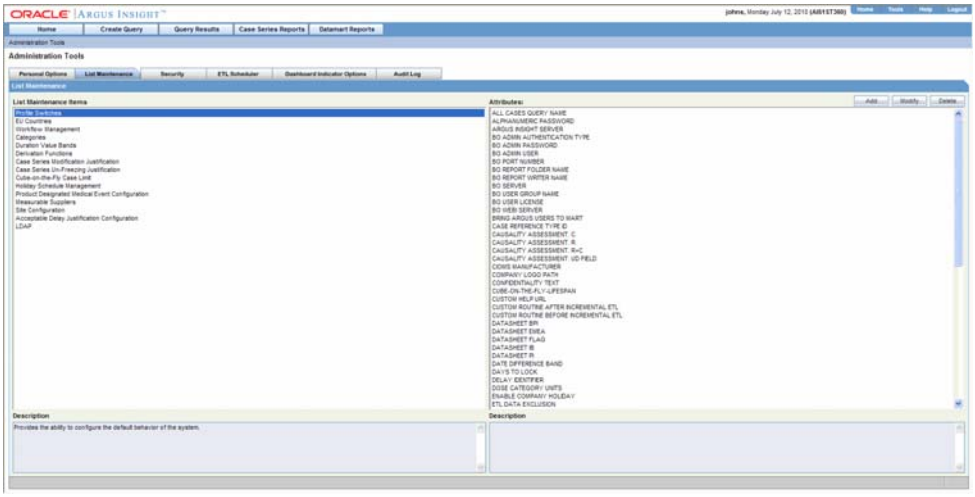
Profile Switch	Description
LDAP SEARCH KEY	Name of LDAP column for User ID. For example. Value for SUN ONE LDAP = uid and Value for ADS = SAMAccountName. In some scenarios it can be CN.
LDAP SEARCH PASSWORD	Password for configured LDAP search user (LDAP_USER).
LDAP SEARCH USER DN	This is the user ID having rights to search in LDAP directory. Provide the complete distinguish name(DN) for search user.
LDAP SERVER NAME	Name or IP Address of LDAP Server.
LDAP SERVER PORT	Port Number of LDAP Server.
LDAP SSL	Set to 1 if SSL is enabled on LDAP Server else 0. Default value - 0
LDAP TIME OUT	LDAP Time out in Seconds. Default value - 120
MARKETED DATASHEET	Allows the user to configure the Marketed Datasheet for the Event Listedness dimension in Medical Analysis and Overdose/Pregnancy/Interaction Cubes.
MEDWATCH MANUFACTURER	Allows the user to configure the Manufacturer information to be printed on the MedWatch Report.
PASSWORD EXPIRATION	Days before password expires.
PASSWORD LENGTH	The minimum length of the Password. It will restrict users from having password length less than the configured limit.
POPULATE AFFILIATE DATA	No Affiliate data will be brought into the Datamart, 1 = Affiliate data will be brought into the Datamart.
POPULATE BLOB DATA	0 = No BLOB data will be brought into the Datamart, 1 = BLOB data will be brought into the Datamart. All Binary LOB (BLOB) data type columns of Argus Owner schema tables and Interchange Schema Owner tables.
POPULATE CUBES FACT DATA	0 = No FACT Table will be populated, 1 = FACT Tables for Business Objects Cubes will be populated, 2 = FACT Tables for Cognos Cubes will be populated, 3 = All FACT Tables will be populated.
POPULATE DLL SLL REPORTS TABLE DATA	0 = Table RPT_CASE_EVENT_PRODUCT required for DLL and SLL Reports will NOT be populated, 1 = Table RPT_CASE_EVENT_PRODUCT required for DLL and SLL Reports will be populated.
POPULATE INTERCHANGE CLOB DATA	0 = No Interchange CLOB data will be brought into the Datamart, 1 = Interchange CLOB data will be brought into the Datamart.
POPULATE INTERCHANGE DATA	0 = No Interchange data will be brought into the Datamart, 1 = All Interchange data will be brought into the Datamart, 2 = Only SAFETYREPORT, MESSAGES and EDI_INFO tables data will be brought into the Datamart.
POPULATE WHO Drug C DATA	0=Do Not Populate WHO Drug C Tables, 1=Populate WHO Drug C Tables
PRODUCT LOGO PATH	Logo File Name with full URL path of product logo. This will appear in header of reports. Please refer cmn_profile document for the report list.
REPORT FOOTER LOGO PATH	Logo File Name with full URL path of report footer logo. This will appear in footer of reports. Please refer cmn_profile document for the report list.
REPORT PROMPTS	User Interface to allow a user to add new report prompts and modify existing report prompts.

Profile Switch	Description
REPORTING TOOL	This is the name of reporting tool/BI tool used with Argus Insight application. Following could be the possible values for reporting tool: BOXI - For Business Objects as BI Tool, COGNOS8 - For Cognos 8 as BI Tool.
RESET PASSWORD	Default value used when resetting a User's password.
UDN Column for SUPPLIER NAME	User Defined Number column of Argus table CASE_MASTER used for SUPPLIER NAME value.
USE BO JOB SERVER	Use the BO Job Server to execute the Reports. 1 - Use Job Server, 0 - Use Report Server (Default)
WHO DRUG BROWSER FORMAT	WHO Drug Browser Format. Possible values: 1. B - All the WHO Drug browsers in the application will show B Format. 2. C - All the WHO Drug browsers in the application will show C Format.

Modifying the Value of a Profile Switch

Use the following procedure to modify the value of an existing profile switch.

1. In the **List Maintenance** page, select the **Profile Switches** item from the **List Maintenance Items** list. The **Attributes** list displays the names of the default profile switches.

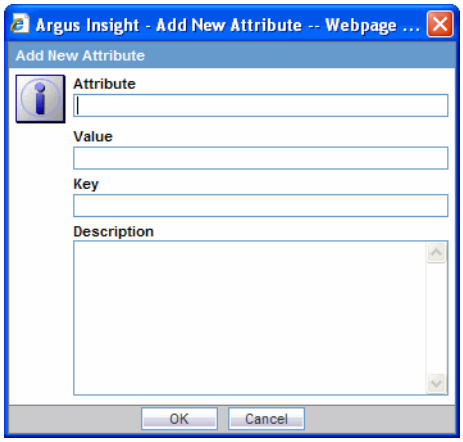


2. From the **Attributes** list, select the profile switch you want to modify.
3. Click **Modify**. The **Modify Attribute** dialog box appears.
4. Modify the values, as appropriate.
5. Click **OK**. The profile switch is updated.

Adding a New Profile Switch

Use the following procedure to add a new profile switch.

1. In the **List Maintenance** page, select the **Profile Switches** item from the **List Maintenance Items** list. The **Attributes** list displays the names of the default profile switches.
2. Click **Add**. The **Add New Attribute** dialog box appears.



3. Enter the profile switch name, key, and, values, as appropriate
4. Click **OK**. The profile switch is added to the system.

Configuring EU Countries

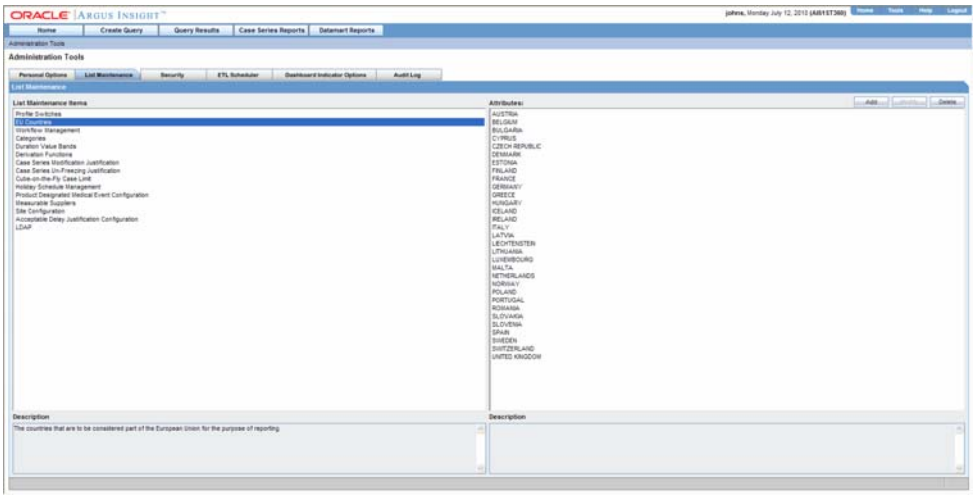
From the **List Maintenance** page, you can configure the list of European Union countries for reporting purposes. The countries can be added and removed as required.

The following table lists the European Union countries included in the factory data:

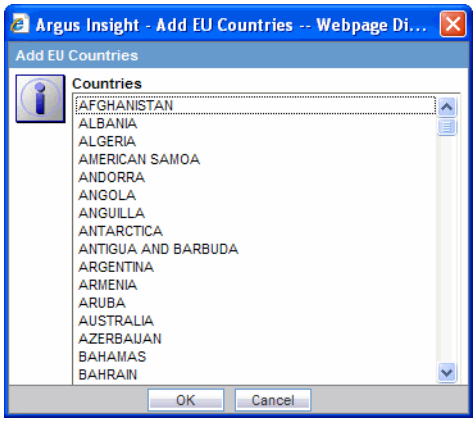
EU Country List		
Austria	Hungary	Norway
Belgium	Iceland	Poland
Bulgaria	Ireland	Portugal
Cyprus	Italy	Romania
Czech Republic	Latvia	Slovakia (Slovak Republic)
Denmark	Liechtenstein	Slovenia
Estonia	Lithuania	Spain
Finland	Luxembourg	Sweden
France	Malta	Switzerland
Germany	Netherlands	United Kingdom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

Use the following procedure to add new countries to this list

1. In the **List Maintenance** page, select **EU Countries** from the **List Maintenance Items** list. The **Attributes** list displays the existing EU country names.



2. Click **Add**. The **Add EU Countries** dialog box appears.
3. Select the country from the **Countries** list in the **Add EU Countries** dialog box.
4. Click **OK**. The new country is added to the EU countries list.



Use the following procedure to delete an existing country from the list.

1. In the **List Maintenance** page, select **EU Countries** from the **List Maintenance Items** list. The **Attributes** list displays the existing EU country names.
2. Select the country you wish to delete from **Attributes** list.
3. Click **Delete**. A delete confirmation dialog box appears.
4. Click **OK** to confirm the delete operation.

Configuring Workflow Management

From the **List Maintenance** page, you can map all the site-specific workflow states to these default groups for the purpose of grouping outputs of certain reports:

- Compliance Metrics - Data Entry Performance - all workflow states that are considered as Data Entry in Data Entry Performance Over Time Report
- Compliance Metrics - HQ Acceptance - all workflow states that indicate Review Completion in Data Entry Performance Over Time Report

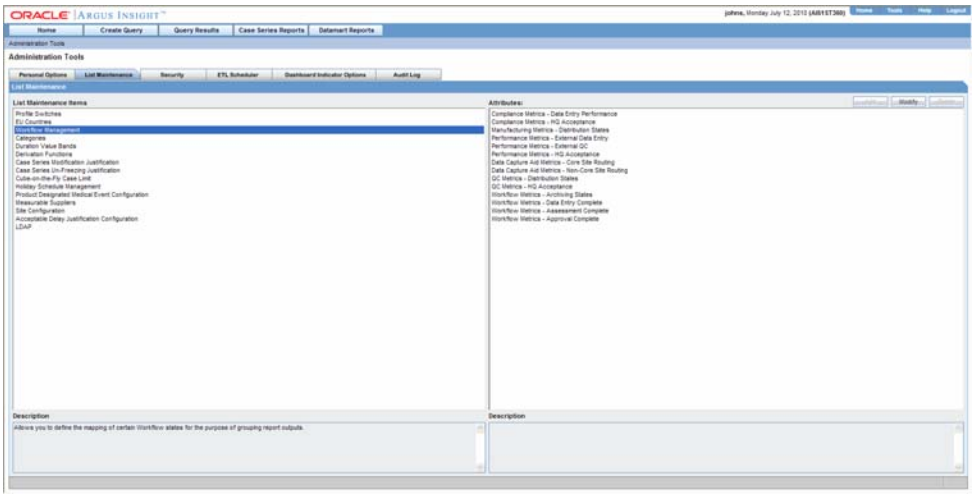
- Manufacturing Metrics - Distribution States - all workflow states that are considered as Distribution in Manufacturing Monthly Report
- Performance Metrics - External Data Entry - all workflow states that are considered as Data Entry in External Clinical QC Report
- Performance Metrics - External QC - workflow states that are considered for a secondary QC check in External Clinical QC Report
- Performance Metrics - HQ Acceptance - all workflow states that indicate QC Review Completion in External Clinical QC Report
- QC Metrics - HQ Acceptance - all workflow states that indicate QC Review Completion in Regulatory Submission and Distribution Compliance Report and Process Performance Report
- Workflow Metrics - Archiving States - all workflow states that are considered as Archived/Closed in Argus
- Workflow Metrics - Data Entry Complete - all workflow states that indicate completion of data entry in Argus
- Workflow Metrics - Assessment Complete - all workflow states that indicate completion of event assessment in Argus
- Workflow Metrics - Approval Complete - all workflow states that indicate that the case is ready for reporting after being locked in Argus

Although these mappings are pre-configured when you install 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.

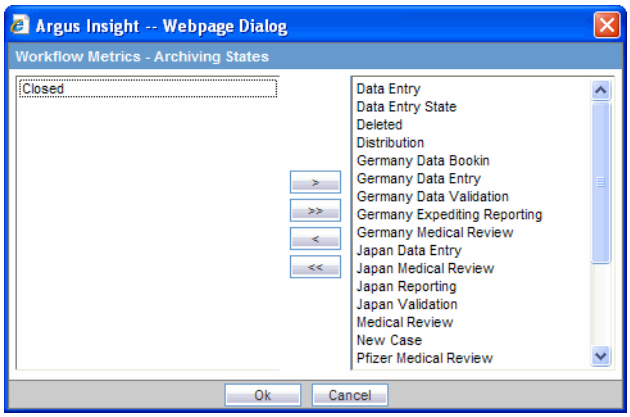
Use the following procedure to modify a workflow mapping

Step 1: Configure Workflow Management

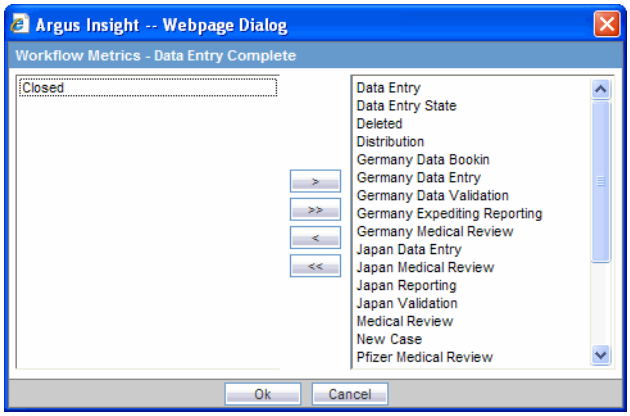
1. Select **Workflow Management** from the List Maintenance Items list.



2. Select Workflow Metrics - Archiving States from the Attributes list.
3. Click Modify.



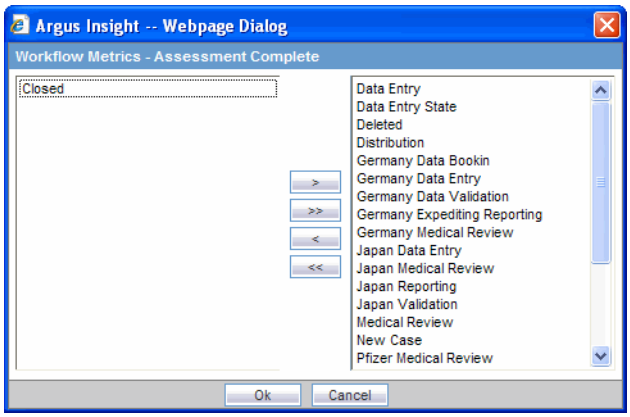
4. Select **Germany Expediting Reporting**, **US-Reporting** and **Japan Reporting** from the list on the left and click > to add them as Archiving States.
5. Click **OK** to save the modification and return to the **List Maintenance** page.
6. Select Workflow Metrics - Data Entry Complete from the Attributes list.
7. Click **Modify**.



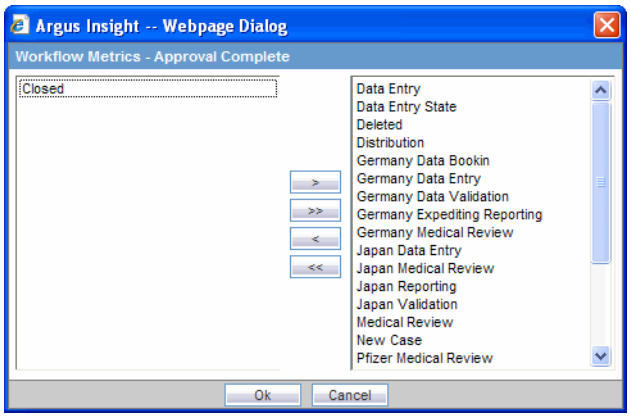
8. Select **Germany Data Validation**, **US-Validation**, and **Japan Validation** from the list on the left and click **>** to add them as Data Entry Complete.
9. Remove the **Closed** item from the list on the right by selecting **Closed** and clicking **<**.
10. Click **OK** to save the modification and return to the **List Maintenance** page.

Step 2: Configure Workflow Metrics Assessment Complete

1. Select **Workflow Metrics - Assessment Complete** from the Attributes list in the List Maintenance page.
2. Click **Modify**.



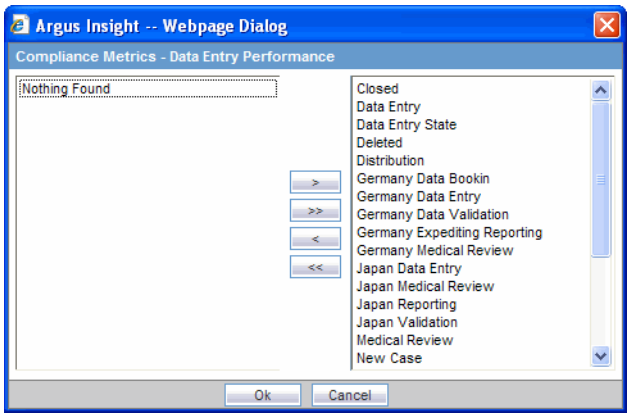
3. Select **Germany Medical Review**, **US Medical Review**, and **Japan Medical Review** from the list on the left and click **>** to add them as Assessment Complete.
4. Remove the **Closed** item from the list on the right by selecting **Closed** and clicking **<**.
5. Click **OK** to save the modification and return to the **List Maintenance** page.
6. Select **Workflow Metrics - Approval Complete** from the **Attributes** list.
7. Click **Modify**.



8. Select **Germany Medical Review**, **US Medical Review**, and **Japan Medical Review** from the list on the left and click > to add them as Approval Complete.
9. Remove the **Closed** item from the list on the right by selecting **Closed** and clicking **<**.
10. Click **OK** to save the modification and return to the **List Maintenance** page.

Step 3: Configure Data Entry Performance

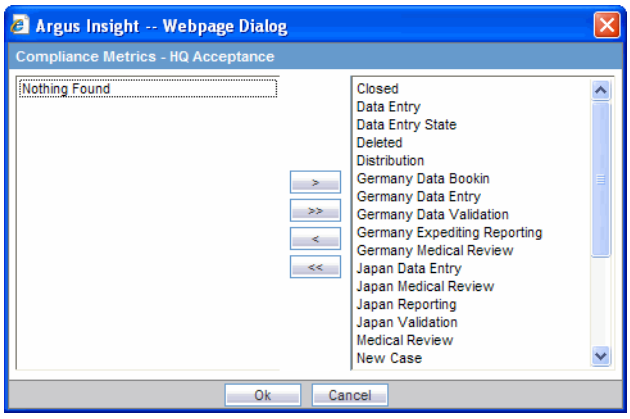
1. Select **Compliance Metrics - Data Entry Performance** from **Attributes** in List Maintenance Items - Workflow Management.
2. Click **Modify**.



3. Make the required selections by selecting the required entities from the list on the left and click > to move them individually or click >> to move all of them together.
4. Alternatively, click the entities to be de-selected from the list on the right and click < to move them individually or click << to move all of them together.

Step 4: Configure HQ Acceptance

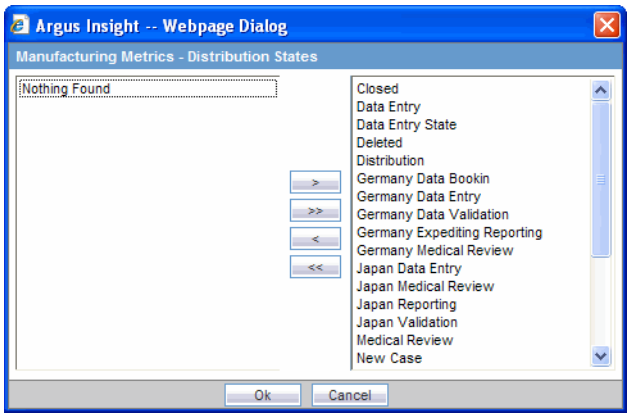
1. Click **OK** to save the modification and return to the **List Maintenance** page.
2. Select **Compliance Metrics - HQ Acceptance** from **Attributes** in List Maintenance Items - Workflow Management.
3. Click **Modify**.



4. Make the required selections by selecting the required entities from the list on the left and click > to move them individually or click >> to move all of them together.
5. Alternatively, click the entities to be de-selected from the list on the right and click < to move them individually or click << to move all of them together.
6. Click **OK** to save the modification and return to the **List Maintenance** page.

Step 5: Configure Distribution States

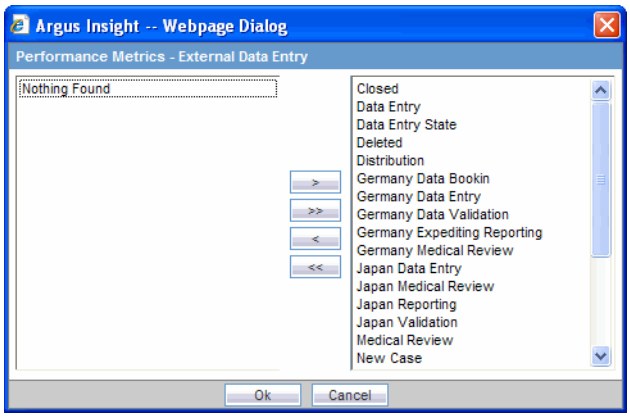
1. Select **Manufacturing Metrics - Distribution States** from **Attributes** in List Maintenance Items - Workflow Management.
2. Click **Modify**.



3. Make the required selections by selecting the required entities from the list on the left and click > to move them individually or click >> to move all of them together.
4. Alternatively, click the entities to be de-selected from the list on the right and click < to move them individually or click << to move all of them together.
5. Click **OK** to save the modification and return to the **List Maintenance** page.

Step 6: Configure External Data Entry

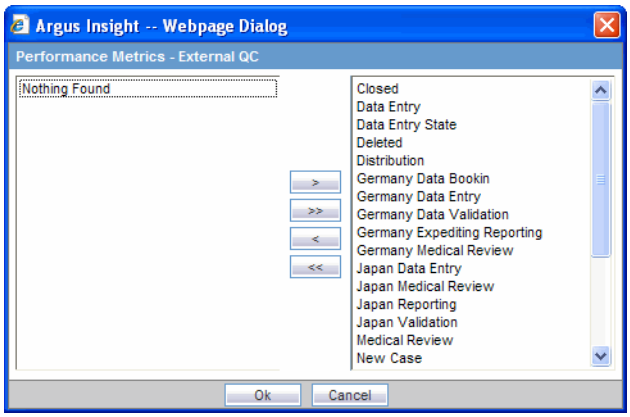
1. Select **Performance Metrics - External Data Entry** from **Attributes** in **List Maintenance Items - Workflow Management**.
2. Click **Modify**.



3. Make the required selections by selecting the required entities from the list on the left and click > to move them individually or click >> to move all of them together.
4. Alternatively, click the entities to be de-selected from the list on the right and click < to move them individually or click << to move all of them together.
5. Click **OK** to save the modification and return to the **List Maintenance** page.

Step 7: Configure External QC

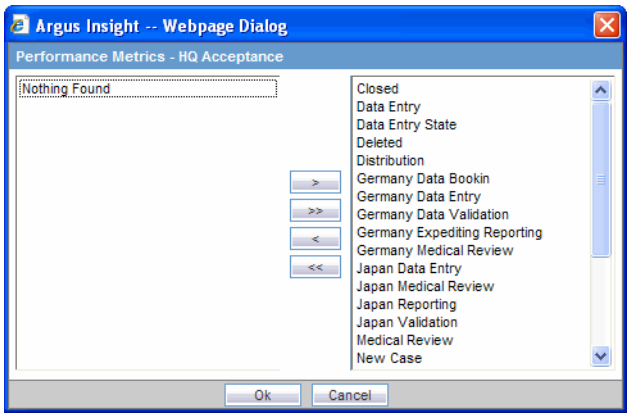
1. Select **Performance Metrics - External QC** from **Attributes** in **List Maintenance Items - Workflow Management**.
2. Click **Modify**.



3. Make the required selections by selecting the required entities from the list on the left and click > to move them individually or click >> to move all of them together.
4. Alternatively, click the entities to be de-selected from the list on the right and click < to move them individually or click << to move all of them together.
5. Click **OK** to save the modification and return to the **List Maintenance** page.

Step 8: Configure Performance Metrics HQ Acceptance

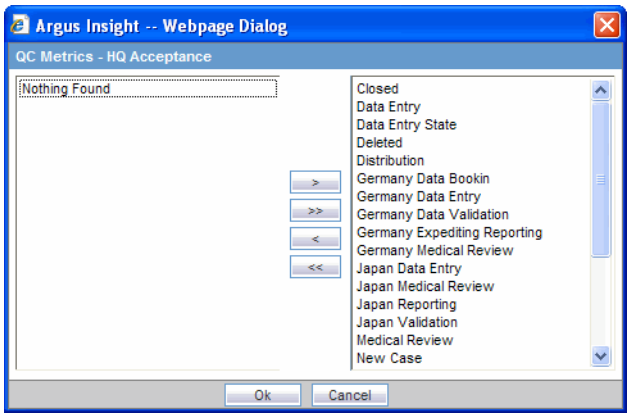
1. Select **Performance Metrics - HQ Acceptance** from **Attributes** in List Maintenance Items - Workflow Management.
2. Click **Modify**.



3. Make the required selections by selecting the required entities from the list on the left and click > to move them individually or click >> to move all of them together.
4. Alternatively, click the entities to be de-selected from the list on the right and click < to move them individually or click << to move all of them together.
5. Click **OK** to save the modification and return to the **List Maintenance** page.

Step 9: Configure QC Metrics HQ Acceptance

1. Select **QC Metrics - HQ Acceptance** from Attributes in List Maintenance Items - Workflow Management.
2. Click **Modify**.



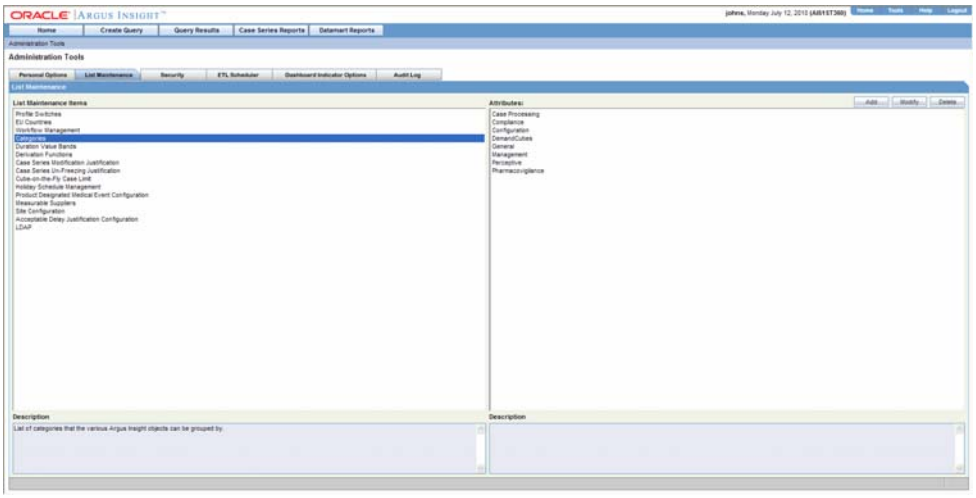
3. Make the required selections by selecting the required entities from the list on the left and click > to move them individually or click >> to move all of them together.
4. Alternatively, click the entities to be de-selected from the list on the right and click < to move them individually or click << to move all of them together.
5. Click **OK** to save the modification and return to the **List Maintenance** page.

Configuring Categories

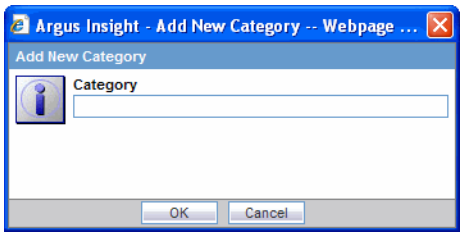
Various Argus Insight objects, such as queries, Case Series, and Standard Reports, can be grouped in five default categories: Compliance, Configuration, General, Management, and Pharmacovigilance. This topic explains how to add, modify, and delete categories.

Use the following procedure to add a new category.

1. In the **List Maintenance** tab, select the **Categories** item from the **List Maintenance Items** list.The **Attributes** list displays the existing categories.



2. Click**Add**. The **Add New Category** dialog box appears.



3. Enter the category name.
4. Click **OK**. The new category is added to Argus Insight.
5. To change the name of an existing category, select the category from the **Attributes** list and click **Modify**. In the **Modify Category** dialog box that appears, change the category name and click **OK**.
6. To delete an existing category, select the category from the **Attributes** list and click **Delete**. In the delete confirmation dialog box that appears, click **OK**.

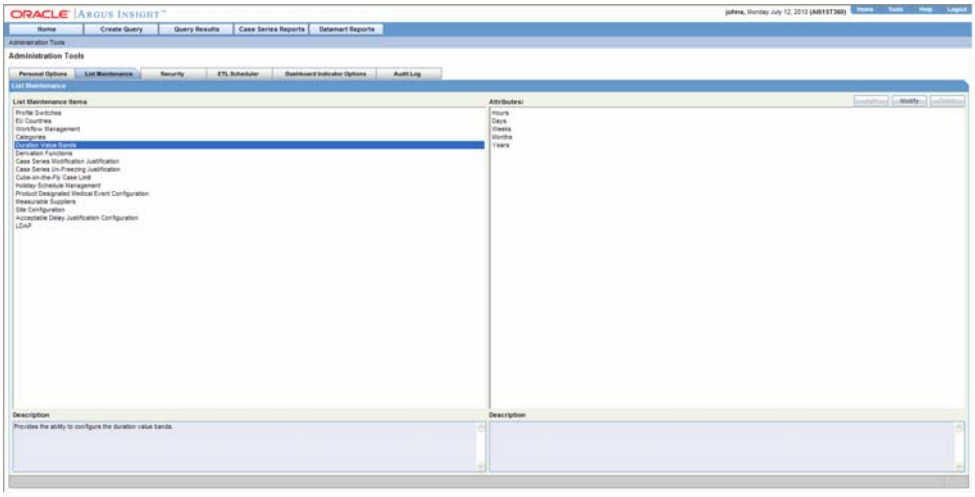
Configuring Duration Value Bands

In Argus Insight, the time values (entered in Argus Safety) in the **Product Tab** > **Drug Duration of Administration**, **Events Tab > Time to Onset from First Dose**, and **Events Tab > Time to Onset from Last Dose** fields can be mapped to specific ranges called Duration Value Bands. This enables you to specify querying criteria based on ranges instead of specific values for the above fields.

The **Duration Values Bands** item in the **List Maintenance** page lets you configure the duration value bands in the hour, day, week, month, and year categories. In each category, you can specify multiple ranges by entering maximum and minimum value for each range item. Any value that falls within a configured range will map to that range.

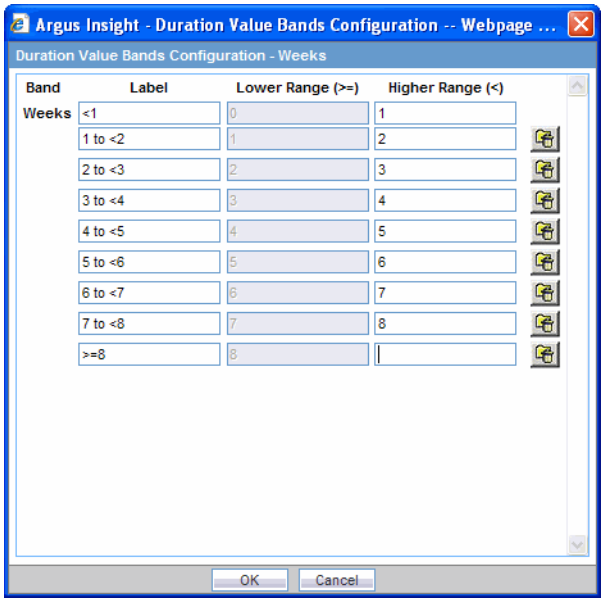
Use the following procedure to configure duration value bands.

1. In the **List Maintenance** tab page, select the **Duration Values Bands item** from the **List Maintenance Items** list.The **Attributes** list displays the existing categories.These are default categories and cannot be modified.



2. Select a category.

3. Click **Modify**. The **Duration Value Bands Configuration** dialog box appears. The factory-configured ranges are displayed. The **Label***column* represents the name of the range. The **Lower Range (>=)** and **Higher Range (<)** columns contain the minimum and maximum values, respectively.



4. Modify the values, as appropriate. In the **Duration Value Bands Configuration** dialog box, you can delete an existing range by clicking the **Delete**icon or you can modify a range by editing the values in the **Lower Range (>=)** and **Higher Range (<)** columns. Note that the lowest band cannot be deleted. Additionally, the highest value band includes values that are greater than the highest range value that you specify. To add a range, enter a higher range compared to the previous highest range in **Higher Range (<)**and press **TAB**. This add a new row.
5. If you delete an intermediate range, the highest value of the deleted range is automatically converted to the lowest value in the next range. However, the range labels do not change.
6. Click **OK** to save the changes.

Configuring Derivation Functions

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

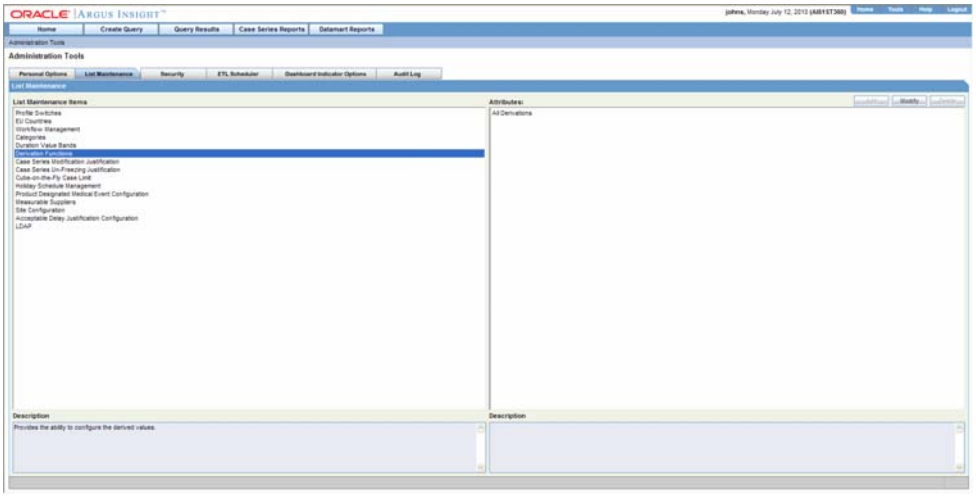
For example, you can create a new List Maintenance item called *Report***Type 1** and derive to this item, all the cases that have the **Report Type** attribute as **Spontaneous**, **Literature**, and **Compassionate Use**. As a result, the **Report Type 1** List Maintenance item appears as an option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

You may also 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 as **Spontaneous**, **Literature**, and **Compassionate Use** and the **Country of Incidence** attribute as **United Sates**.

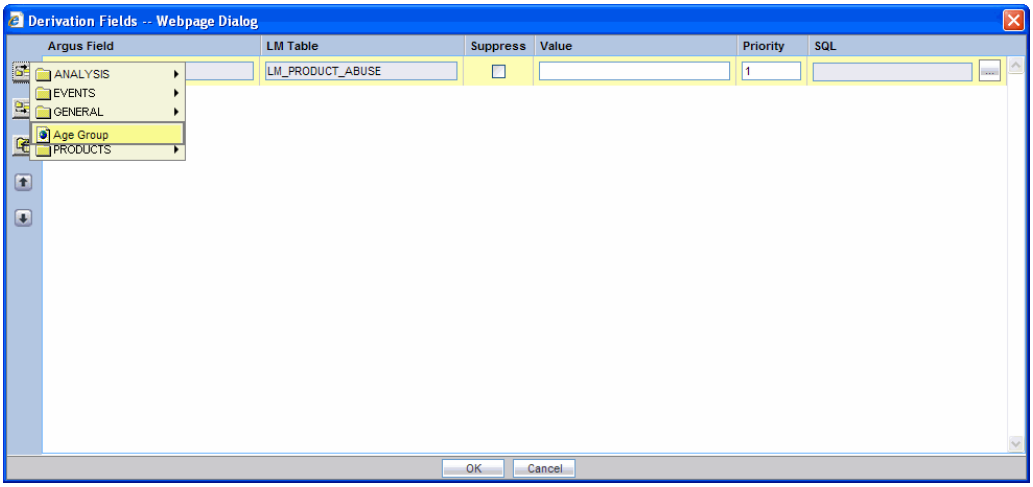
Note: In some configuration situations two different List Maintenance items need to be created containing similar attributes (in the SQL criteria). In this case, you can assign a priority level to individual List Maintenance items. The priority level determines which LM item SQL is executed first.

Use the following procedure to configure derivation functions.

1. In the **List Maintenance** tab page, select the **Derivation Functions item** from the **List Maintenance Items** list.The **Attributes** list displays the existing categories.This is a default category and cannot be modified.



2. Select the category **All derivations**.
3. Click **Modify**. Use the icons (described below) to add/delete/rearrange rows in the Derivation Fields window.



Refer to the brief descriptions for the explanation of the fields as displayed in the **Derivation Fields** window.

Argus *Field* The Argus Field Mapping derivation rules are applicable as shown below:

- ANALYSIS > BfArM Information > Causality

- ANALYSIS > Case Assessment > Listedness Determination
- ANALYSIS > Case Assessment > Case Outcome
- EVENTS > Event Information > Lack of Efficacy
- GENERAL > General Information > Report Type
- GENERAL > General Information > Pregnancy
- PATIENT > Patient Information > Age Group
- PATIENT > Patient Information > Patient weight BMI desc
- PRODUCTS > Product Drug > Derived Overdose
- PRODUCTS > Product Drug > Derived Drug Interaction
- PRODUCTS > Product Drug > Last daily dose

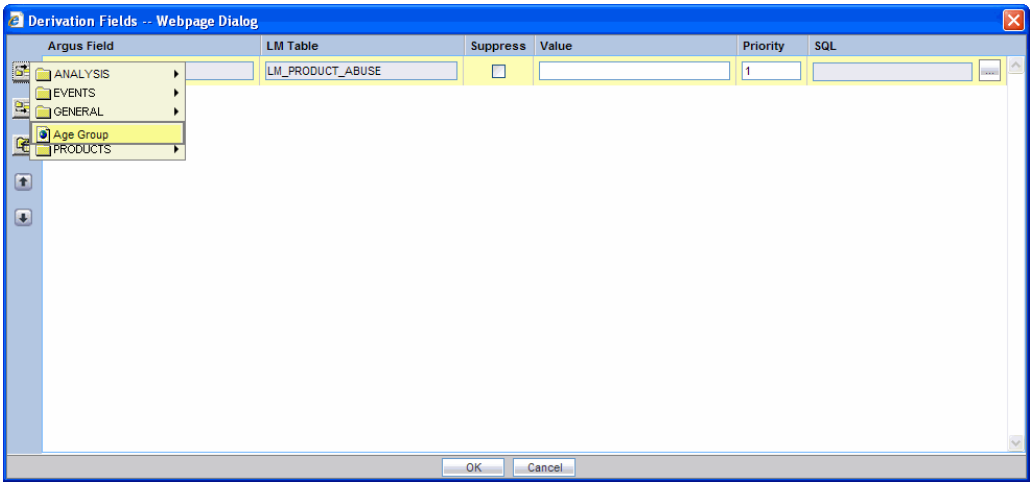
Note: If there are no cases present in the active series of Argus, an error message appears indicating the same. **Age Group, Causality, Last daily dose** and **Report Type** are comma separated Derivation rules.

LM Table This field is the table name of the selected Argus field i.e automatically populated.

Suppress This functionality is available only if the selected field has a list maintenance table. When this field is not enabled, the value of the derivation field is saved along with a new value in the corresponding LM (List Maintenance) table.

When this field is enabled, the old value of the derivation field is replaced with a new value in the corresponding LM (List Maintenance) table.

If **Suppress** is checked while creating the derivation rule, LM tables will have only those values which are present in the corresponding case tables. For example, if derivation rule is created for **Gender** field with **Suppress** checkbox checked and case data has **Gender** values as **Male**, **Female** and value satisfying '**Unknown/<Unspecified>**'derivation rule, **DM_LM_GENDER** table will be populated with **Male**, **Female** and **Unknown/<Unspecified>** values only.



Note: This is applicable only if the condition specified in the SQL text box covers all the cases having the selected LM field

Value This is a textbox which captures the value for the new derivation field.

Note: For the following rules the system expects the user to enter the rule's new value as a comma separated value.

Verify that the values for these rules are entered as mentioned below. Unexpected results and/or ETL error might result if the values are not entered as specified.

a. **Age Group rule**: VALUE,GROUP_LOW,GROUP_HIGH

Parameter	Parameter Description
VALUE	New value for the rule
GROUP_LOW	Lower value of the Group
GROUP_HIGH	Higher value of the Group

Example: NewAgeGroup,25,50

If you do not want to specify the High Value then the comma is mandatory in the end. For example, Unknown,70

b. **Causality**: VALUE,REPORTABILITY

Parameter	Parameter Description
VALUE	New value for the rule
REPORTABILITY	Lower value of the Group

Example: NewCausality,1

c. **Last Daily Dose:** VALUE, DAILY_DOSE_SORTING_ORDER

Parameter	Parameter Description
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 are more than 1 rule for Last Daily Dose field

Examples:

Example:1 > 0to1,1

Example:2 > 2to3,2

Example:3 > 5to8,3

d. **Report Type:** VALUE, INC_LIT, INC_TRIAL,ABRV

Parameter	Parameter Description

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

Priority

This field captures the priority for a list of derivation rules applied to a single LM field. The value should be which is a value from 1 to 255.

SQL In this textbox we specify the SQL statement to capture the cases for which the derivation rule is applicable.

> **Note:** The SQL statement should follow the correct syntax.
>
> The UI does not validate the length of the new values against the database.
>
> Verify that new values getting inserted into the MART do no exceed the limit defined in the database.

The SQL query configured against a rule should only have the primary key *column* name(s) of the field in the SELECT clause. It should also not contain the table name.

Example:

- select case_id from rpt_case where ….. (CORRECT)
- select rpt_case.case_id from rpt_case where …. (INCORRECT)

Verify that there is only one space after the select clause in the SQL query.

Example:

- select case_id, seq_num from rpt_product where ….. (CORRECT)
- select case_id, seq_num from rpt_product where …. (INCORRECT)

Verify that no oracle keyword (such as distinct) is used after the select clause in the SQL query.

Example:

- select case_id, seq_num from rpt_product where ….. (CORRECT)
- select distinct case_id, seq_num from rpt_product where.. (INCORRECT)

Configuring Case Series Modification Justification

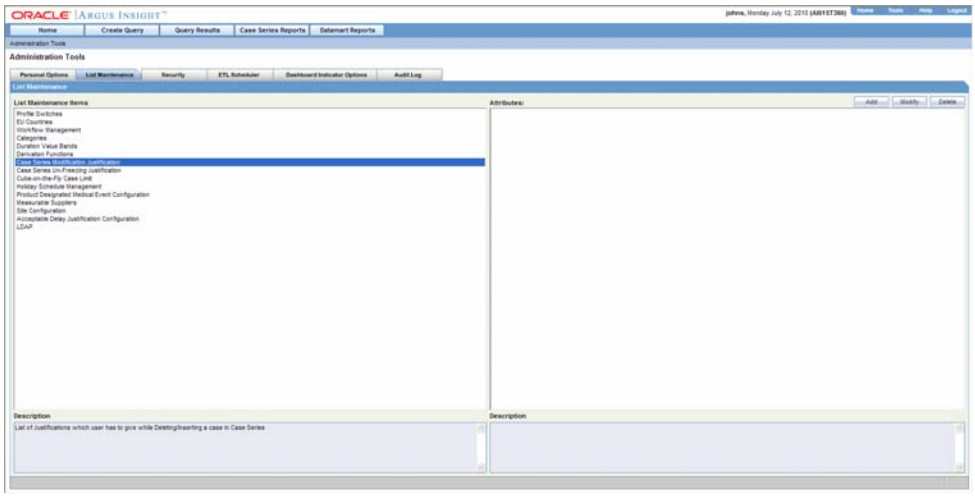
Argus Insight lets you configure justification messages (which can be used by Argus Insight users) to justify any modifications to a case. This topic explains how to configure the text for justifying changes made to a case series, using the Case Series Modification Justification feature.

The **Case Series Modification justification** feature helps you to capture the reason for modifying a Case Series. This message must be captured for maintaining the case series history.

Note: To modify a case, the user must select a relevant justification (text) from the **Justification** drop-down list box.

The **Case Series Modification Justification** item in the **List Maintenance** page lets you configure the messages that appear in the **Justification** list box. Use the following procedure to configure the messages

1. In the **List Maintenance** tab page, select the **Case Series Modification Justification** item from the **List Maintenance Items** list.The **Attributes** list displays the existing configured justification text, if any.



2. Click **Add**. The following dialog box appears.

3. Enter the required justification text in the dialog box.
4. Click **OK**. The text is saved to the system as a justification for modifying a case series.

Configuring Case Series Un-freezing Justification

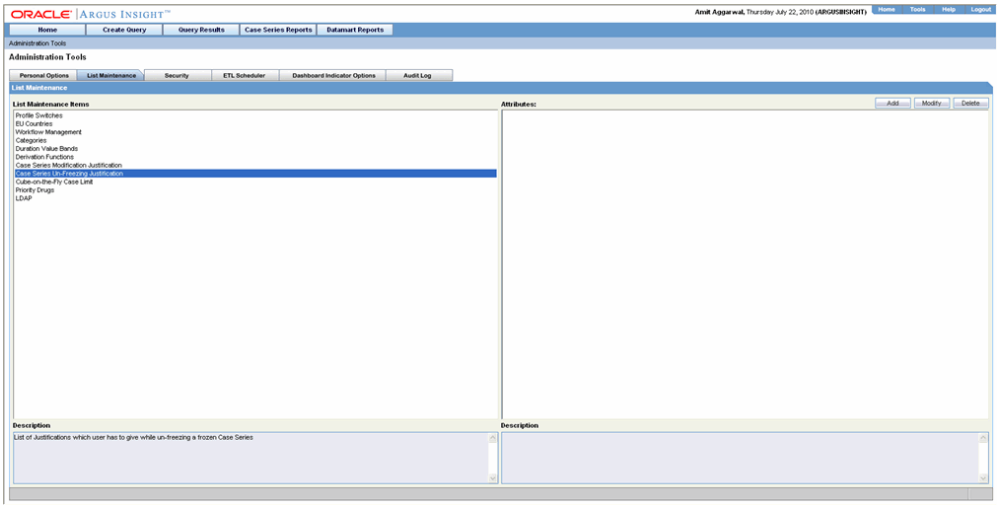
Argus Insight lets you configure un-freezing messages (which can be used by Argus Insight users) to justify any un-freezing to a case. This topic explains how to configure the text for justifying unfreezing a case series, using the Case Series Un-freezing Justification feature.

The **Case Series Un-freezing Justification** feature helps you to capture the reason for unrfeezing a Case Series. This message must be captured for maintaining the case series history.

Note: When unfreezing a case, the **user** must select a relevant justification (text) from the **Justification** drop-down list box.

The **Case Series Un-freezing Justification** item in the **List Maintenance** page lets you configure the messages that appear in the **Un-freezing** list box. Use the following procedure to configure the messages.

1. In the **List Maintenance** tab page, select the **Case Series Un-freezing Justification** item from the **List Maintenance Items** list. The **Attributes** list displays the existing configured justification text, if any.



2. Click **Add**. The following dialog box appears.

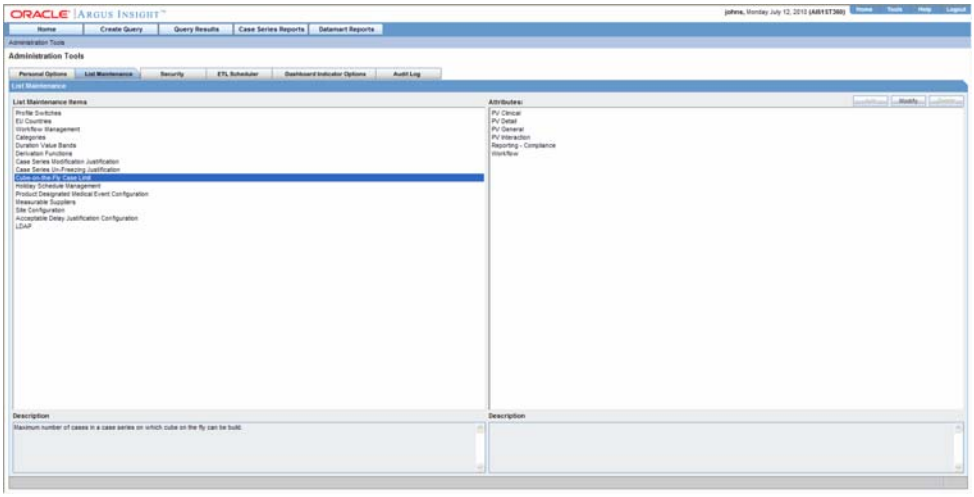
3. Enter the required justification text in the dialog box.
4. Click **OK**. The text is saved to the system as a justification for un-freezing a case series.

Configuring Cube-on-the-Fly Case Limit

Argus Insight lets you configure custom cubes to work with a certain maximum number of cases for cubes on the fly. The **Cubes-on-the-Fly Case Limit** feature helps you to limit the case series to a certain number of cases.

The **Cube-on-the-Fly Case Limit** item in the **List Maintenance** page lets the system administrator configure the attribute values for cubes. Use the following procedure to configure attribute values (to limit the maximum number of cases in a case series on which a demand cube can be built).

1. In the **List Maintenance** tab page, select the **Cube-on-the-Fly Case Limit** item from the **List Maintenance Items** list. The **Attributes** list displays the associated values for the case series.



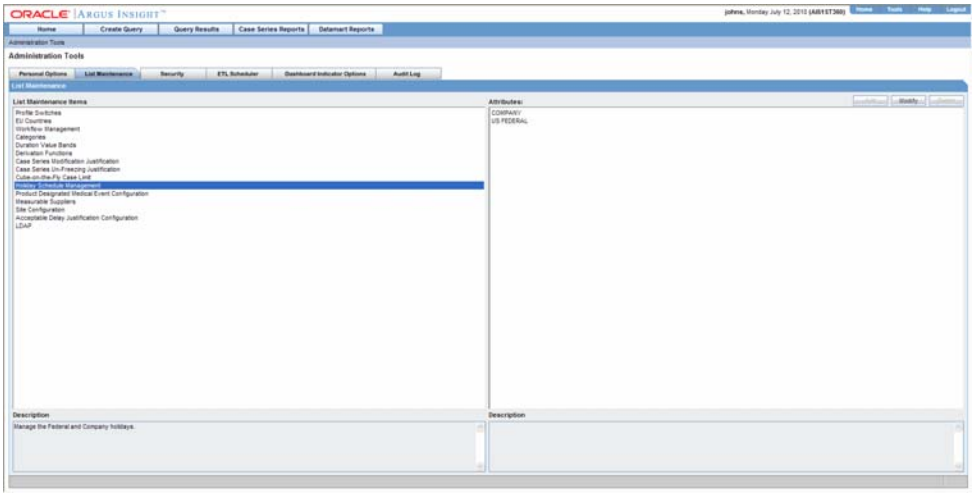
Note: Six (6)different standard cube names are displayed in the attributes list.

2. Click **Modify**.
3. Enter the value for the attribute in the dialog box. This value is the maximum number of cases, within a case series, which can be used to build a demand cube.
4. Click **OK**. The value is saved to the system.

Configuring Holiday Schedule Management

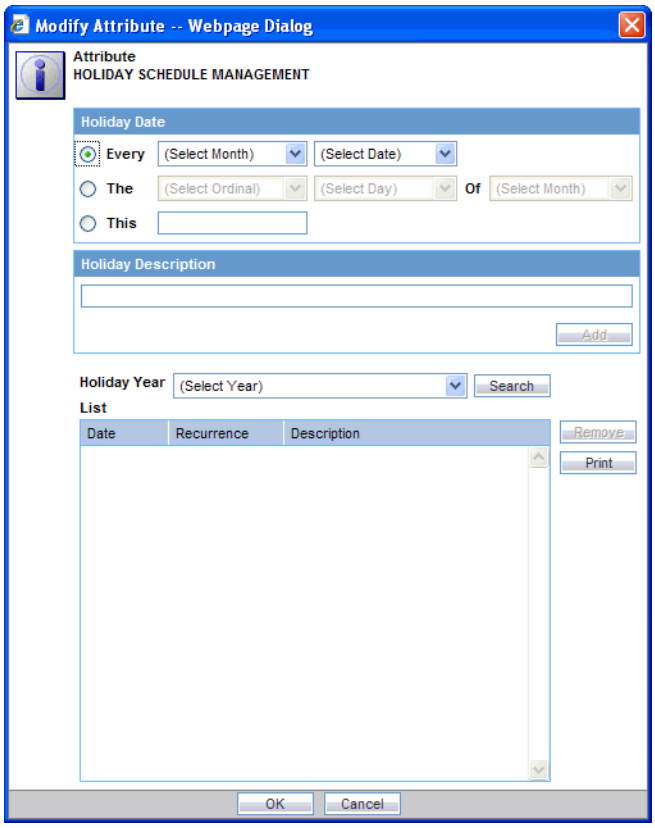
Use the following procedure to configure or manage a Holiday Schedule.

1. Select **Holiday Schedule Management** from the List Maintenance Items list.



2. Select from **Company** or **US Federal** from the **Attributes** list.

3. Click **Modify**.

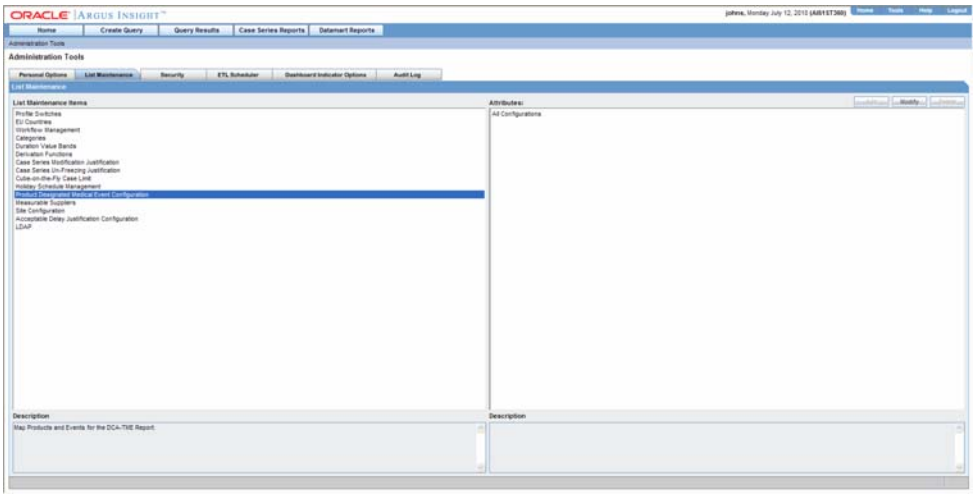


4. Make the required holiday selections and click **OK** to return to List Maintenance.

Configuring PDMECs

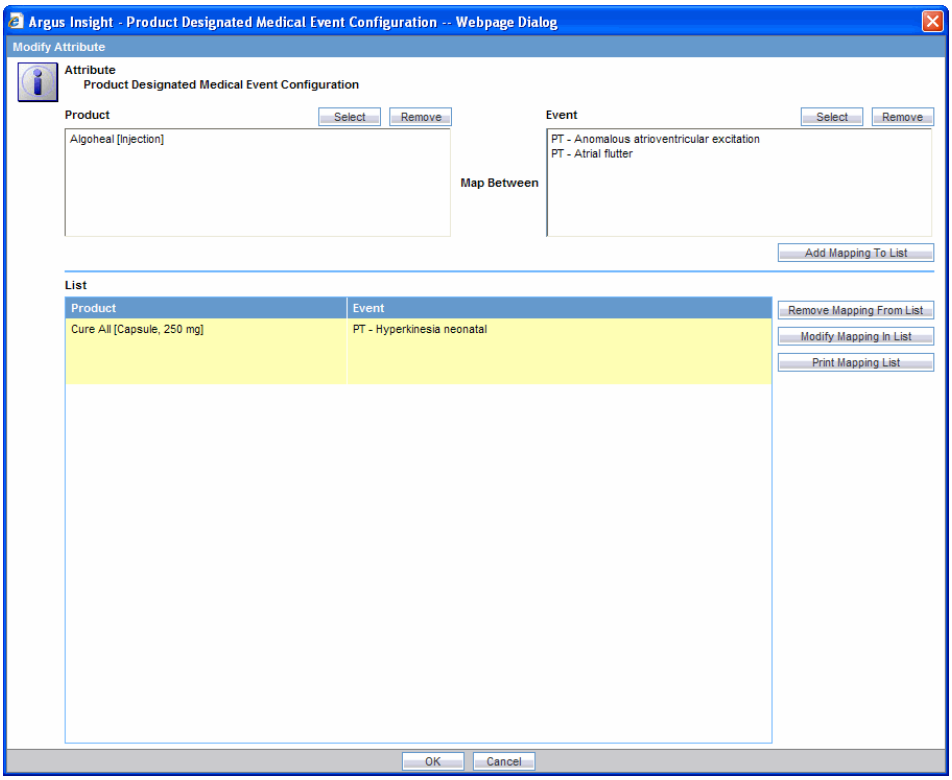
A PDMEC is the abbreviated form for a Product Designated Medical Event Configuration. Use the following procedure to configure or manage a PDMEC:

1. Select Product Designated Medical Event Configuration from the List Maintenance **Items** list.



2. Select **All Configurations** from the **Attributes** list.

3. Click **Modify**.

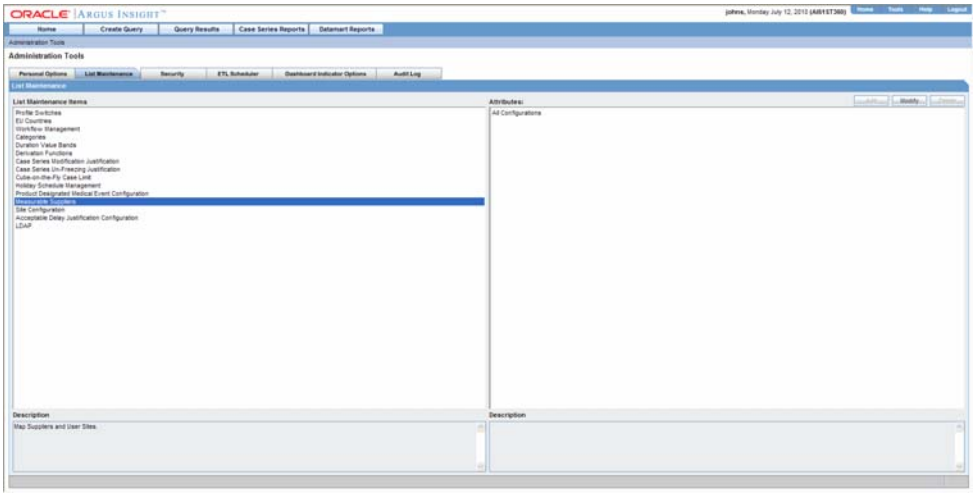


4. Make the required selections and click **OK** to return to **List Maintenance**

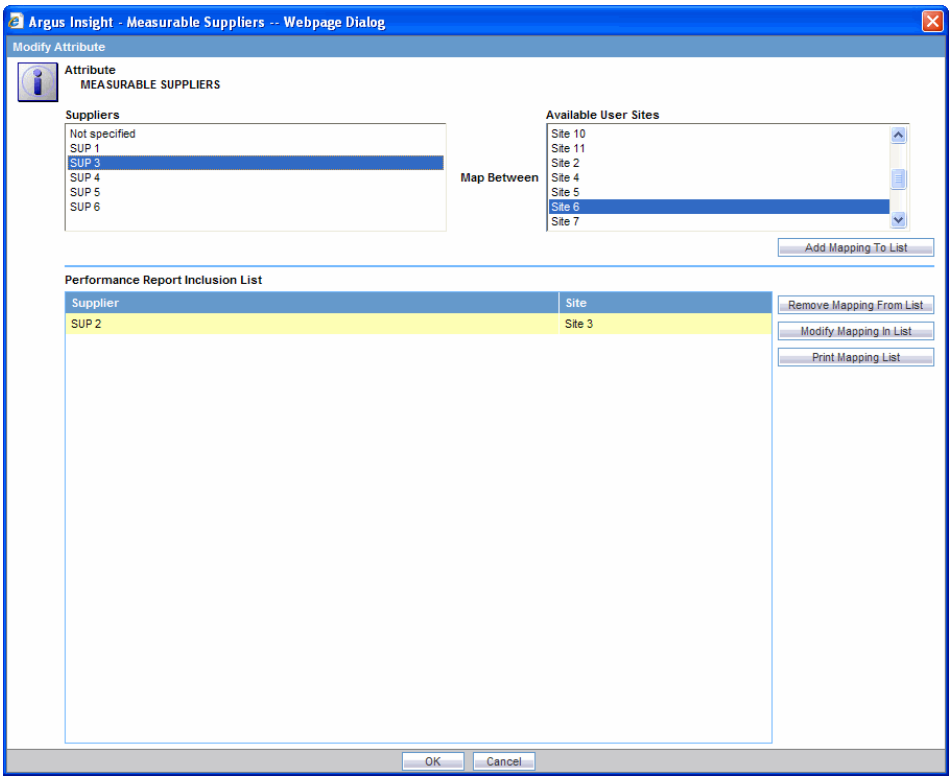
Configuring Measurable Suppliers

Use the following procedure to configure or manage Measurable Suppliers.

1. Select All Configurations under Attributes from List Maintenance Items - Measurable Suppliers.



2. Click **Modify**.

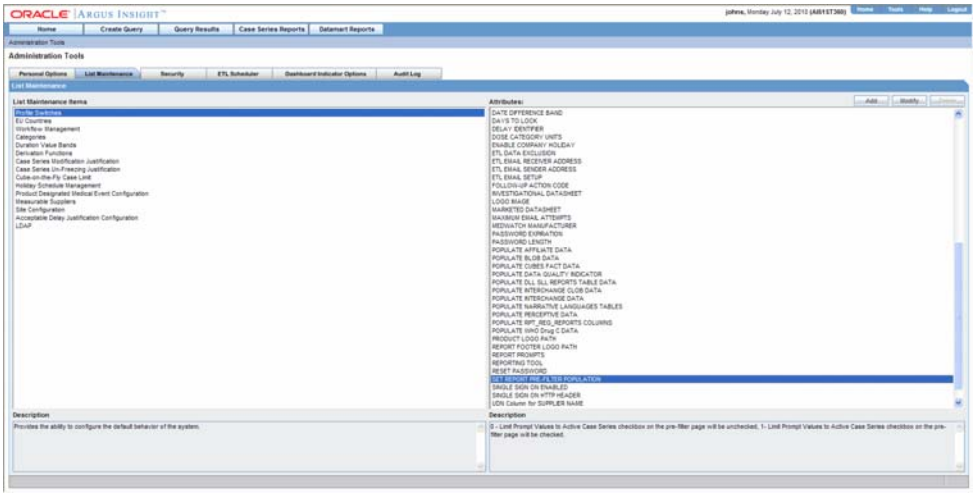


3. Make the required selections and click **OK** to return to **List Maintenance**.
4. Click the **Logout** button in the upper-left corner of the page to exit Argus Insight.

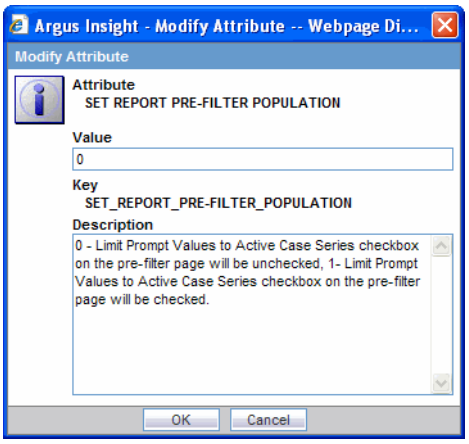
Configuring Report Pre-Filter Population

Use the following procedure to configure or manage Report Pre-Filter Population.

1. Select Set Report Pre-Filter Population under Attributes from List Maintenance Items - Profile Switches.



2. Click **Modify**.



Note: When the profile switch is set to 0, the Limit Prompt Values to Active Case Series checkbox on the pre-filter page is unchecked.

When the profile switch is set to 1, the Limit Prompt Values to Active Case Series checkbox is checked. The default value is 1.

3. Make the required selections and click **OK** to return to **List Maintenance**.
4. Click the **Logout** button in the upper-left corner of the page to exit Argus Insight.

Configuring User Groups and Accounts

The Argus Insight installation program automatically creates the **Administrators** group that contains a user account for the system administrator. The default user name and password for the system administrator is **administrator** and **password**, respectively. More accounts can be added to this group.

To create non-administration user accounts, you first need to create additional groups and configure the access rights. Next, you can create the various user accounts and assign them to one or more groups you created.

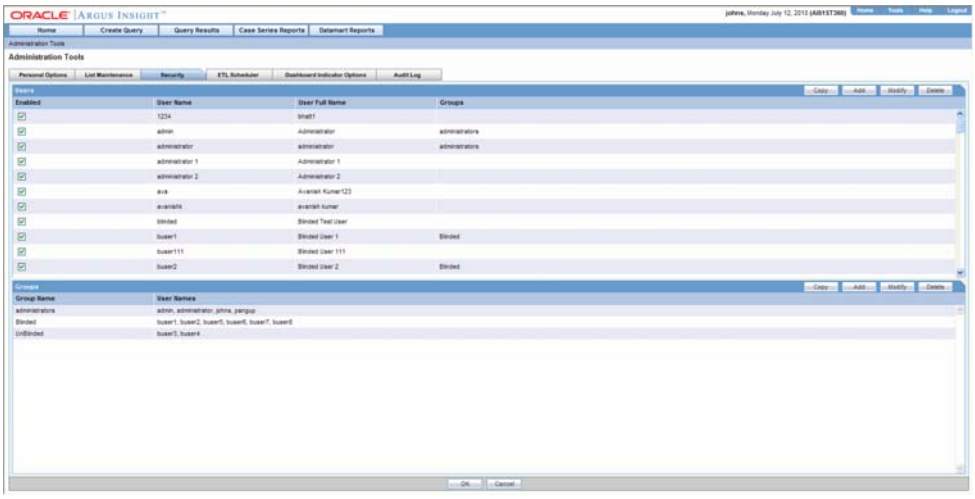
Additionally, all the existing Argus Safety user names and their passwords are replicated in Argus Insight.

The following sections explain how to create and manage user groups and accounts.

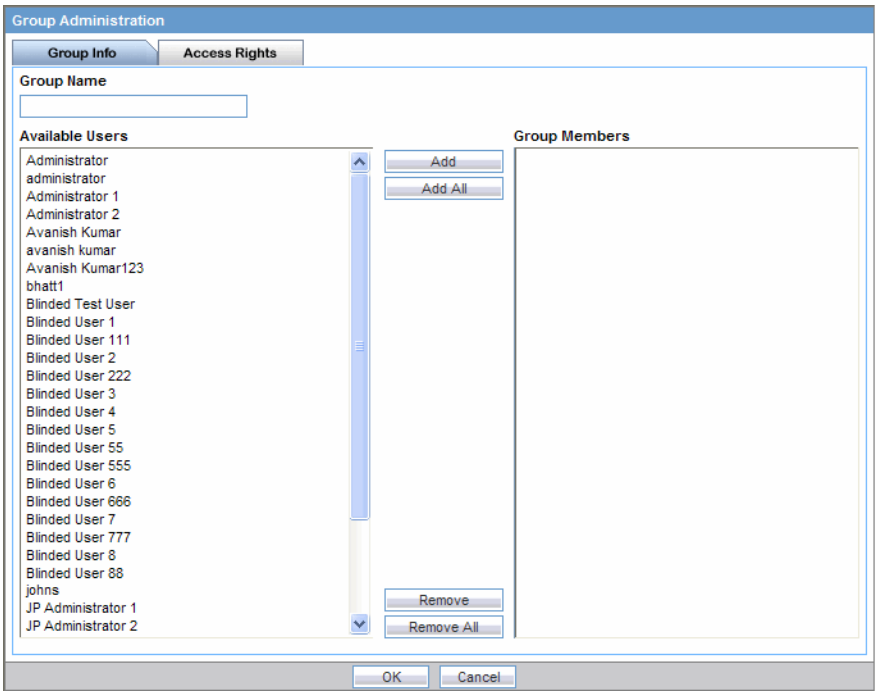
Creating New Groups and Accounts

Use the following procedure to create new groups and accounts.

1. Create groups.
2. Select the **Security** tab in the **Administration Tools** page. The **Security** page appears.



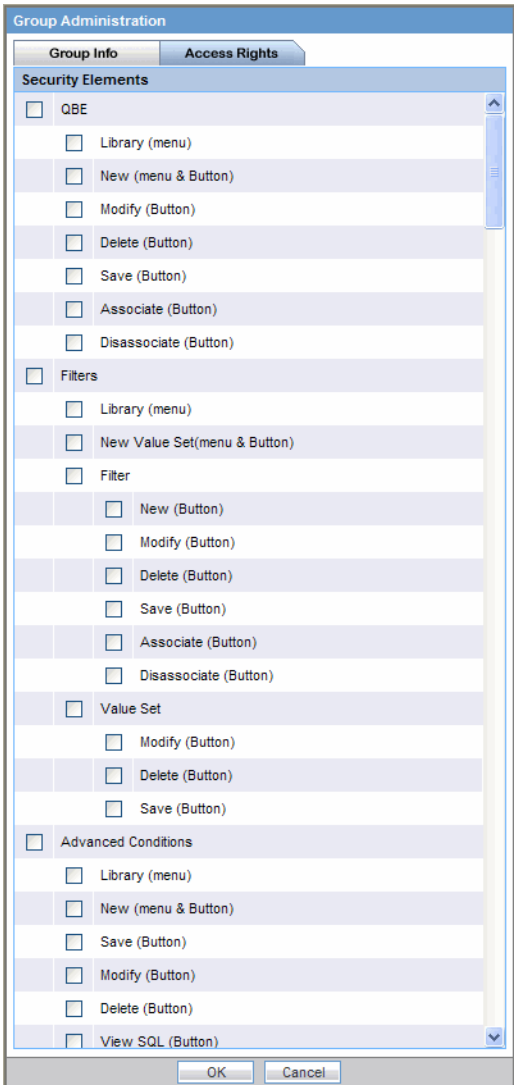
3. Click **Add** in the **Groups** section. The **Group Administration** dialog box opens.



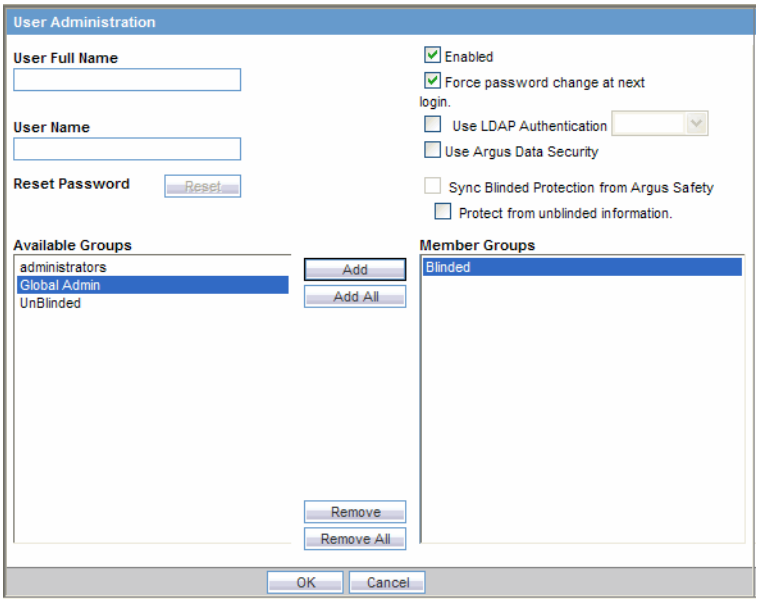
4. Enter a group name in the **Group Name** text box.

> **Note:** When you first log in to Argus Insight, the **Available Users** list in the **Group Administration** dialog box only displays the **administrator** user name. After you have created additional user accounts, the **Available Users** list will show all the existing user names.
>
> While creating a new group, you can directly add existing user names to the group by selecting a user name from the **Available Users** list and clicking **Add** in the **Group Administration** dialog box.

5. Select the **Access Rights** tab in the **Group Administration** dialog box. The **Access Rights** tab opens.



6. Check the items in the **Security Elements** list to enable access to those elements, as appropriate.
7. Click **OK**. The list in the **Groups** section displays the group you created.
8. Click **Add** in the **Users** section. The **User Administration** dialog box opens.



9. Enter the user name and user ID in the **User Full Name** and **User Name** text boxes, respectively.

> **Note:** Argus Insight assigns the default password as password for the new users you create.
>
> The checked **Force Password Change at next login** checkbox indicates that the user would need to change the password at the first login. If you require the new password to be alphanumeric, set the **ALPHANUMERIC PASSWORD** profile switch to 1.
>
> The checked **Enabled** checkbox indicates that the user account is enabled. If you clear this checkbox, the user will not be able to log in to Argus Insight.

10. Check the **Use Argus Data Security** checkbox if you want to implement the Argus' product, site, and *study* security policies for the user account.
11. By default, the **Sync Blinded Protection from Argus Safety** checkbox is checked. For users who exist in Argus Insight only (no access to Argus Safety), this checkbox is unchecked and disabled. If this checkbox is checked, it means that Single Sign On is used to sync blinded protection from Argus Safety for that user.
12. By default, the **Protect from unblinded information** checkbox is disabled. If the **Sync Blinded Protection from Argus Safety** checkbox is unchecked, the **Protect from unblinded information** checkbox is enabled. Also, for users who exist in Argus Insight only (no access to Argus Safety), the **Protect from unblinded information** checkbox is again enabled and unchecked.

> **Note:** For Argus versions other than Argus Safety 6.0, the status of "Protect from unblinded information" checkbox of an Argus user can be updated only by running the next incremental ETL in real time through Single Sign On in Argus Insight.

13. From the **Available Groups** list, select a group with which you want to associate the user account.
14. Click **Add**. The selected group name appears in the **Member Groups** list indicating that the account has been associated.
15. Repeat steps 4 and 5 to associate the user account with other existing groups.
16. Click **OK**. The list in the **Users** section displays the details of the user account you created.

Copying Groups and Accounts

Once you have created a user group or account, 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.

Use the following procedure to create a new group or account by copying information from an existing group or account.

1. In the **Security** page, select a user name or a group name you wish to copy.
2. Click **Copy** in the **Users** or **Groups** section, as appropriate. The **User Administration** or **Group Administration** dialog box appears.
3. Enter a group name in the **Group Name** text box or the user name and user ID in the **User Name** and **User ID** text boxes, as appropriate.
4. Click **OK**. Settings from the copied group/account are carried over to the new group/account.

Modifying Existing Groups and Accounts

Use the following procedure to modify a group or user account details.

1. In the **Security** page, select a user name or a group name you wish to modify.
2. Click **Modify** in the **Users** or **Groups** section, as appropriate. The **User Administration** or **Group Administration** dialog box appears.
3. Modify the settings, as appropriate.
4. To reset the existing password of the user to the default password (**password**), click the **Reset** button.
5. Click **OK** to save the modifications to the selected group or account. The modifications are saved.

Deleting Existing Groups and Accounts

Use the following procedure to delete a group or account.

1. In the Security page, select a user name or a group name you wish to delete.
2. Click Delete in the User or Group section, as appropriate. A delete confirmation dialog box appears.

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

3. Click **OK** to delete the selected account or group.The selected account or group is deleted.

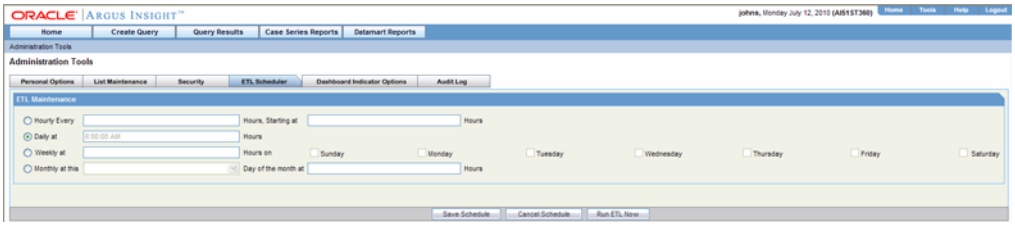
Scheduling the ETL

ETL stands for extract, transform and load processes that enable you to move data from your drug safety database, reformat it, and load it into another database (datamart) for querying, drill-down analysis, and *report* generation.

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

> **Note:** Incremental ETL should not be run for more than 30,000 cases. If the number of cases exceeds 30000, run the Initial ETL again. The **Argus Insight Installation Guide** explains how to run the initial ETL.

The **ETL Scheduler** tab page lets you schedule the incremental ETL process to run automatically and update the datamart.

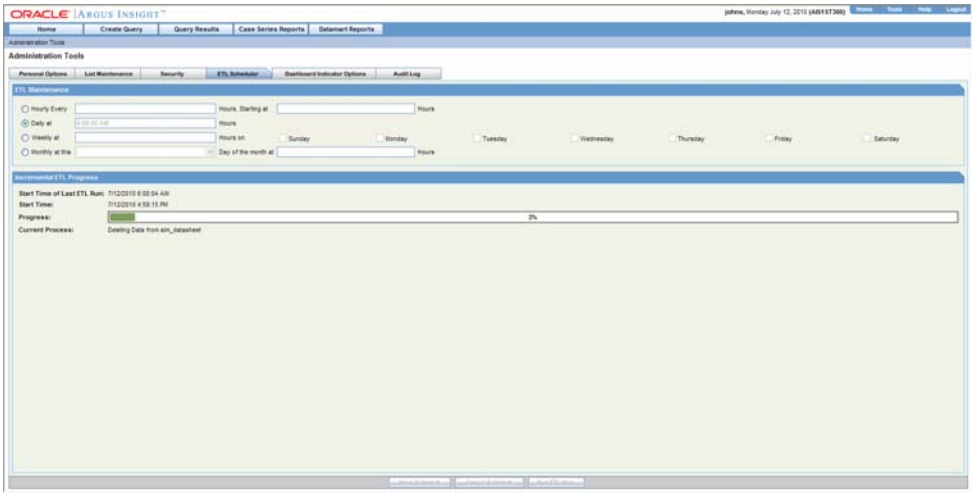


Use the following procedure to schedule the ETL.

1. In the **ETL Scheduler** tab page, check the checkboxes corresponding to the days of week when you wish to run the ETL.
2. In the **Select Start Time** text box, enter the time (HH:MM:SS) when you want to start the ETL on the days you selected. The time should be entered in the 24-hour format.
3. Click **Save** to save your settings.

You can also run the ETL immediately by clicking **Run ETL Now**. Running the ETL immediately does not affect the scheduled ETL.

During the execution of the ETL, a Progress Meter displays the progress of the ETL on your screen.



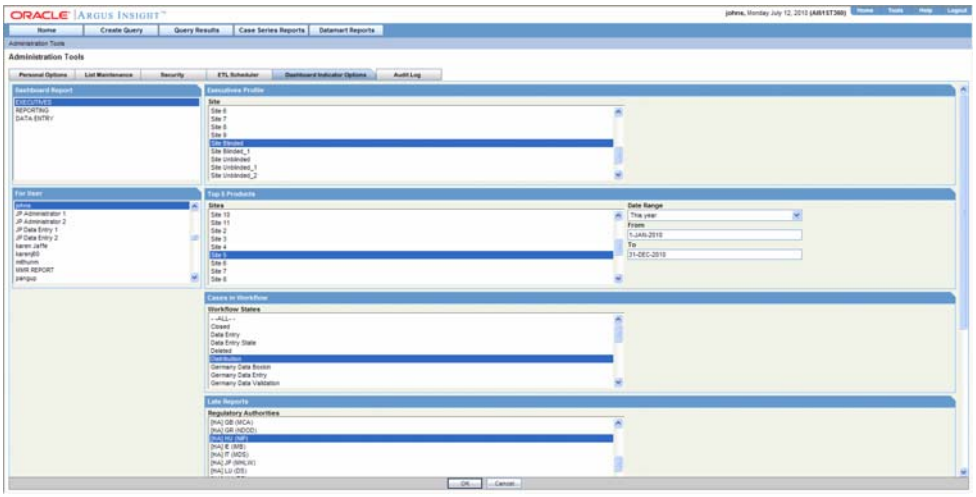
If an error occurs during the ETL execution, ETL is stopped and the error message is displayed on your screen.

After the ETL execution is over, the system generates ETL reports. The ETL report details follow these guidelines:

- ETL initial execution can be reviewed in the balancing log. These files can be viewed in the database installation folder.
- ETL incremental execution log is generated for:
- Argus to Staging
- Staging to Mart (with the List maintenance tables and configuration tables, also case by case log is generated).
- The last incremental execution can be reviewed in Case Series Reports > Standard Reports > Configuration
- ETL log Argus to Staging
- ETL log staging to mart
- Earlier history of all ETL executions can be reviewed in the ETL log summary report

Configuring Dashboard Indicators

Argus Insight has three Dashboard Indicator reports: **Executives**, **Reporting**, and **Data Entry**. Based on a user's profile, you can assign a specific Dashboard Indicator *report* to a user by using the options in the **Dashboard Indicator Options** page. Only one report can be assigned to a user.



Each Dashboard Indicator report consists of a number of sub-reports. In turn, each sub-report has a set of *filter* elements associated to it. You need to set the filter elements for only those sub-reports that you wish to display in the Dashboard Indicator report output.

The selection of a particular Dashboard Indicator report and the sub-reports that appear in it is based on the profile and the reporting requirement of the user who would view these reports.

The following table lists the sub-reports for each Dashboard Indicator report and the filter elements associated with each sub-report.

Dashboard Indicator Report	Sub-Report		Filter Element	
	Name	Description	Name	Description
Executives	Executives Profile	This report provides a tabulation of case count for each site. The total count of serious cases for all sites is also listed.	Site	List of all sites as configured in Argus You can select specific sites or select **All**
	Top 5 Products	This report is a listing of the top 5 products having the largest total case count sorted in descending order. The serious case count for each product is also listed.	Sites	List of all sites as configured in Argus You can select specific sites or select **All**
			Date Range	List of pre-configured date ranges Select a date range from this list
			From	Date *field* for specifying the start date for a custom date range
			To	Date field for specifying the end date for a custom date range
	Cases in Workflow	This report is a graphical summary of the initial, follow up, and total case count in each workflow state.	Workflow States	List of all Argus workflow states You can select specific states or select **All**
	Late Reports	This report is a detailed listing of all cases for which reports are past the due date. Days past the due date are provided for each destination.	Regulatory Authorities	List of all regulatory authorities as configured in Argus You can select specific entities or select **All**

Dashboard Indicator Report	Sub-Report		Filter Element	
	Name	**Description**	**Name**	**Description**
	Reporting Compliance	This report provides a graphical overview of reporting compliance count broken down by days remaining to due date and days past due date.	Date Range	List of pre-configured date ranges Select a date range from this list
			From	Date field for specifying the start date for a custom date range
			To	Date field for specifying the end date for a custom date range
			Regulatory Authorities	List of all regulatory authorities as configured in Argus You can select specific entities or select **All**
	Receipt Latency	This report provides a graphical overview of receipt latency (from initial receipt date to central received date) by country of origin.	Sites	List of all sites as configured in Argus You can select specific sites or select **All**
			Date Range	List of pre-configured date ranges Select a date range from this list
			From	Date field for specifying the start date for a custom date range
			To	Date field for specifying the end date for a custom date range
Reporting	Reporting Profile	This report is a summary of scheduled report and past due report count for all the reporting groups.	Groups	List of all reporting groups as configured in Argus You can select specific groups or select **All**

Dashboard Indicator Report	Sub-Report		Filter Element	
	Name	**Description**	**Name**	**Description**
	Reporting Compliance (Count)	This report provides a graphical overview of reporting compliance count for each reporting destination. The counts are broken down by days remaining to due date and days past due date.	Regulatory Authorities	List of all regulatory authorities as configured in Argus You can select specific entities or select **All**
			Date Range	List of pre-configured date ranges Select a date range from this list
			From	Date field for specifying the start date for a custom date range
			To	Date field for specifying the end date for a custom date range
	Reporting Compliance (Percentage)	This report provides a graphical overview of reporting compliance percentage broken down by days remaining to due date and days past due date.	Regulatory Authorities	List of all regulatory authorities as configured in Argus You can select specific entities or select **All**
			Date Range	List of pre-configured date ranges Select a date range from this list of values
			From	Date field for specifying the start date for a custom date range
			To	Date field for specifying the end date for a custom date range

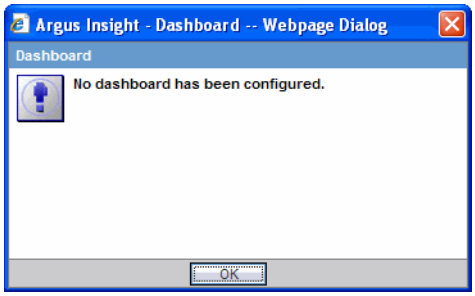
Dashboard Indicator Report	Sub-Report		Filter Element	
	Name	**Description**	**Name**	**Description**
	Outstanding Submissions by Responsible Group (Summary)	For the selected reporting groups, this sub-report shows the outstanding report count by reporting destinations. Against each destination, the outstanding report count is further broken up in these groups: Due in greater then seven days Due in 3-7 Days Due in 0-2 days Past the due date	Regulatory Authorities	List of all regulatory authorities as configured in Argus You can select specific entities or select **All**
			Date Range	List of pre-configured date ranges Select a date range from this list of values
			From	Date field for specifying the start date for a custom date range
			To	Date field for specifying the end date for a custom date range
	Outstanding Submissions by Responsible Group (Listing)	This report provides a detailed listing of cases for which report submissions are coming up. The listing is grouped by the responsible group. Within each group, the listing is sorted in ascending order of days remaining for submission.	Regulatory Authorities	List of all regulatory authorities as configured in Argus You can select specific entities or select **All**

Dashboard Indicator Report	Sub-Report		Filter Element	
	Name	**Description**	**Name**	**Description**
Data Entry	Data Entry Profile	This report provides a tabulation of case count for each site. The total count of serious cases for all sites is also listed.	Site	List of all sites as configured in Argus You can select specific sites or select **All**
	Receipt Latency	This report provides a graphical overview of receipt latency (from initial receipt date to central received date) by country of origin.	Sites	List of all sites as configured in Argus You can select specific sites or select **All**
			Date Range	List of pre-configured date ranges
				Select a date range from this list of values
			From	Date field for specifying the start date for a custom date range
			To	Date field for specifying the end date for a custom date range
	Cases in Workflow	This report is a graphical summary of the initial, follow up, and total case count in each workflow state.	Workflow States	List of all Argus workflow states You can select specific states or select **All**
	Case Load	This report provides a tabulation of cases received, cases in processing, and pending case counts for each workflow state.	Workflow States	List of all Argus workflow states You can select specific states or select **All**
	Case Workload by Site and Country	This report provides a tabulation of serious, non-serious, and total case counts grouped by site. For each site, the counts are displayed for each country.	Sites	List of all sites as configured in Argus You can select specific sites or select **All**

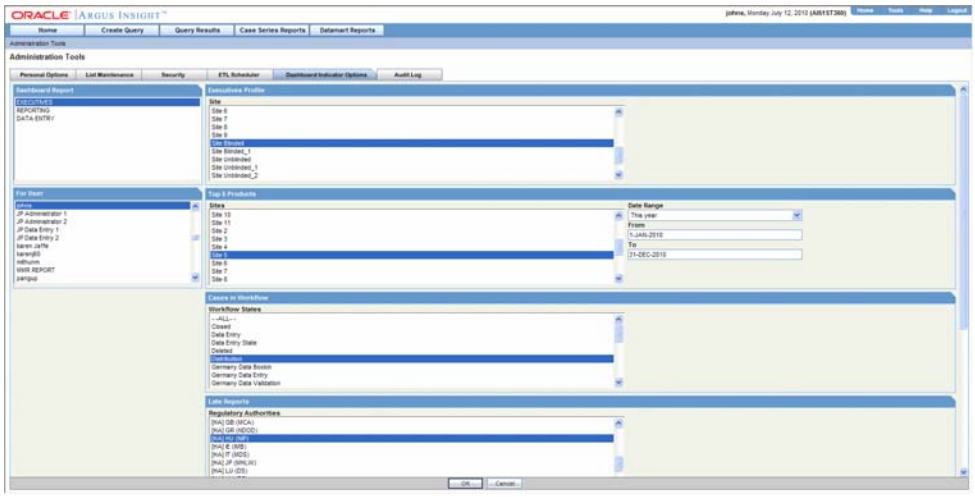
Note: The date range in reports is based on the ETL execution date. For example, if you select **Yesterday** for the **Date Range** filter element, the date populated for "Yesterday" will be the day before the ETL was last run.

Use the following procedure to configure a Dashboard Indicator report for a user.

1. In the **Dashboard Indicator Options** page, use the list box in the **For User** section to select the user for who you wish to configure the Dashboard Indicator Report. If no report is configured for this user, the following dialog box appears. Click **OK** in this dialog box and proceed.



2. Depending on the profile and reporting requirement for the selected user, select a type of Dashboard Indicator Report from the list in the **Dashboard Report** section.Depending on the type of Dashboard Indicator report you selected, the **Dashboard Indicator Options** page displays the filter elements for the associated sub-reports.



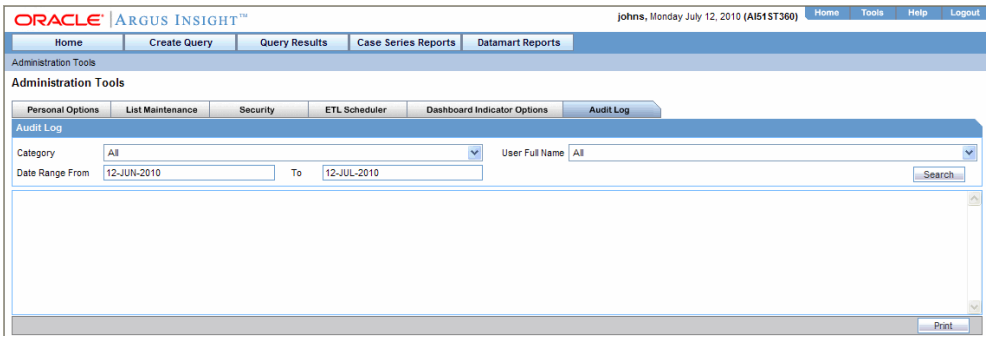
3. Set the filter elements for the sub-reports you wish to display in the Dashboard Indicator report. See the table above for descriptions of sub-reports and filter elements.
4. Click **OK** to save the settings.

Viewing the Audit Log

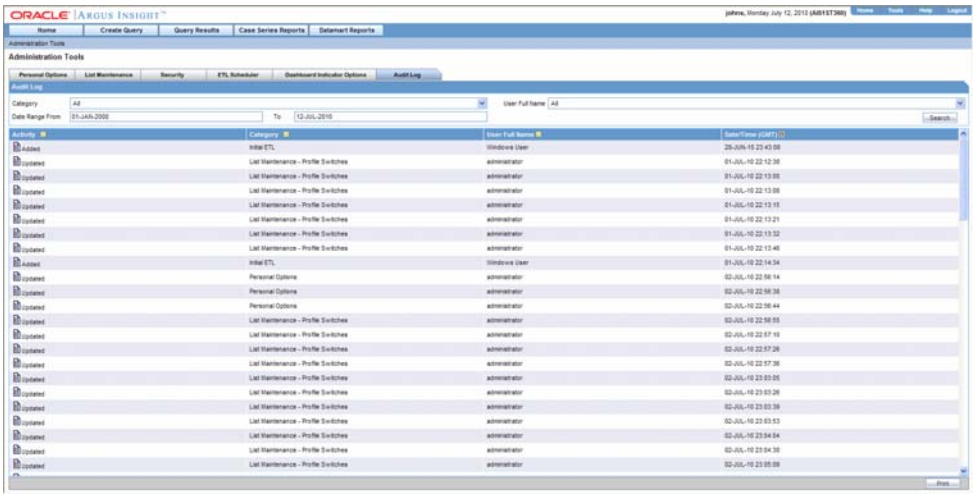
From the **Audit Log** page, you can view the configuration activities performed by an Argus Insight user during a particular period.

Use the following procedure to view the Audit Log.

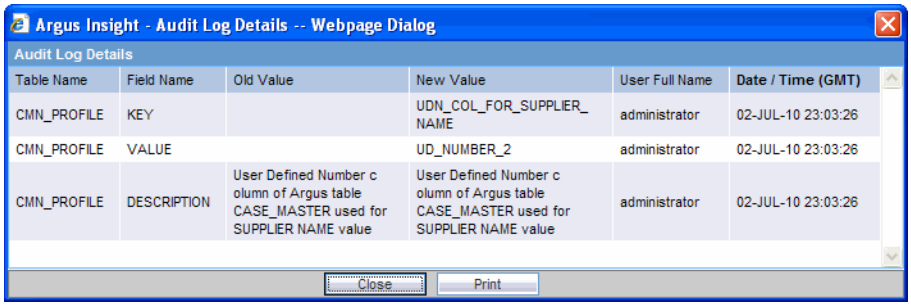
1. In the **Administration Tools** page, click the **Audit Log** tab.The **Audit Log** page appears.



2. Select the activity category from the **Category** list box.
3. Select the user name from the **User** list box.
4. Enter a date range in the **Date Range From** and **To** text boxes.
5. Click **Search**. The **Audit Log** page displays the list of activities according to the criteria you specified. You can print the list of activities by clicking **Print** at the bottom of the page.



6. Click the **Audit Log Details** icon for an activity. A dialog box displays the activity details.You can print the activity details by clicking **Print** in the dialog box.



Note: The Argus Insight application logs all failure activities such as execution of Reports, Cubes, QBE, Filters, Advanced Conditions and Scheduler etc. at the following location **<Power Reports Folder>\Power Reports\Bin\Log.**

Glossary

Glossary Term Element Structure is GlossEntry Followed by GlossTerm

The definition follows in a GlossDef element and a child Para or other appropriate element. The GlossDef element can contain informal examples, lists, and so on.

A LINE_OF_SYNTAX

```
Or you might have a line of code as part of your definition.
```

#

.CSV

In computers, a CSV (comma-separated values) 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.

A

Adverse Experience

Any adverse event (AE) associated with the use of a drug or biological product in humans, whether or not considered product-related, including the following: 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; and 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), 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.

C

Causality Assessment

Determination of whether there is a reasonable possibility that the product is etiologically related to the adverse experience. Causality assessment includes (for example) 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.

Command

A way to start database administration functions to access and maintain the database manager. A statement used to initiate an action or start a service. A command consists of the command name abbreviation, and its parameters and flags if applicable.

D

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 Mart ETL

In Data Warehouse, the extract, transform, and load (ETL) process that extracts a subset of data from the central data warehouse, transforms it, and loads it into one or more star schemas. These schemas then can be included in data marts to answer specific business questions.

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.

E

Electronic Document

A document that is stored on the computer, instead of printed on paper.

Encode

Use the following procedure to convert data by the use of a code in such a manner that reconversion to the original form is possible.

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.

F

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.

H

Home Page

The top-level web page of a portal. Sometimes used as a synonym for default portal page.

I

Initial Reporter

The original source of information concerning an adverse experience (e.g., consumer, healthcare professional).

L

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.

N

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.

P

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

Q

Query

A request for information from the database based on specific conditions.

R

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, the 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 that a user can perform and the resources to which a user has access. A user can be assigned one or more roles. A definition of the access levels that users have and the specific resources that they can modify at those levels. Users are limited in how they can access information if they do not have the proper role. Multiple roles are permissible.

S

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 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 (e.g. health care professional, consumer) 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 (e.g., adverse experience information derived from a clinical trial, 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 as 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.

T

Type Ahead

The functionality that offers you to type-in a value and the like values are displayed in the listbox. It also enables you to select the desired value from the list of values.

U

Unexpected Adverse Experience

Adverse experience not included in any section of the current FDA-approved labeling for the drug or licensed biological product. This includes an adverse experience that may differ from a labeled adverse experience because of greater severity or specificity (e.g., abnormal liver function versus hepatic necrosis). 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 (e.g., rash with antibiotic X would be unexpected if the labeling said "rash may be associated with antibiotics"). This is 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.

W

Web-based application

An application that is downloaded from the Web each time it is run. The advantage is that 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.

Web Site

A related collection of files available on the Web that is managed by a single entity (an organization or an individual) and contains information in hypertext for its users. A Web site often includes hypertext links to other Web sites.

World Wide Web (WWW Web)

A network of servers that contain programs and files. Many of the files contain hypertext links to other documents available through the network