Oracle® Argus Insight

User's Guide

Release 7.0

E22886-01

April 2011

ORACLE®

Oracle Argus Insight User's Guide, Release 7.0

E22886-01

Contents

4 Creating Queries

5 Working with Case Series

6 Generating Standard Reports

7 Creating Custom Reports

8 Using Cubes

9 Multi Tenancy

Glossary

Preface

Audience

This document is intended for all Argus Insight administrators.

Documentation Accessibility

Our goal is to make Oracle products, services, and supporting documentation accessible to all users, including users that are disabled. To that end, our documentation includes features that make information available to users of assistive technology. This documentation is available in HTML format, and contains markup to facilitate access by the disabled community. Accessibility standards will continue to evolve over time, and Oracle is actively engaged with other market-leading technology vendors to address technical obstacles so that our documentation can be accessible to all of our customers. For more information, visit the Oracle Accessibility Program Web site at http://www.oracle.com/accessibility/.

Accessibility of Code Examples in Documentation

Screen readers may not always correctly read the code examples in this document. The conventions for writing code require that closing braces should appear on an otherwise empty line; however, some screen readers may not always read a line of text that consists solely of a bracket or brace.

Accessibility of Links to External Web Sites in Documentation

This documentation may contain links to Web sites of other companies or organizations that Oracle does not own or control. Oracle neither evaluates nor makes any representations regarding the accessibility of these Web sites.

TTY Access to Oracle Support Services

To reach AT&T Customer Assistants, dial 711 or 1.800.855.2880. An AT&T Customer Assistant will relay information between the customer and Oracle Support Services at 1.800.223.1711. Complete instructions for using the AT&T relay services are available at http://www.consumer.att.com/relay/tty/standard2.html. After the AT&T Customer Assistant contacts Oracle Support Services, an Oracle Support Services engineer will handle technical issues and provide customer support according to the Oracle service request process.

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.

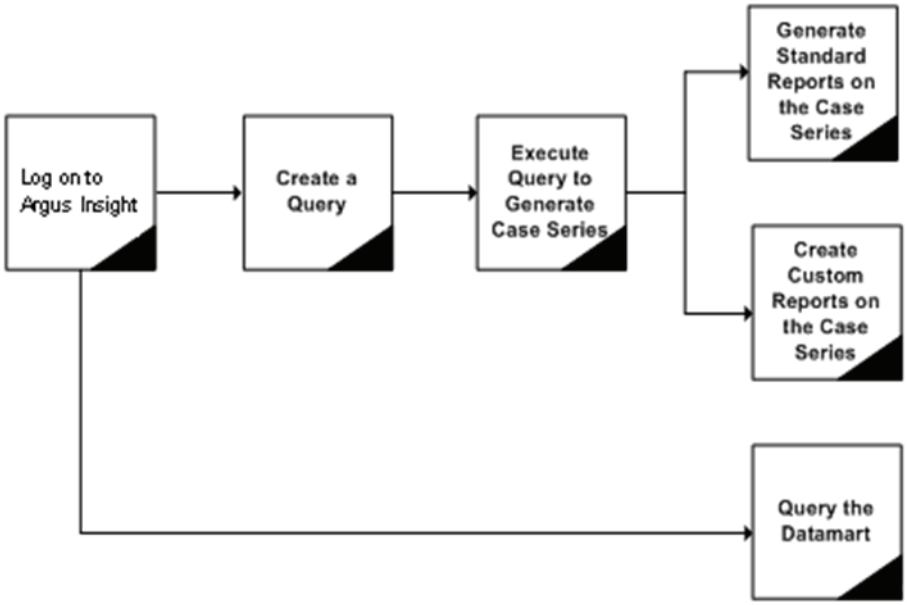
Note: The Report Writer is primarily used to directly query the datamart and create custom reports. However, you can apply the active Case Series*filter* on the reports to reduce the data set and improve report performance. Please note, that the Case Series might become obsolete each time the datamart 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

2

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 version of Insight from Argus Insight version 5.1. After completing the upgrade, you must execute an initial ETL.

Argus Insight 5.1 single-tenant users can upgrade to Argus Safety 7.0 multi-tenant environment.

The Argus Insight 5.1 single-tenant users can upgrade to Argus Safety 7.0 single-tenant users by using the Migration Utility. This utility overwrites any configuration data existing for an enterprise. It is necessary for all such upgrade that Argus Safety be upgraded to 7.0.

The upgrade path is to be as follows -

i. Upgrade Argus Safety application to Argus Safety 7.0 (this step is required only for multi tenant environment).

ii. Install Argus Insight 7.0 application (in multi tenant mode if Argus Safety is installed in multi tenant mode).

iii. Create the enterprise in Argus Insight

iv. Run the Migration Utility for that enterprise.

v. Run the Initial ETL.

The Migration Utility supports copying the entire Argus Insight specific configuration (including Case Series Freezing data) from a single tenant Argus Insight 5.1 application to Argus Insight 7.0 single/multi tenant application after setting an Enterprise ID.

It is possible to set an appropriate Enterprise ID during the configuration copy.

User-specific configuration data is copied only for those users in an enterprise who also exists in Argus Safety for that enterprise.

Existing customers should configure the User Roles section.

Global Profile switches cannot be updated by the migration utility.

Product Compatibility

This version of Insight is compatible with the following products:

- Argus Safety 7.0
- Argus Safety 6.0*
- Argus Safety 5.1*

Note: The versions listed with the asterisk (*) denote that they are available for only single-tenant installations. Therefore, multi-tenant features such as Global Enterprise Management and Global User Management are available only from Argus Safety 7.0 onwards.

Note: For Argus Safety 5.1 and 6.0, Argus Insight users will sync up with Argus Safety users after the Incremental ETL is completed.

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

Copy Configuration

The Copy Configuration utility copies the entire Argus Insight-specific configuration from a single-tenant Argus Insight 5.1 application to a multi-tenant Argus Insight 7.0 application, after setting an Enterprise ID. The Enterprise ID can be created during the Copy Configuration phase.

The utility copies all the enterprise data from one Multi-tenant enterprise to another multi-tenant enterprise in Argus Insight, including the ones which are marked as 'Inactive'.

Migrating Custom Reports to Argus Insight 7.0 is a manual step.

You can Import configuration information from the following Insight versions and export it to Argus Insight 7.0 through the Copy Configuration utility:

- Argus Safety 5.1 and 6.0 users in single-tenant environment can be upgraded to either the Argus Insight 7.0 Multi-tenant environment or to the Argus Insight 7.0 Single-tenant environment.

  For such upgrades, a pre-requisite is to first ensure that the Argus Safety application is upgraded to version 7.0.

- A password-encryption utility is also available for user migration from Argus Insight 5.1 to Argus Insight 7.0.

Upgrading to the Argus Insight 7.0 Multi-tenant Environment

Execute the following steps to upgrade to Argus Insight 7.0:

- Upgrade your current Argus Safety application to the Argus Safety 7.0 Multi-tenant environment.
- Install the Argus Insight 7.0 application in Multi-tenant mode.
- Create the enterprise in Argus Insight.

- Run the Copy Configuration utility for that enterprise.
- Run the Initial ETL.

Exporting the Configuration Data to Argus Insight 7.0

You can import all the Configuration Data from the following Argus Insight versions and export them to Argus Insight 7.0:

- Single tenant to single tenant.
- Multi-tenant to multi-tenant - All the enterprises data is copied including the enterprises which are marked "Inactive".
- Source enterprises are mapped to target enterprises based on enterprise short name.
- User-specific configuration data is copied only for those users in an enterprise who exist in Argus Safety as well for that enterprise.
- Configuration of those Enterprises which does not exist in Target system is not brought-in.
- Configuration of additional enterprise that exists in Target system is not overwritten.

3

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

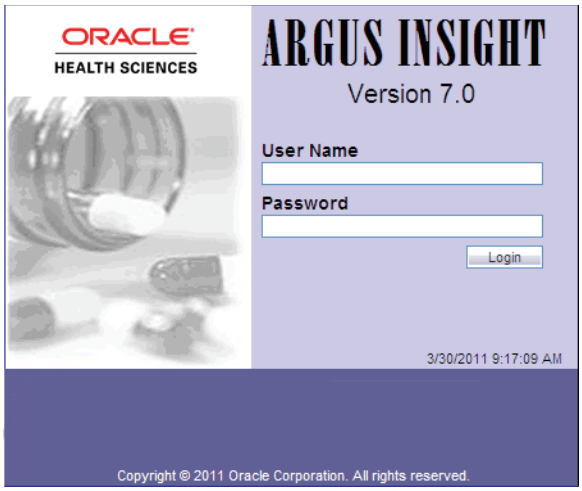
The following tasks help you get started with Argus Insight.

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. With Single Sign On (SSO), users' log-in authentication is done using a centralized authentication system. With this, users do not need to enter their log-in credentials for each application they access, every single time. Cognos uses the Power Reports namespace.
- The 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 Safety and Argus 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 (Argus 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.

Logging In

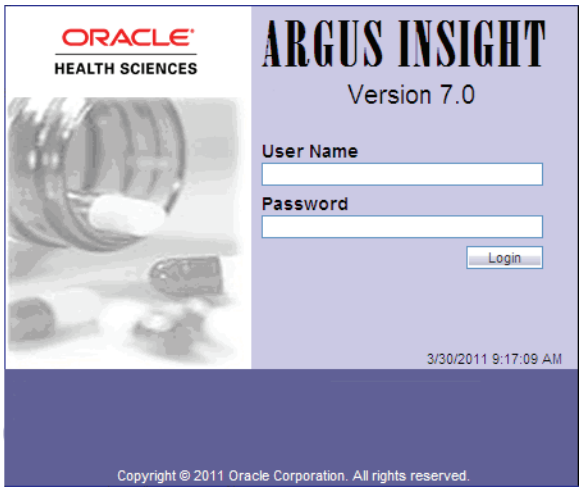
The Argus Insight installation program automatically creates an account for the system administrator and assigns the default user name and password as **administrator** and **password**, respectively. The administrator account cannot be deleted. This ensures that the system administrator can always log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

Users can access Argus Insight directly by using the Argus Insight application URL. Argus Insight checks if Enterprise ID is already present in the request coming to it. If the Enterprise ID exists, it opens Argus Insight for that enterprise.

To log on to Argus Insight as an administrator:

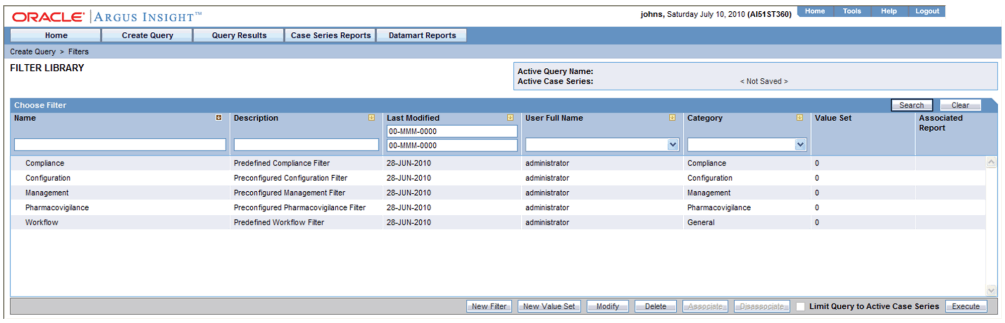
1. Start Internet Explorer.
2. Type the Argus Insight Universal Resource Locator (URL) in the address bar.
3. Press Enter. The Argus Insight login screen appears.



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

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

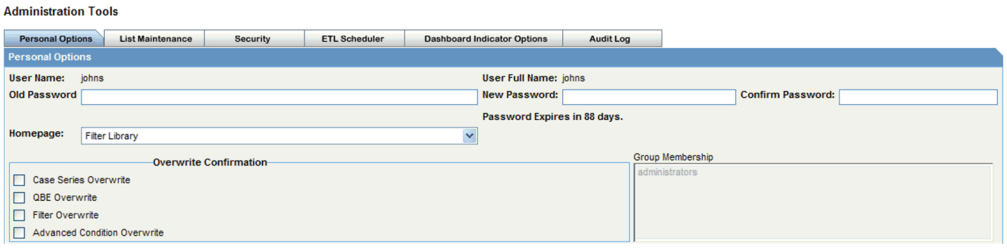
5. Click **Login**. The Argus Insight home page appears.



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.

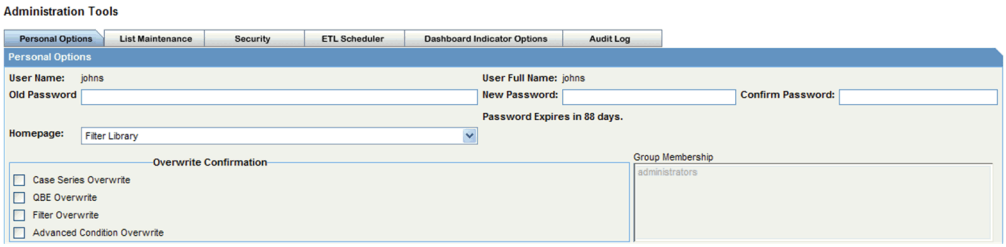
Note: Argus Insight passwords are **case sensitive**. The password requirements are configured by the Administrator.

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
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

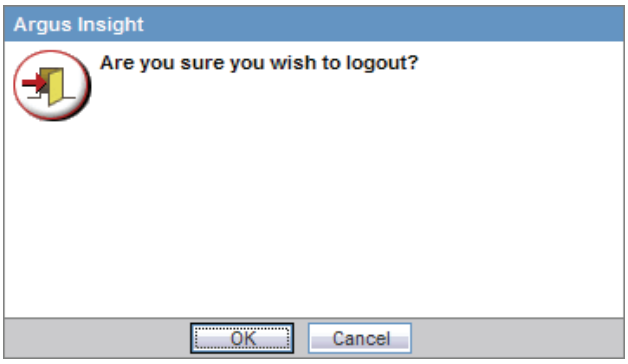
Getting Help

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.

4

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

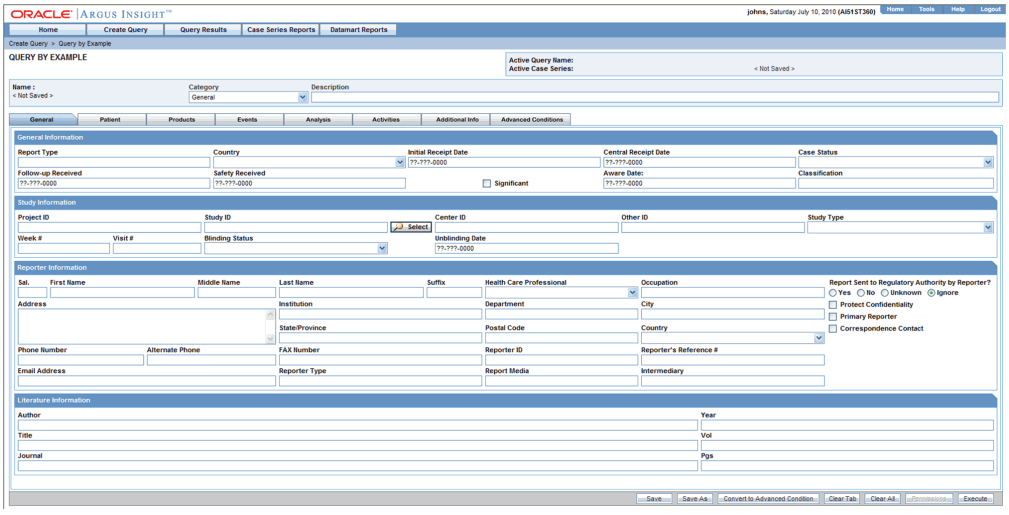
Anatomical Locations	Attachment Classification	Birth Type	Case Classification	Causality Category
Condition Type	Contact Type	Delivery Types	Device Subcomponents	Device Type
Dosage Frequency	Dosage Units	Ethnicity	Event Frequency	Event Intensity
Event Outcome	Fetal Outcome	Formulation	Gender	Group (Activities:contact 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:

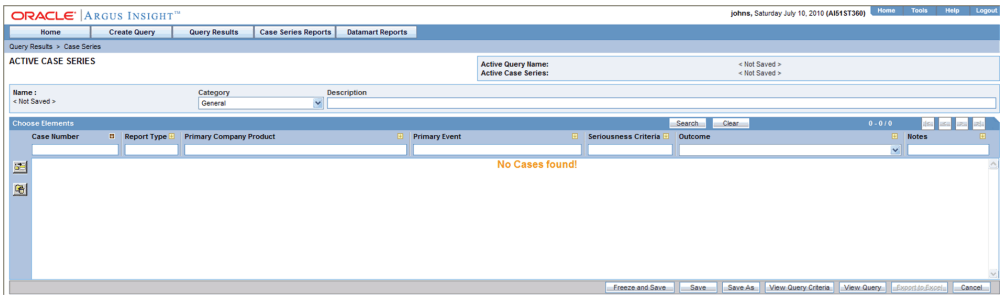
Note: The QBE field labels are displayed as per the field labels configured in Argus

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

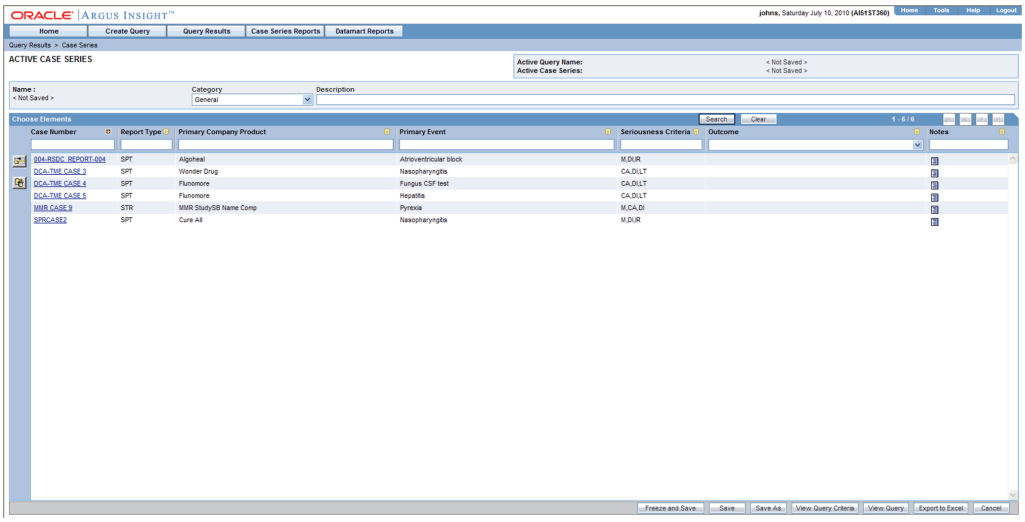
Tip: While entering values in a tab, if you wish to clear all the values you entered, click the **Clear Tab** button. If you wish to clear all the values you entered in all the tabs, click the **Clear All** button.

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.

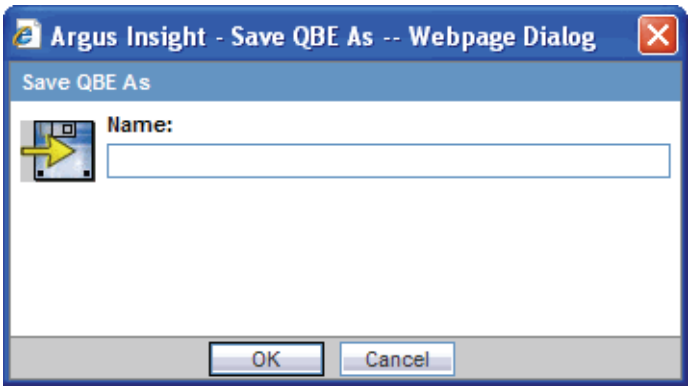
7. If required, modify the QBE and examine the result again or proceed to save the QBE.

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.

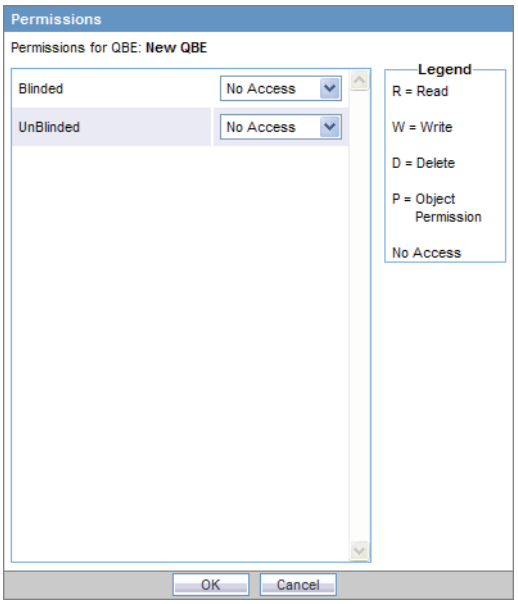
> **Tip:** If you make modifications to the field values after you have saved the QBE to the system, use the Save button to save the changed field values.

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

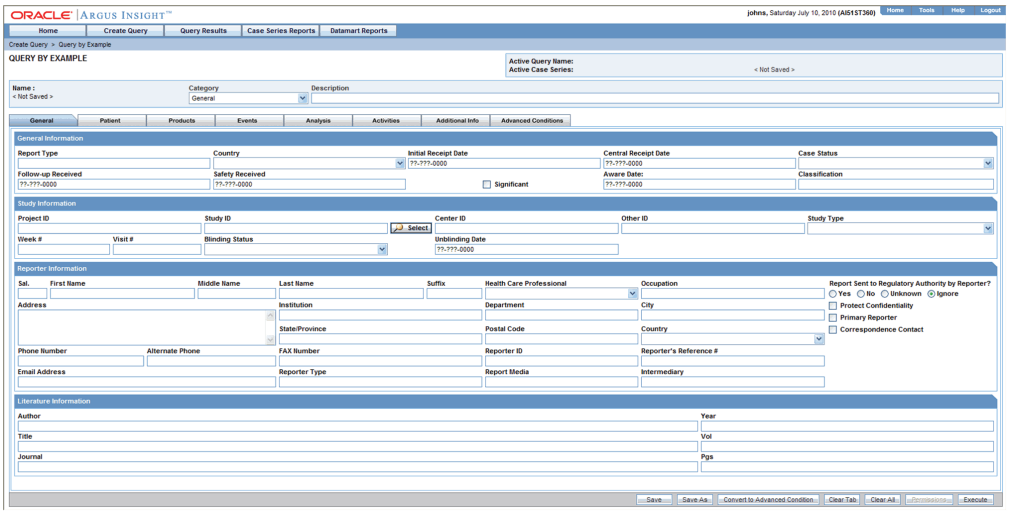
2. Click **OK**. The system saves the permission settings.
3. Execute the QBE.
4. Click **Execute**. The system retrieves the list of cases that match the QBE criteria and displays it in the **Active Case Series** page.

   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.

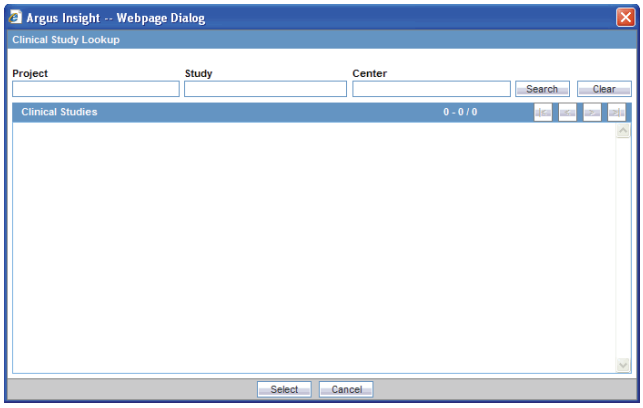
Selecting the Study Number

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:

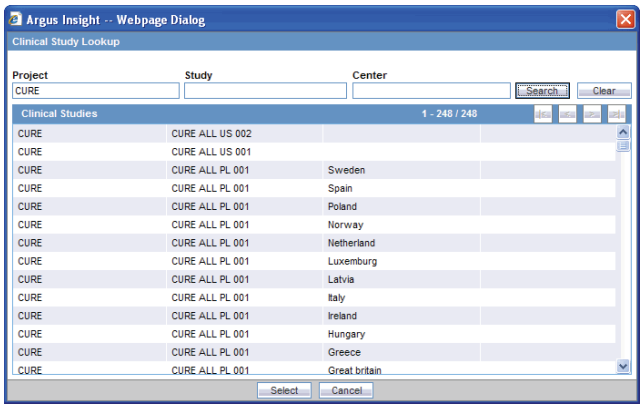
1. Click the **Select** button associated with the **Study Num** field. The **Clinical Study Lookup** dialog box appears.



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.



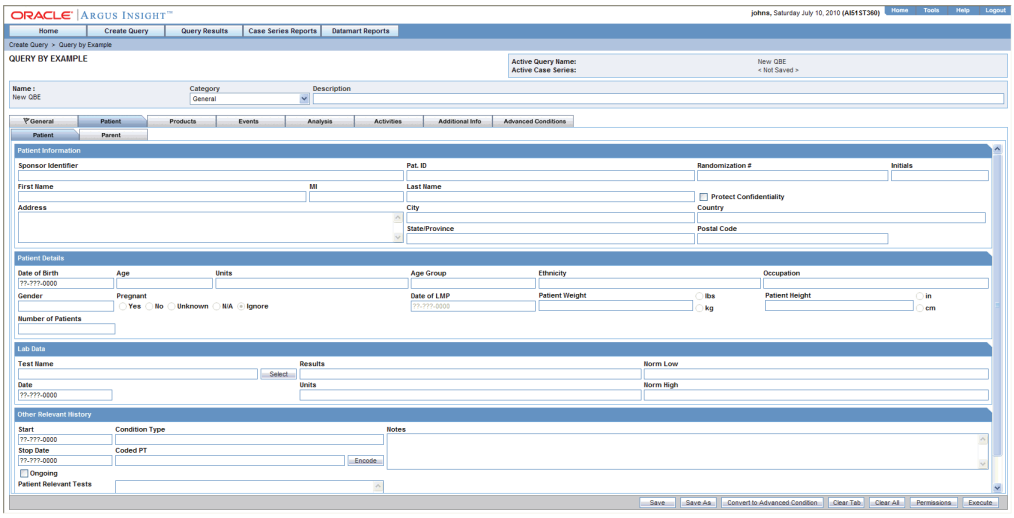
4. Select a study from the **Clinical Studies** listed.
5. Click **Select** in the **Clinical Study Lookup** dialog box. The **Study Protocol # , Study Num (*)** and **Center ID(*)** fields in the **Study Information** section of the QBE *form* are automatically selected.

> **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

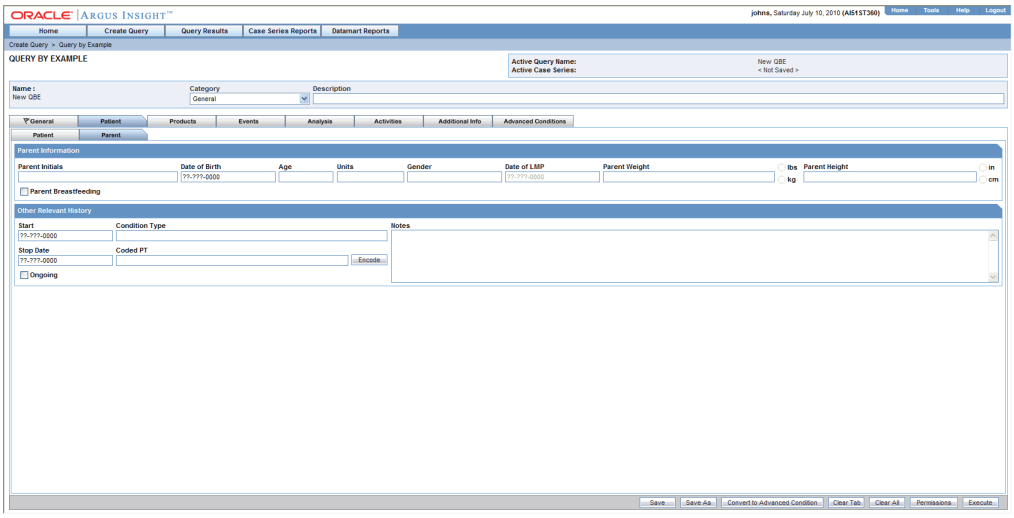
You need to scroll down the page to view all the fields available.

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.

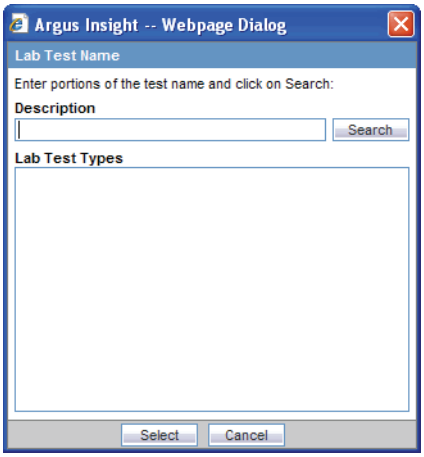
Section	Field	Description
Parent	Parent Initials	In this text box, enter the parent's initials that the query should look for in cases.
	Parent Age	In this text box, enter the parent's age that the query should look for in cases.
	Parent Age Unit	Select the age unit for the value you specified in the **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.

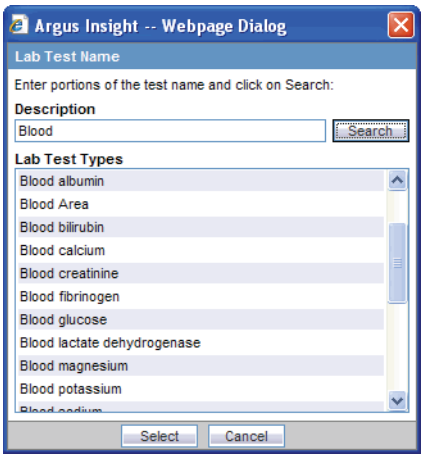
Selecting a Lab Test

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.

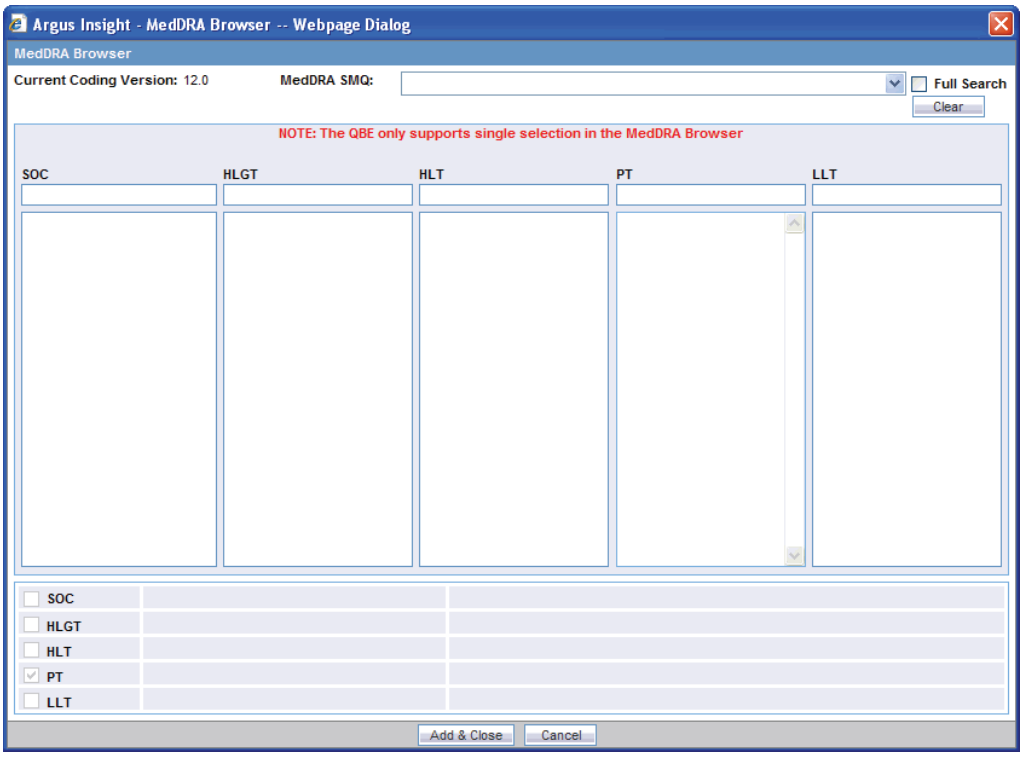


4. Select the required test name.
5. Click **Select**. The test name appears in the **Lab Data Test Name** field in the QBE *form*.

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.



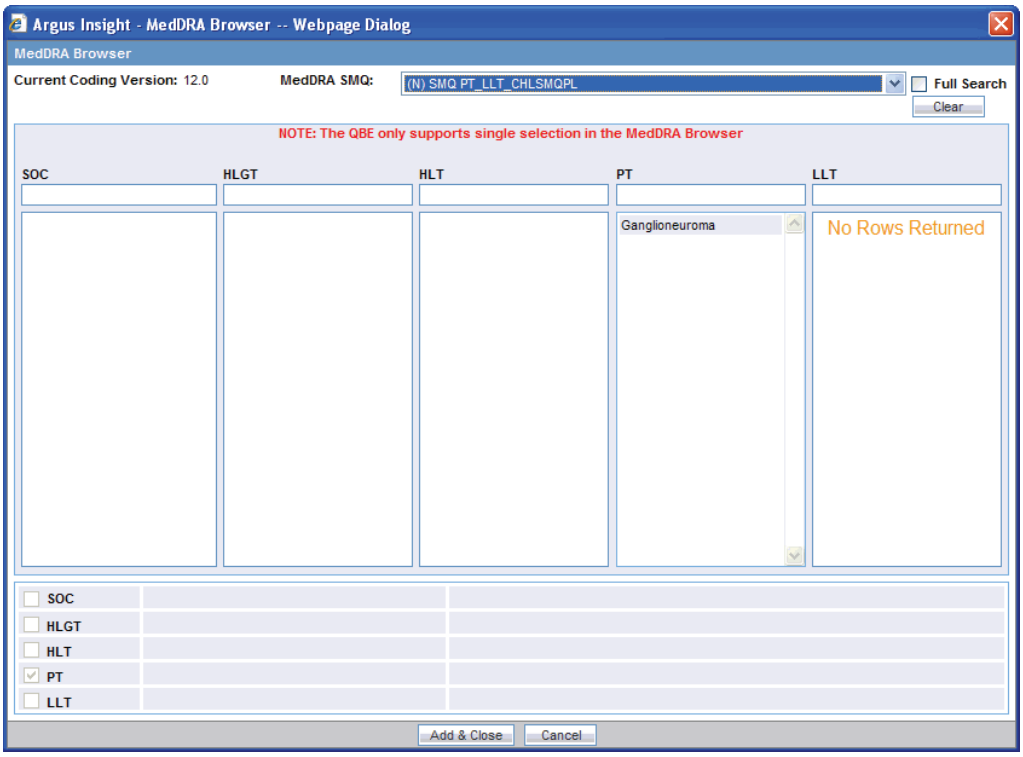
Note: The output returned by the MedDRA browser for the **Patient**, **Product** and **Analysis** tabs of QBE is the **Preferred Term (PT)**. The **Events** tab of QBE provides output for multiple options. You can select and search the required term(s), based on the **Seriousness Criteria**.

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.

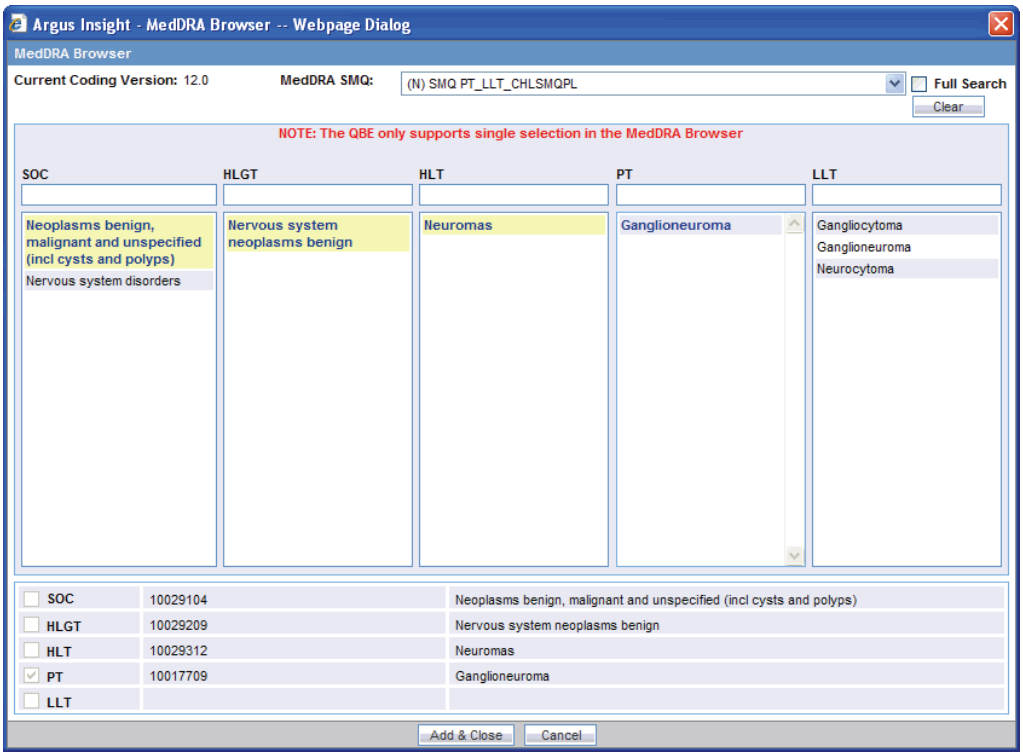
Note: The Special Category drop-down list displays all the SMQs that can be selected. The selected SMQ searches across PT and LLT levels of the MedDRA dictionary.

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.



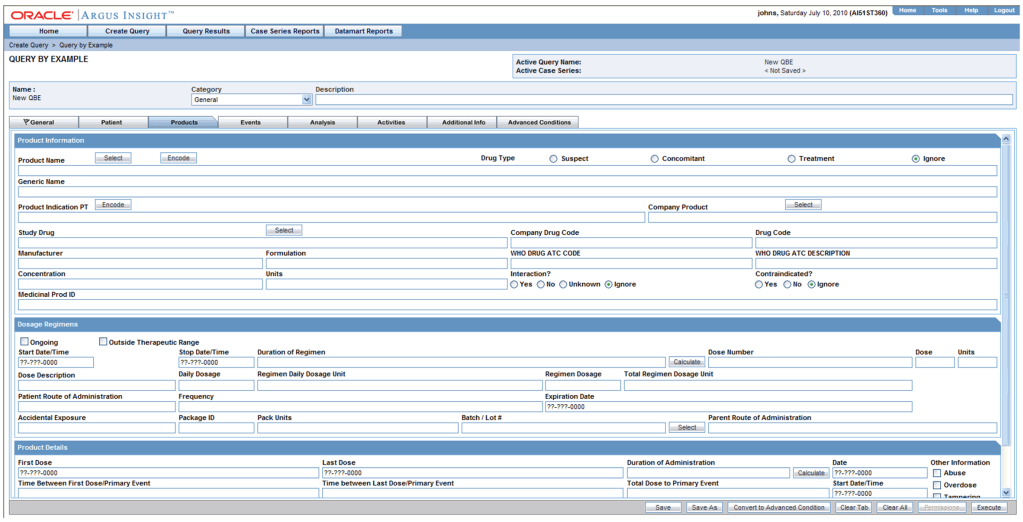
If the row color is...	This signifies...
Yellow	The selected hierarchy is the primary SOC path.
Grey	The selected hierarchy is not the primary SOC path.

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

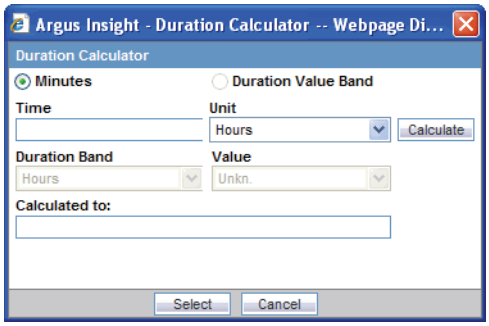
The **Products** page differs from what you might be used to seeing in Argus in the following ways:

- 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.

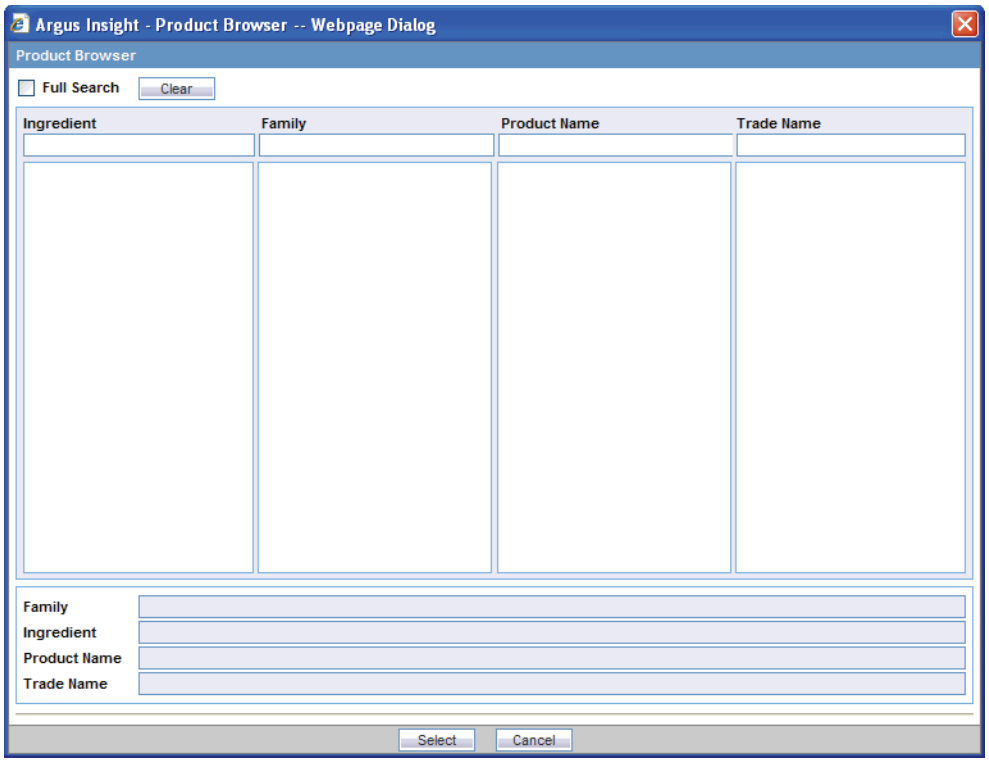
Section	Field	Description
	Dosage Regimen Duration	 In this text box, enter the dosage regimen duration in minutes as the query criteria. OR Click **Calculate** to view the duration calculator, to calculate the dosage regimen duration in minutes or duration value bands. 1. Click the associated **Calculate** 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.

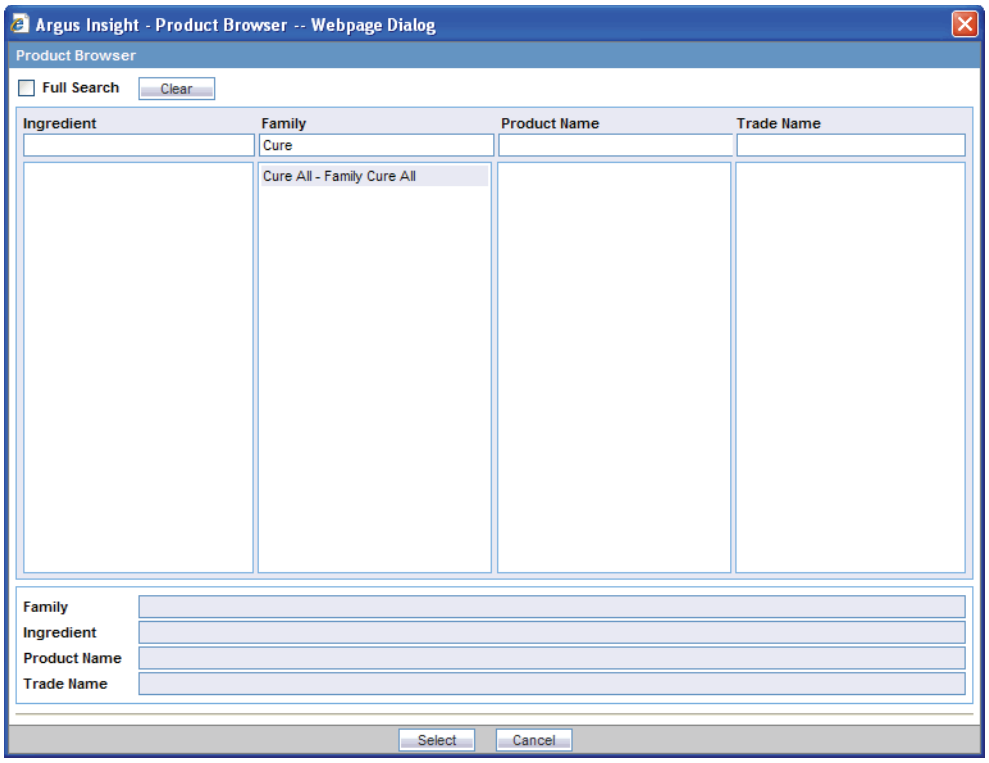
Using the Product Browser

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

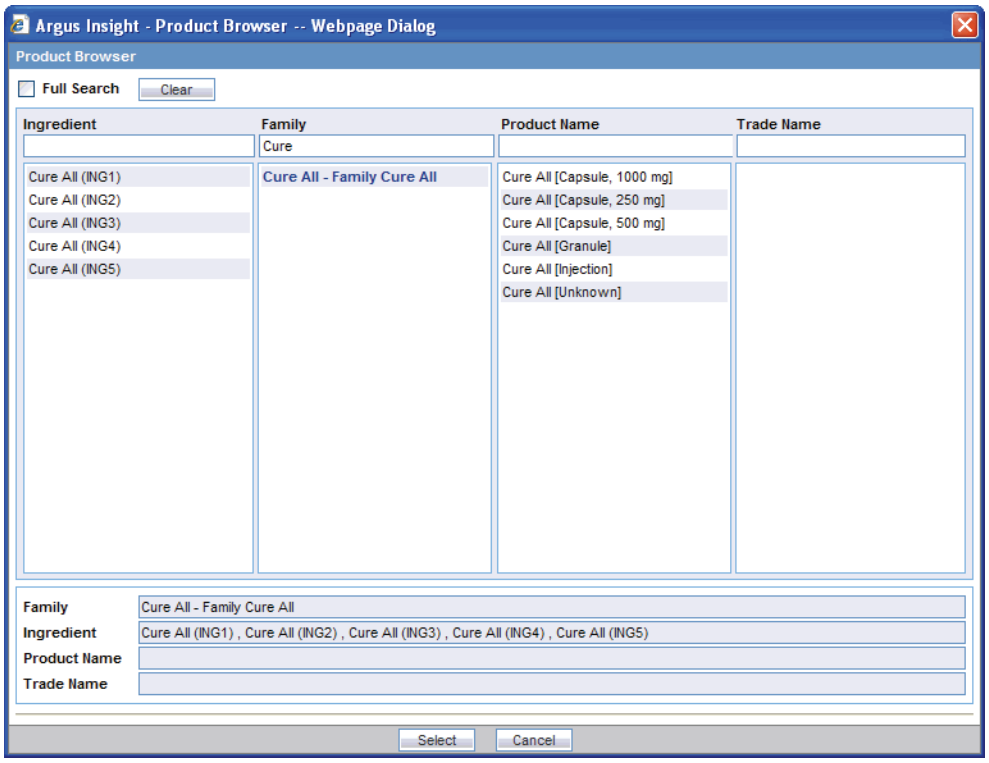
1. Click the **Select** button associated with the **Product Name** field. The Product Browser appears.



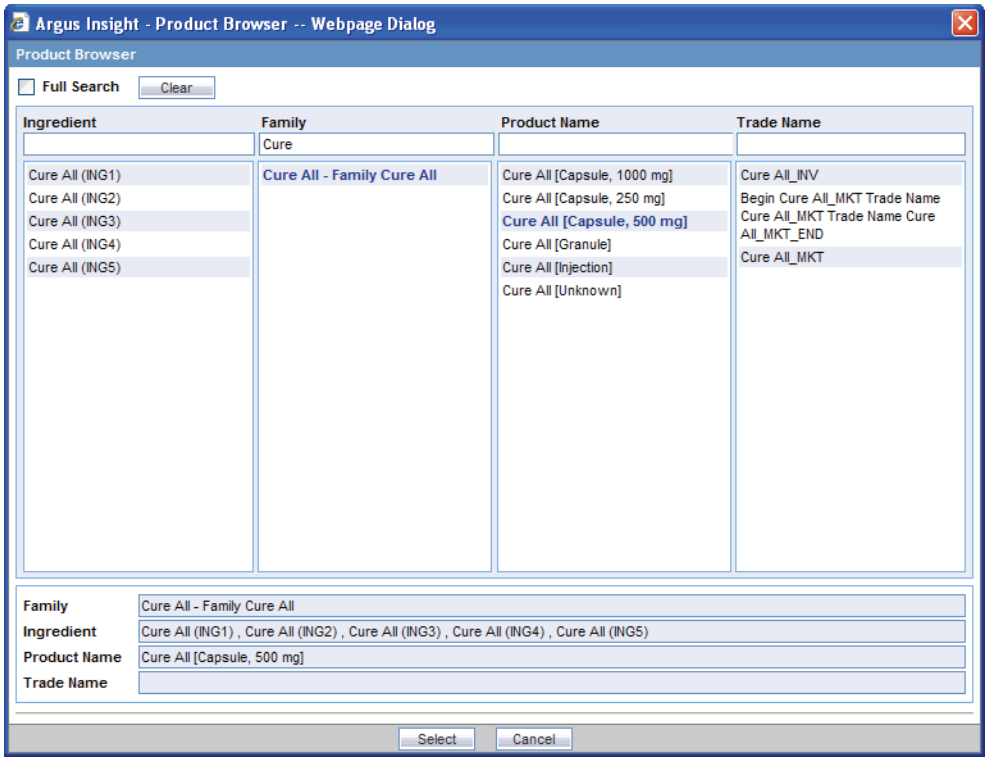
2. Enter the first few letters of the product ingredient, family name, product name, or trade name in the respective text box. If you want the system to search for the specified string in the entire product information, check the **Full Search** checkbox.
3. Press Tab. The system searches the database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

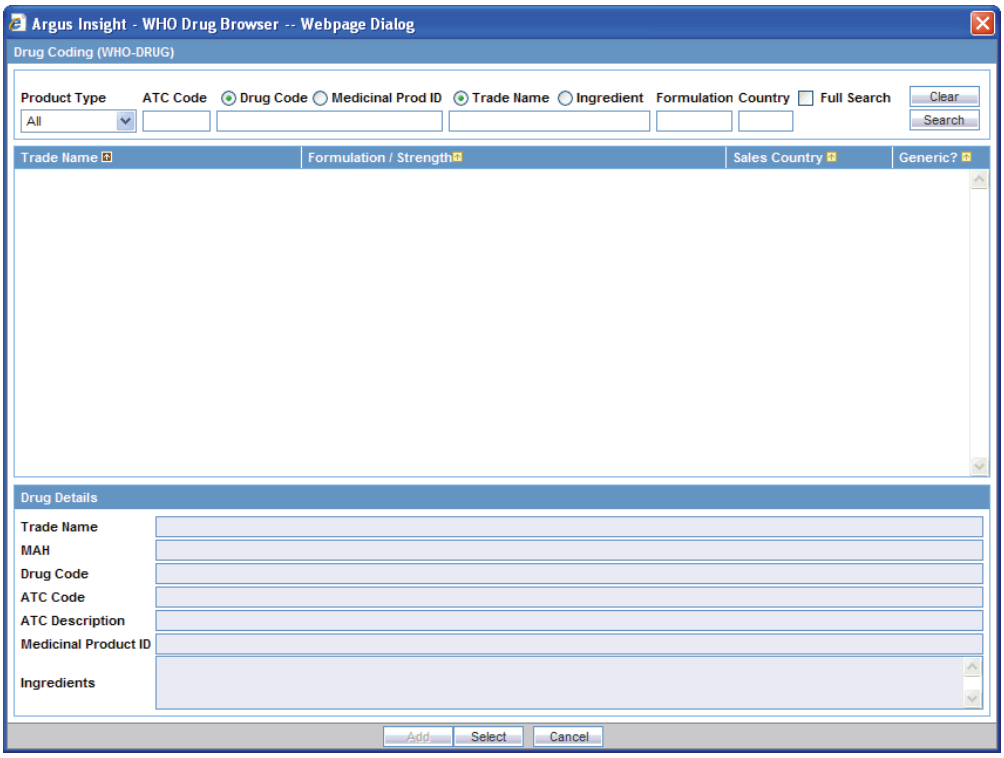


6. Click **Select**. The Product Name, Product Generic Name, Company Drug Code, Drug Formulation, Drug Concentration and Drug Product Concentration Units ID fields in the QBE form are automatically populated with the details of the selected product.

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.

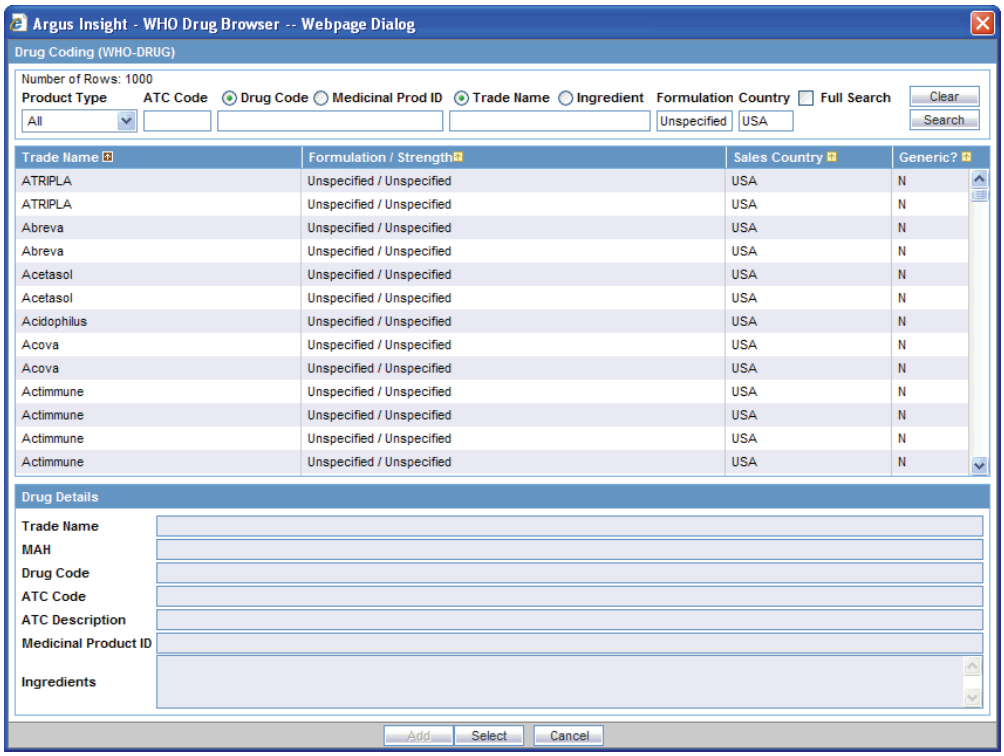
The primary difference between the two browsers is the availability of the following fields in WHO Drug Browser:

- **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.

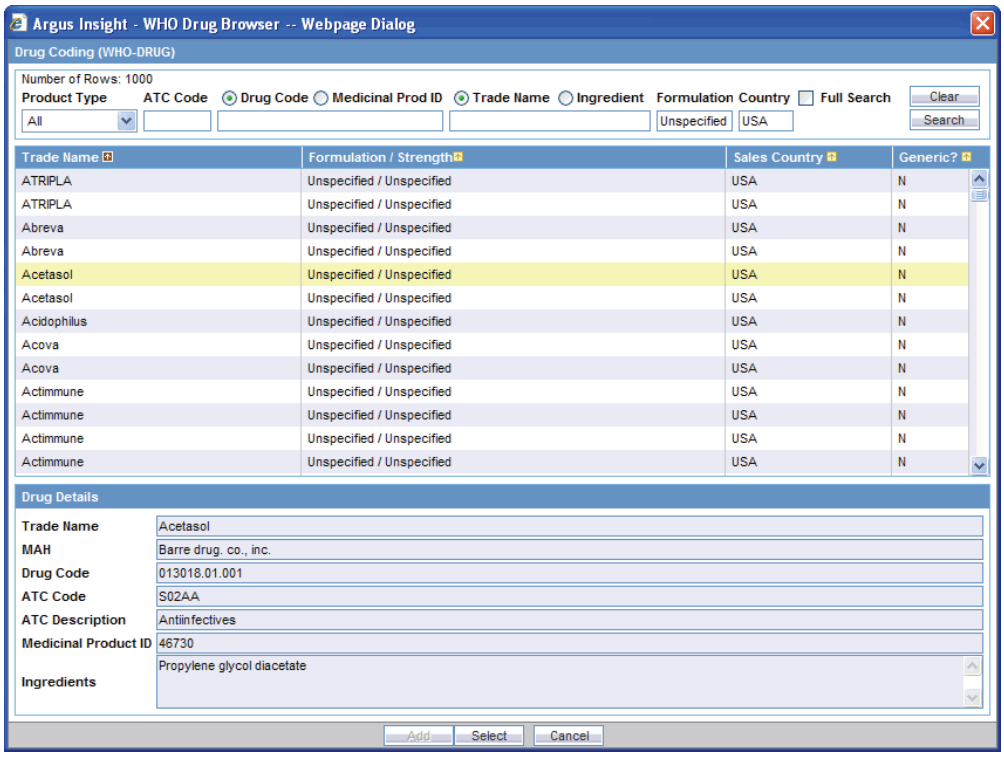
2. Select the **Product Type** as the drug search criteria. The default value is **All**.
3. Enter the first few letters of the **ATC code**, **ATC description**, **Code**, or **Description** in the respective text box. Check the **Ingredient** checkbox to search for the drugs (whose drug ingredients) 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.



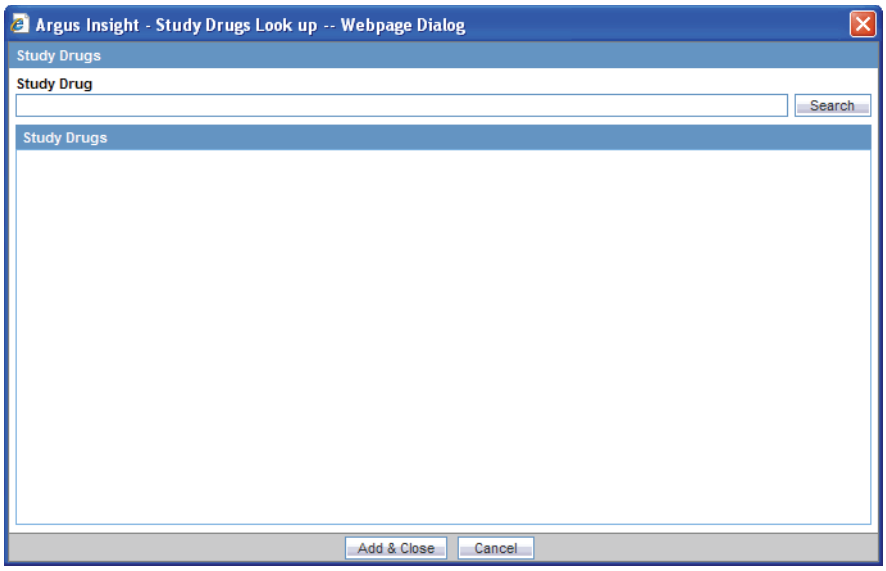
10. Click **Select**. The **Product Name**, **Product WHO Drug Code, Generic Name, ATC Code** and **ATC Text** fields in the QBE form are populated with the selected WHO drug code.

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

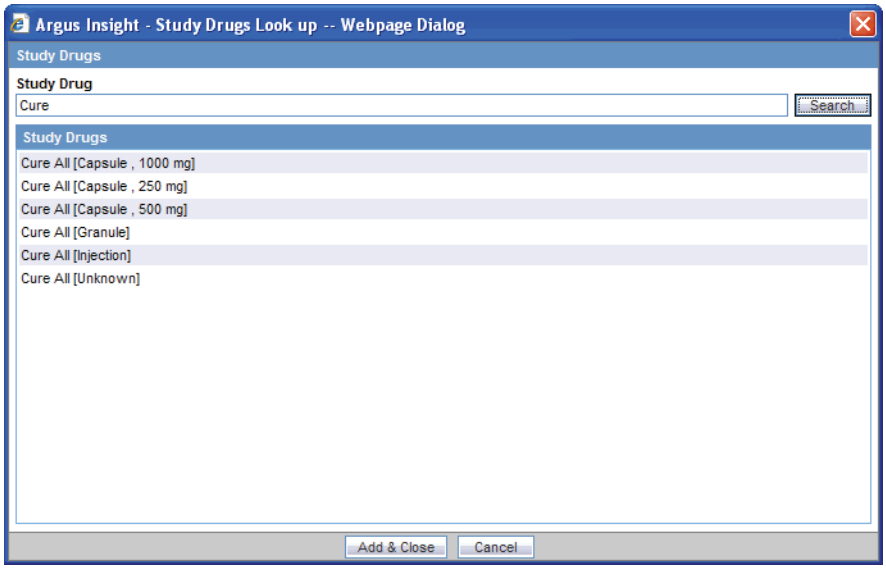
Using the Study Drug Lookup

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.



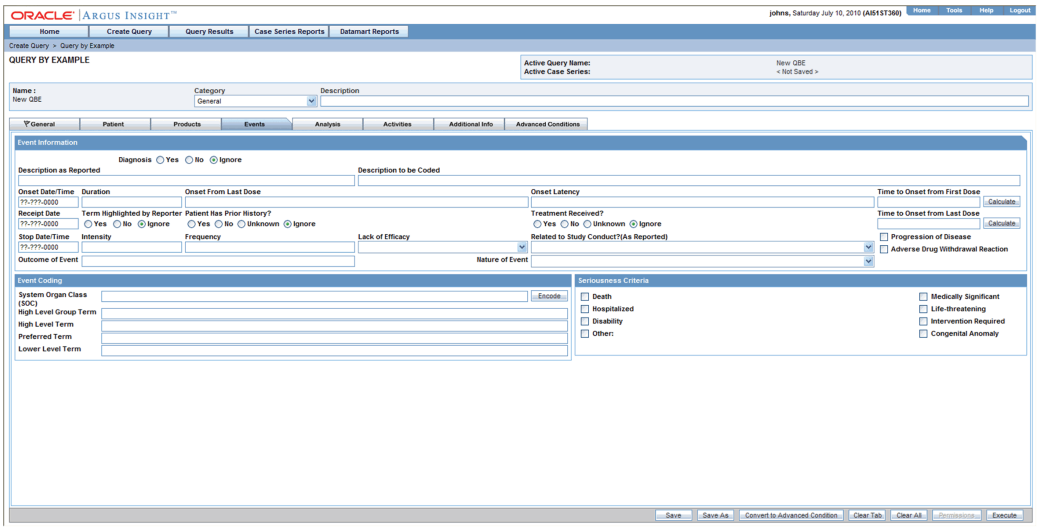
2. Enter the first few letters of the study drug name in the **Study Drug** dialog box.
3. Click **Search**. The system searches the database for the specified search string. The **Study Drug** dialog box displays the search result in a grid format.



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.



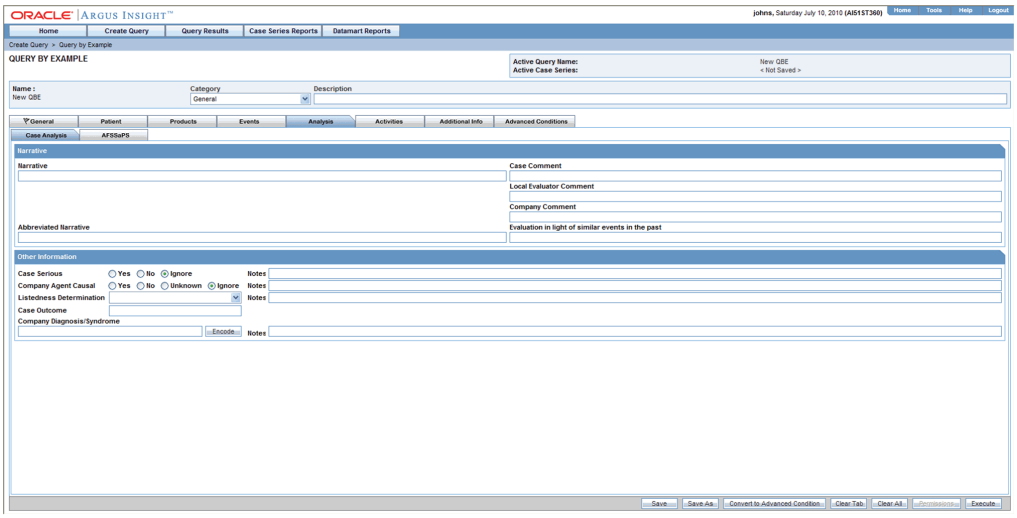
The following table describes the various fields in the **Events** page. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

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.

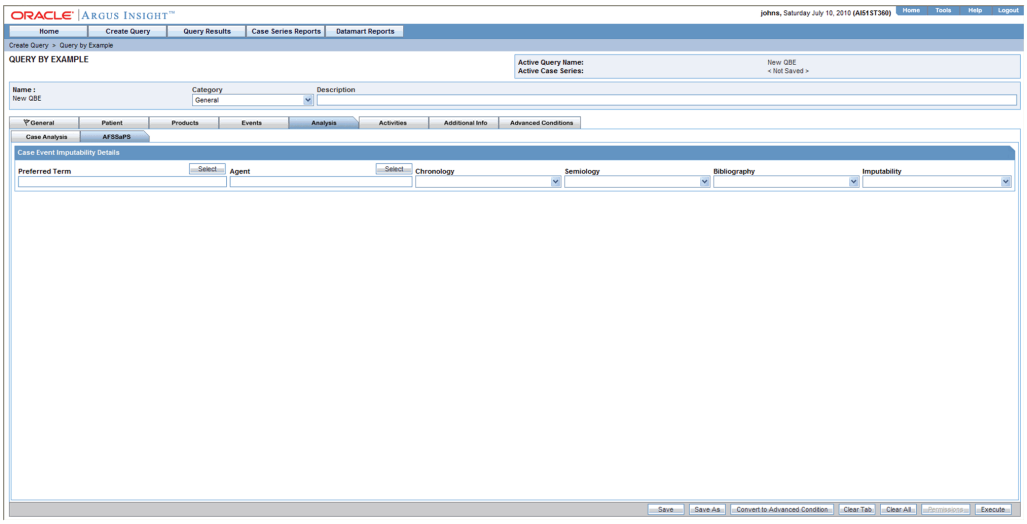


The following table describes all the fields in the **Case Analysis** view. The field values you specify are used as the *query* criteria to retrieve matching cases.

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.

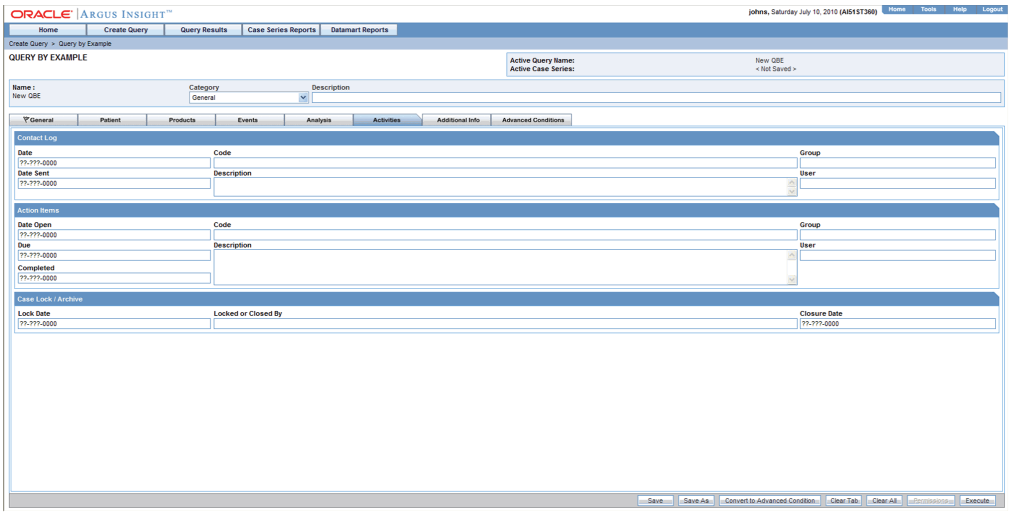
The following table describes all the fields in the **AFSSaPS** page. The field values you specify are used as the query criteria to retrieve matching cases.



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

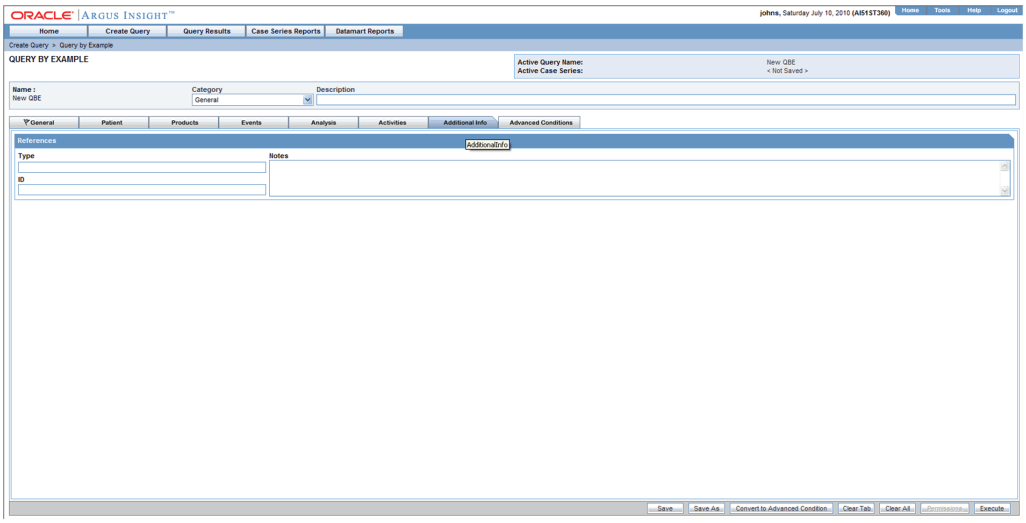
The following table describes all the fields in the **Activities** page. The *field* values you specify are used as the *query* criteria to retrieve matching cases.

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

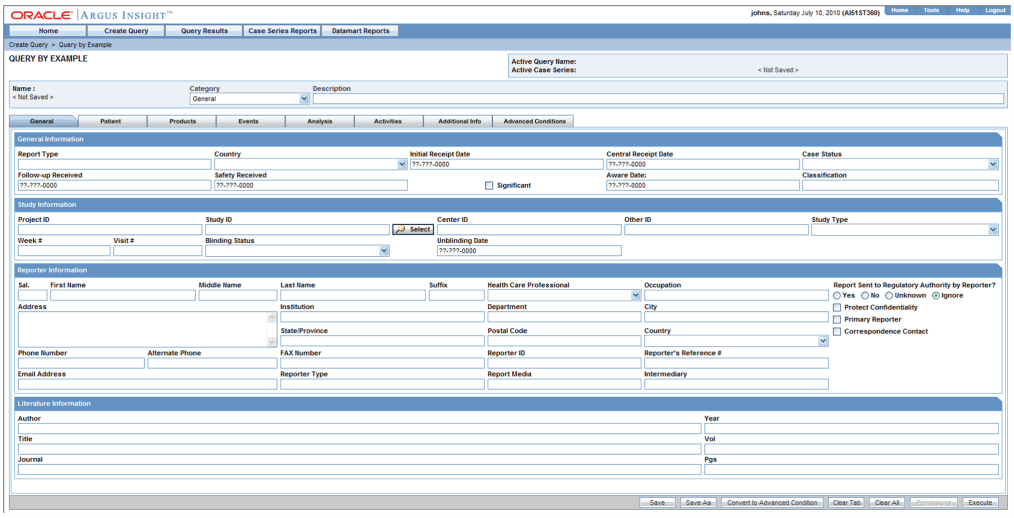
This topic explains how to view the QBE you last modified or executed.

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:

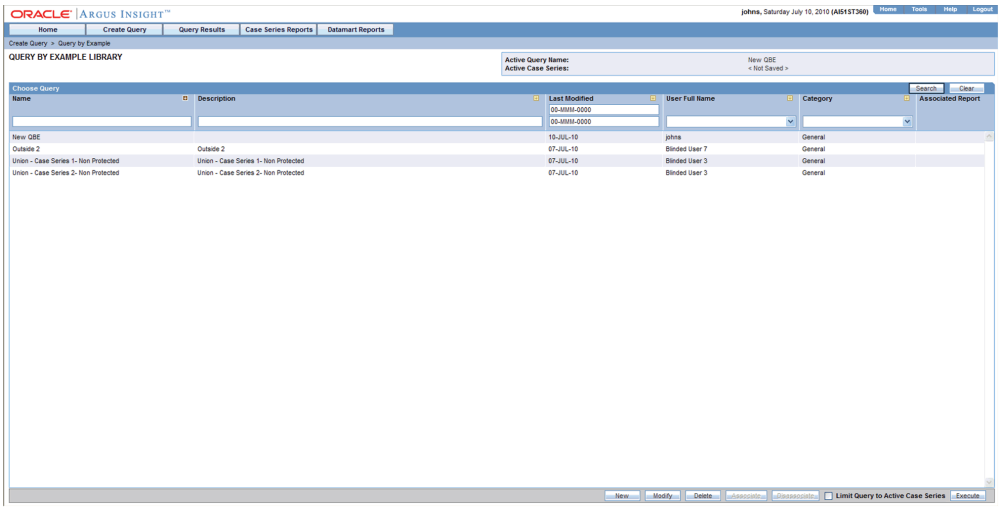
Task	Description
Modify the values in the QBE form	If required, you can modify the *field* values in the QBE form. See theCreating a New QBEtopic for information on entering values in the QBE form. While entering values in a tab, if you wish to clear all the values you entered, click the **Clear Tab 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

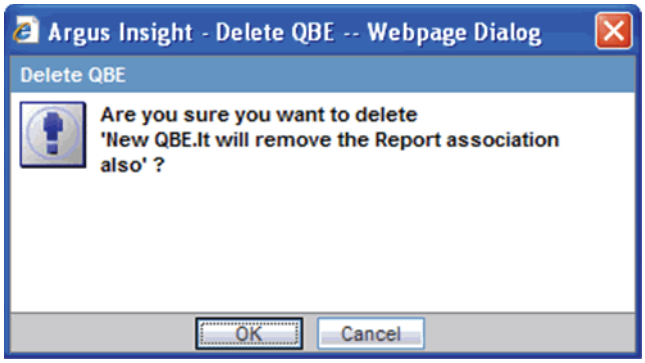
Use the following procedure to modify a saved QBE:

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

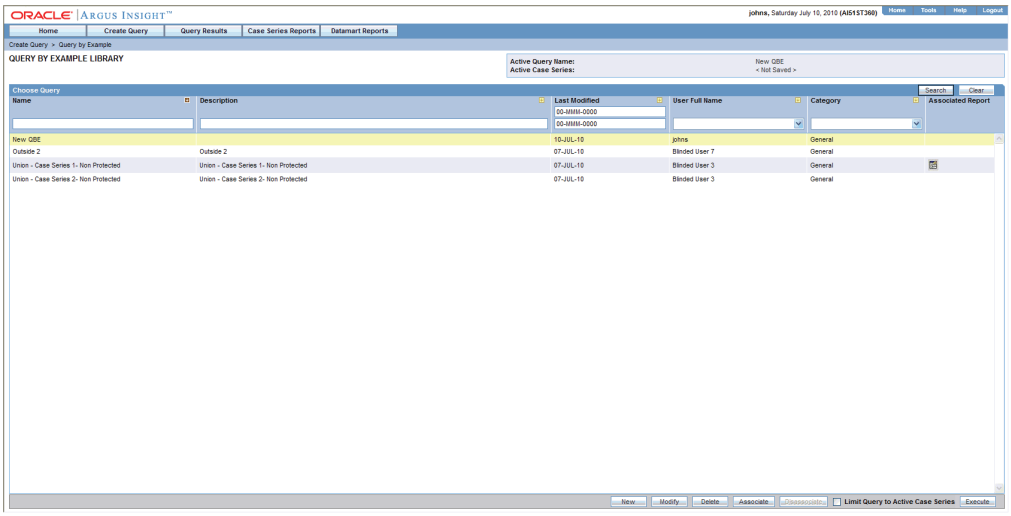
Argus Insight lets you associate a QBE to a particular Standard Report and schedule a time when the report needs to be generated and sent to another user through email. This is helpful in situations when you need to generate the latest Case Series and run a report on it each time the datamart is refreshed.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

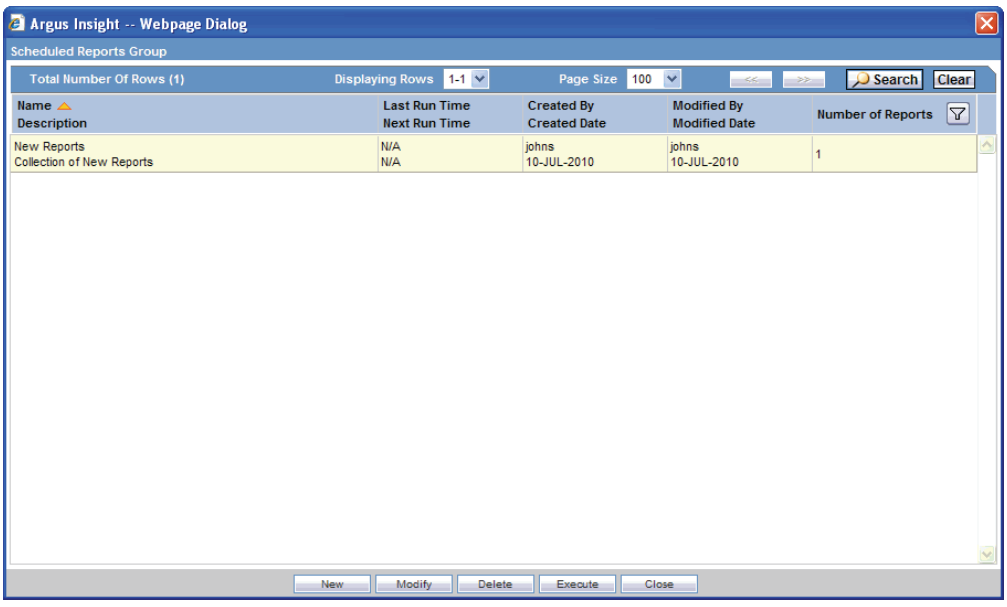
Use the following procedure to associate a QBE with a Standard Report:

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

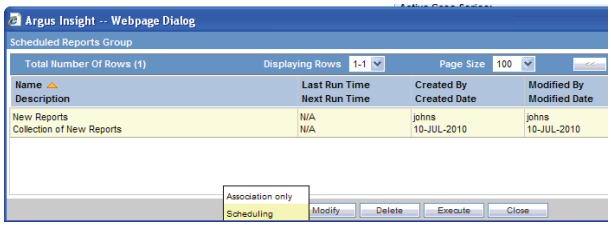


2. Associate the QBE with a Standard Report.

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.

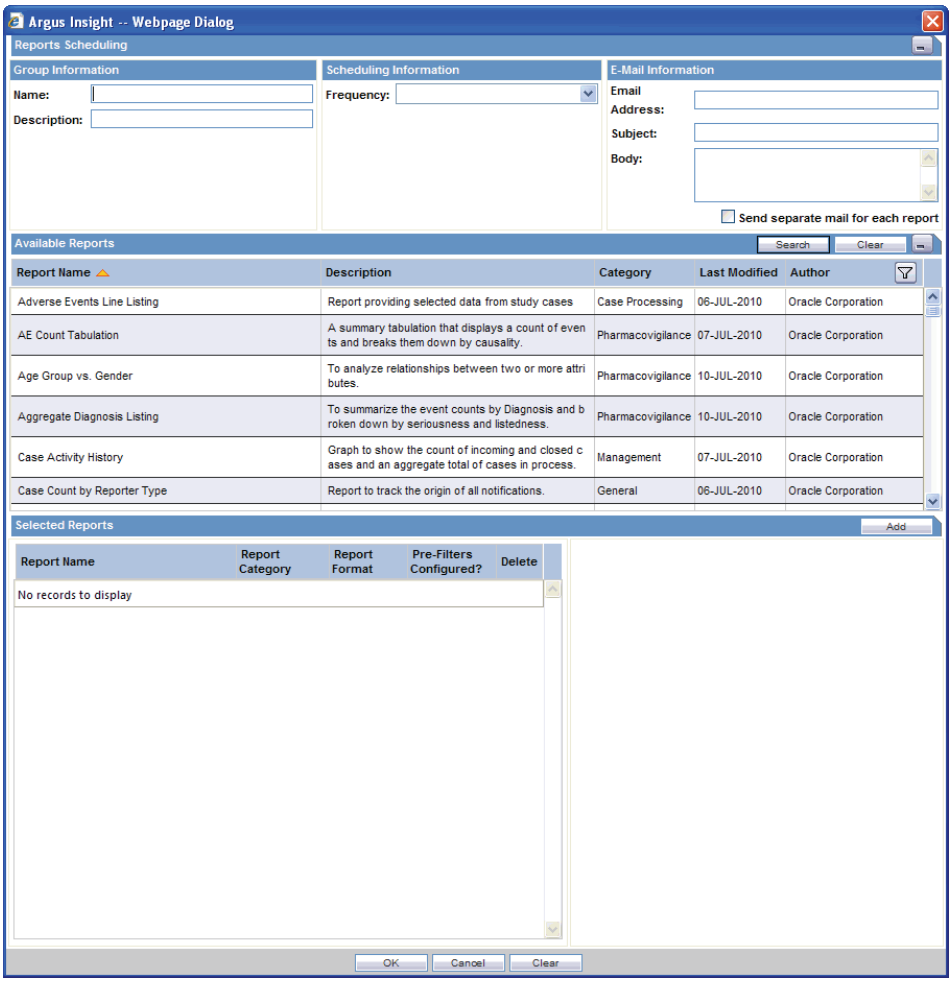


4. Click **New**. It enables you to either do Report **Association Only** or to perform Report **Scheduling**.



5. Schedule the report.

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



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

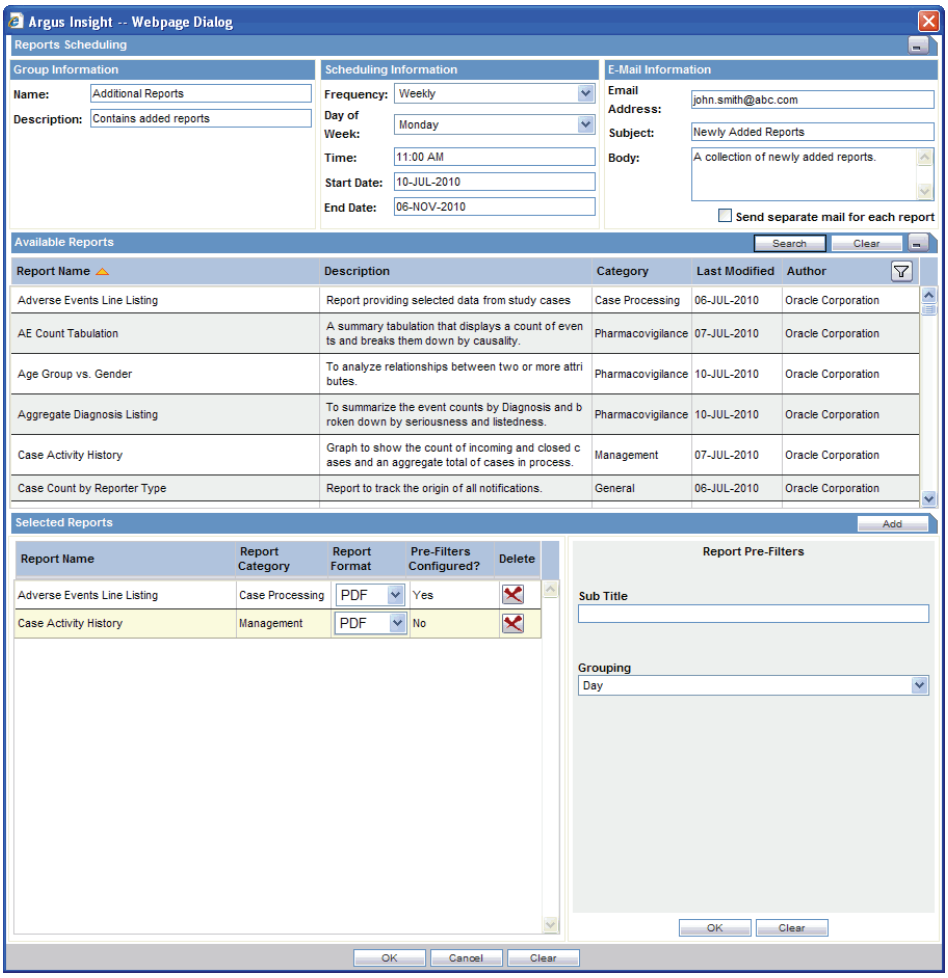
8. Use the **Frequency** list box to specify how often you wish to have the system run the selected QBE and generate the selected report. The options available are: **Once**, **Daily**, **Weekly**, **Monthly**, **Quarterly**, and **Yearly**.

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

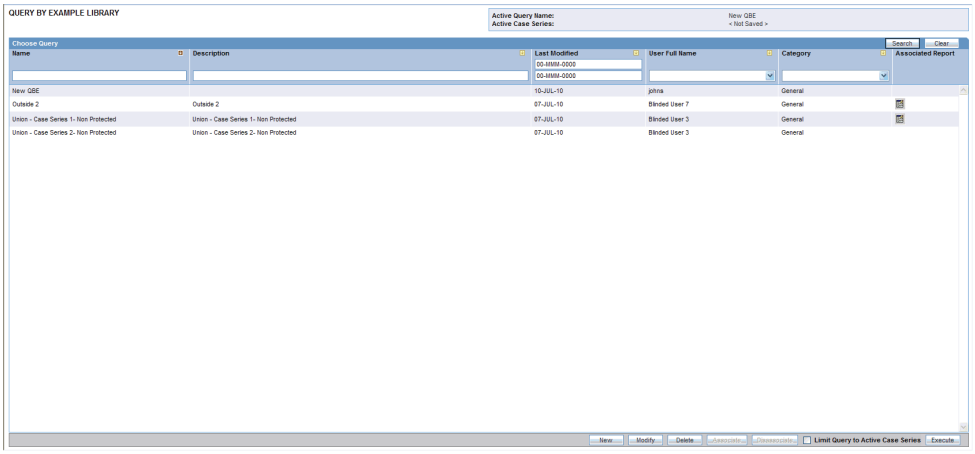
10. Based on the option you selected in the step above, specify the instant when you want the report generated as described in the table below.

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.

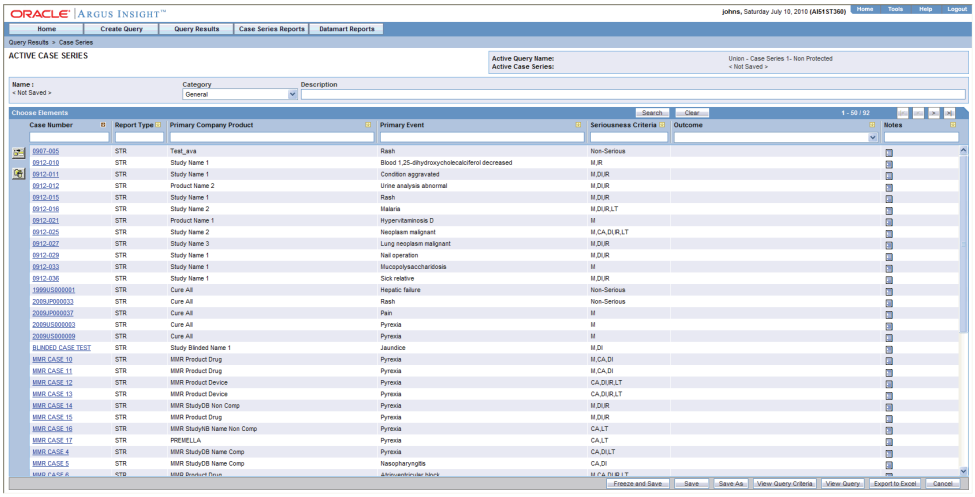


Note: Refer to the Associated Library and Query Library sections in the Library chapter, to view the steps on how to disassociate reports in those libraries

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.

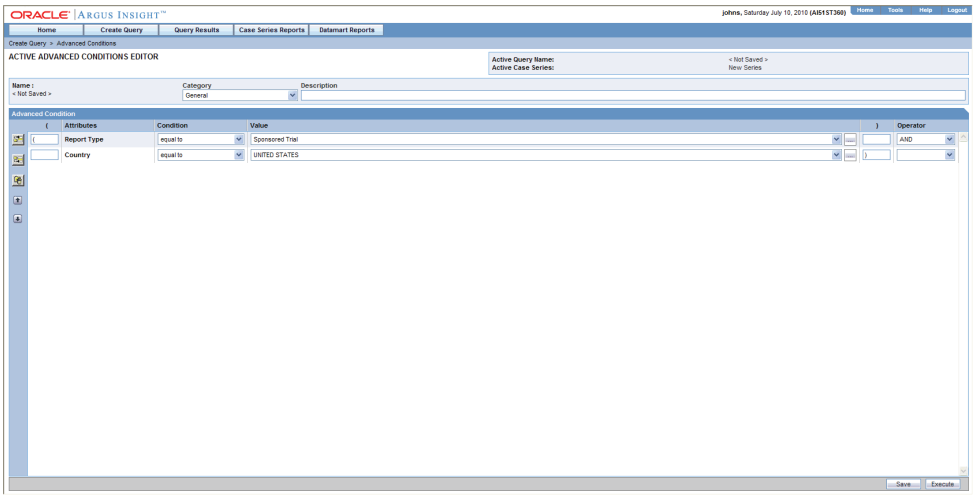
- Converting a QBE to an Advanced Condition
- Integrating a QBE with an Advanced Condition

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

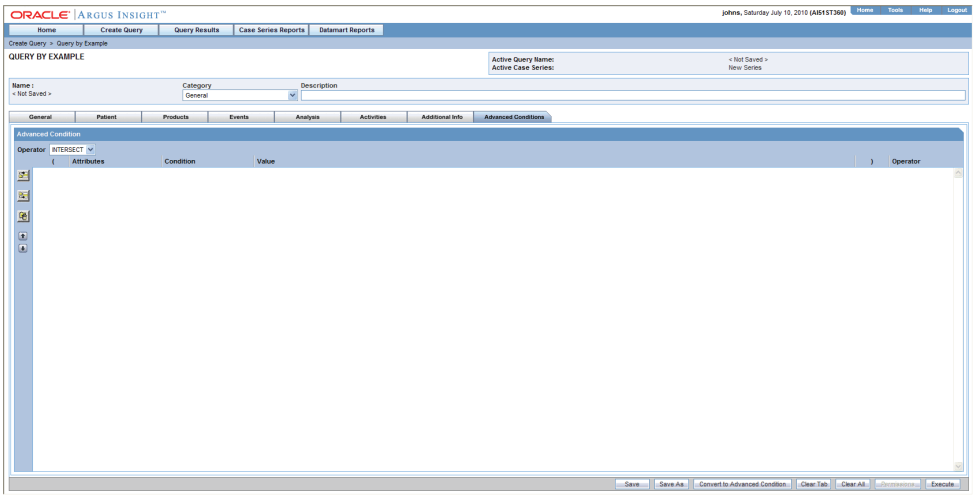
See the Advanced Conditionschapter for detailed information on building Advanced Conditions by using the options in the Advanced Condition editor.

Integrating a QBE with an Advanced Condition

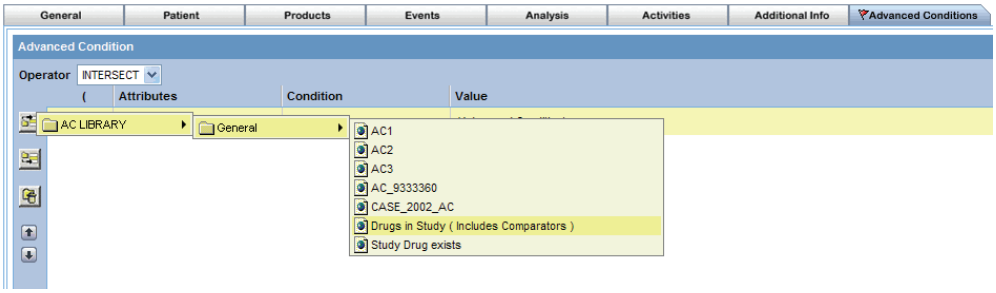
Argus Insight lets you integrate a new, active, or saved QBE with an existing Advanced Condition through these Set operators: Intersect, Minus, or Union. If required, you can integrate your QBE with multiple Advanced Conditions. The multiple Advanced Conditions can have Set or Boolean operations between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

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

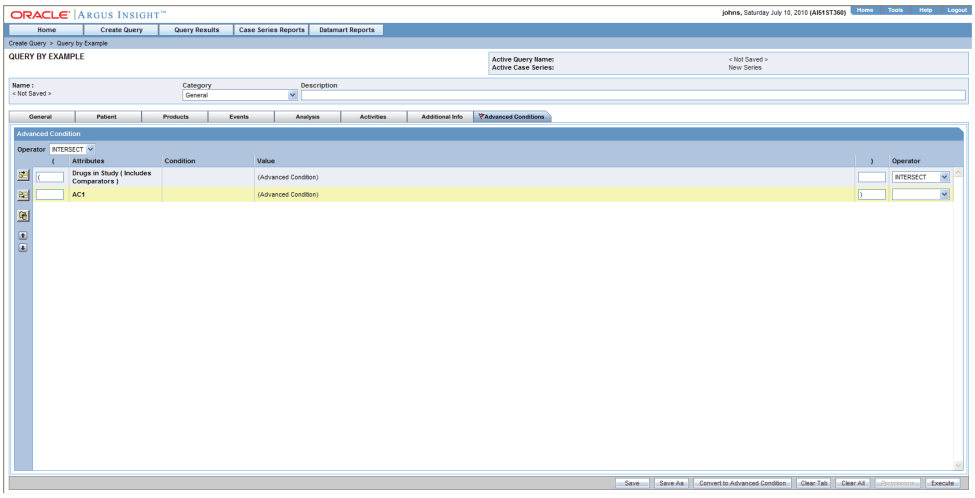
1. Open a QBE *form* bystarting a new QBE, opening the Active QBE, or opening a saved QBE.
2. Verify the *field* values you specified in the various tab pages in the QBE form.
3. Click the **Advanced Conditions** tab in the QBE form. The **Advanced Condition** tab page displays the Advanced Condition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

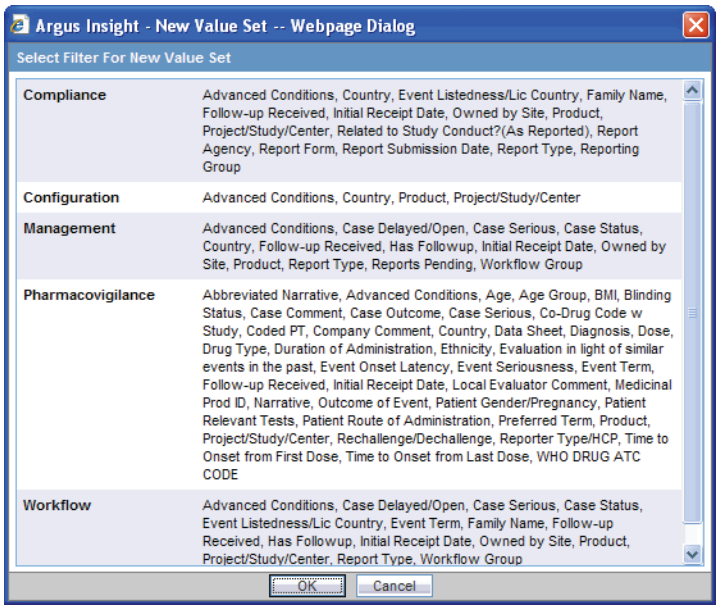
- Select a predefined *Filter*
- Create a Value Set for the predefined Filter by entering values in the associated elements

- Generate a Case Series by executing the Value Set

Selecting a Predefined Filter

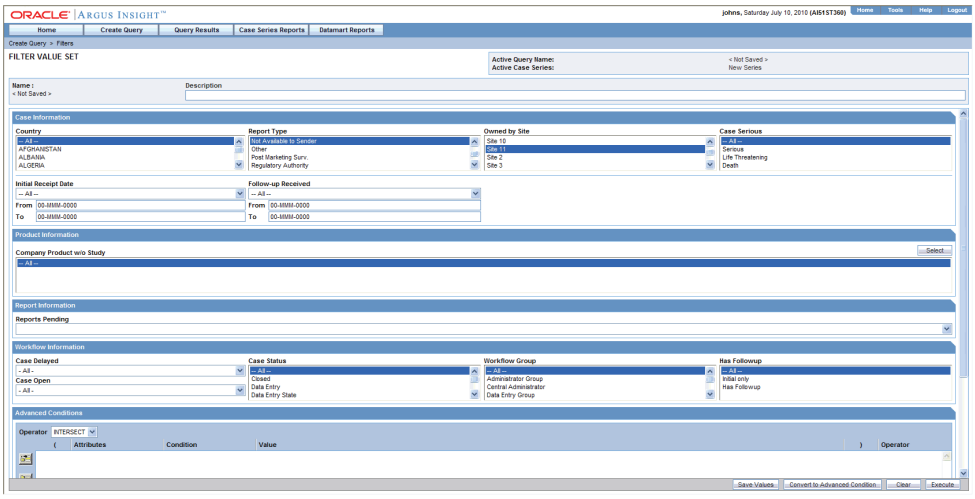
Use the following procedure to select a predefined filter.

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		

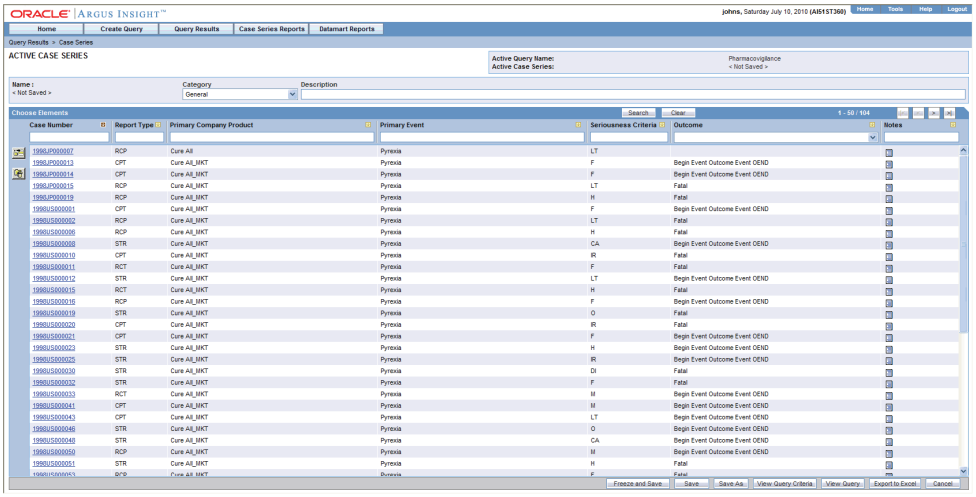
Sections in the New Value Set Page	Associated Elements (Fields)		
Event Information	Event Seriousness	Event Term	Onset Latency (minutes)
	Outcome of Event	Event Listedness/Lic Country	Related to Study Conduct? (As Reported)
Workflow Information	Workflow Group	Has Followup	Case Status
	Case Delayed/Open		
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.

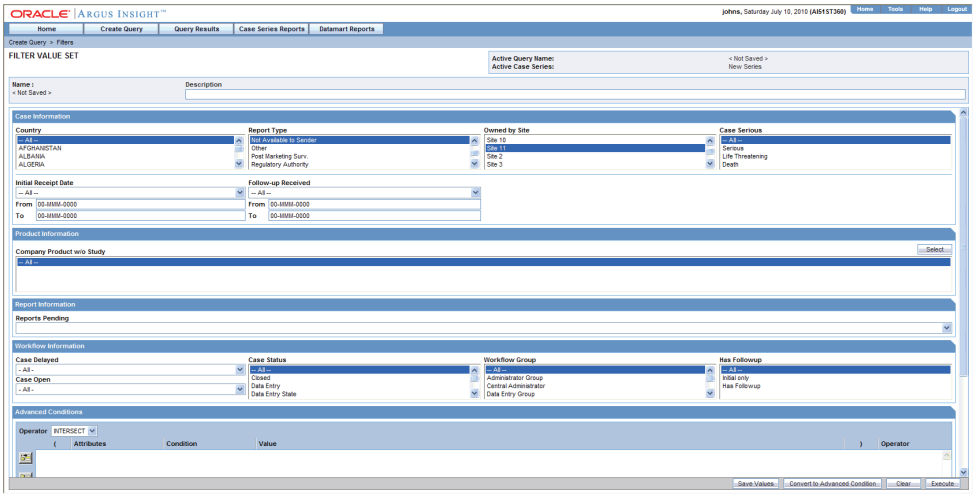
Tip: You may cancel the query execution at this point and return to the **Filter Value Set** page by clicking **Cancel Query** in the dialog box above.

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.

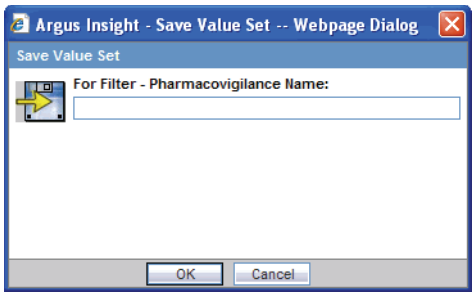
6. To return to the **Filter Value Set** page, click **View Query** in the **Active Case Series** page. The **Filter Value Set** page appears.



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.

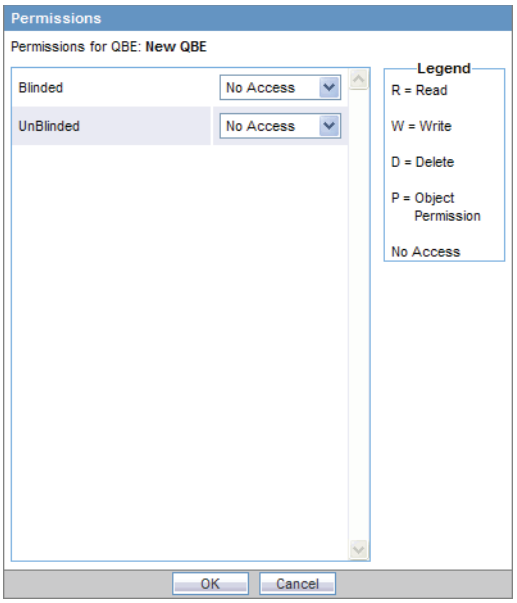
8. Save the Value Set to the system.
9. Type a description of the Value Set in the **Description** text box. For example, you can describe the type of cases the Value Set retrieves.
10. Click **Save Values**. The **Save Value Set** dialog box appears.



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

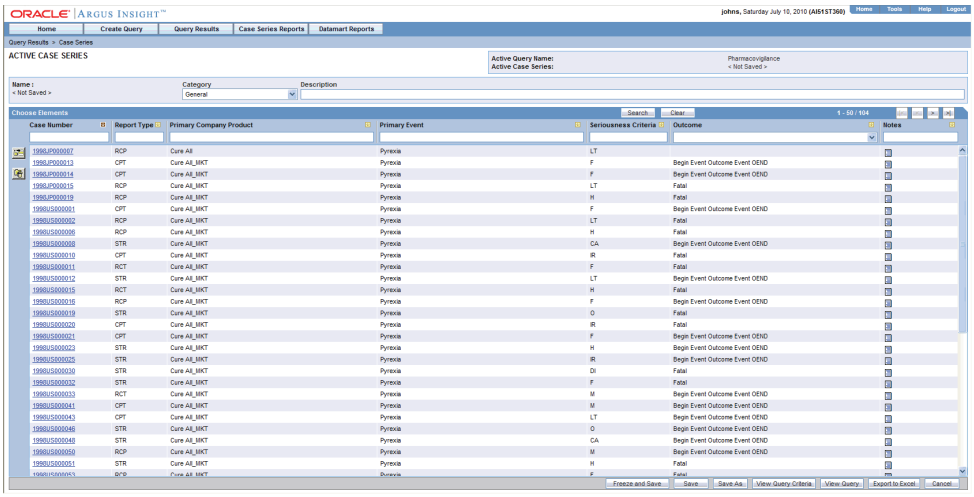
Note: The author of the Value Set always has the highest level of permission (R/W/D/P) on it. For example, you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a Value Set that you create. In this case, while you will continue to have the highest 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

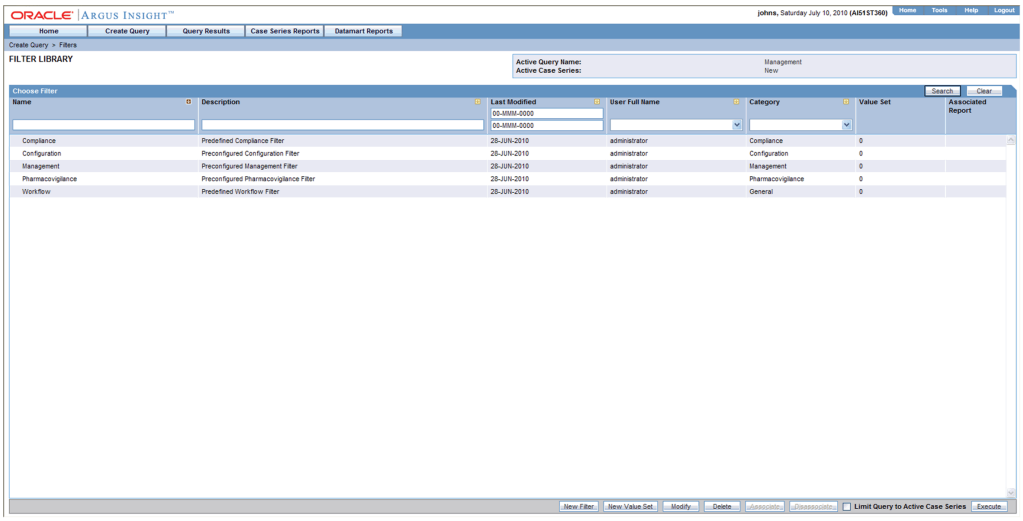
This topic explains how to:

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

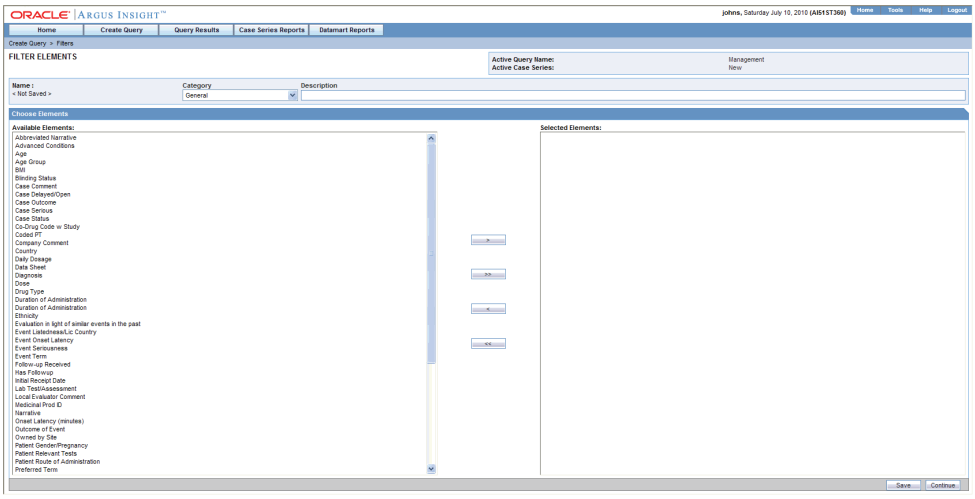
Creating a Custom Filter

Use the following procedure to create a custom filter.

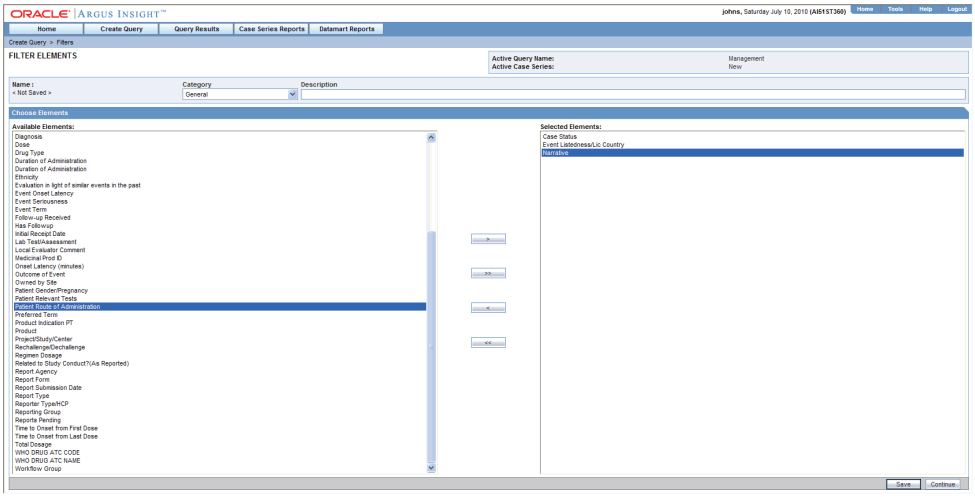
1. Select **Create Query > Filters > Library**. The **Filter Library** page appears. This page lists the predefined as well as custom Filters and their values sets in a control tree format.



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.



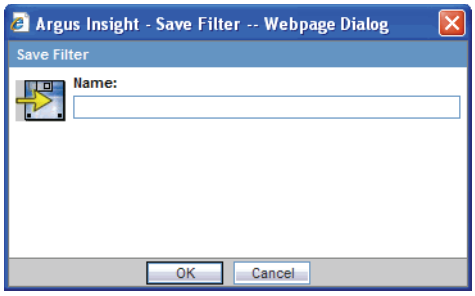
Tip: To add all the elements in **Available Elements** list to the **Selected Elements** list, click the >> button.

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

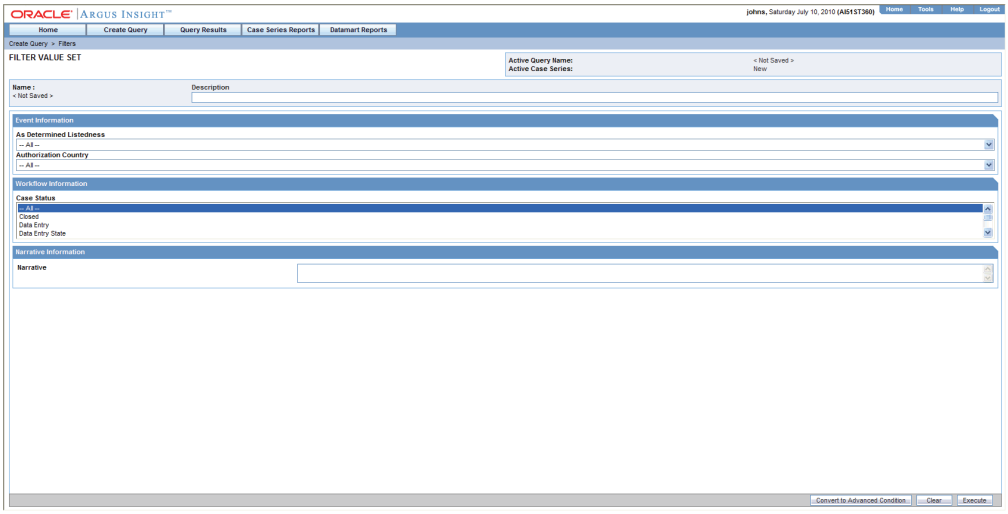
Note: The author of the Filter always has the highest level of permission (R/W/D/P) on the Filter. For example, you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a Filter that you create. In this case, while you will continue to have the highest 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.

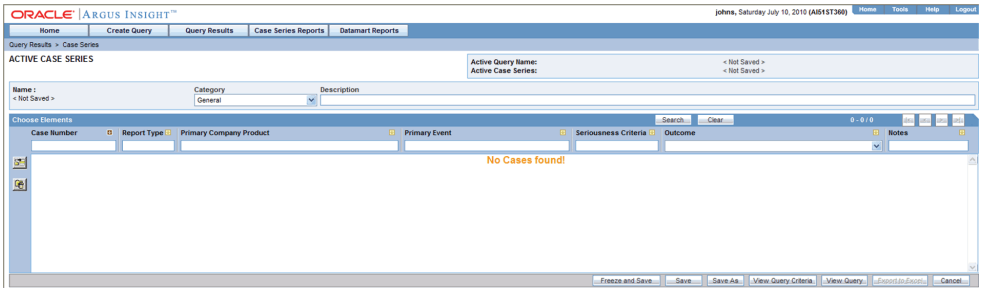


Note: In the **Filter Value Set** page, all the elements associated with the Filter are organized in sections. You need to scroll down the page to view all the sections. If you included the **Advanced Condition** element while creating your Filter in step 2, the **Filter Value Set** page displays an 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.

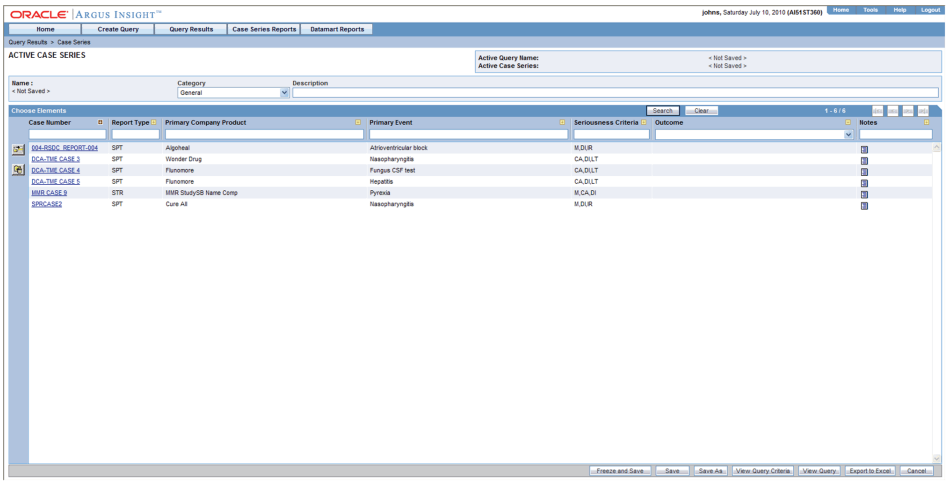
2. Specify values for the Filter elements. See step 2 in the Using Predefined Filters topic for details.
3. Examine the Value Set result.
4. Click **Execute**. While the system searches for matching cases, the following dialog box is displayed.

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.

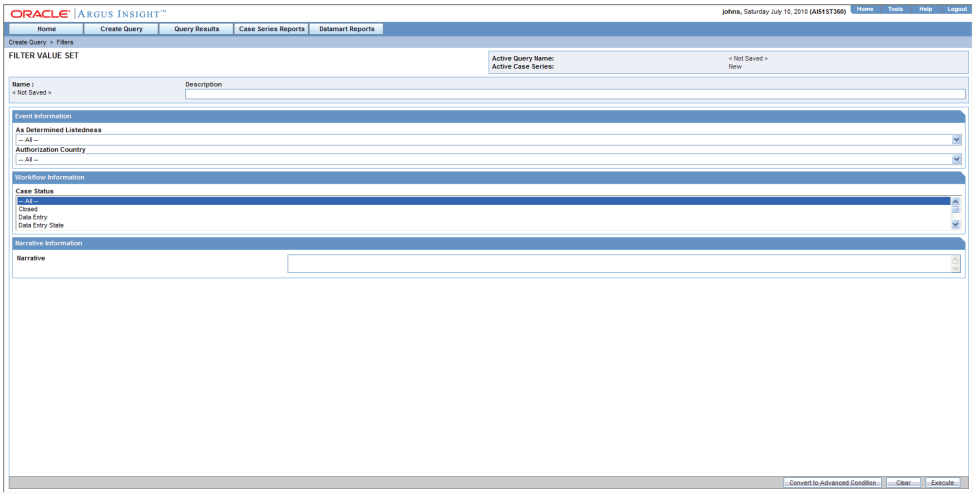


6. If the system finds cases that match the query criteria, a list of such cases is displayed in the **Active Case Series** page.



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.

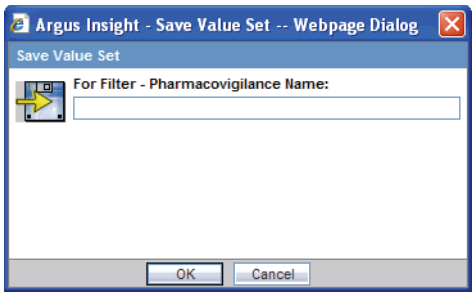


9. If required, modify the Value Set and examine the result again or proceed to save the Value Set.

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.

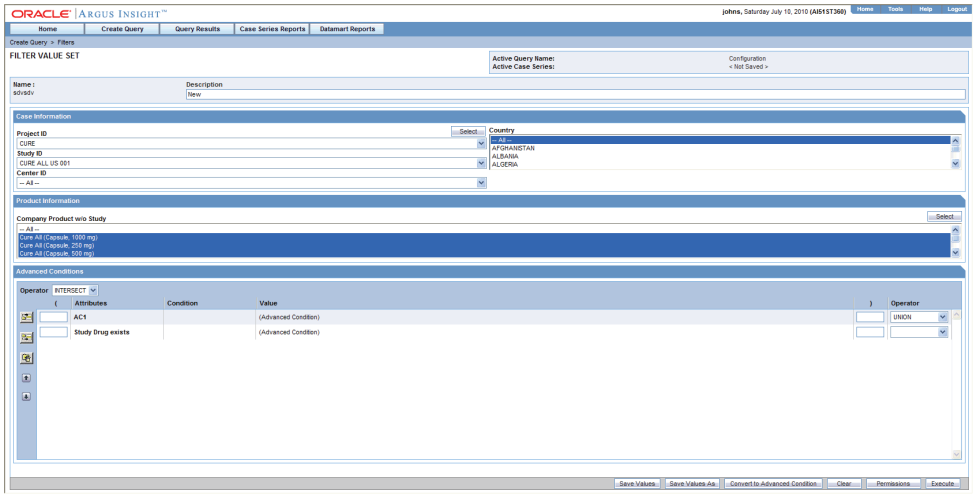
12. Click **Save Values**. The **Save Value Set** dialog box appears.



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**.

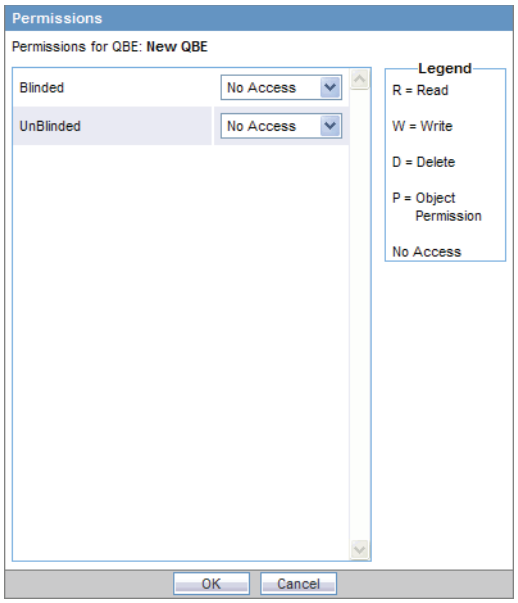


> **Note:** The **Filter Library** page displays the custom as well as predefined Filters and their Values Sets in a control tree format. From this page you can select a Value Set and directly execute it. See theWorking with Saved Filters and Value Sets topic for more information on the **Filter Library**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

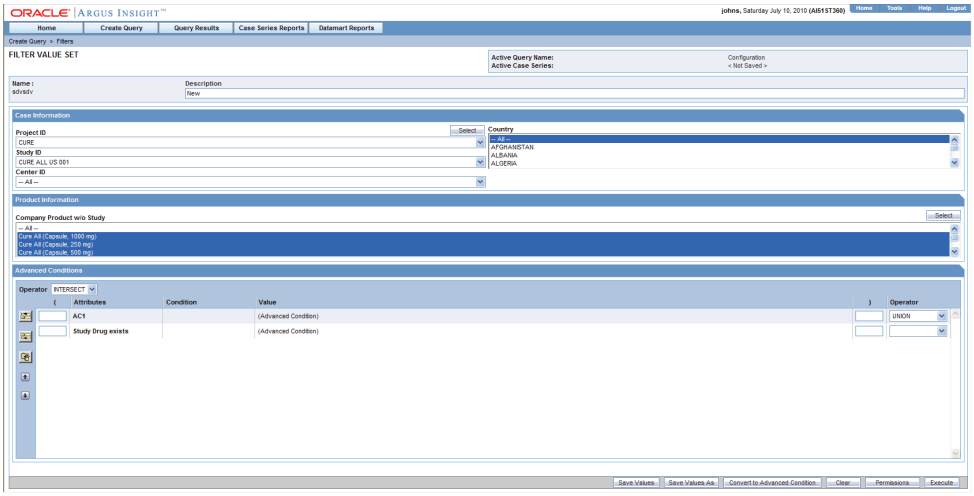
This topic explains how to view the Value Set you last modified or executed.

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**.**



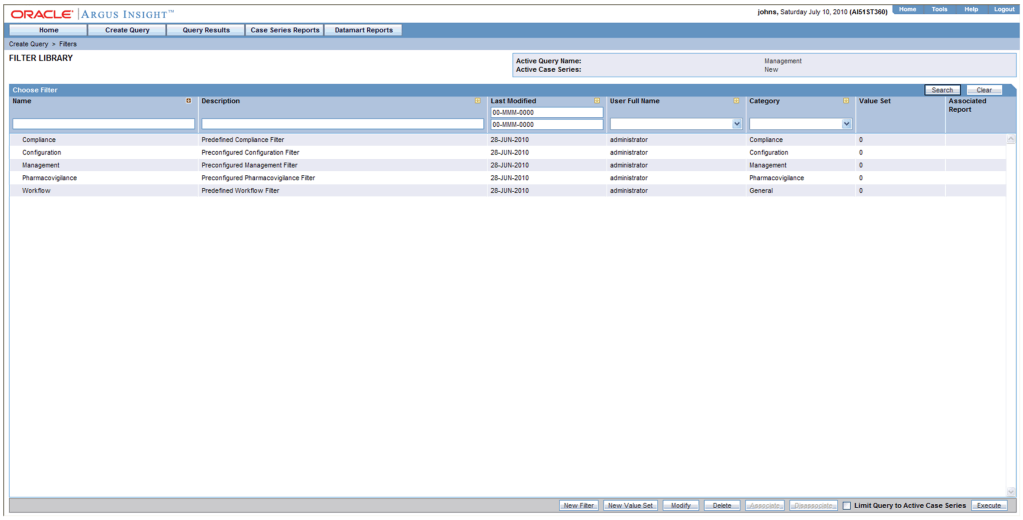
2. If the Value Set was saved to the system before executing, the name of the Value Set appears next to **Name** label. In addition, the name of the Filter appears next to the **Active Query Name** label.
3. However, if the Value Set was not saved to the system before executing, the text <Not Saved> 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.

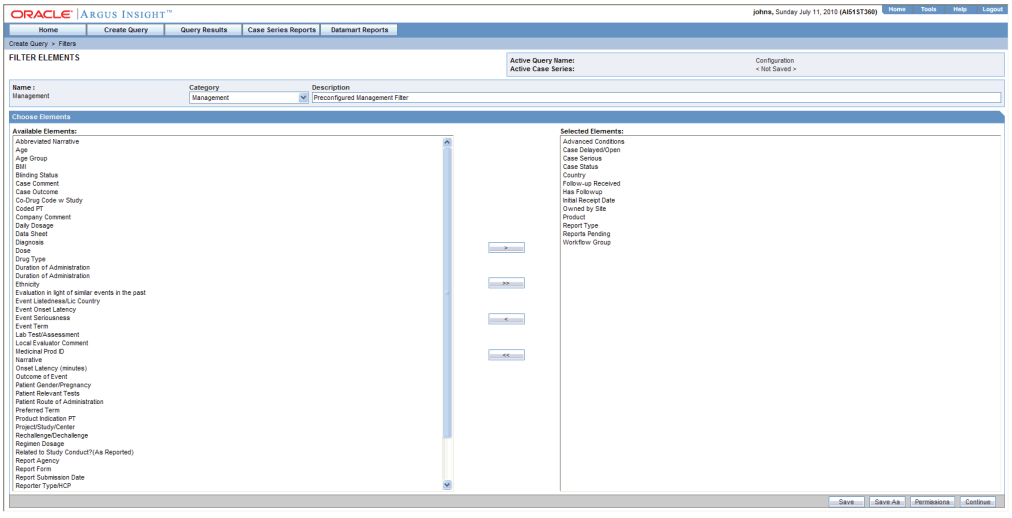
Creating a New Value Set

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.

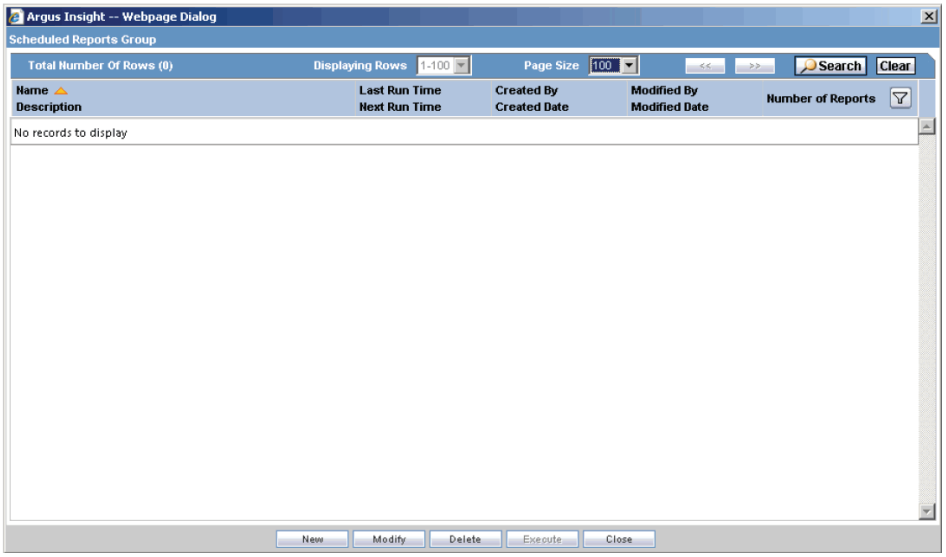
> **Note:** The user who is scheduling reports should have an enterprise login configured in Cognos to schedule the report.

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

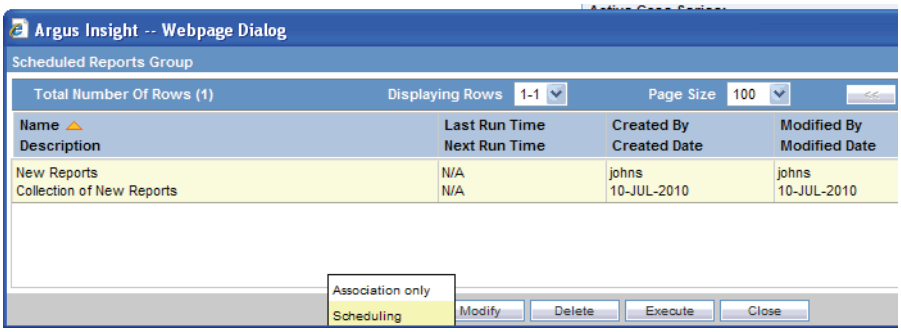
1. In the **Filter Library** page, select the Value Set that you wish to associate with a Standard Report.

   Associate the Value Set with a Standard Report.

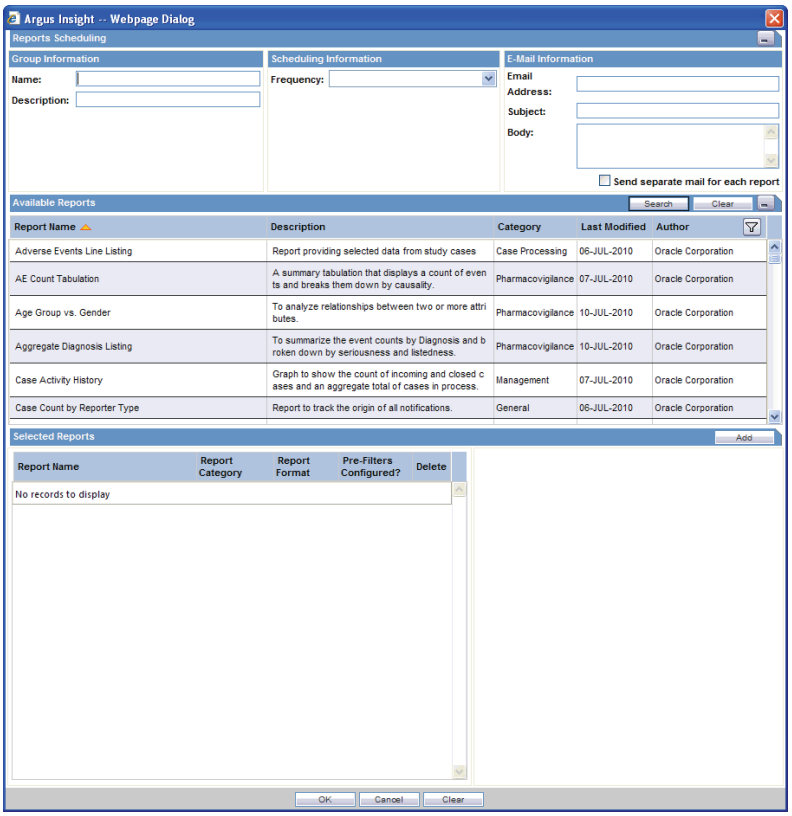
2. Click **Associate**. The **Scheduled Reports Group** dialog box appears. This page displays a list of all groups of reports which were scheduled or associated with the query.



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



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

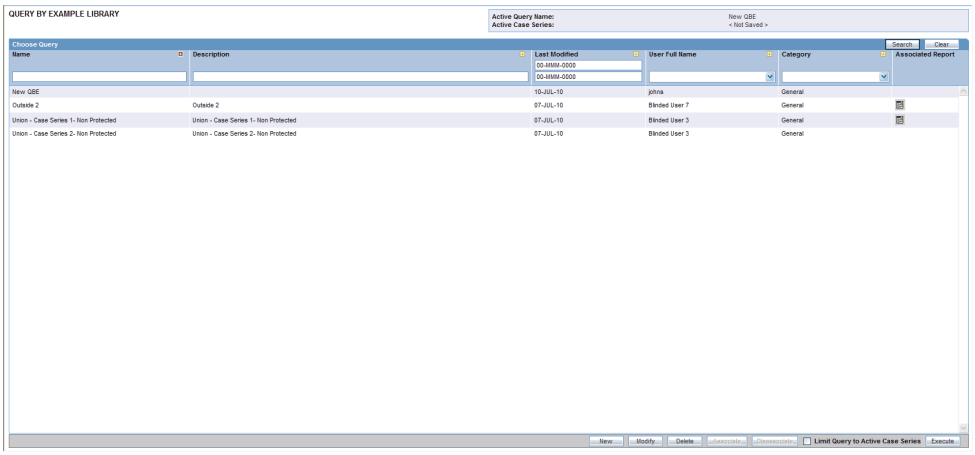


5. On this window, you can schedule multiple reports at once.
6. Schedule the report.
7. This window has 3 main sections:
   - **Scheduling Information** - The Schedule timing and E-Mail information.
   - **Available Reports** - All the available reports in the system that can be scheduled.
   - **Selected 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.

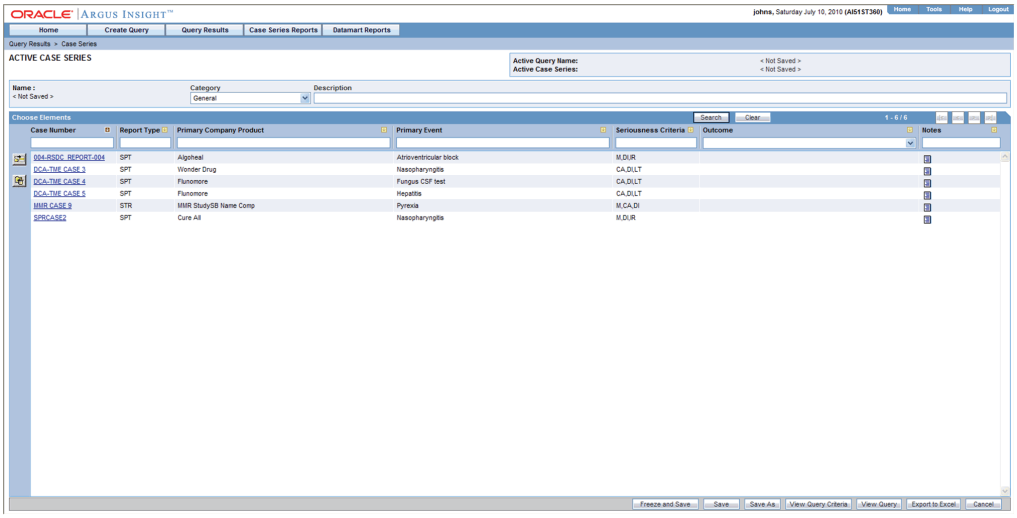


Note: Refer to the Associated Library and Query Library sections in the Library chapter, to view the steps on how to disassociate reports in those libraries.

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

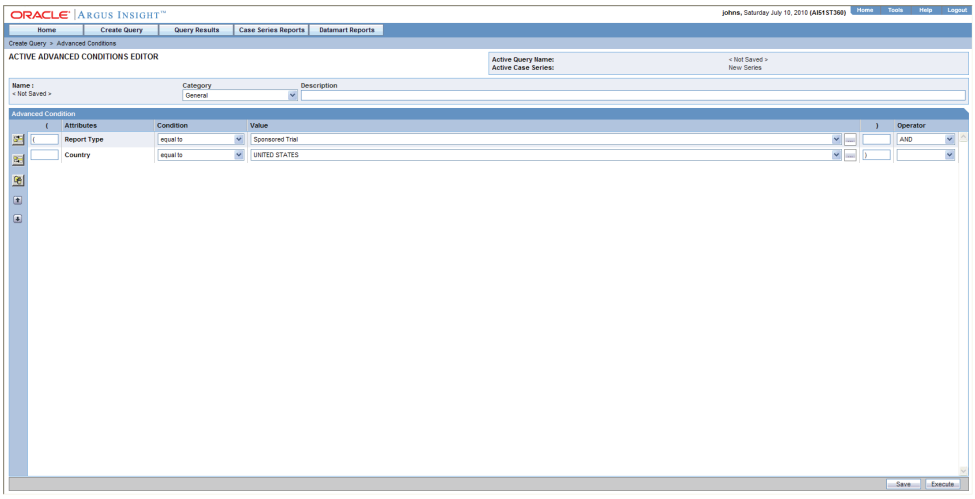
Converting a Value Set to an Advanced Condition

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

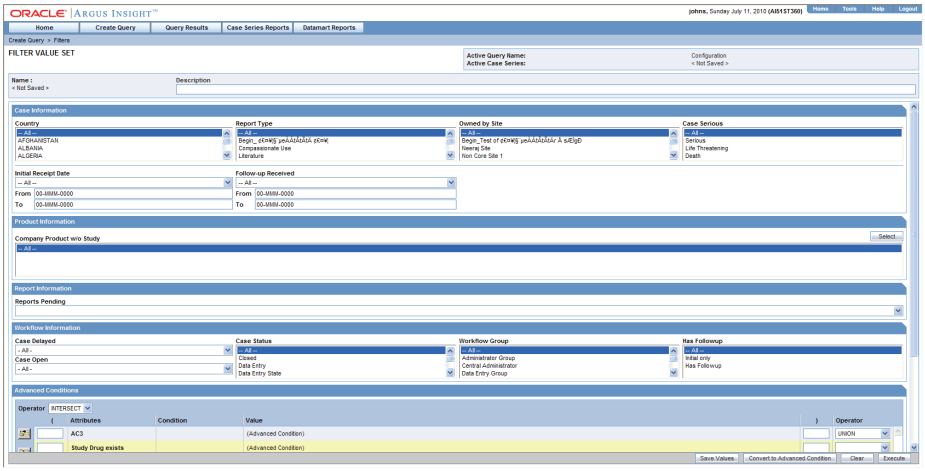
Argus Insight lets you integrate a Value Set with an existing Advanced Condition through these Set operators: Intersect, Minus, or Union. If required, you can integrate a Value Set with multiple Advanced Conditions. The multiple Advanced Conditions can have Set or Boolean operations between them.

> **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.

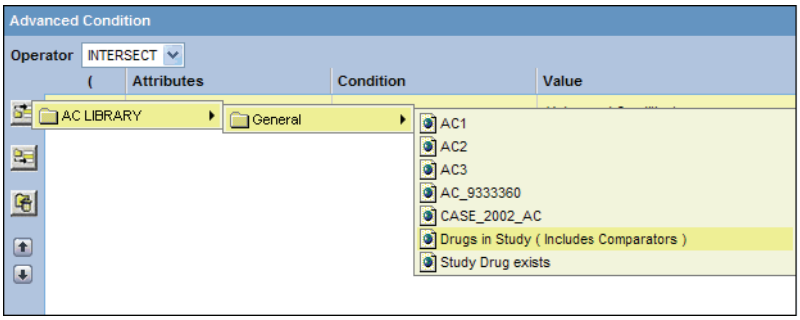
Use the following procedure to integrate a Value Set with existing Advanced Conditions.

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

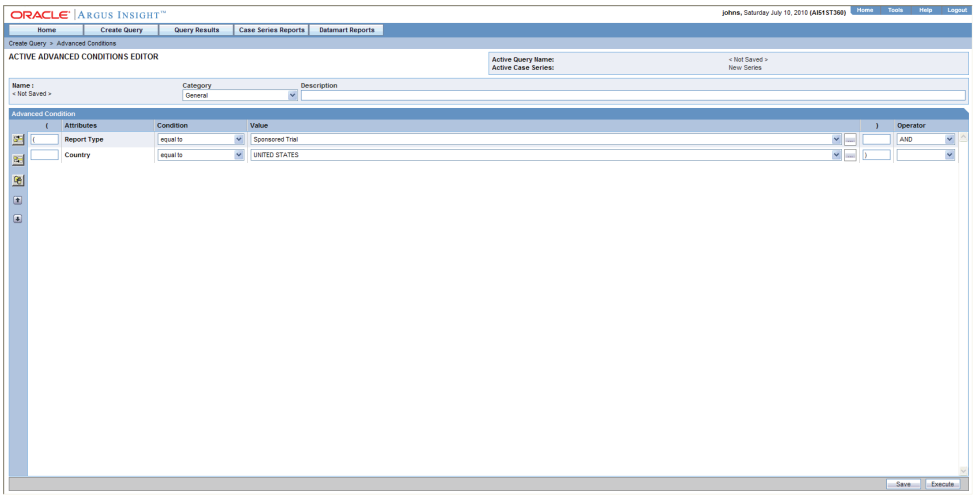
This topic explains how to:

- 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.



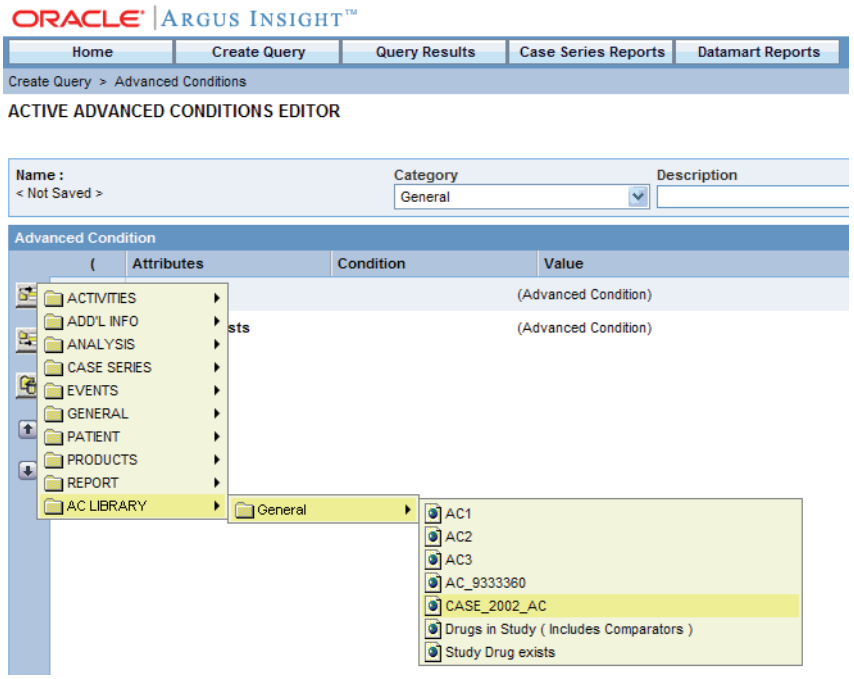
> **Note:** You can also start an Advanced Condition by converting a Advanced Condition or a *Filter* Value Set to Advanced Condition. See these topics for details: Converting a Advanced Condition to an Advanced Condition and Converting a Value Set to an Advanced Condition.

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

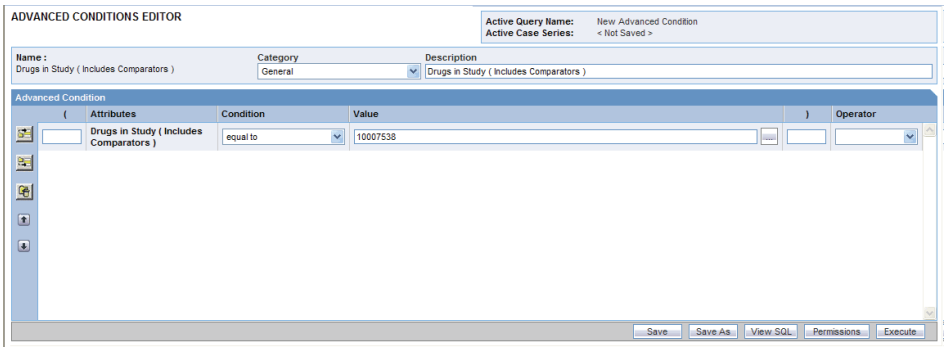
3. Click the context menu icon. A context menu appears. In the context menu, the first seven categories (**Activities**, **Additional Info**, **Analysis**, **Events**, **General**, **Patients**, and **Products**) represent the Argus case form tabs. In these categories, the various datamart fields that 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.



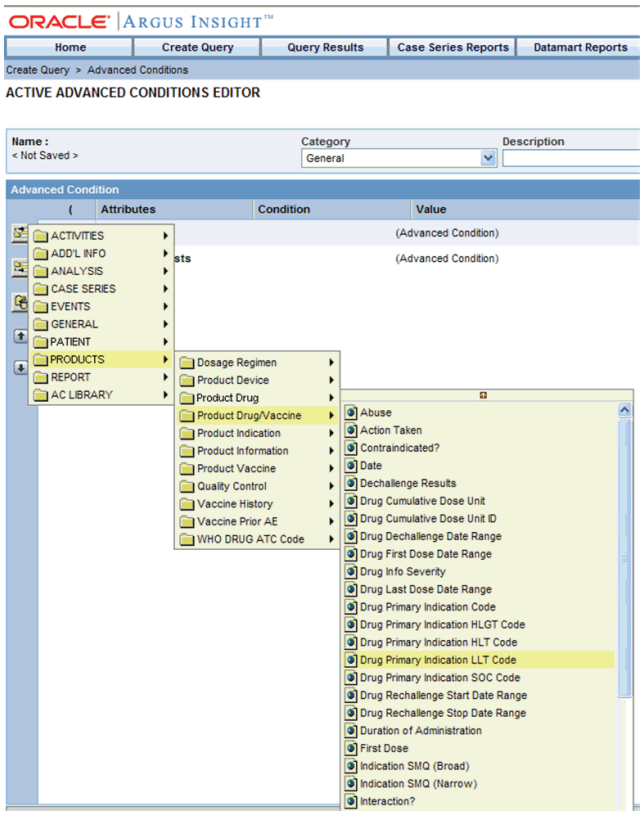
> **Note:** The user defined fields in Argus which have been converted as a look up are also available as attributes for the advanced condition search.

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.	

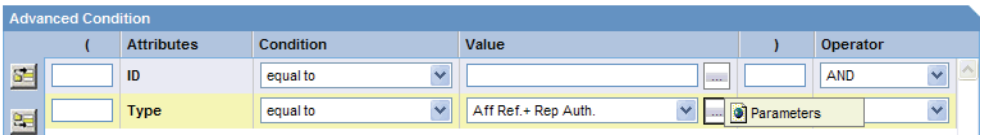
Tip: You can change the structure of the **Advanced Condition** query by changing the order of attribute rows in the editor. Use the following procedure to do this, select a row and click the Up or Down arrow buttons to move the row up or down. To delete a row from the editor, select the row and click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

7. Specify runtime parameters, as appropriate.

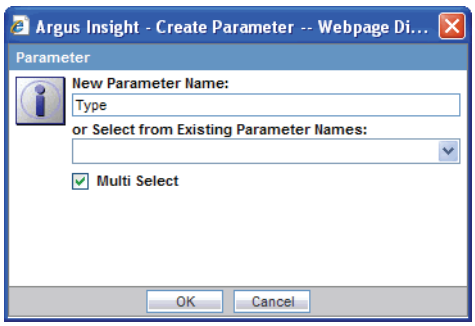
Note: Argus Insight lets you create Advanced Conditions which when executed, ask for user-specified values for certain attributes to generate the Case Series. For example, you may create an Advanced Condition in which the Case Number or the Product name may be specified only at the time of execution.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

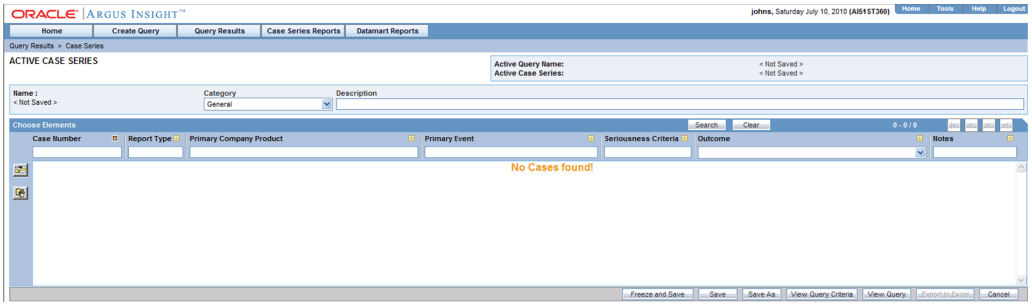
Tip: You may cancel the query execution at this point and return to the Advanced Condition Editor by clicking **Cancel Query** in the dialog box above.

- 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.

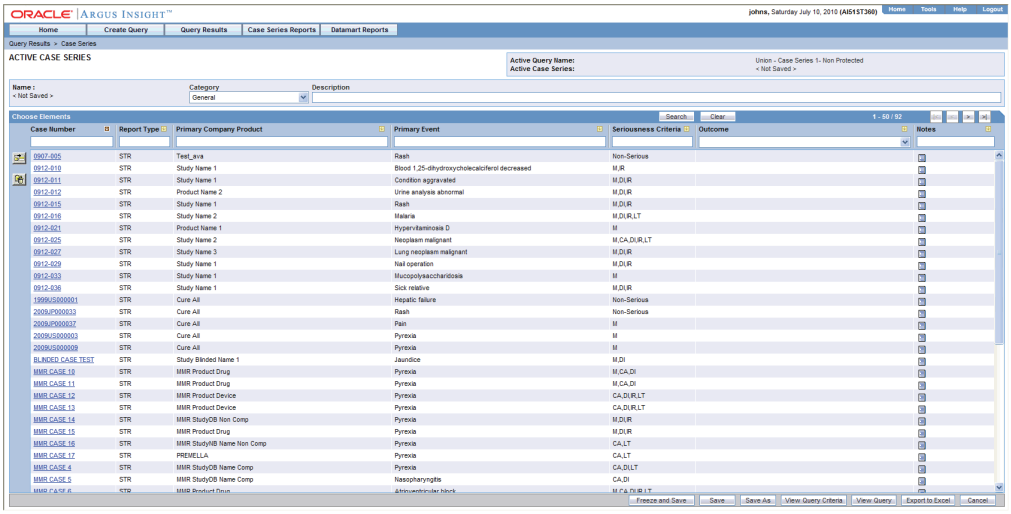
  Tip: If you select one run-time parameter and execute the search, you must enter a field.

  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.



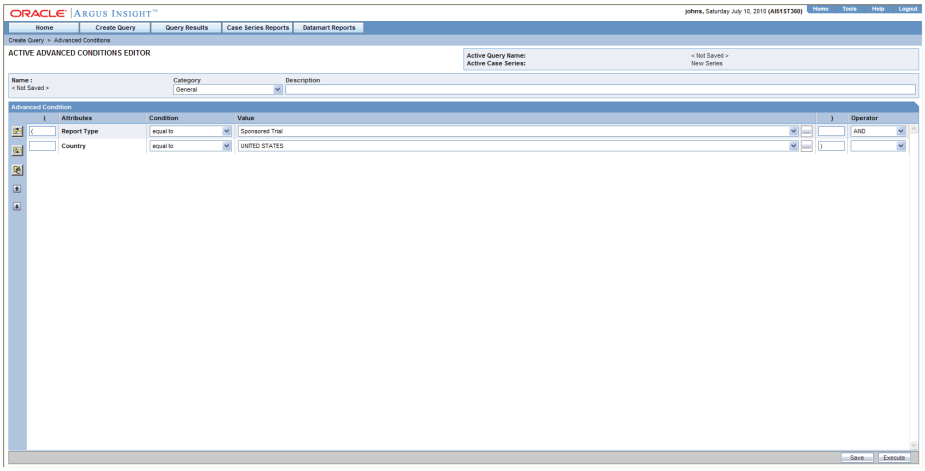
17. Examine the Case Series. If the Case Series is too large, you may want to modify the Advanced Condition by specifying additional attributes or changing values. Alternatively, if you find the Case Series to be appropriate, you can save the Advanced Condition to the system.

    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.



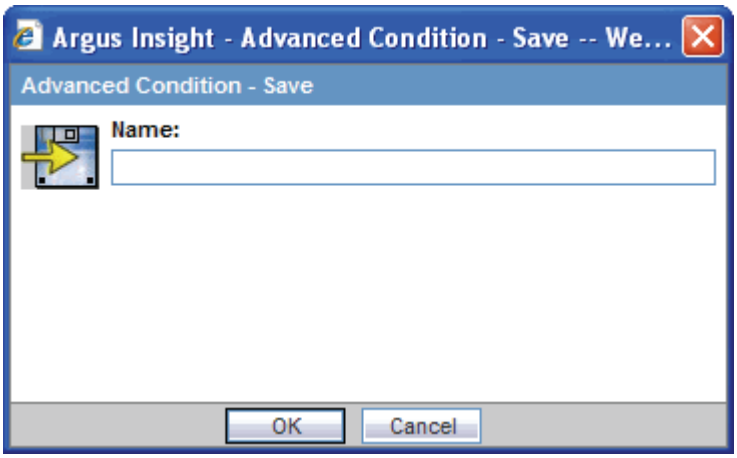
> **Note:** When you save the modifications to an Advanced Condition or execute it, the system assigns the Active status to the Advanced Condition. Therefore, when you return to the editor after executing the Advanced Condition, the page title changes to **ActiveAdvanced Condition Editor**. The field 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**.

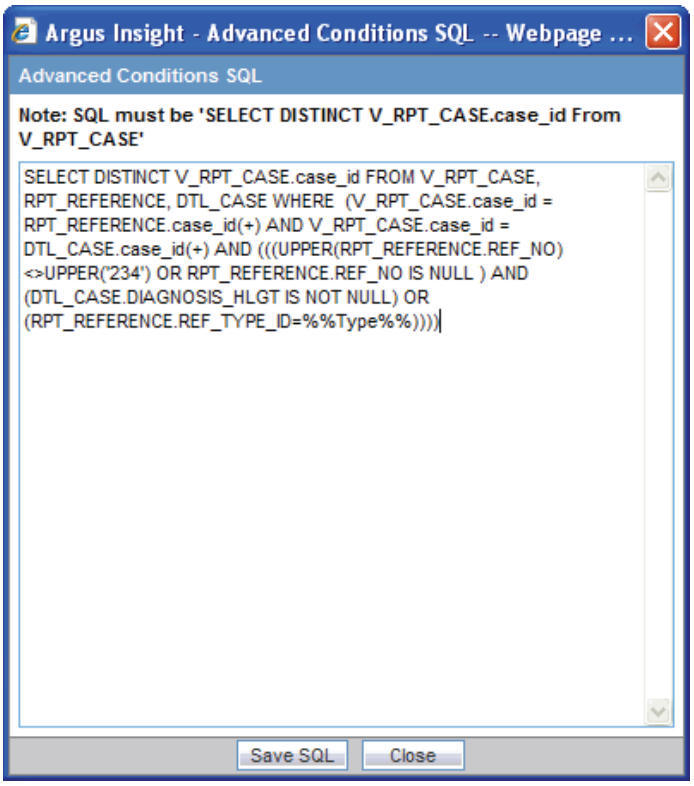
Note: All the Advanced Conditions that you save to the system are listed in the **Advanced Condition Library** page. TheWorking with Saved Advanced Conditions topic explains how to work with saved Advanced Conditions

---

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.

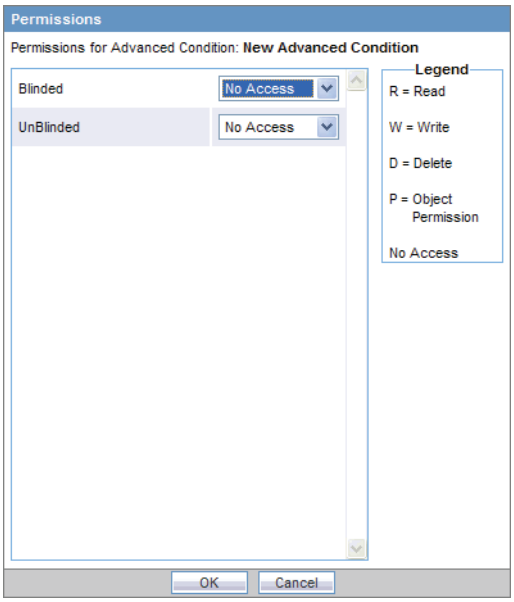
Note: When using this Save SQL functionality the Advanced Condition can be executed only from the Advanced Conditions library and the Query Library page.

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)

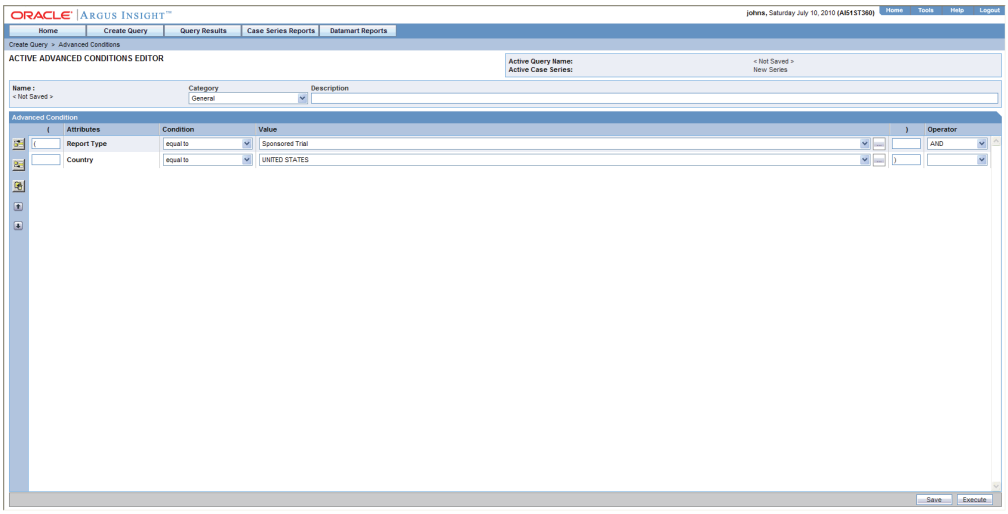
OR (v_rpt_case.country_id = 223))

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:

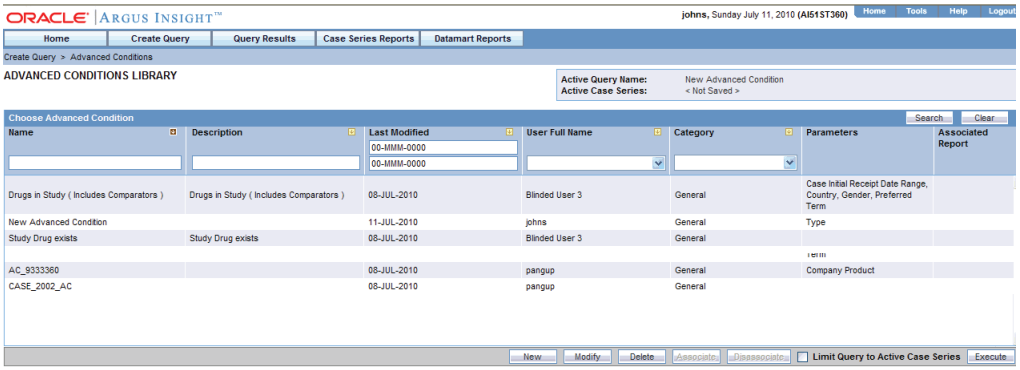
Task	Description
Modify the attributes in the Advanced Condition editor	If required, you can modify the attributes (fields and values) in the Advanced Condition editor. See theCreating a New Advanced Conditiontopic for information on working with the Advanced Condition editor. Use the **Save** button 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

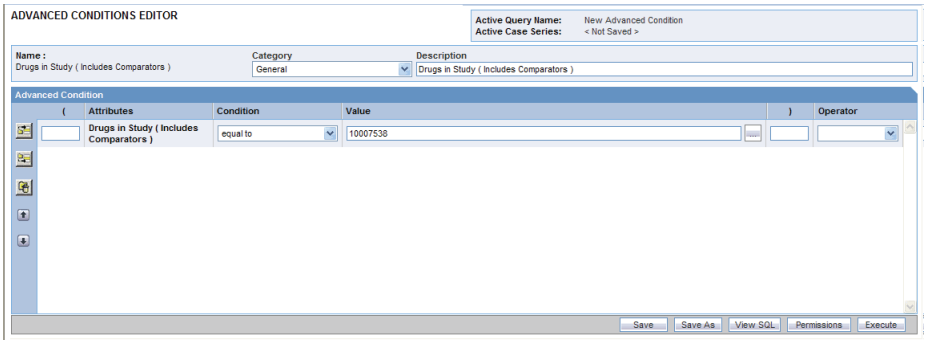
Use the following procedure to modify an Advanced Condition:

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.

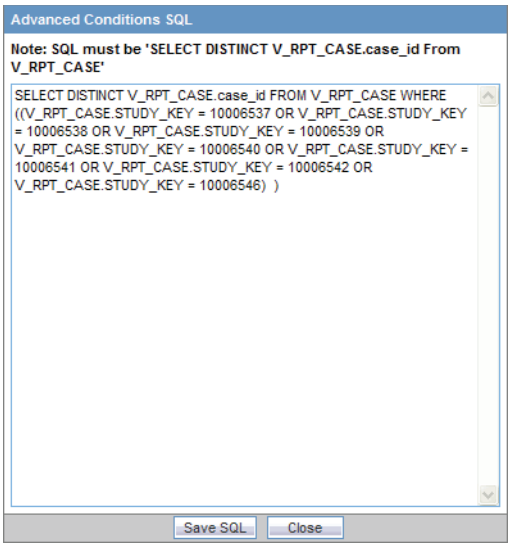
Modifying the SQL of an Advanced Condition

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.

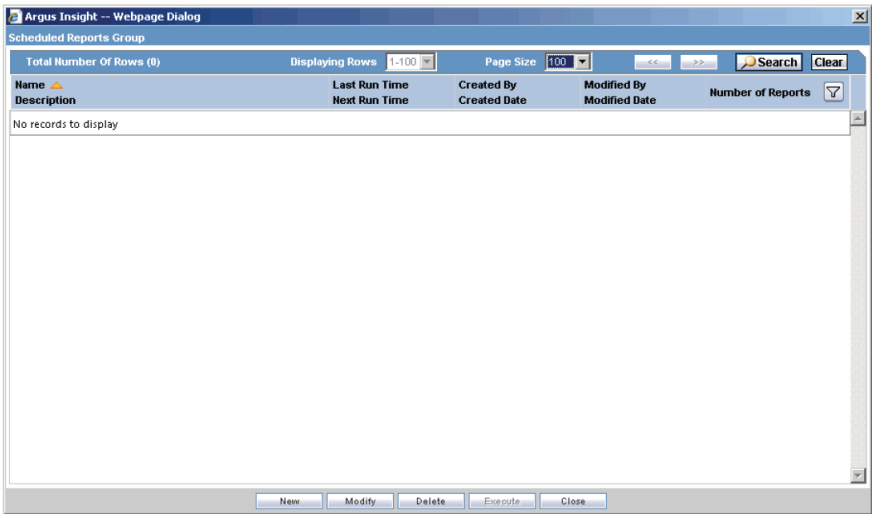
Associating an Advanced Condition with a Report

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:

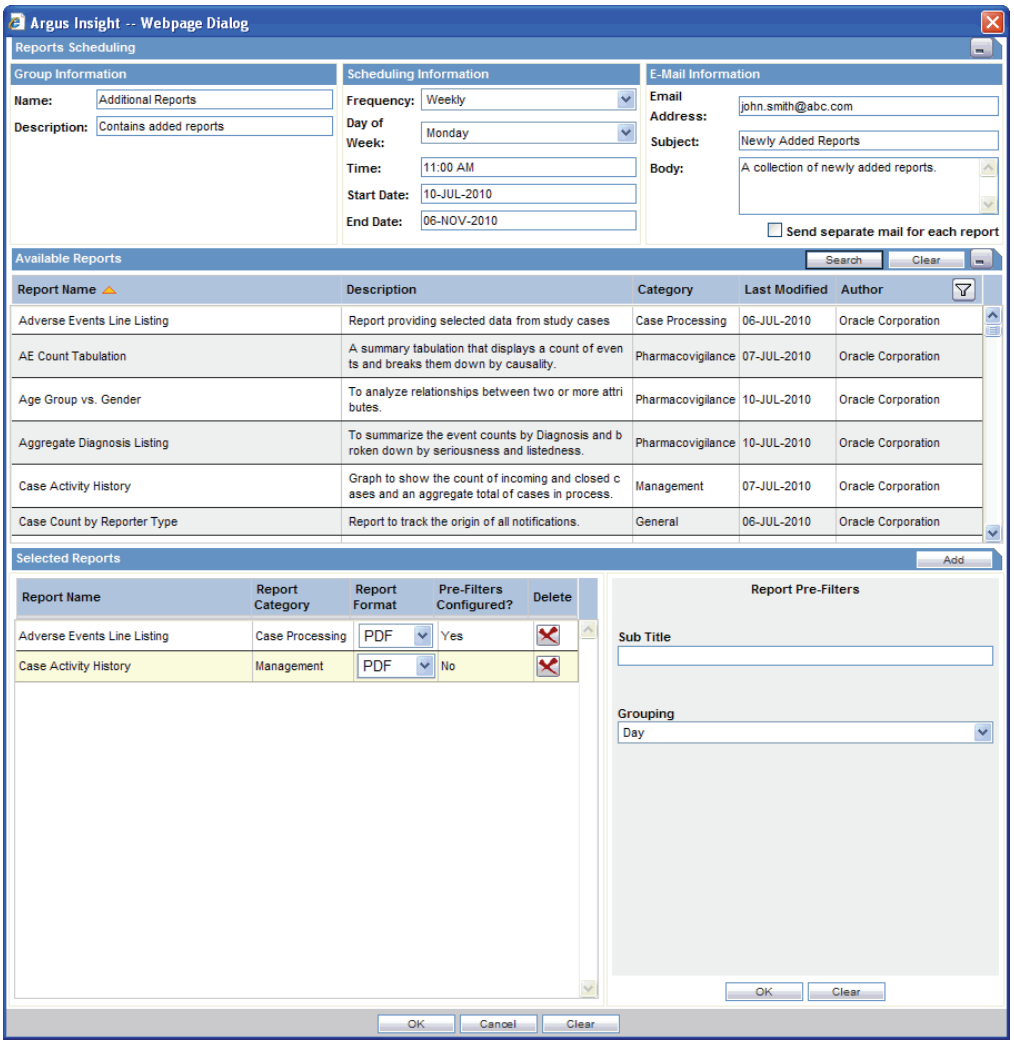
1. On the **Advanced Condition Library** page, select the Advanced Condition that you wish to associate with a Standard Report.
2. Associate the Advanced Condition with a Standard Report.
3. Click **Associate**. The **Scheduled Reports Group** dialog box appears. This page displays a list of all groups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

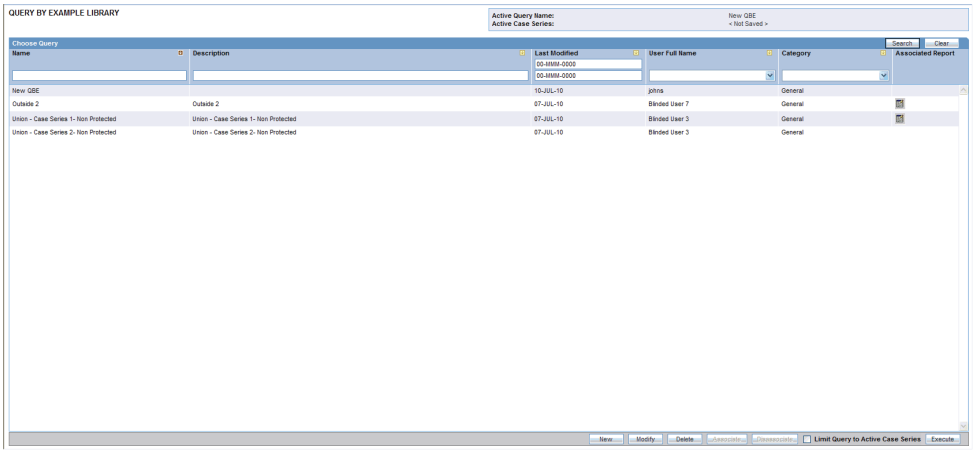


8. Provide a Name for your reports group along with description.
9. Use the **Frequency** list box to specify how often you wish to have the system run the selected QBE and generate the selected report. The options available are: **Once**, **Daily**, **Weekly**, **Monthly**, **Quarterly**, and **Yearly**.
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.

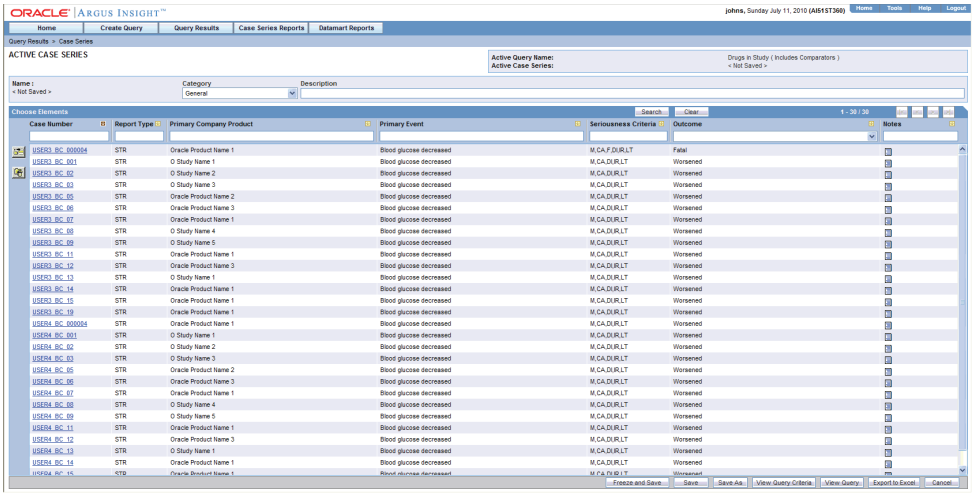


Refer to the Associated Library and Query Library sections in the Library chapter, to view the steps on how to disassociate reports in those libraries.

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.

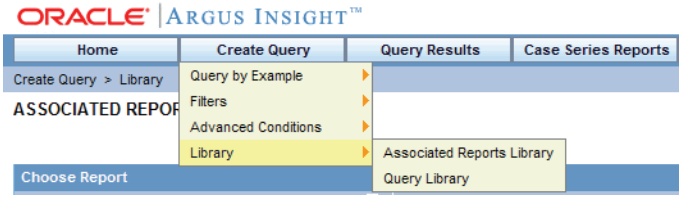
1. Generate the Case Series on which you wish to run another Value Set:
   - You can generate the Case Series by either using QBE, Filters, or Advanced Conditions. This Case Series automatically becomes the Active Case Series and remains so until you execute another query to generate a different Case 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

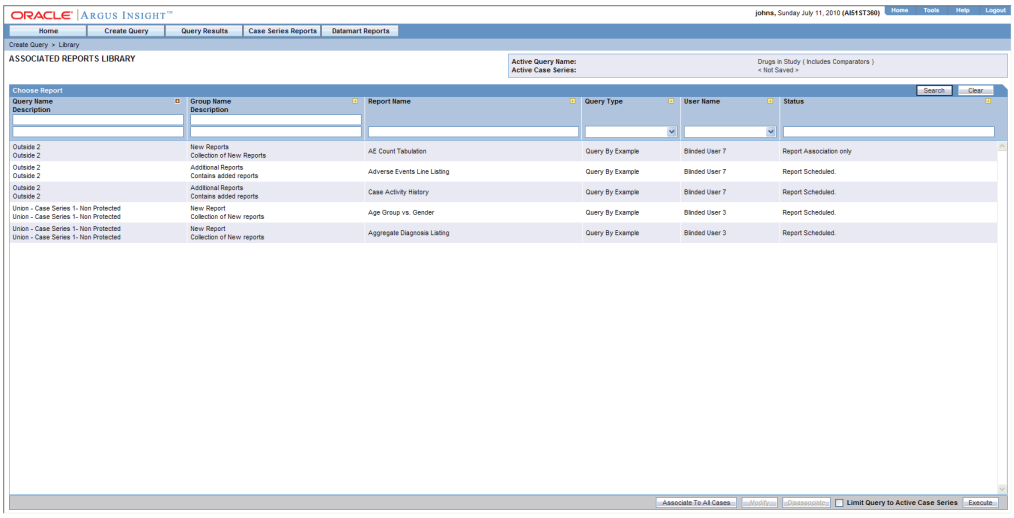
> **Note:** To use LDAP configuration in Argus Insight, your Cognos administrator must configure LDAP on the Cognos Server.

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:

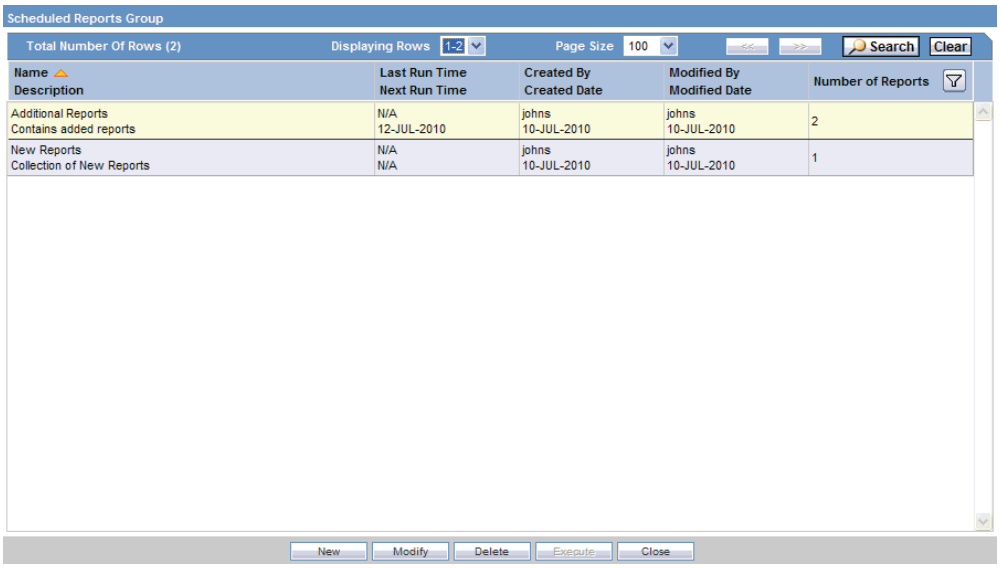
Column	Description
Name	Displays the name of the query that is associated with the report.
Description	Displays the description of the query associated with the report.
Last Modified	Displays the date when the query was last modified.
Query Type	Displays the type of query associated with the report.
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

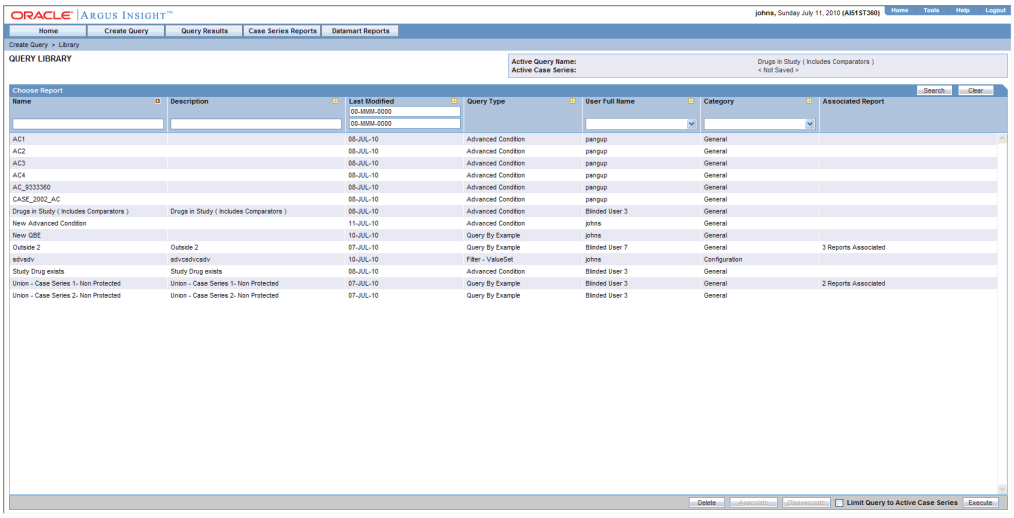
Use the following procedure to disassociate a report from the associated report library:

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:

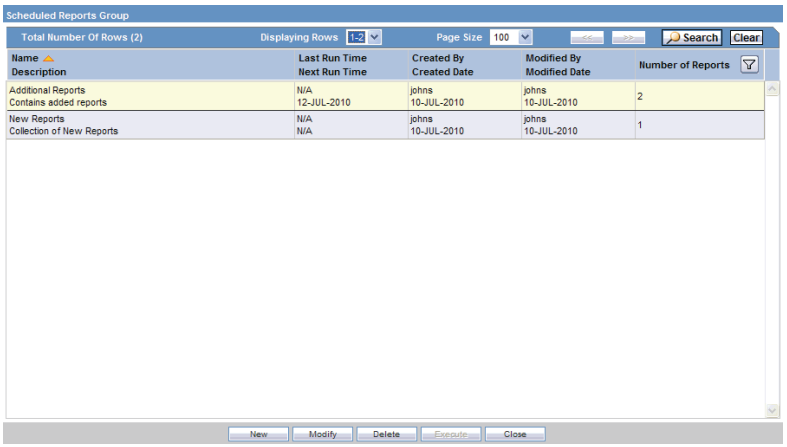
Column	Description
Name	Displays the name of the query.
Description	Displays the description of the query.
Last Modified	Displays the date when the query was last modified.
Query Type	Displays the type of query.
User Full Name	Displays the name of the author of the query.
Category	Displays the category 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:

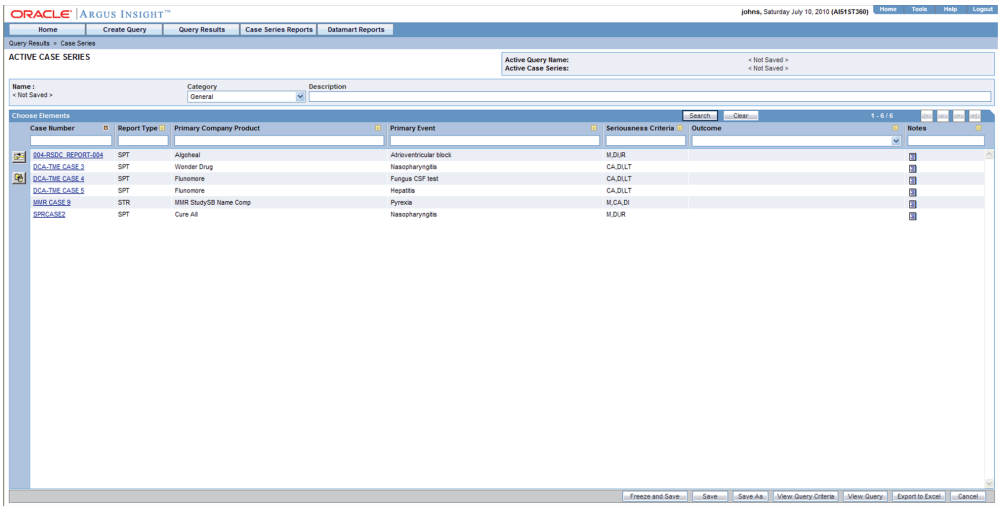
1. Select the report from the list in the **Query Library** page.
2. Click **Disassociate**.
3. The **Disassociate Report** dialog appears.
4. Click **OK**.

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 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:

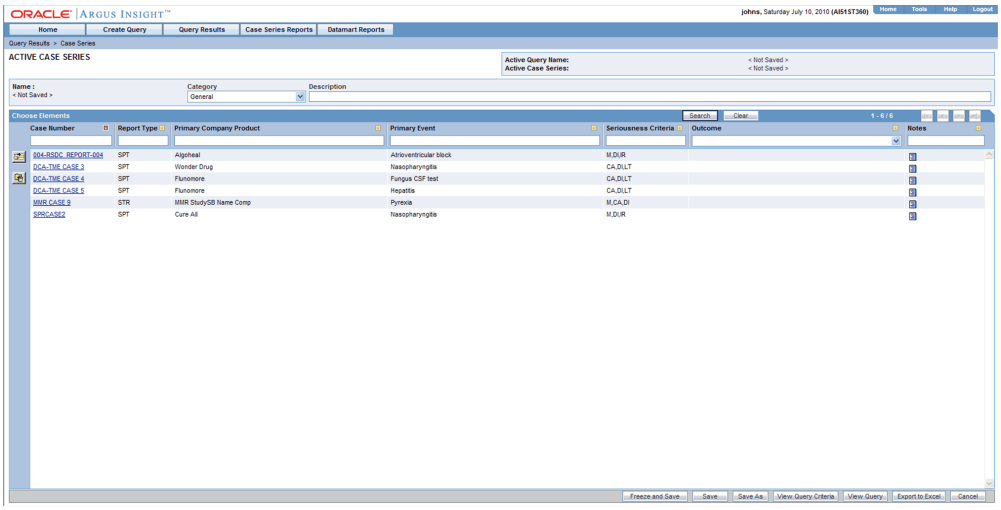
- Freezes the Case Series data that needs to be analyzed
- Displays case details using either the standard reports or the CIOMS II line listing (available in Insight) after the regular queries, case series, and their subsets are completed.

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.

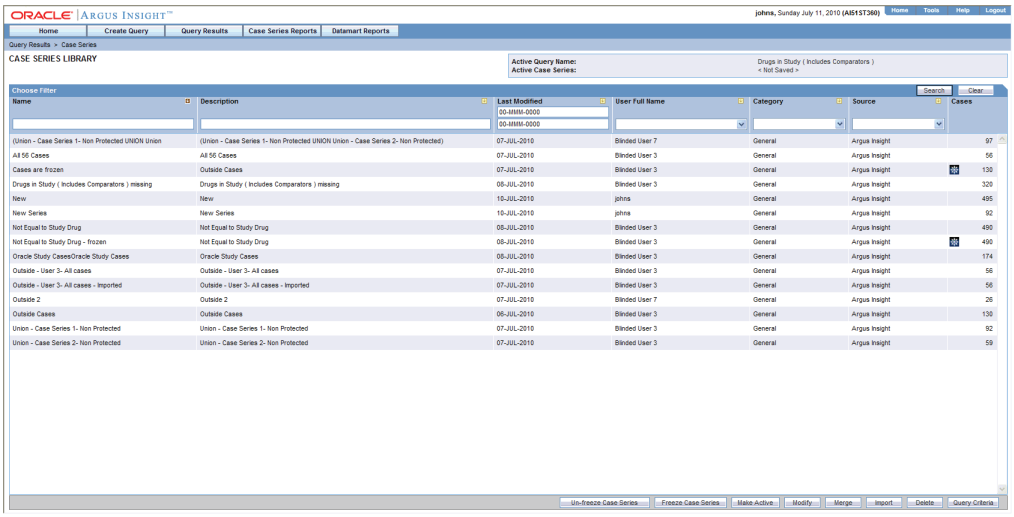
    The system freezes the case series and presents the user with the standard Case Series Save dialog. The user must enter the name of the saved case series.



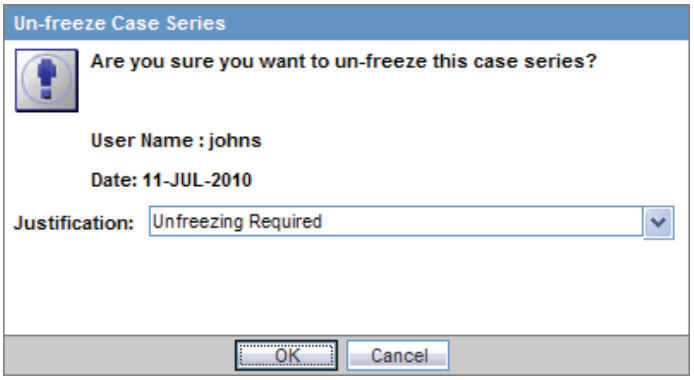
- If the user has not yet saved the case series from the active case series screen and clicks the Freeze and Save button, the system saves only one copy of the frozen case in the library. The frozen case series should then be the active case series.
- In the Case Series Library the User can view a frozen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

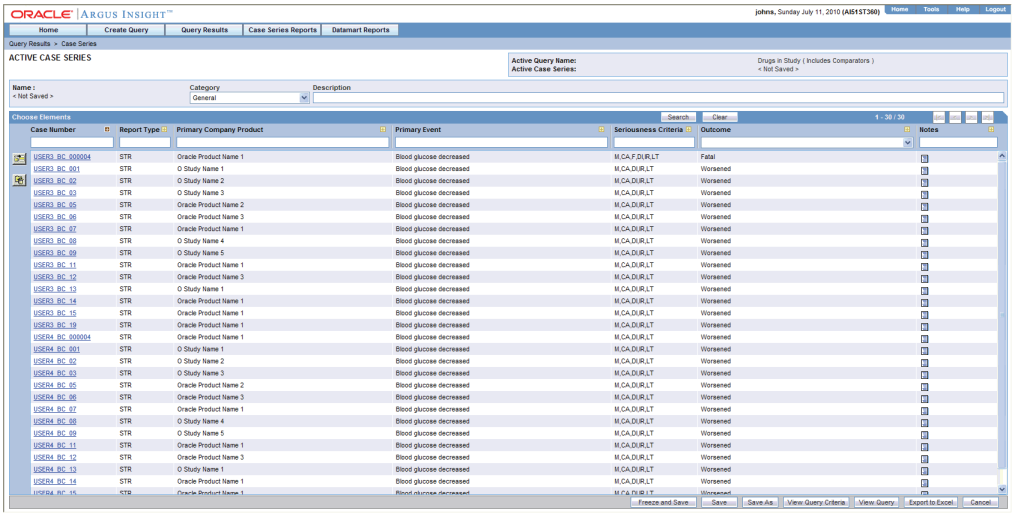
- Saving a Case Series
- Viewing Case Series Generation Criteria within the Query Interface
- Modifying the Case Series
- Deleting a Case from a Case Series

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.

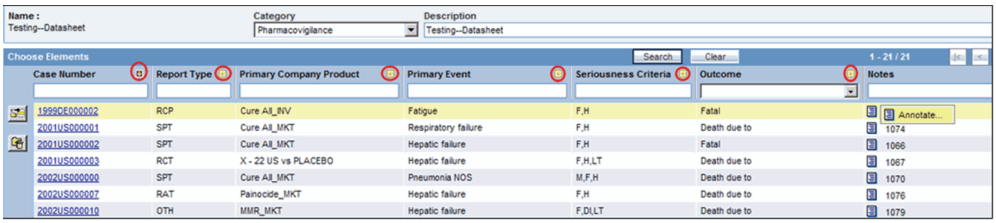


In the **Active Case Series** page, the **Active Query Name** label displays the name of the saved query (QBE, *Filter*, or Advanced Condition) that generated the Case Series. If the query was not saved, the label displays the text **<Not Saved>**.

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**

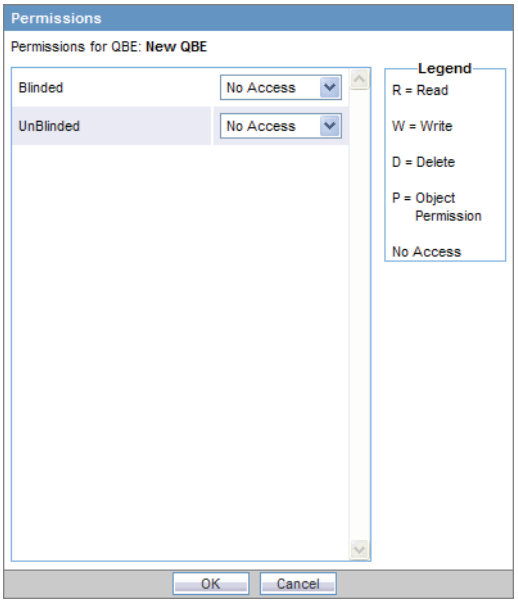
Setting Access Permissions

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

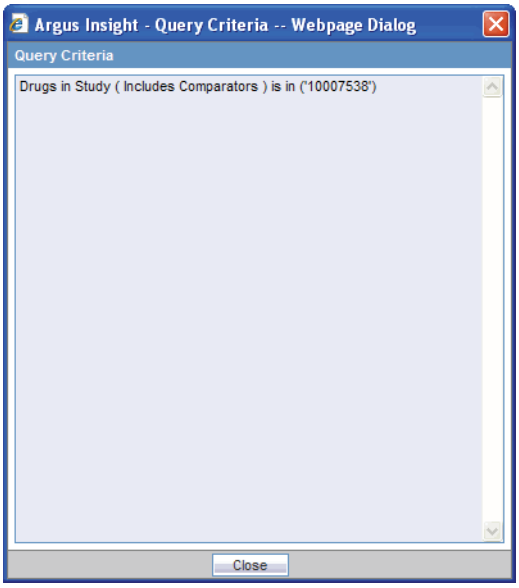
Note: The author of the Case Series always has the highest level of permission (R/W/D/P). For example, you belong to the Data Entry group and you assign the **No Access** permission level to the Data Entry group on a Case Series that you generate. In this case, while you will continue to have the highest 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.

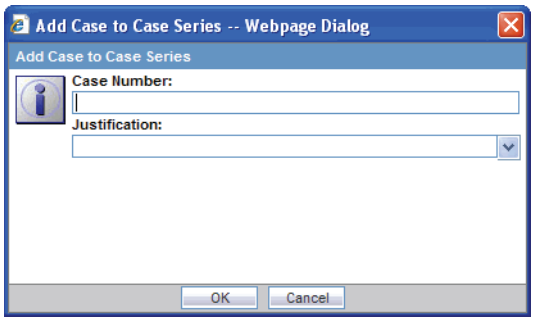
1. Click the **View Query Criteria** button to view the Case Series Generation criteria in a statement format within a dialog box.



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:

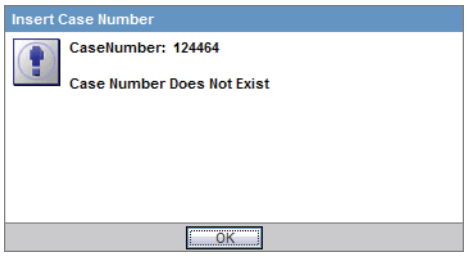
1. Click the icon on the left bar in the **Active Case Series** page. The **Add Case to Case Series** dialog box appears.



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.

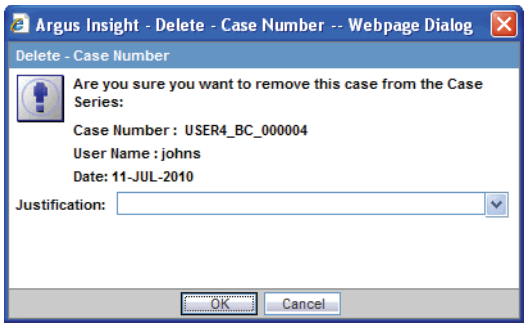


5. Click **Save As** to save the modified Case Series by another name. Note that if you have not yet saved the Case Series to the system, clicking either the **Save** or **Save As** buttons will prompt you to save the Case Series to the system by assigning a name to it.

Deleting a Case from a Case Series

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

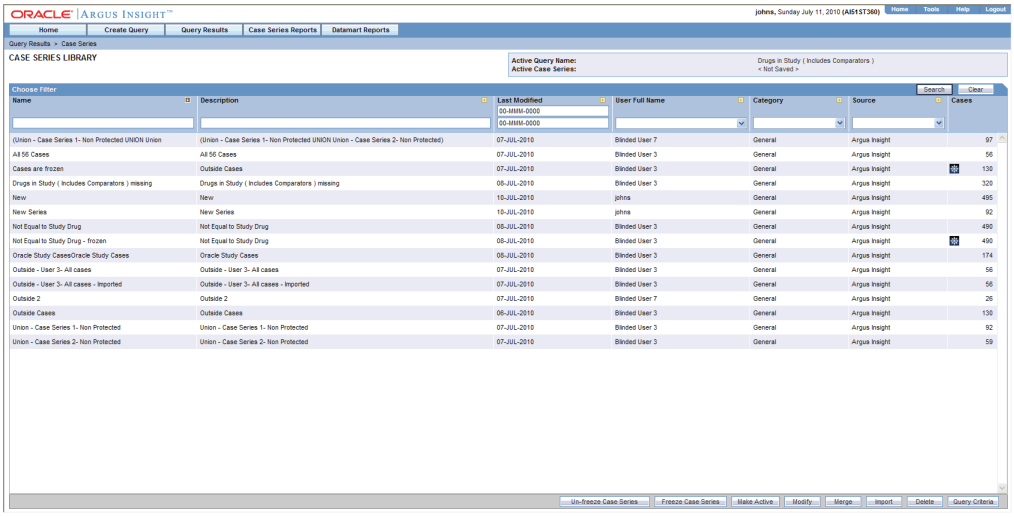
1. In the **Active Case Series** page, select the case you want to delete.
2. Click the icon on the left bar in the **Active Case Series** page. The **Delete Case Number** dialog box appears.



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 or CSV files

Column	Description
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.

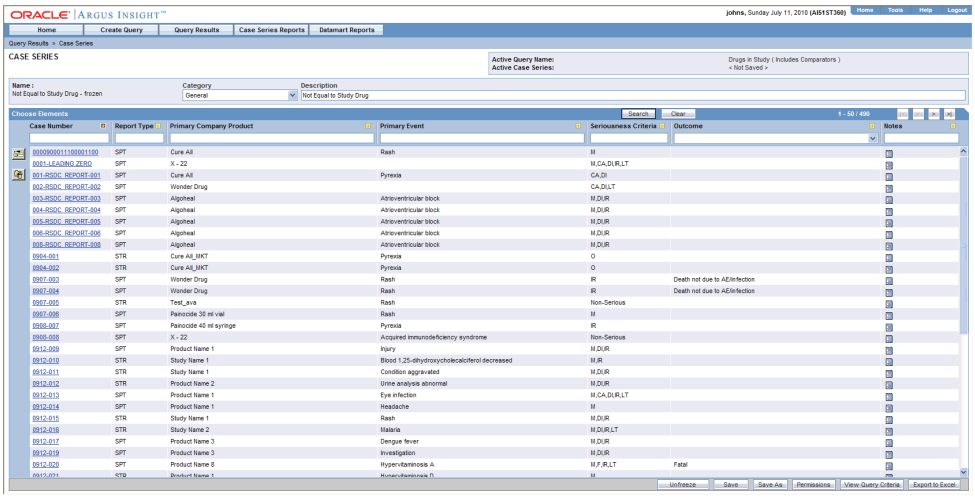
1. In the Case **Series Library** page, select the Case Series you want to make Active.
2. Click **Make Active**. The **Active Case Series** label in the upper-right corner of the **Case Series Library** page displays the name of the Case Series you made Active.

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.



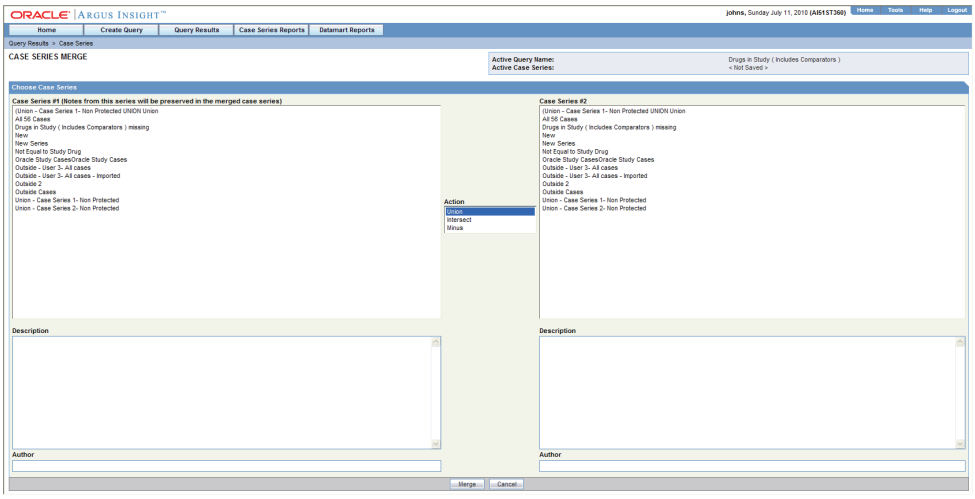
Merging Case Series

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.

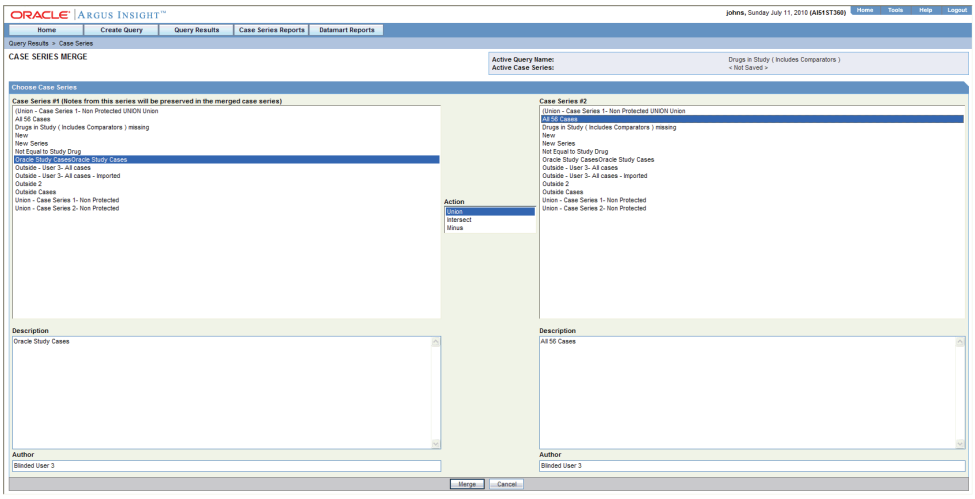
Use the following procedure to generate a merged Case Series:

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

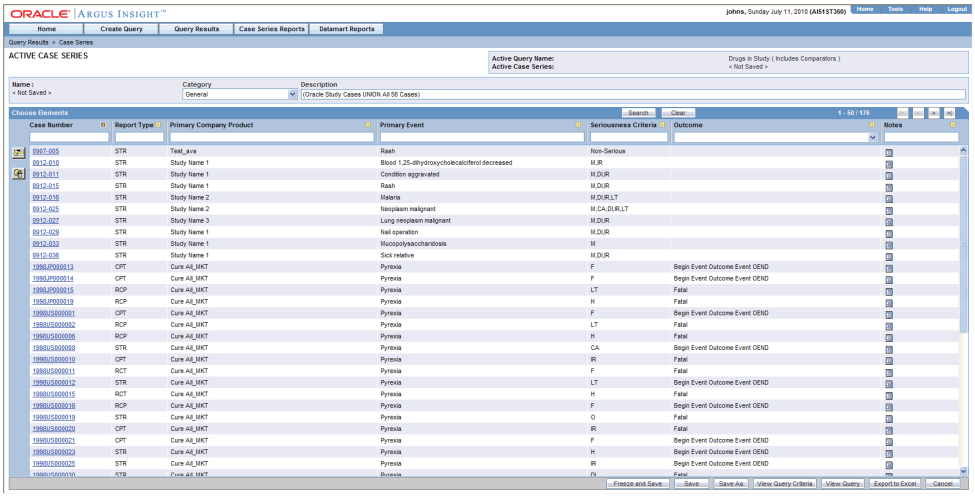


2. Select the two Case Series you wish to merge.
3. Select the first Case Series from the **Case Series # 1** list.
4. Select the second Case Series from the **Case Series # 2** list.

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.



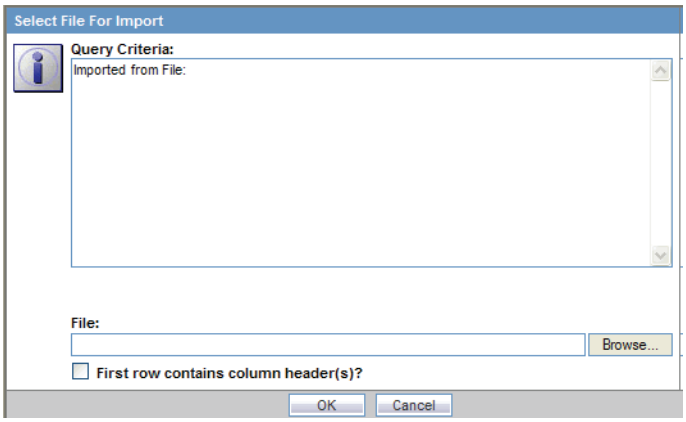
6. Click **Merge**. The system merges the selected Case Series and displays the resultant Case Series in the **Active Case Series** page.



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.

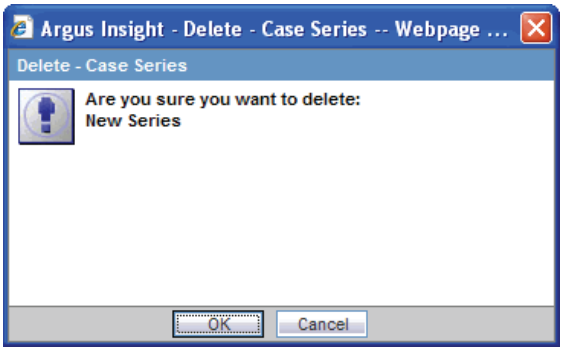
6. Click **OK** to view the imported Case Series in the **Active Case Series** page.

> **Note:** Case Series Import supports only Case Numbers that are separated by either an ENTER or a ';' character.

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.

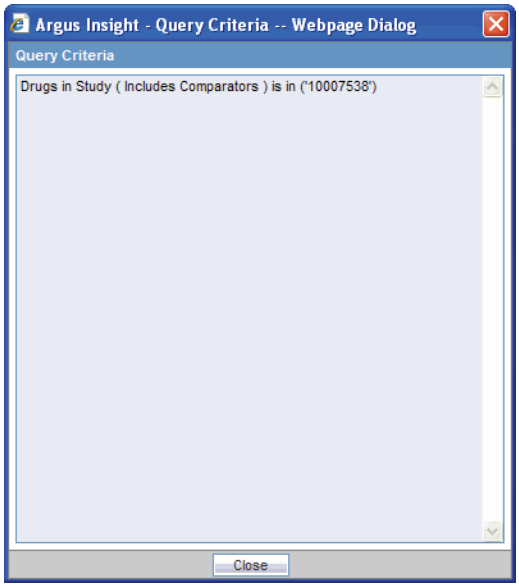


3. Click **OK**. The system deletes the selected Case Series; the **Case Series Library** page appears.

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:.

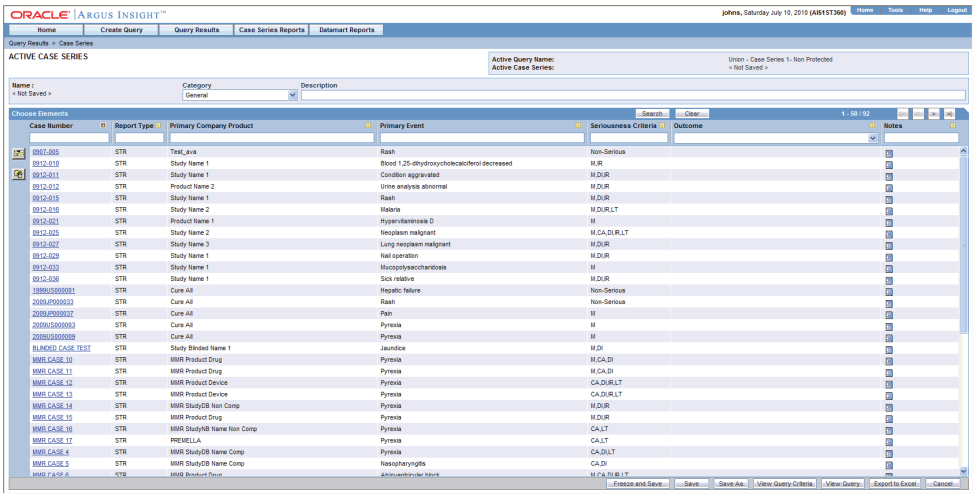
1. In the **Case Series Library** page, select a Case Series.
2. Click **Query Criteria**. The **Query Criteria** dialog box displays the criteria.



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.

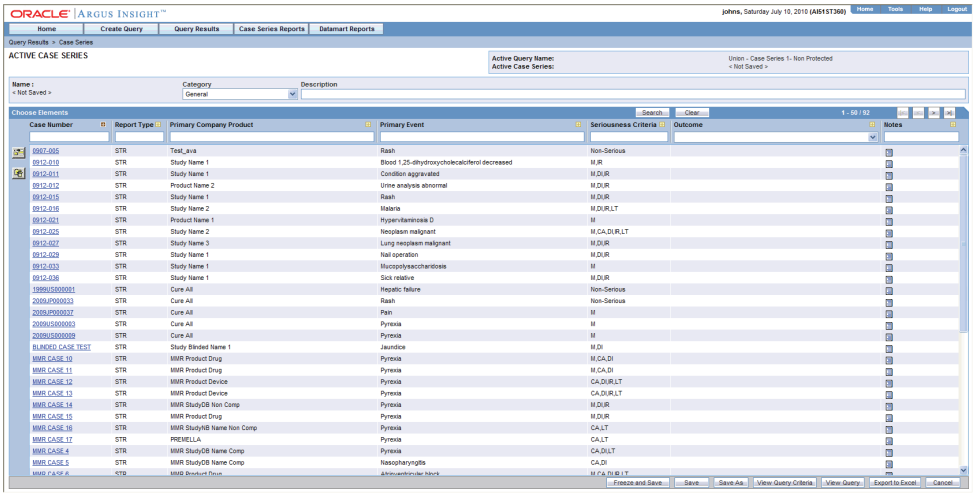
3. Save the case series using the **Save** or **Save As** feature.

> **Note:** Customers on Argus Safety 6.0 can share Frozen Case Series with Argus Insight 7.0.

Exporting Case Series to Excel

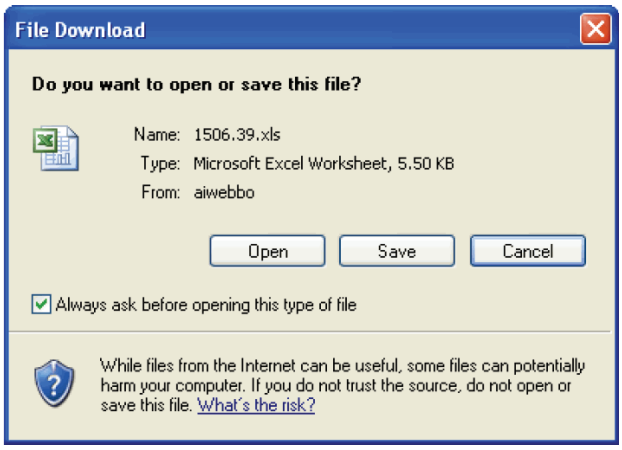
Use the following procedure to export a case series to an Excel file.

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							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							
20							
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

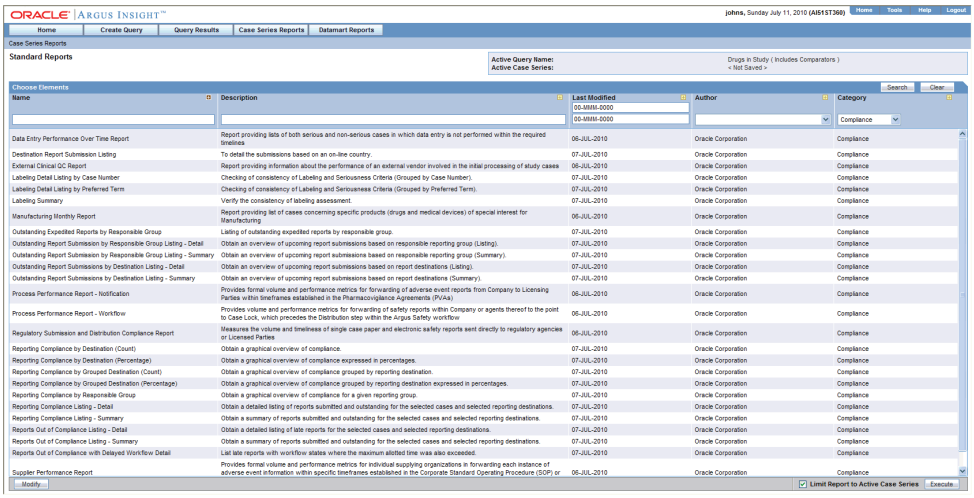
Before generating reports, you should be aware of information regarding the following:

- 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:

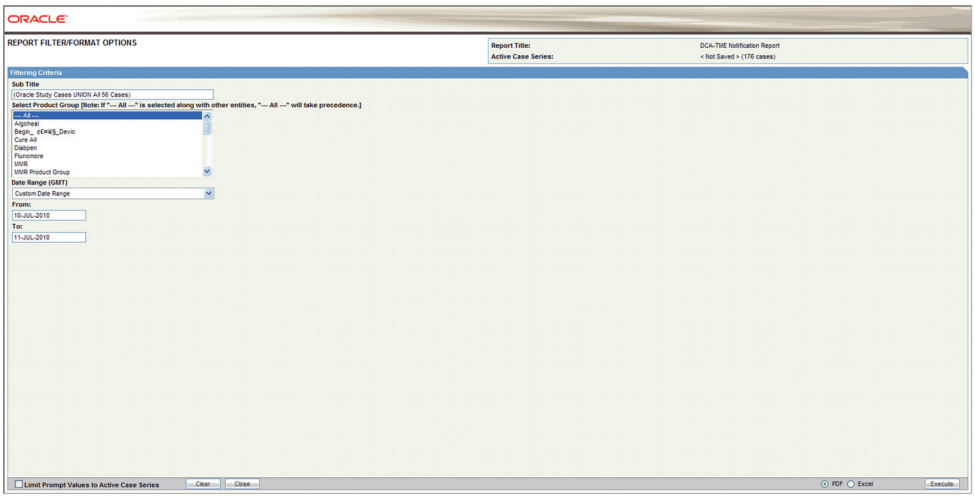
1. Select the **Case Series Reports > Standard Reports >Compliance**. The **Standard Reports** page displays a list of all the standard Compliance reports. The description of a report is displayed next to its name.



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.

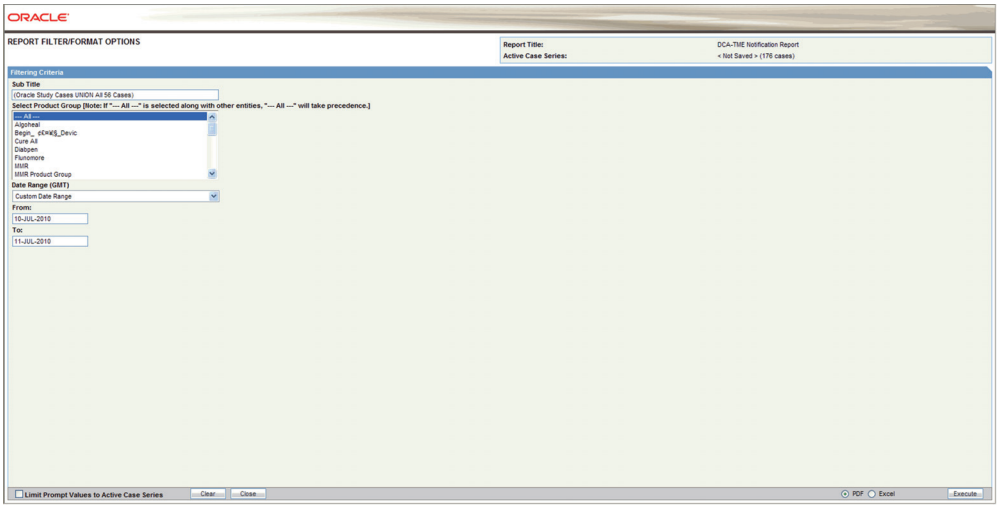
5. Specify the pre-filter options, as appropriate.
6. Select the **PDF** or **Excel** option button to specify the report output format.
7. Click **Execute** in the **Report Filter** page. The system generates the report output and displays it in the selected format. You can print this report or save 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.
- 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:

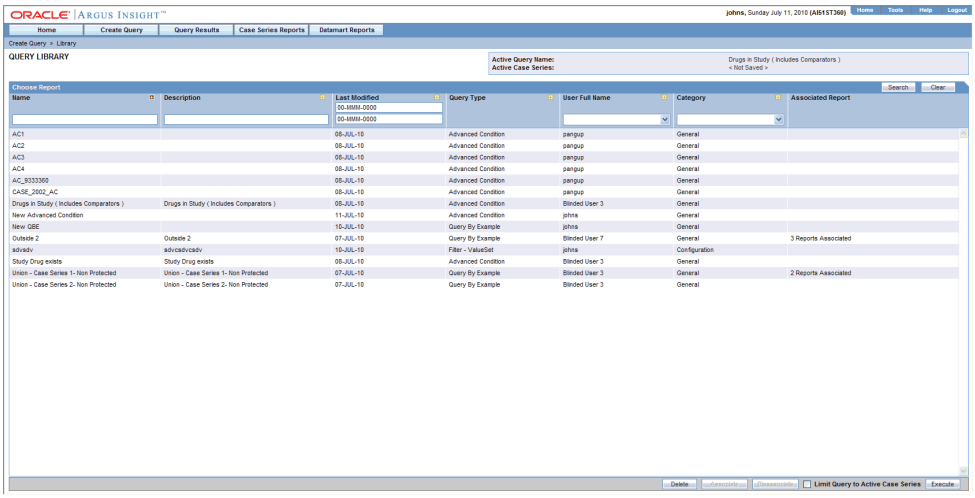
- Scheduling Multiple Reports Against a Single Query
- Scheduling a Report without a Query

Scheduling Multiple Reports Against a Single Query

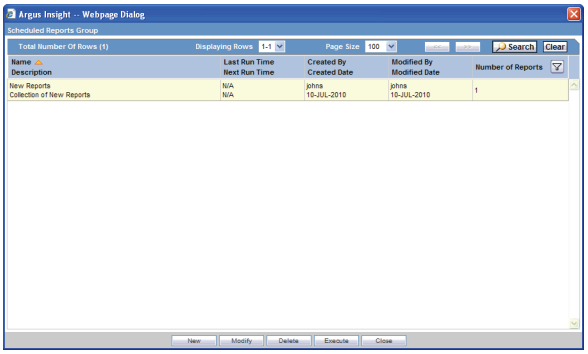
The system enables users to schedule multiple reports in a single query. A set of reports run on a weekly or periodic basis can be scheduled with the same report and run as a package.

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.

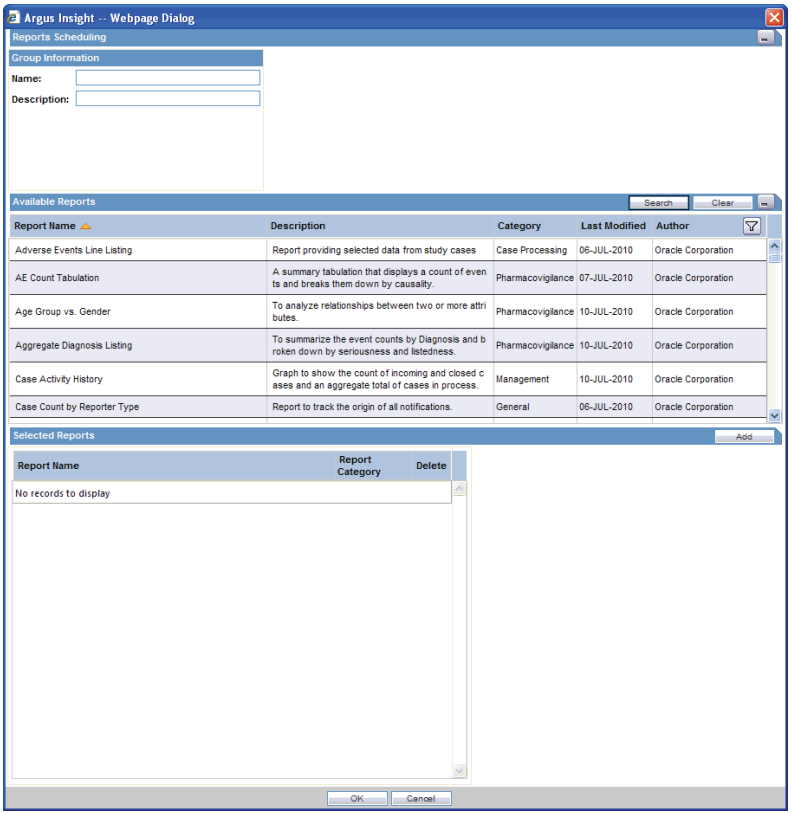


This window includes the following features:

- 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.

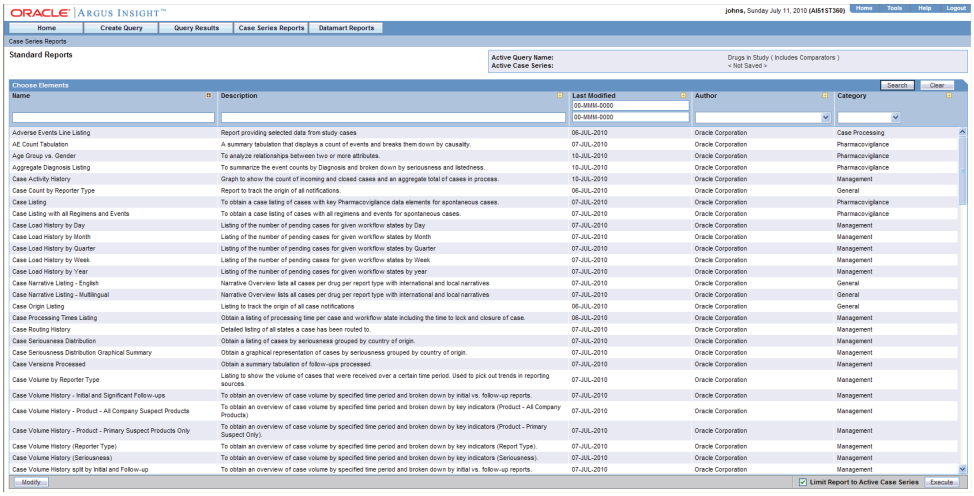
- This page has a button named "Associate to <All Cases>."

- 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.

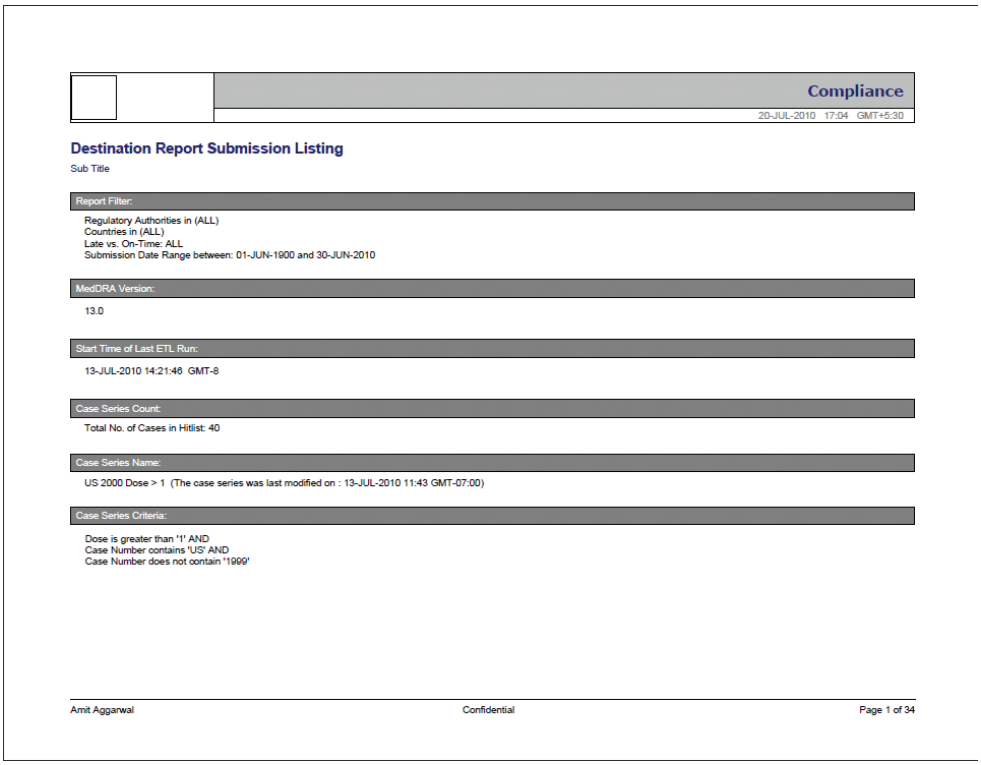
Column	Description
Name	Displays the name of the Standard Report
Description	Displays the Standard Report description
Last Modified	Displays the date when the Standard Report was last modified
Author	Displays the name of the Standard Report author
Category	Displays the Standard Report Category

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.

- 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.

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.
Global Audit Listing	Use this report to view case information relating to adverse event. This report is a listing of case information relating to adverse event, listedness, seriousness, and submission record information for suspect products, used to support external audit.
KPI List Report Country Group 1	Listing of case submission information for submissions in Group 1 countries (countries with clock starting from first receipt globally) grouped by Agency (submission destination) to support compliance KPI generation.
KPI List Report Country Group 2	Listing of case submission information for submissions in Group 2 countries (countries with clock starting from receipt in that country, i.e aware date for domestic cases and generated date for foreign cases) grouped by Agency(submission destination) to support compliance KPI generation.
KPI Overview Report Group 1	Table of submission count, late submission count and overall compliance figures for submissions in Group 1 countries (countries with clock starting from receipt globally) grouped by Agency(submission destination) to support compliance KPI generation.
KPI Overview Report Group 2	Table of submission count, late submission count and overall compliance figures for submissions in Group 2 countries (countries with clock starting from receipt in that country, i.e aware date for domestic cases and generated date for foreign cases y) grouped by Agency(submission destination) to support compliance KPI generation.
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.

Report Title	Description
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.
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 %.

Report Title	Description
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.
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
Audit Review Listing	This report provides a listing of case information in tabular format relating to adverse event, listedness, seriousness for Novartis suspect products, used to support internal audit.
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

Report Title	Description
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.
Clinical Medical Review List	This report provides a listing of serious clinical trial events grouped by study ID.
Detailed Line Listing by Case Number	This report is a listing of case details (suspect drugs, concom drugs, events, outcome, indication, narrative, demographics, relevant history) grouped by study number, center number, patient number and sorted by case number. Used to support data reconciliation process.
Detailed Line Listing by SOC	This report is a listing of case details (suspect drugs, concom drugs, events, outcome, indication, narrative, demographics, relevant history) grouped by SOC and sorted by SOC to support medical review, analysis and documentation. This listing is used widely and often provided to internal and external customers.
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).
MSE Review List For Non Serious SR	This report lists the basic case information(events, suspect drugs) - grouped by MSE (based on MSE-Drug responsibility configuration) to assist MSE in weekly review of non-serious SR and unrelated CT cases
MSE Review List for Unrelated CT	This report lists the basic case information(events, suspect drugs) - grouped by MSE (based on MSE-Drug responsibility configuration) to assist MSE in weekly review of non-serious SR and unrelated CT cases
Relevant Medical History listing	This report is a listing of all relevant histories for the selected cases.
SAE Clinical Trial Co-Medication	This report is a listing of case concomitant medication details - sorted by case number. Used to assist medical investigation.
SAE Clinical Trial Detail Listing	This report is a listing of case details(events, demographics, study details, treatment details) - sorted by case number. Used to assist medical investigation.
SAE Clinical Trial Laboratory Test	This report is a listing of case laboratory tests - sorted by case number. Used to assist medical investigation
SAE Clinical Trial Medical Conditions	This report is a listing of case current conditions, family history, past medical history - sorted by case number. Used to assist medical investigation.
SAE Clinical Trial Narratives	This report is a listing of case narratives and study details - grouped by protocol number and sorted by case number. Used to assist medical investigation.
SAE Clinical Trial Project Overview	This report is in tabular data of number of distinct cases and receipt date range, create date range flags - grouped by protocol number, study number, report type.
Simple Line Listing by Case Number	This report is a listing of key case information - grouped and sorted by case number to provide high level overview and quick review.
Simple Line Listing by SOC	This report is a listing of key case information - grouped and sorted by SOC of primary event, drug, and case number to provide high level overview and quick review.

Report Title	Description
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 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.
Case Volume History - Initial and Significant Follow-ups	Use the following procedure to obtain 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	Use the following procedure to obtain 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	Use the following procedure to obtain an overview of case volume by specified time period and broken down by key indicators (Product - Primary Suspect Only).
Case Volume History (Reporter Type)	Use the following procedure to obtain an overview of case volume by specified time period and broken down by key indicators (Report Type).
Case Volume History (Seriousness)	Use the following procedure to obtain an overview of case volume by specified time period and broken down by key indicators (Seriousness).

Report Title	Description
Case Volume History split by Initial and Follow-up	Use the following procedure to obtain 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 Tabulation	Use the following procedure to compare the number of cases from each reporter type.
Delayed Workflow Listing by Case	Obtain a list of cases where the max time has been exceeded.
Delayed Workflow Listing by Workflow State	Obtain a list of cases where the max time has been exceeded.
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.
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.
Reports By Causality	Graph of number of reports processed grouped by case causality to verify workload, productivity. The counts show the number of case locks (initial or follow-up) with initial or follow-up information during the report period.
Reports by Country	Graph of number of reports processed - grouped by country of incidence and sorted by descending counts to verify workload, productivity. The counts show the number of case locks (initial or follow-up) for cases originating from that country during the report period.
Reports by Month	Graph of number of reports processed - grouped by month and sorted by numeric month to verify workload, productivity. The counts show the number of case locks (initial or follow up) in that month.

Report Title	Description
Reports By Product Family	Graph of number of reports processed - grouped and sorted by descending counts to verify workload, productivity. The counts show the number of case locks (initial or follow up) where the primary suspect is in that Drug Family during the report period.
Reports by Report Type	Graph of number of reports processed - grouped by report type; such as Spontaneous Report, Clinical Trial(non-PMS), PMS, or Literature. The counts show the number of case locks (initial or follow-up) during the report period.
Reports by Seriousness	Graph of number of reports processed - grouped by case seriousness to verify workload, productivity. The counts show the number of case locks (initial or follow-up) during the report period.
Reports by Year	Graph of number of reports processed - grouped by year and sorted chronologically. The counts show the number of case locks (initial or follow-up) in that year.
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.
Annual Product Review	This report is a listing of all cases for a drug family grouped by primary suspect drug, SOC and sorted by drug, SOC to review cases potentially associated with quality compliant or lack of efficacy.
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.

Report Title	Description
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
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.
Death Cases	This report provides the listing of cases with death details, event details where the patient has had a fatal outcome - grouped by SOC.
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.
Duration of Treatment until Event (Time to onset) per Event	This report captures the table of event counts categorized by time to onset - grouped and sorted by event.
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.

Report Title	Description
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.
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.
Gender Group by Age Group	This report is required to capture the Gender Group by Age Group
MedDRA SOC-PT group report type, event seriousness, causality	This report is required to capture the Table of event, case count categorized by report type, event seriousness, causality - grouped and sorted by preferred term to support medical analysis.
MedDRA SOC-PT Group by Age Group	This report is required to capture the Table of event, case count categorized by chronological Age group - grouped by preferred term to support medical analysis.
MedDRA SOC-PT Group by Daily Dose	This report is required to capture the Table of event, case count categorized by Daily Dose bands - grouped and sorted by preferred term to support medical analysis
MedDRA SOC-PT Group by Gender	This report is required to capture the Table of event, case count categorized by gender - grouped and sorted by preferred term to support medical analysis.
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

Creating 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 five 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 topics that follow explain how to use the custom report tools.

- General Report Writer Information
- Creating a New Report
- Editing Reports
- Changing the Report Layout
- Saving and Accessing Saved Reports

General Report Writer Information

In this version of Argus Insight, *Report* Writer utilizes the features of Cognos® 8 Query Studio to let you create custom reports by directly selecting datamart fields and viewing the result (report output) on the fly. The Report Writer interface provides a list of database fields organized in a tree structure. Use the following procedure to create a report, expand the trees corresponding to the required database fields and select the fields to be displayed as columns in your report.

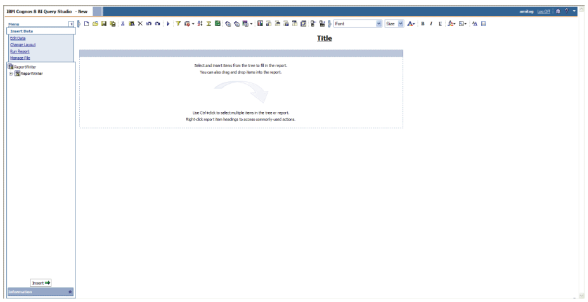
Once you have created your report, you can edit the report, change the report layout, run the report in specific formats, and save the report.

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

Creating a New Report

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**. Query Analysis starts. In the left frame, the **Insert Data** menu option is selected.

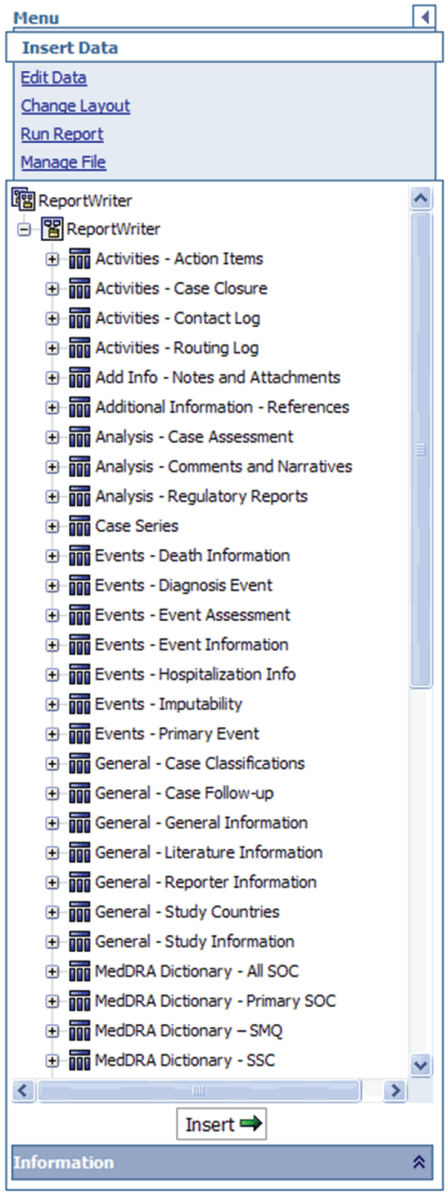


2. Select the Active Case Series *Filter*.

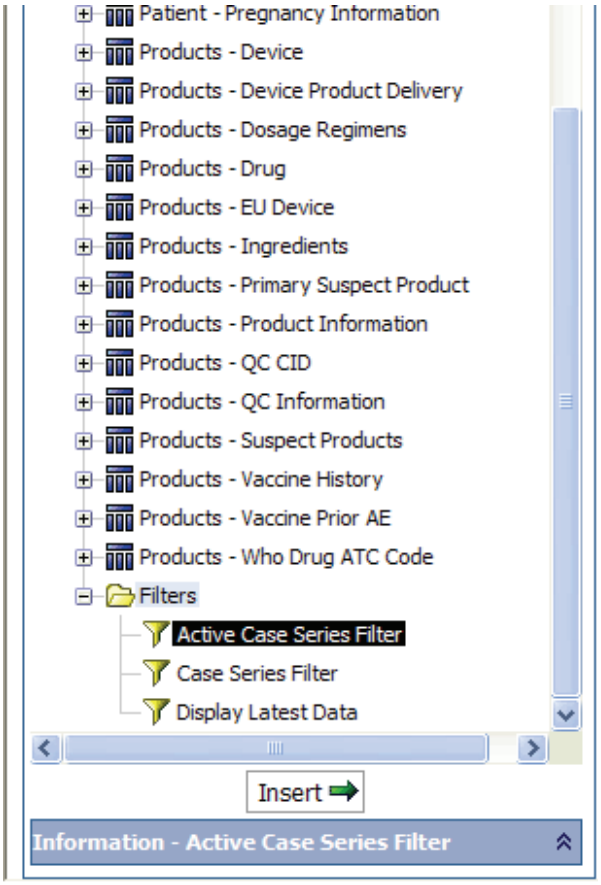
Note: Select the Active Case Series Filter before selecting datamart fields for your report. This prevents Report Writer from querying the entire datamart and slowing down the report output generation.

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.

3. In the left frame, expand the **Report Writer** control tree. The various datamart views are displayed.



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



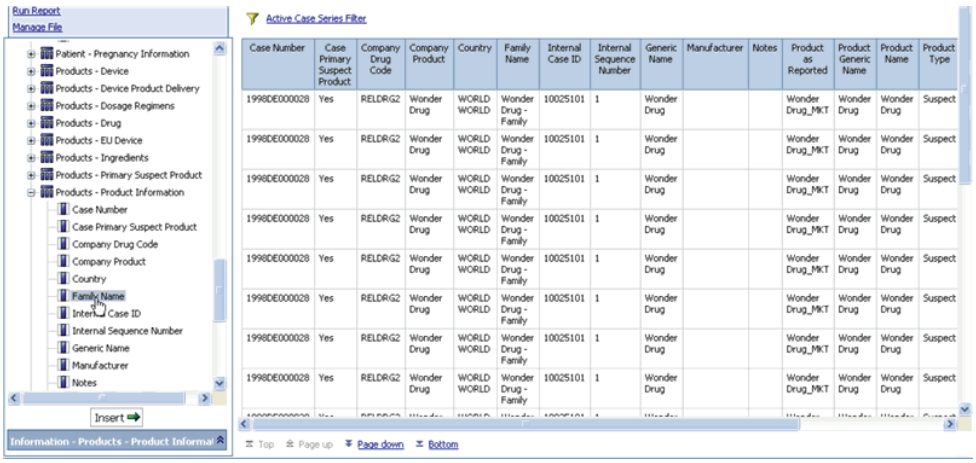
6. Select the Active Case Series Filter.
7. Click **Insert**. The selected filter appears in the right frame.

8. Select the datamart fields to include in your report.
9. In the left frame, expand the **Report Writer** control tree. The various datamart views are displayed.
10. Expand the datamart view tree, as appropriate. The datamart fields corresponding to the tree are displayed.

11. Select the datamart fields, as appropriate.

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

12. Click the **Insert** button. 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.



    Tip: Select multiple fields as follows:

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

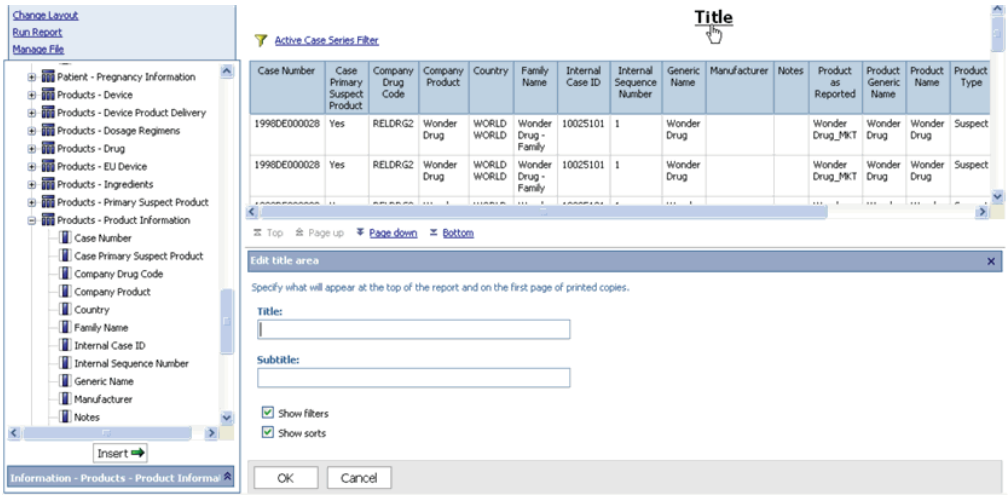
13. Repeat the steps listed above to insert additional fields into the report.

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

    You can revert or repeat any actions you perform in Query Studio by using the **Undo**or **Redo**toolbar button, respectively.

14. Enter the report title.

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



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

Using Case Series Criteria and Case Series Name in new Report.

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

1. Select the Case Series Criteria and Case Series Name objects from the Case Series class.
2. The Report Writer queries the datamart, to get all the **Case Series Criteria** and **Case Series Name**.

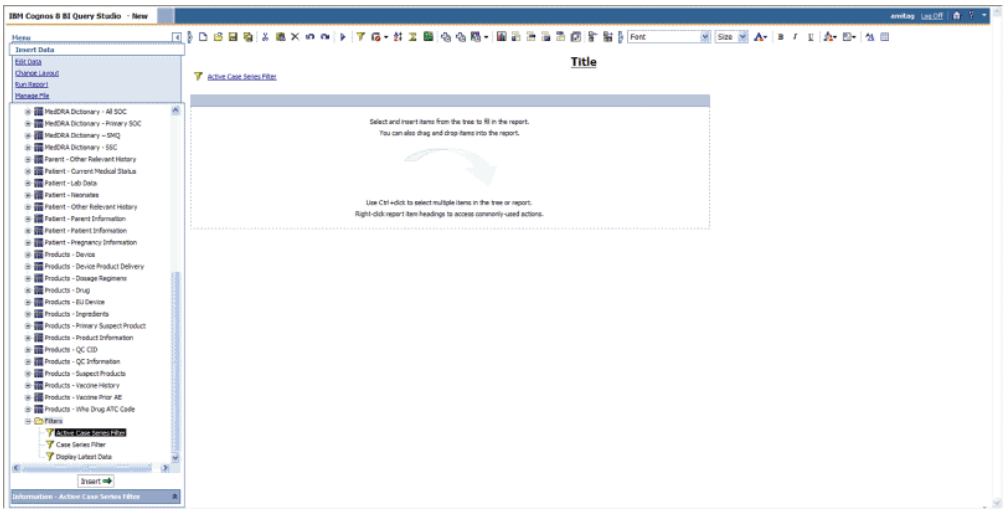
Note: Temporary Case Series Criteria and Case Series names will not be displayed.

Using Case Series Criteria and Name with Other Objects

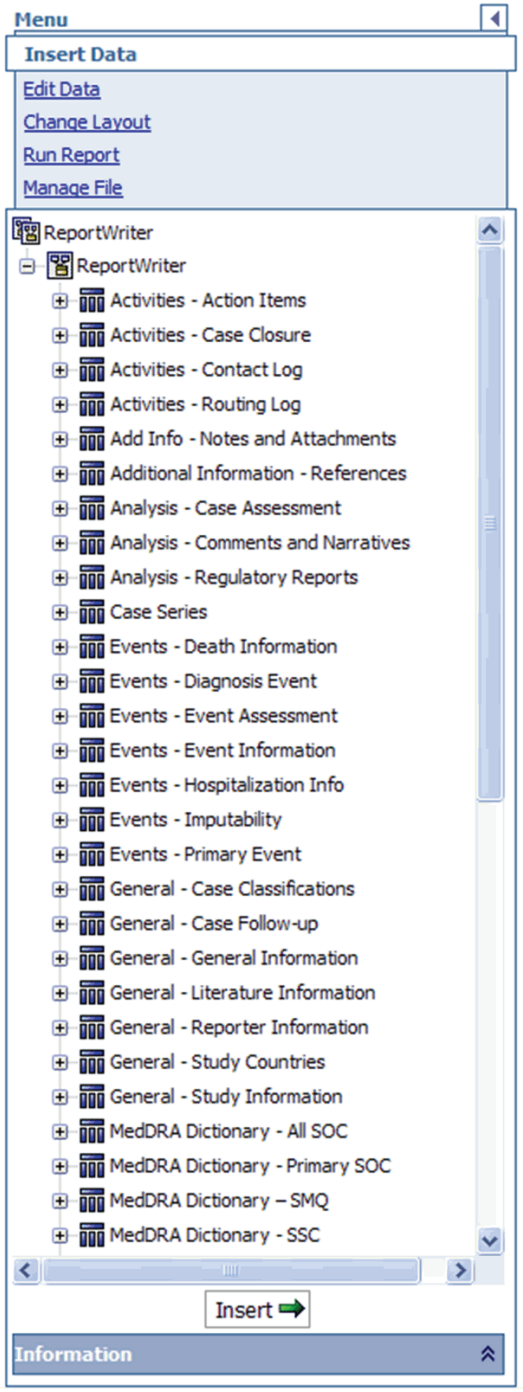
Use the following procedure to use the Case Series Criteria and Case Series Name with other objects.

1. In the left frame, expand the class folders under **Report Writer**.

2. The dimensions for the class category are displayed.
3. Scroll down the list of views so that the **Filters** folder is visible.
4. Expand the **Filters** folder.
5. The built in **Active Case Series Filter** is displayed.



6. Select the Filter.
7. Click **Insert**.
8. The selected filter appears in the right frame.
9. In the left frame, expand the Report Writer control tree.
10. The various datamart views are displayed.

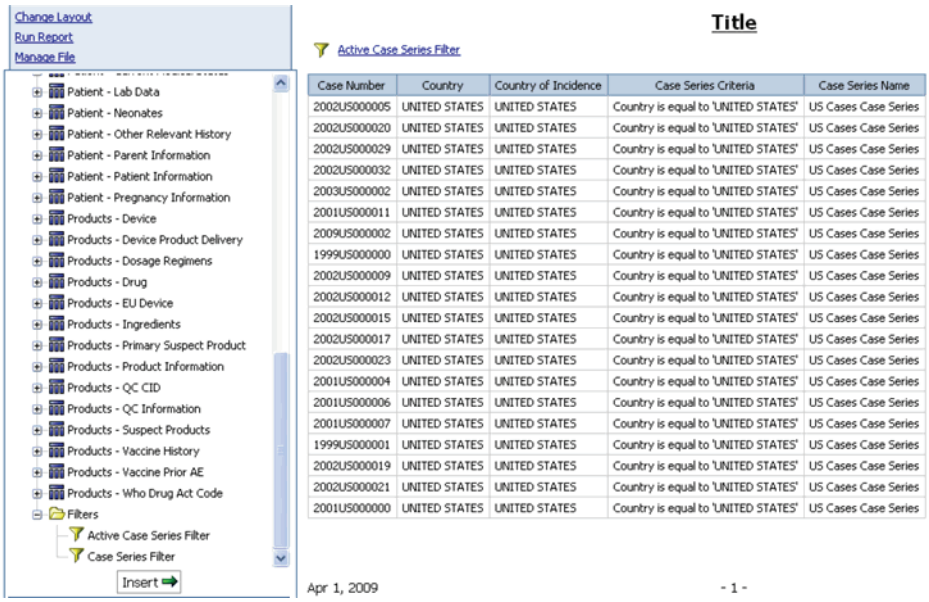


11. Expand the datamart view tree, as appropriate.
12. Select the datamart fields, as appropriate along with **Case Series Criteria** and **Case Series Name** from **Case Series** class.

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

13. Click the **Insert** button.

14. 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 along with **Case Series Criteria** and **Case Series Name**.



Tip: Use the following procedure to select multiple fields, hold down the CTRL key and select the fields. You can also insert an entire datamart view in your report by selecting the datamart view entity in the left frame and clicking Insert.

You can also drag the field entities to the report output area.

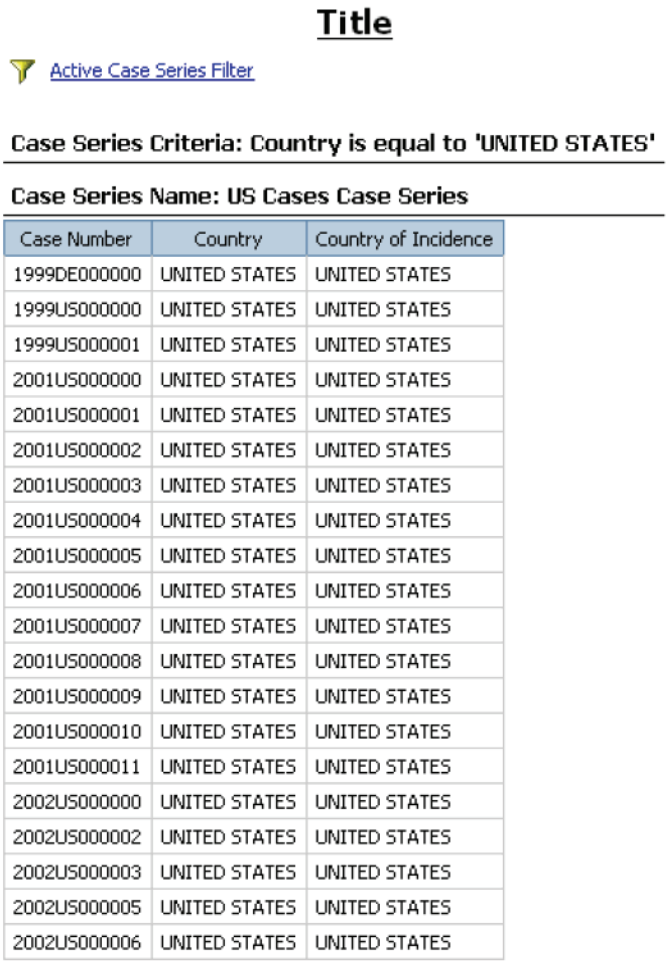
15. Select Case Series Criteria and click Create Sections icon.

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

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

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

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



Title

Active Case Series Filter

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

Case Series Name: US Cases Case Series

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

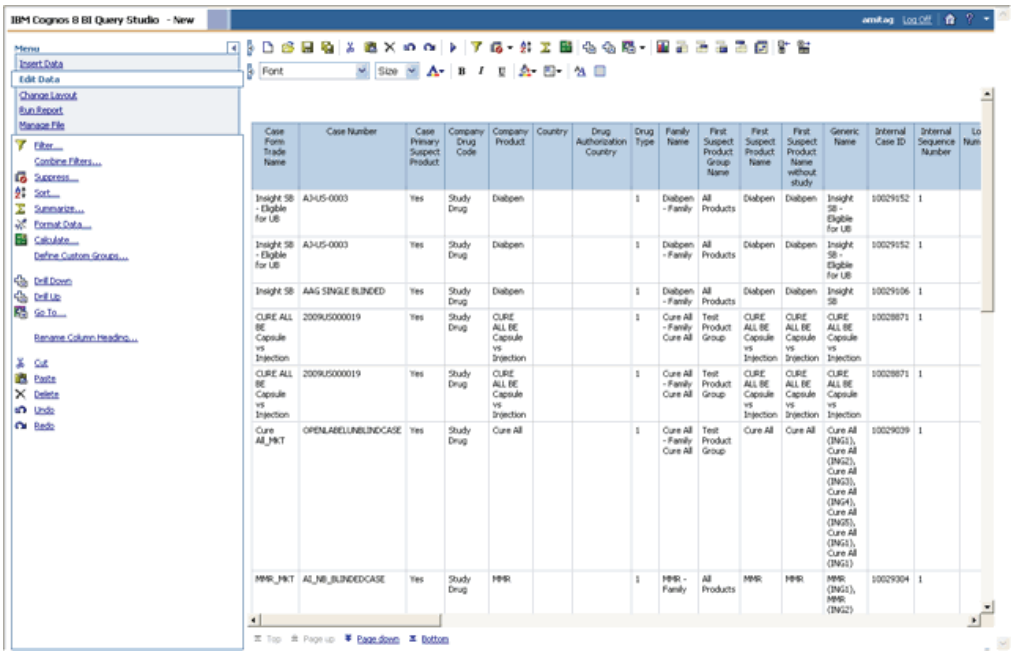
Note: Always use Active Case Series Filter while using Case Series Criteria and Case Series Name with other objects. As, it may leads to undesirable results.

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.

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

Editing Reports

You can access Query Studio's *report* editing options by selecting the **Edit Data** menu option. The report editing options let you control what data appears in your report as well as how it is formatted, calculated, and sorted. None of the edit operations you perform are stored in the database.



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

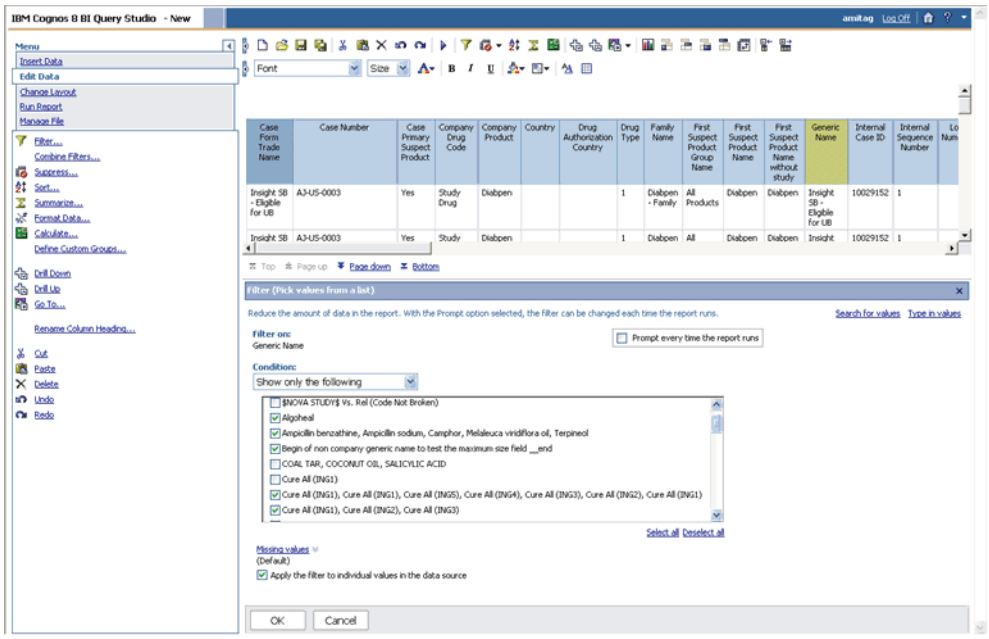
Filtering Data

You can use the filtering option to reduce data in your report. Use the following procedure to *filter* your report.

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

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

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



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

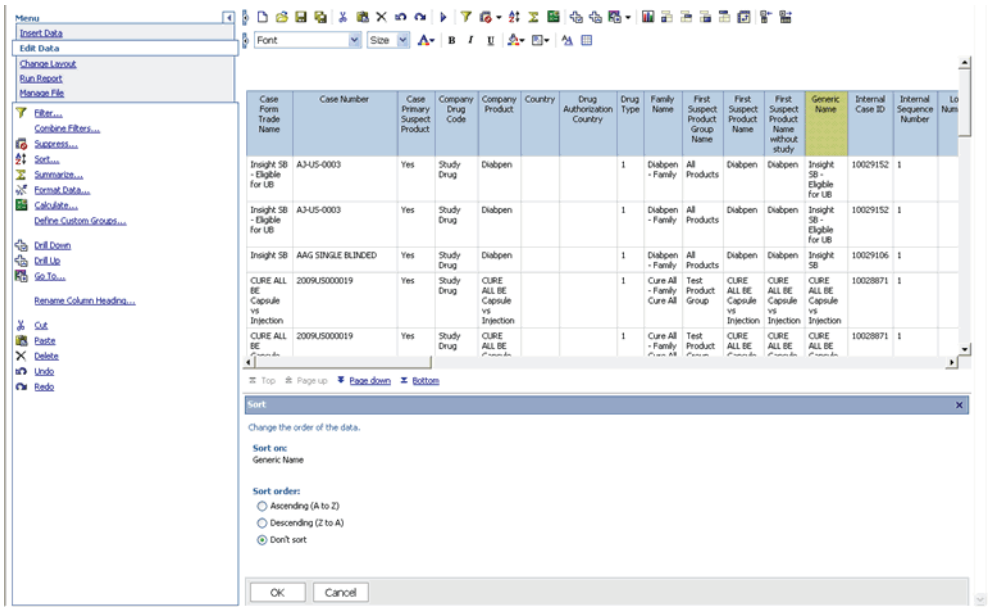
> **Note:** The **Show only the following** list may not display all the values if the list of values is very large. If you cannot find the desired values to filter on, click the **Search for values** link and search for the value by typing the value you are looking for.

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

Sorting Data

Use the following procedure to change the sort order in your report.

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

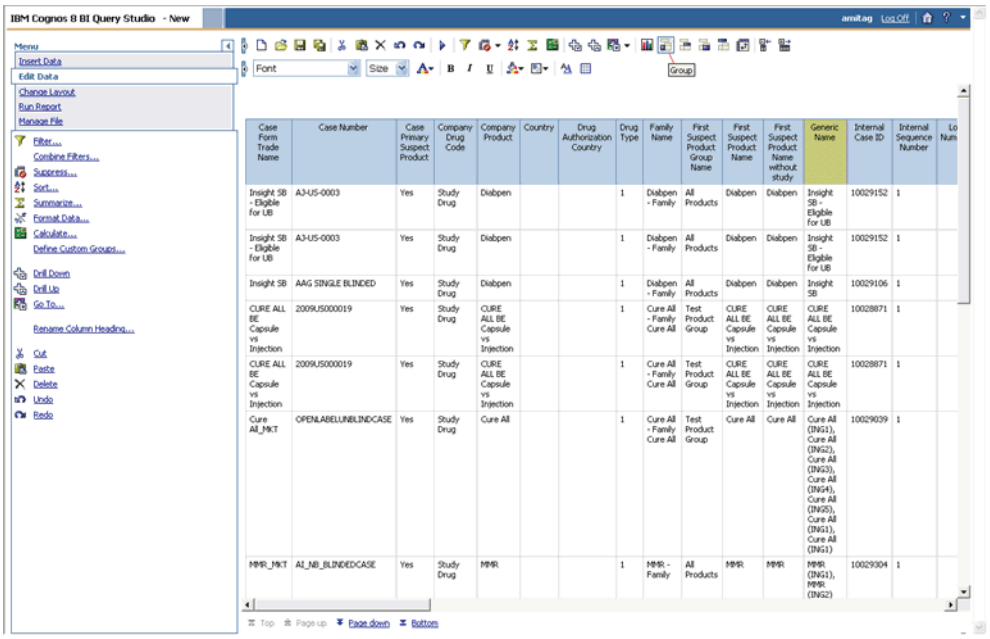


3. Select the required sorting option by using the **Sort Order** option buttons.
4. Click **OK**. The system refreshes the report and displays the sorted output.

Summarizing Data

You can use the predefined summary options to calculate the total, count, maximum, minimum, or average of the values in columns of your reports. The summary options available to you depend on the type of data in the column you 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.

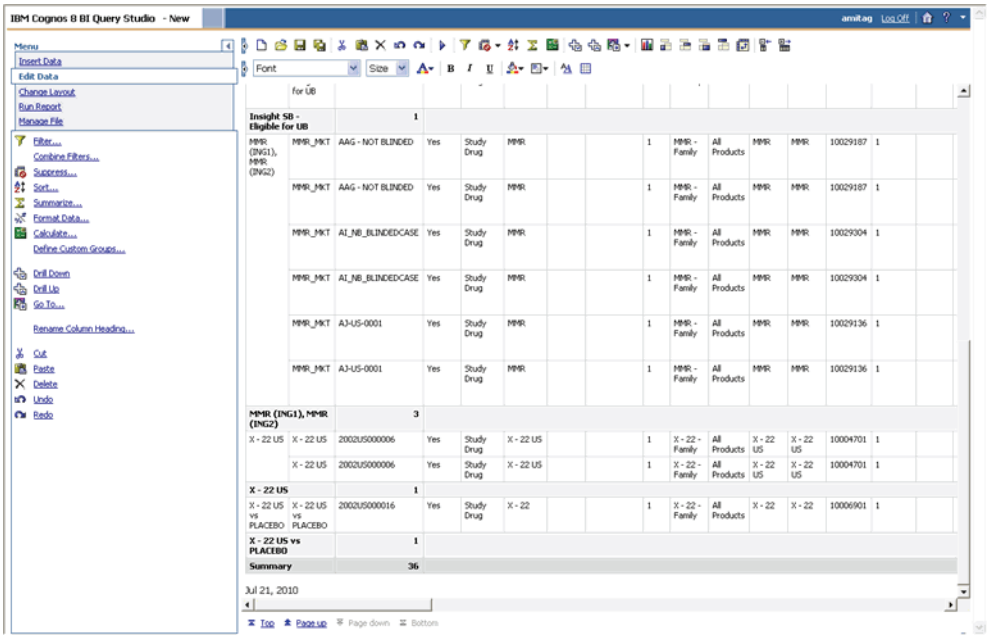
1. In the report output area, click the column that you wish to summarize. The selected column is highlighted.
2. Select the column to be grouped and click on the Group icon placed in the grouping menu in the top panel. The selected column is grouped.



3. Select **Summarize** from the **Edit Data** menu options in the left frame. The **Summarize** section appears below the report output in the right frame.

4. From the **Summary for footers** list box, select the required summary option. The options available depend on the type of values the select column contains.

5. Click **OK**. The report output displays the column summary at the bottom of the report. Click the **Bottom** link to view the footer. If your report is grouped, the summary values are displayed for each group**.**



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

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 Query Studio. Use default to remove formatting.
Text	Use the text format to specify the number of characters that should be visible in the text string.
Number	Use the number format to change the number of decimal places, to specify whether to use a thousands separator, to choose different symbols to represent negative numbers, and to scale large numbers.
Currency	You can choose from many world currencies. Use either the currency symbol or the international code. For example the currency symbol for the euro is and the international code is EUR. 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.
Percentage	This format shows a number multiplied by 100, using two decimal places and a percent sign. For example, 0.7356 appears as 73.56%.
Scientific	This format shows a number in exponential notation. For example, the number 224,110 is 2.24110E+05 in scientific notation.
Date and Time	·You can choose from a list of date and time formats, including the 12 or 24 hour clock.

1. In the report output area, click within the header of the column that you wish to format. The selected column is highlighted.
2. Select **Format** from the **Edit Data** menu options in the left frame. The **Format** section appears below the report output in the right frame.
3. Select the data format from the **Category** list box, as appropriate. The options for setting the format appear.
4. Set the formatting options, as appropriate.
5. Click **OK**. The report output is refreshed and displays the formatted data.

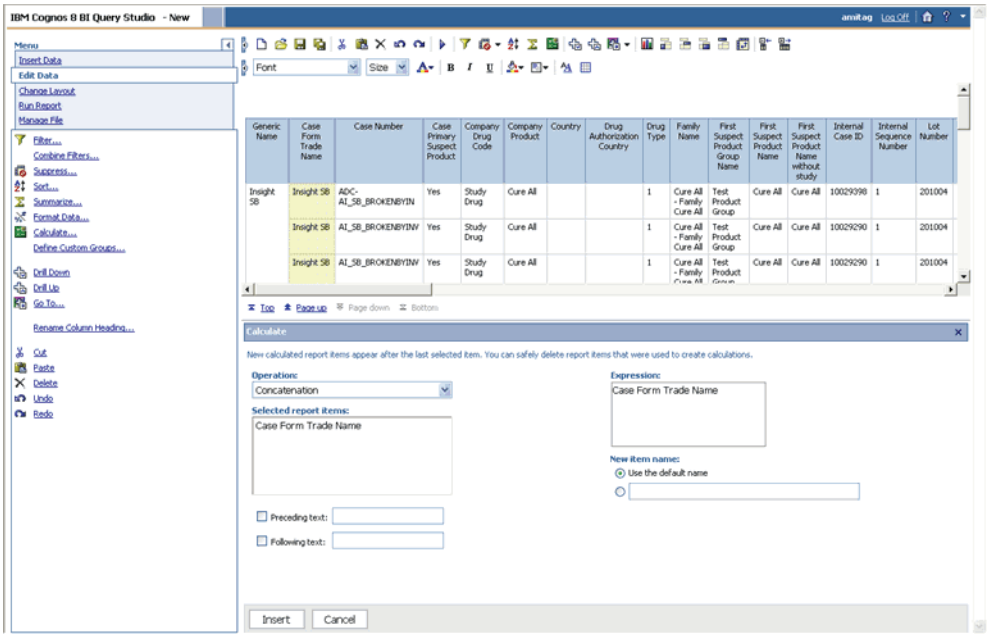
Performing Calculations

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

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

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

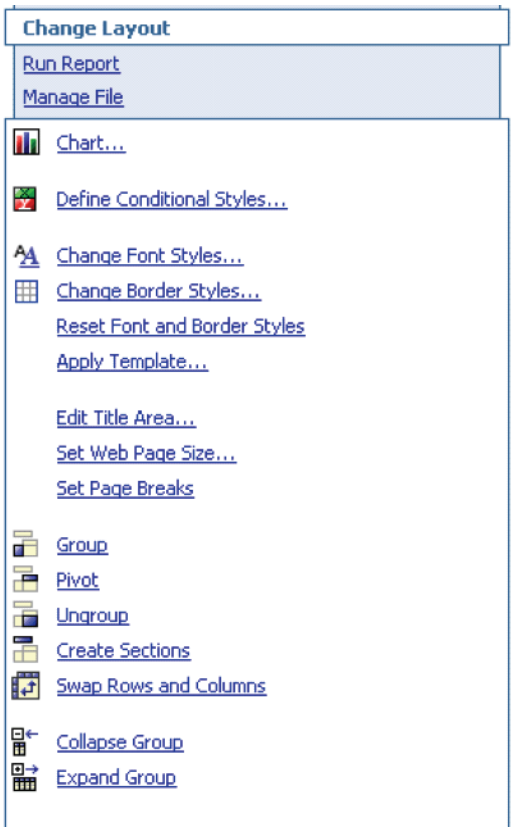
1. In the report output area, select the columns on which you wish to perform calculations. The selected columns are highlighted.
2. Select **Calculate** from the **Edit Data** menu options in the left frame. The **Calculate** section appears below the report output in the right frame.



3. From the **Operation Type** list box select the type of operation you wish to perform. The operation types available depend on the type of information the selected columns contain, such as text or numeric.
4. From the **Operation** list box, select the operator. The operators available depend on the type of operation you specified.
5. Depending on the operator you selected, additional options may appear in the **Calculate** section. Specify those options.
6. Use the **New item name** option buttons to specify whether you want to the result column to have a new header title.
7. Click the **Insert** button in the **Calculate** section. The report output is refreshed and displays the calculation result.

Changing the Report Layout

You can access Query Studio's *report* layout options by selecting the **Change Layout** menu option. The layout options let you change the appearance of your reports without changing the underlying data. For example, you can convert your report into a *chart* or group the report into crosstab *column* headers. You can also group your report by a specific column, swap rows and columns, or create sections within your report.



Report Agency	Internal Case ID
EMEA - PHY	9
EMEA - XML	1
[AF] BR (JCB)	50
[AF] MX (JCM)	49
[HA] AT (GSK)	107
[HA] BE (BPV)	104
[HA] CA (TPD)	73
[HA] CH (IKS)	33
[HA] DE (BfArM)	125
[HA] DK (NBH)	103
[HA] ES (FES)	105
[HA] FI (NBH)	102
[HA] FR (FMA)	132
[HA] GB (MCA)	112
[HA] GR (NDOD)	63
[HA] HU (NIP)	102
[HA] IE (IMB)	101
[HA] IT (MDS)	102
[HA] JP (MHLW)	215
[HA] LU (DS)	102

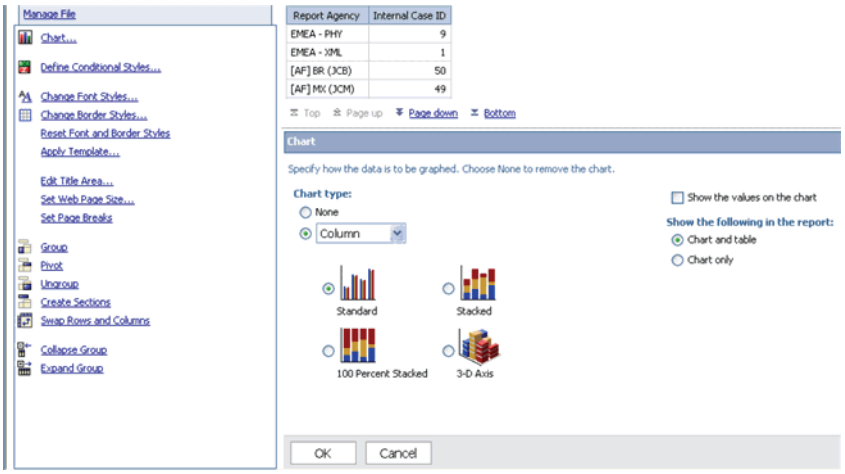
The sections explain how to use the various report layout options.

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

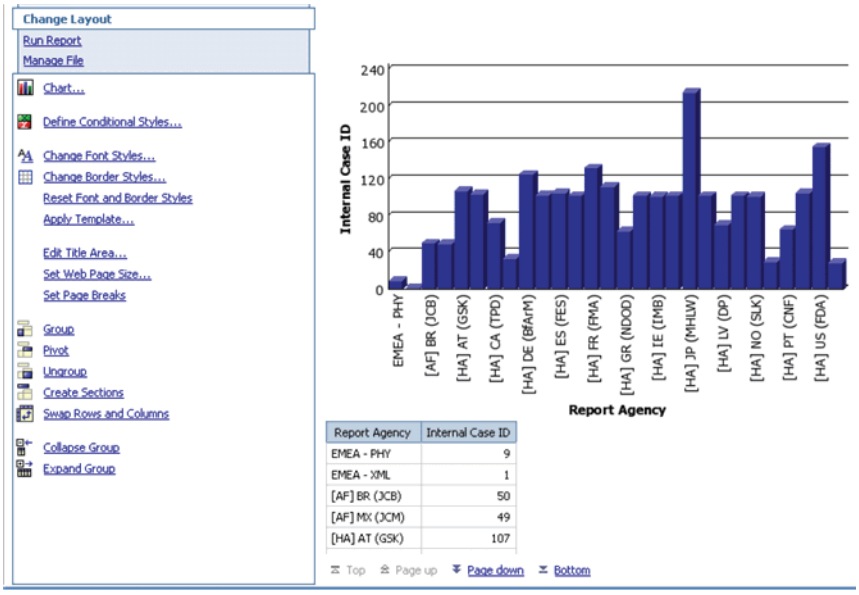
Creating a Chart

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

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



2. Use the **Chart Type** list box to select the type of chart you want to create. For example, column, pie, radar, and so on.
3. Check the **Show the values on chart** checkbox if you wish to display the measure value in the chart.
4. Use the **Show the following in the report** option buttons to specify whether you want the output to display only the chart or both chart and table.
5. Click **OK**. The report output refreshes. The chart is displayed.



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

Grouping by Row Headings

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

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

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

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

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

To Ungroup a Report

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

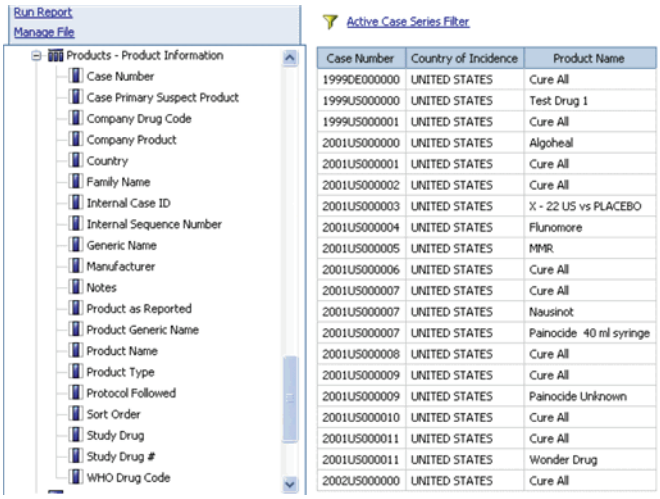
Creating Crosstab Reports

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

Note: You cannot create crosstab reports directly in Query Studio nor does Query Studio permit you define measures. Use the following procedure to create sophisticated reports, such as crosstab reports, use the Cognos 8 Report Studio tool. The steps that follow explain how to create a crosstab report by performing the "Count" operation on each cell of the Case Number column to convert it into a measure. You can use this method to create similar crosstab reports in Query Studio.

Tip: To create a crosstab report using the Count operation

1. Select the following datamart fields to include in your report.
   - General - General Information > Case Number
   - General - General Information > Country of Incidence
   - Product - Product Information > Product Name
2. The Report Writer queries the 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.



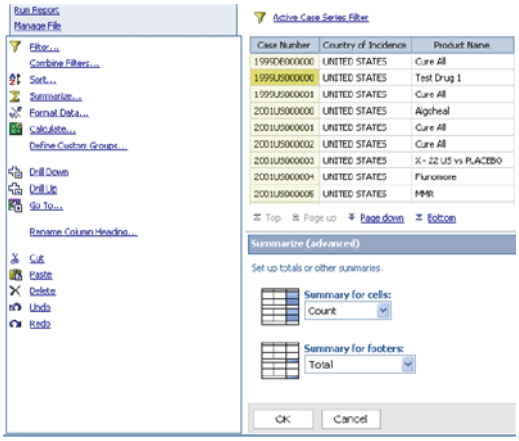
Case Number	Country of Incidence	Product Name
1999DE000000	UNITED STATES	Cure All
1999US000000	UNITED STATES	Test Drug 1
1999US000001	UNITED STATES	Cure All
2001US000000	UNITED STATES	Algoheal
2001US000001	UNITED STATES	Cure All
2001US000002	UNITED STATES	Cure All
2001US000003	UNITED STATES	X - 22 US vs PLACEBO
2001US000004	UNITED STATES	Flunomore
2001US000005	UNITED STATES	MMR
2001US000006	UNITED STATES	Cure All
2001US000007	UNITED STATES	Cure All
2001US000007	UNITED STATES	Nausinot
2001US000007	UNITED STATES	Painocide 40 ml syringe
2001US000008	UNITED STATES	Cure All
2001US000009	UNITED STATES	Cure All
2001US000009	UNITED STATES	Painocide Unknown
2001US000010	UNITED STATES	Cure All
2001US000011	UNITED STATES	Cure All
2001US000011	UNITED STATES	Wonder Drug
2002US000000	UNITED STATES	Cure All

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

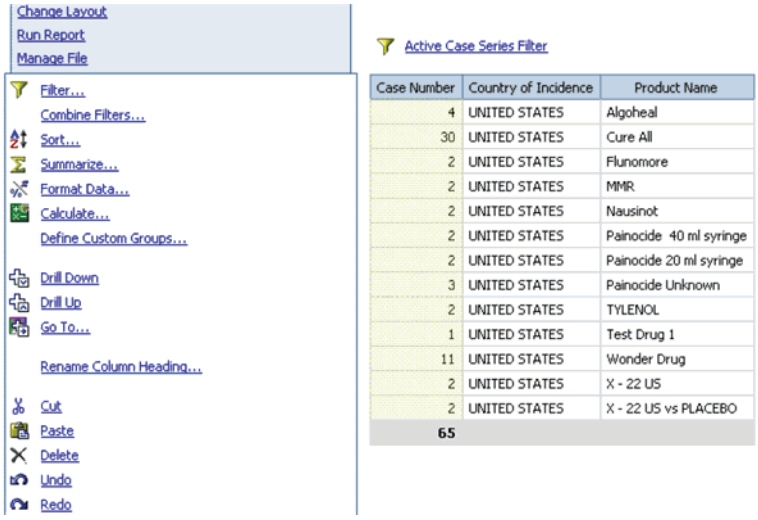
Summarize the Sections in the Report

Use the following procedure to summarize the sections in a report.

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



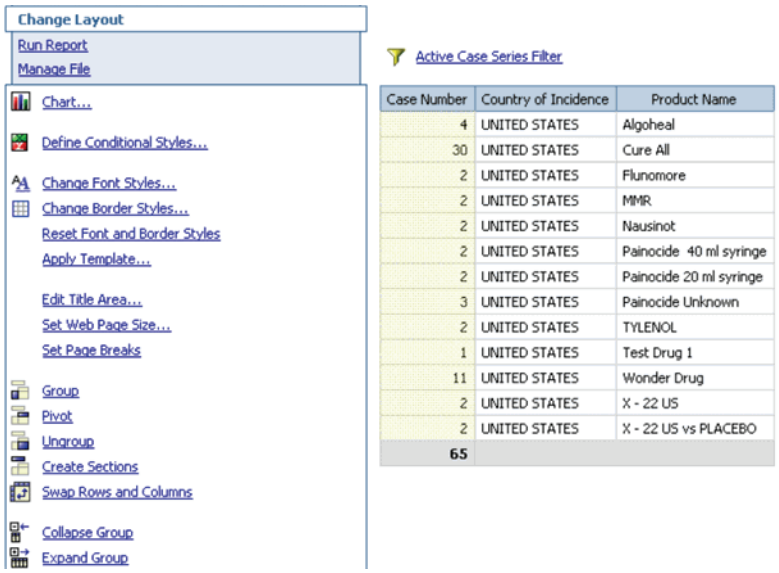
3. Select **Count** from the **Summary for cells** list box.
4. Select **Total** from the **Summary for footer** list box.
5. Click **OK**. The report output refreshes. The **Case Number** column now shows the case count for each row.



Convert to a Crosstab Report

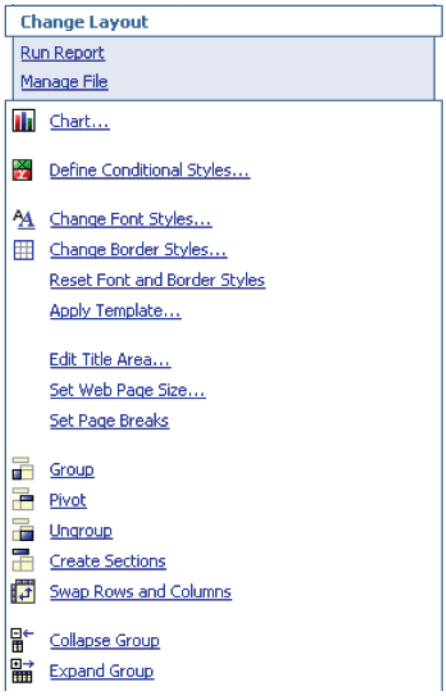
Use the following procedure to convert to a Crosstab report.

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



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

2. Select the **Country of Incidence** column in the report output. The column is highlighted. The values of the selected column will appear as columns in your crosstab report.
3. Select the **Pivot** from the **Change Layout** menu options. The report output refreshes. The crosstab report is displayed.



Active Case Series Filter

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

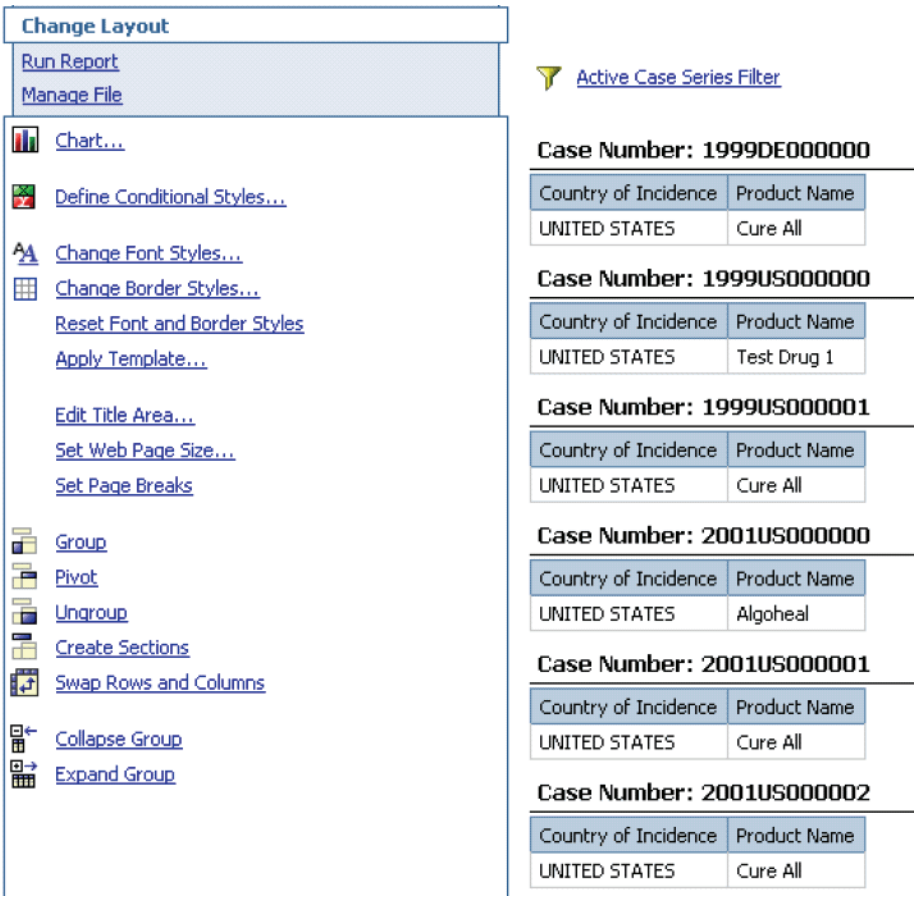
Creating Sections in the Report

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

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

Case Number	Country of Incidence	Product Name
1999DE000000	UNITED STATES	Cure All
1999US000000	UNITED STATES	Test Drug 1
1999US000001	UNITED STATES	Cure All
2001US000000	UNITED STATES	Algoheal
2001US000001	UNITED STATES	Cure All
2001US000002	UNITED STATES	Cure All
2001US000003	UNITED STATES	X - 22 US vs PLACEBO
2001US000004	UNITED STATES	Flunomore
2001US000005	UNITED STATES	MMR
2001US000006	UNITED STATES	Cure All
2001US000007	UNITED STATES	Cure All
2001US000007	UNITED STATES	Nausinot
2001US000007	UNITED STATES	Painocide 40 ml syringe
2001US000008	UNITED STATES	Cure All
2001US000009	UNITED STATES	Cure All
2001US000009	UNITED STATES	Painocide Unknown
2001US000010	UNITED STATES	Cure All
2001US000011	UNITED STATES	Cure All
2001US000011	UNITED STATES	Wonder Drug
2002US000000	UNITED STATES	Cure All

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



Swapping Rows and Columns

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

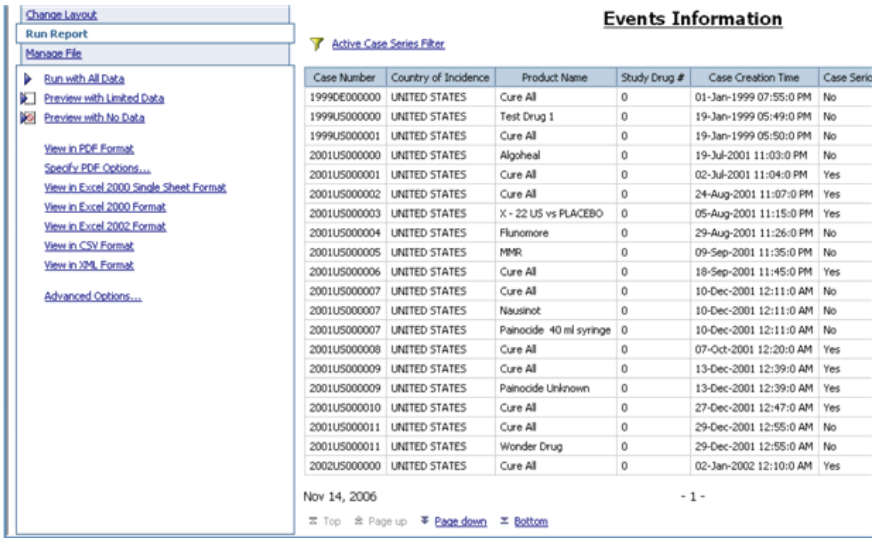
Swapping rows and columns is useful in situations where a crosstab report has few rows and many columns.

Use the following procedure to make the report shown above easier to read, you can select the **Swap Rows and Columns** and interchange rows with columns.

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

Running the Report in Specific Formats

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

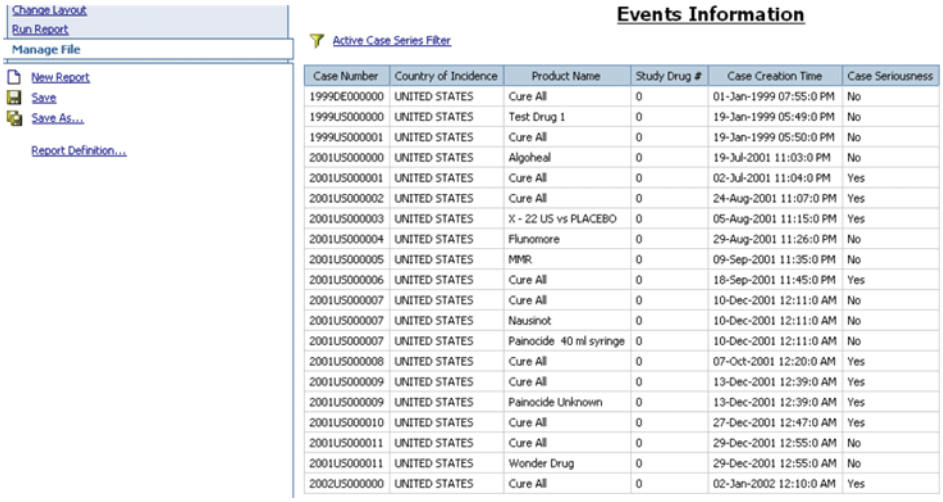


The following table describes the various **Run Report** options available in Query Studio.

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

Saving and Accessing Saved Reports

Use the **Manage File** menu option to save the reports you create by using *Report* Writer. You can save your reports in either Personal or Public folders. The reports you save are not a snapshot of the data displayed in the report output. Instead, the system stores the specific set of instructions (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.



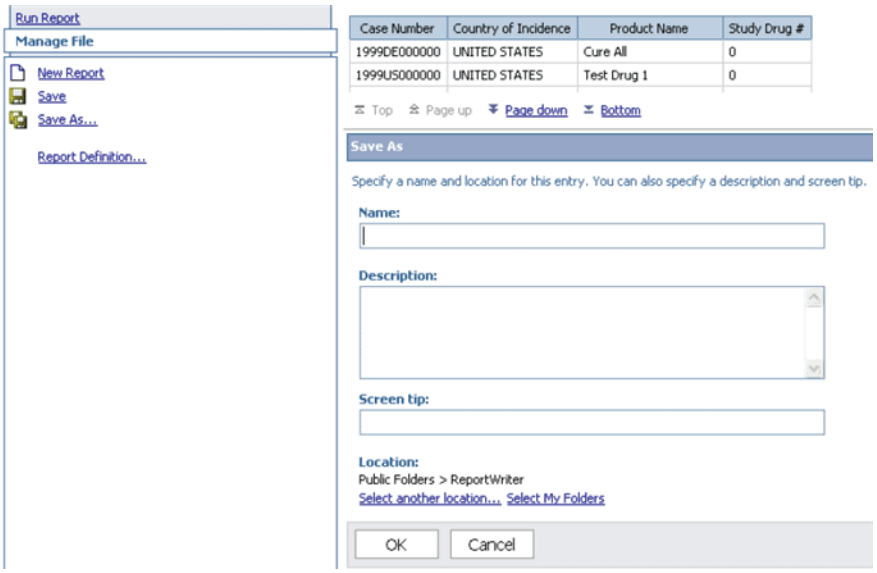
Case Number	Country of Incidence	Product Name	Study Drug #	Case Creation Time	Case Seriousness
1999DE000000	UNITED STATES	Cure All	0	01-Jan-1999 07:55:0 PM	No
1999US000000	UNITED STATES	Test Drug 1	0	19-Jan-1999 05:49:0 PM	No
1999US000001	UNITED STATES	Cure All	0	19-Jan-1999 05:50:0 PM	No
2001US000000	UNITED STATES	Algoheal	0	19-Jul-2001 11:03:0 PM	No
2001US000001	UNITED STATES	Cure All	0	02-Jul-2001 11:04:0 PM	Yes
2001US000002	UNITED STATES	Cure All	0	24-Aug-2001 11:07:0 PM	Yes
2001US000003	UNITED STATES	X - 22 US vs PLACEBO	0	05-Aug-2001 11:15:0 PM	Yes
2001US000004	UNITED STATES	Flunomore	0	29-Aug-2001 11:26:0 PM	No
2001US000005	UNITED STATES	MMR	0	09-Sep-2001 11:35:0 PM	No
2001US000006	UNITED STATES	Cure All	0	18-Sep-2001 11:45:0 PM	Yes
2001US000007	UNITED STATES	Cure All	0	10-Dec-2001 12:11:0 AM	No
2001US000007	UNITED STATES	Nausinot	0	10-Dec-2001 12:11:0 AM	No
2001US000007	UNITED STATES	Painocide 40 ml syringe	0	10-Dec-2001 12:11:0 AM	No
2001US000008	UNITED STATES	Cure All	0	07-Oct-2001 12:20:0 AM	Yes
2001US000009	UNITED STATES	Cure All	0	13-Dec-2001 12:39:0 AM	Yes
2001US000009	UNITED STATES	Painocide Unknown	0	13-Dec-2001 12:39:0 AM	Yes
2001US000010	UNITED STATES	Cure All	0	27-Dec-2001 12:47:0 AM	Yes
2001US000011	UNITED STATES	Cure All	0	29-Dec-2001 12:55:0 AM	No
2001US000011	UNITED STATES	Wonder Drug	0	29-Dec-2001 12:55:0 AM	No
2002US000000	UNITED STATES	Cure All	0	02-Jan-2002 12:10:0 AM	Yes

The sections that follow explain how to save reports and access saved reports.

Saving Reports

Use the following procedure to save a report.

1. Select the **Manage File** menu option in the left frame. The options for saving the report appear.
2. Select the **Save** from the **Manage File** menu options. The **Save As** section appears below the report output in the right frame.



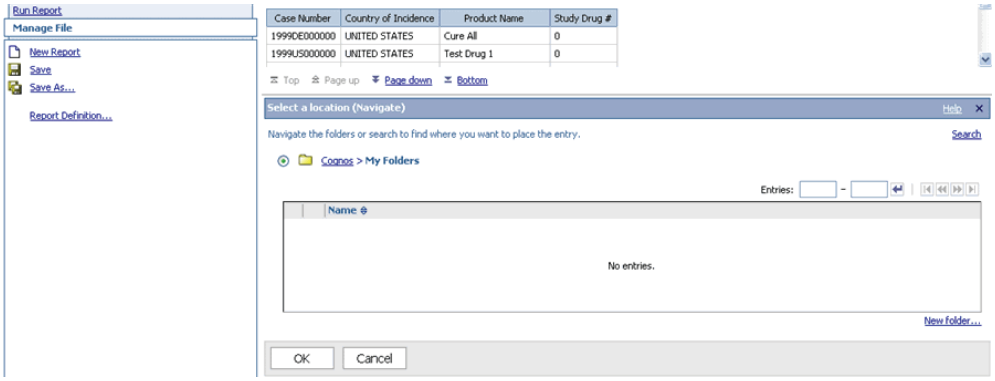
3. Enter the report name in the **Name** text box.
4. Enter the report description in the **Description** text area.
5. In the **Screen tip** text box, enter the screen tip text that should appear when a user points at the report in the Report Writer interface.
6. Select a **Location** option button to specify the location where the report needs to be saved:

- Select the **Public Folders > Report Writer** option button if you want all users to be able access the report
- Select the **My Folders** option button if you wish to save the report as a personal document.

Saving a Report in a New Folder

Use the following procedure to save a report in a new folder within **Public Folders > Report Writer** or **My Folders**

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



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

Accessing Report Writer Library

The reports you save can be accessed from the Report Writer Library. Use the following procedure to open the Report Writer Library, select **Case Series Reports > Report Writer > Library** in Argus Insight. **My Folders** is the default location that appears when you open the Report Writer Library. All the reports you save as personal documents are listed in the **My Folders** location.

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

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

You can edit a saved report by clicking the report name. The report opens in the Query Studio interface. After you edit the report, you can save it by another name by using the **Save As** option in the **Manage Files** menu.

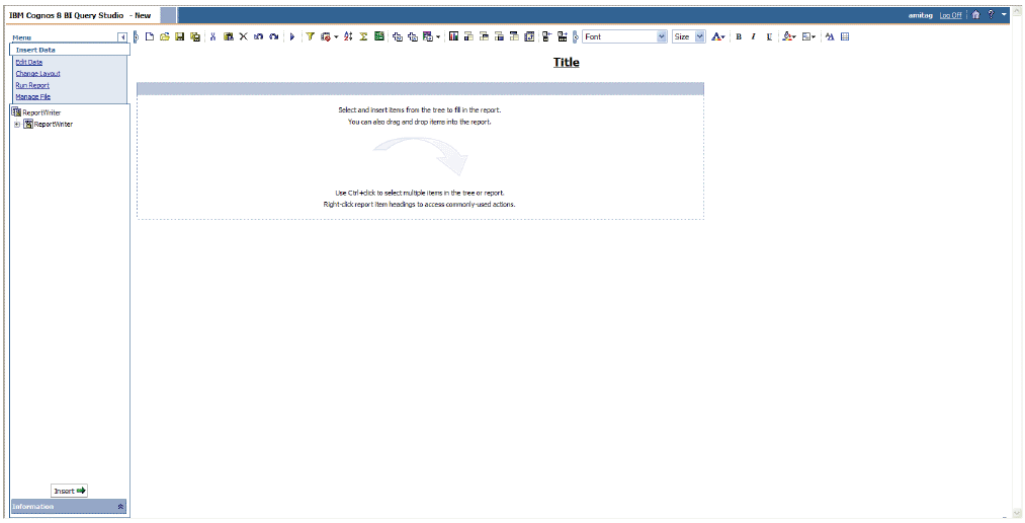
Using SMQs in Report Writer

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.

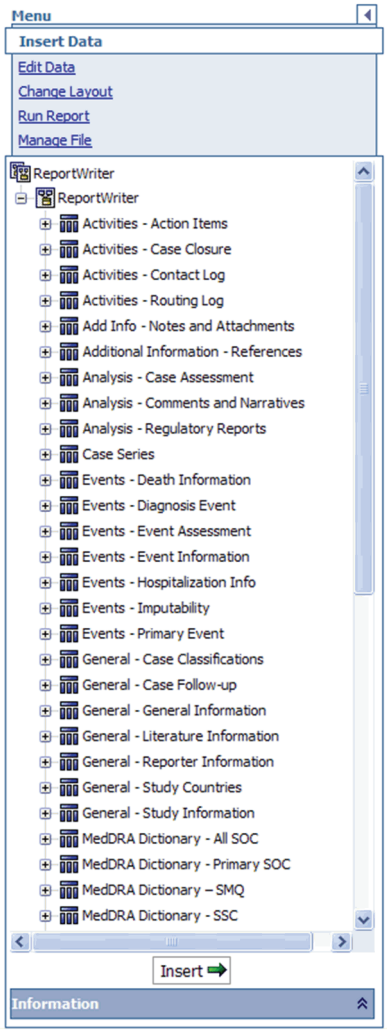
Using SMQs

Use the following procedure to use SMQs in report writer.

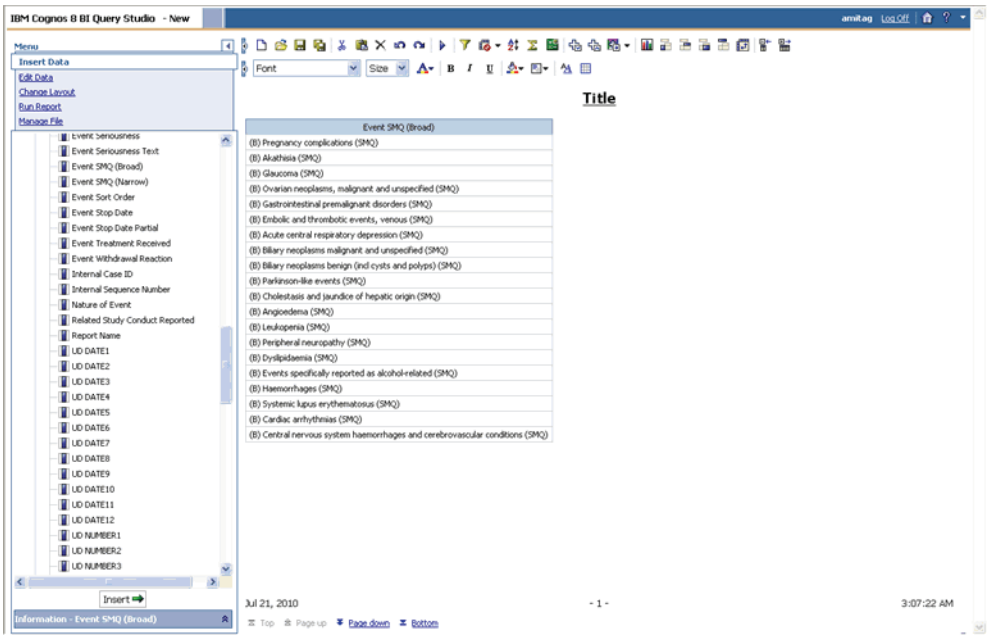
1. Go to **Case Series Reports > Report Writer > New**. The following window is displayed.



2. In the left frame, expand the **Report Writer** control tree. The various datamart views are displayed.



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

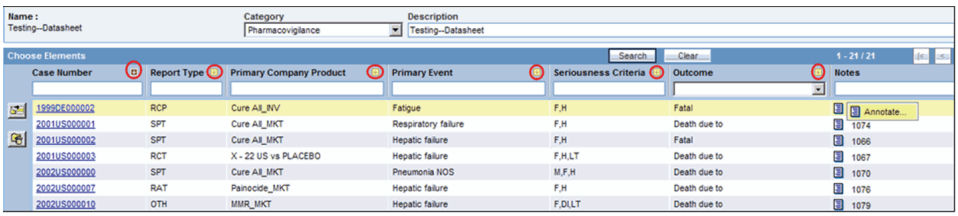


4. Perform a similar operation as shown in the above step for **Event SMQ (Narrow)**.
5. Under **Events - Event Information**, either double-click **Case Number** or drag-and-drop it to the **right** pane. This displays all the case numbers that correspond to the selected SMQ.

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.

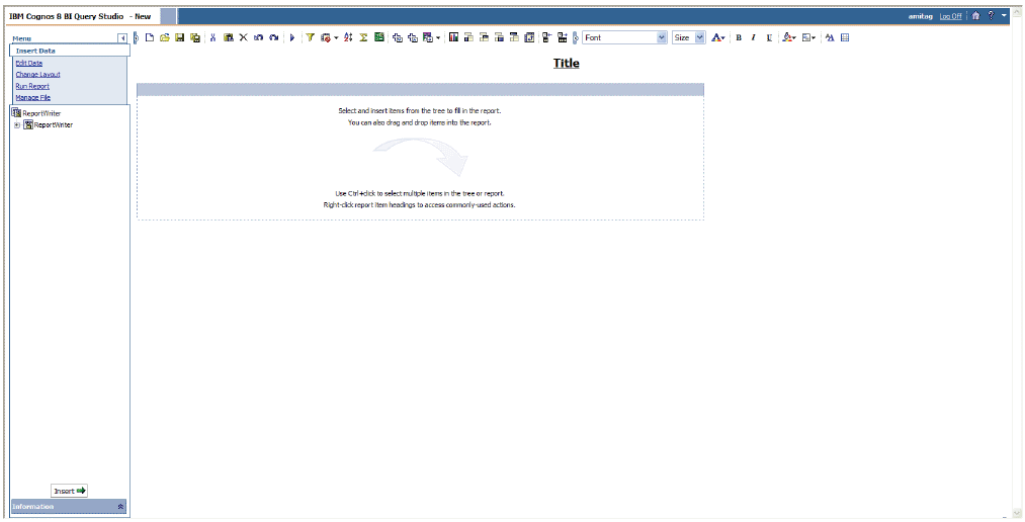
To use notes in Advanced Conditions, go to Case Series > Cases > Case Annotations. This field is a free hand text type field and supports single select only.

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

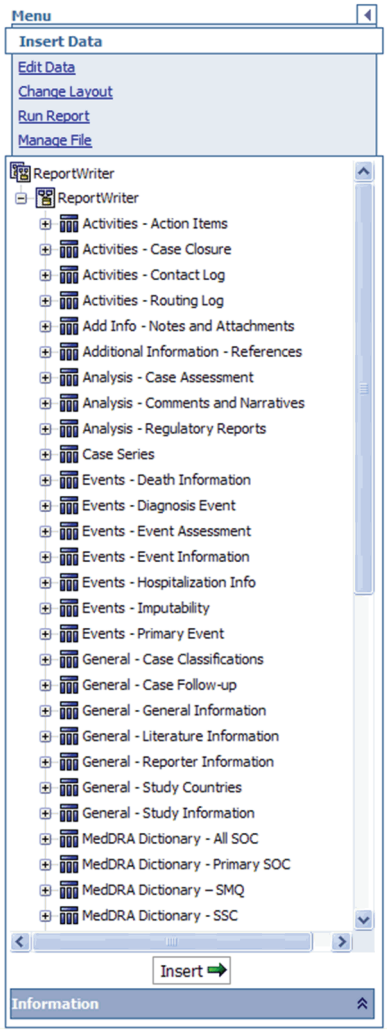
Using Case Annotations

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

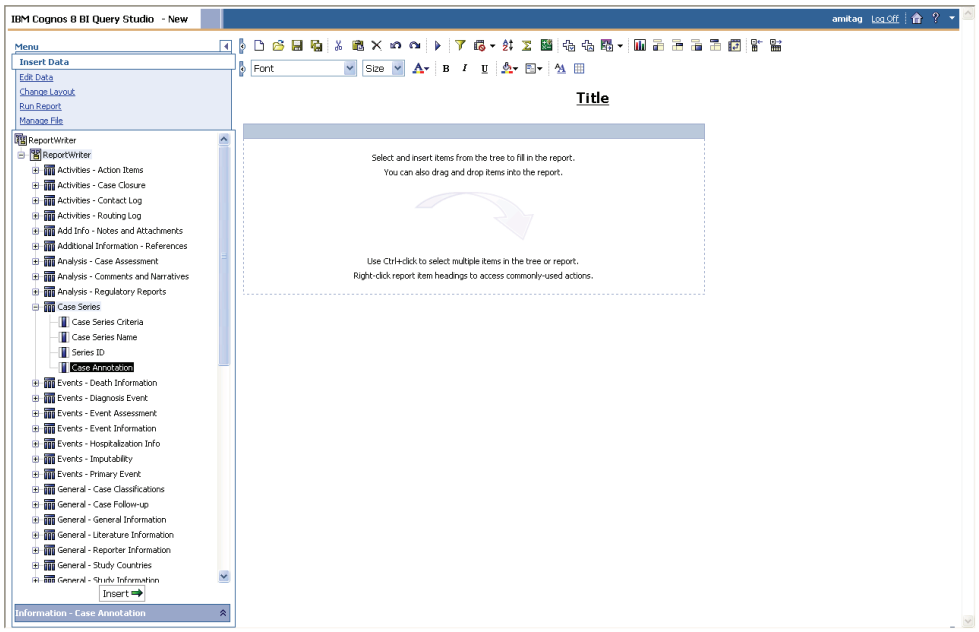
1. Go to **Case Series Reports > Report Writer > New**. The following window is displayed.



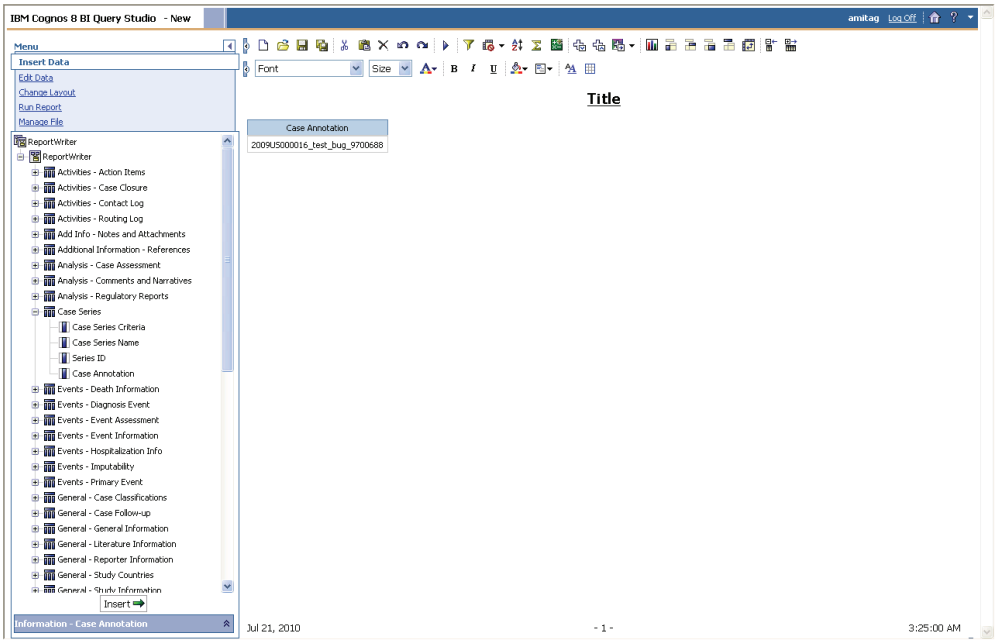
2. In the left frame, expand the **Report Writer** control tree. The various datamart views are displayed.



3. Under **Case Series**, click Case Annotation.



4. Click Insert. This displays all the case numbers that correspond to the selected SMQ.



8

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 Cognos® Analysis Studio Web Explorer interface. The interface uses a *web browser* and provides access to available dimensions and measures.

Using cubes enables you to run complex queries by selecting various datamart fields as dimensions and display the output on the fly. You can also select the desired measures. Use the following procedure 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 only specific case series for the required data.

The structure of a demand Cube is similar to the structure of the standard Cube you select to build the demand Cube.

The following topics explain how to work with Cubes.

- Cubes Available in Argus Insight
- Creating Demand Cubes
- Saving Cubes Views
- Refreshing Cubes

Cubes Available in Argus Insight

Argus Insight provides five different Cubes grouped in categories to let you analyze your safety data from Compliance, Management and Pharmacovigilance perspectives.

Category	Cube Name
Compliance	Submission Statistics

Management	Administration Statistics
Pharmacovigilance	Clinical Trial Analysis
	Medical Analysis
	Overdose-Pregnancy-Interaction

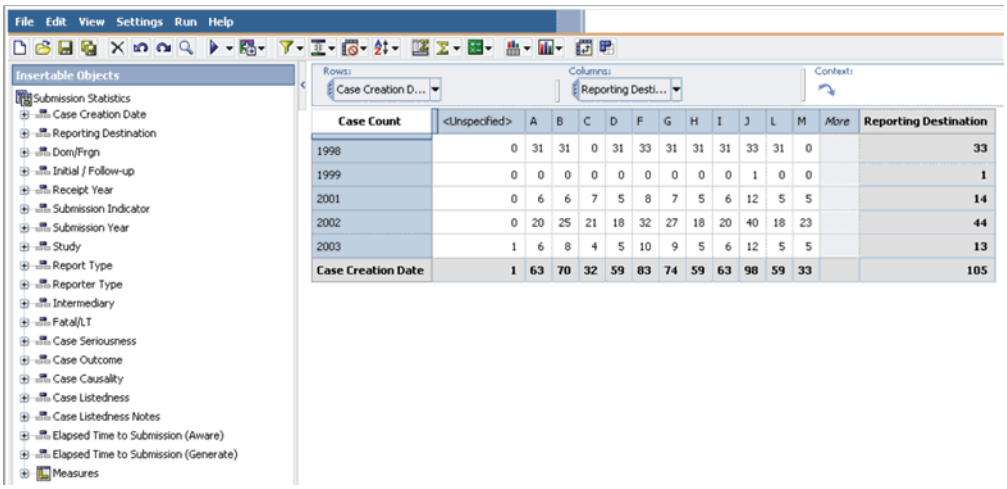
The dimensions available in a Demand Cube depend on the type of analysis that the Cube lets you perform. The following types of measures are available.

Measures	Available in
Case Count	All Cubes in Pharmacovigilance, Management and Compliance categories.
Case Version Count	Available in Management category, Administration Statistics Cube.
Record Count	Available in Compliance category, Submission Statistics.
Event Count	Available in Pharmacovigilance and Management categories.

The sections that follow describe the various Cubes available in Argus Insight. For information on executing and working with Cubes, see theWorking with Cubestopic.

Compliance Cubes

The Compliance category consists of the Submission Statistics Cube



Submission Statistics

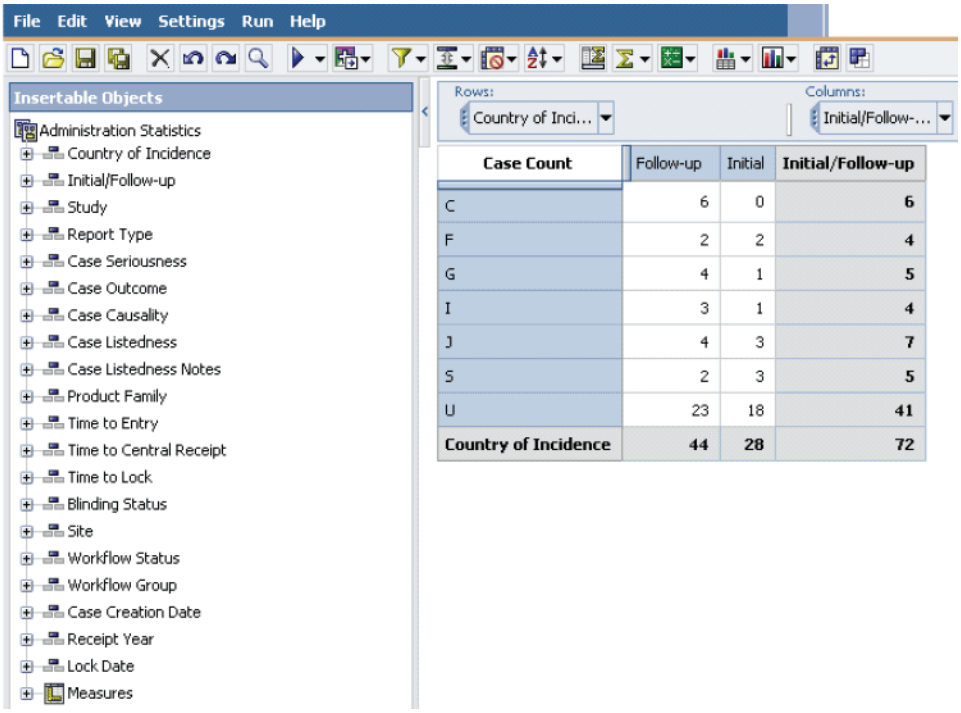
The Submission Statistics standard cube can be generated only for cases that have an initial or follow-up date within the last 365 days. The Submission Statistics cube lets you explore these dimensions:

Case Creation Date Year (YYYY) Quarter (Q1, Q2, Q3, Q4) Month	Reporting Destination Country of Agency Agency
Dom/Frgn Country of incidence Domestic/Foreign indicator (Country of Incidence = Country of Agency or not)	Initial / Follow-up Initial Follow-up Significant or Not

Receipt Year Year (YYYY) Quarter (Q1, Q2, Q3, Q4) Month	Submission Indicator (Not-Required/Non-Blank/Blank Submission Date) Submission Year Month
*Study*Protocol Number Study Number Center Number	Report Type: (SR/LIT/CT/PMS- based on derivation rule)
Reporter Type (HCP/Non-HCP/Unknown) (Primary Reporter only)	Intermediary
Fatal/LT: Fatal/LT indicator (Any event with Death or LT)	Case Seriousness (Serious/Non-Serious)
Case Outcome (Died/Improving/…)	Case Causality (Related / Not Related)
Case Listedness (Listed / Unlisted / Unknown)	Case Listedness Notes
Elapsed Time to Submission(Aware): Time to Submission	Elapsed Time to Submission(Generated): Time to Submission

Management Cubes

The Management category consists of the Administration Statistics Cube.



Administration Statistics

The Administration Statistics cube lets you explore these dimensions:

Case Creation Date Year (YYYY) Quarter (Q1, Q2, Q3, Q4) Month	Country of Incidence: Country of incidence
Initial / Follow-up: Initial Follow-up Significant or Not	Receipt Year Year (YYYY) Quarter (Q1, Q2, Q3, Q4) Month
Study Protocol Number Study Number Center Number	Report Type: (SR/LIT/CT/PMS- based on derivation rule)

Case Seriousness (Serious/Non-Serious)	Case Outcome (Died/Improving/…)
Case Causality (Related / Not Related)	Case Listedness (Listed / Unlisted / Unknown)
Case Listedness Notes	Product Family: Family Name (Primary Suspect Drugs)
Time to Entry (In days, based on derivation rule)	Time to Central Receipt
Time to Lock	Lock Date Lock Year Lock Month
Blinding Status: Unblinded Status (Blinded / Broken by sponsor / Broken after study / Open Label Trial / Not Blinded)	Site: Master owned by Site
Workflow Status	Workflow Group Workflow group User Name

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 three Cubes: Clinical Trial Analysis, Medical Analysis and Overdose-Pregnancy-Interaction.

Clinical Trial Analysis

The Clinical Trial Analysis Cube can be generated only for clinical trial cases and enables you explore these dimensions.

Rows: Report Type Columns: Country of Inci...

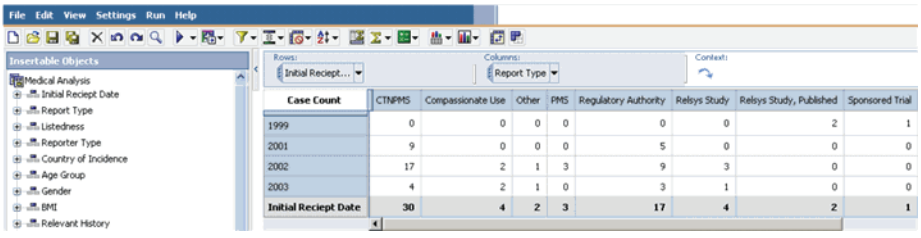
Case Count	B	D	F	G	I	J	N	P	S	U	Country of Incidence
Compassionate Use	1	0	0	0	2	0	0	0	2	0	5
Non Relsys Study	0	0	0	1	0	0	0	0	0	0	1
Post Marketing Surv.	0	1	0	0	1	0	0	0	0	0	2
Relsys Study	0	0	2	1	3	2	0	0	0	4	12
Relsys Study, Published	0	0	0	2	0	0	0	1	2	0	5
Sponsored Trial	0	0	0	0	1	0	1	0	0	2	4
Report Type	**1**	**1**	**2**	**4**	**7**	**2**	**1**	**1**	**4**	**6**	**29**

Initial Receipt Date Year (YYYY) Quarter (Q1, Q2, Q3, Q4) Month	Report Type: (SR/LIT/CT/PMS- based on derivation rule)
Country of Incidence	Age Group
Gender	Relevant History: Description PT
Events: (all events) SOC HLGT HLT PT LLT	Case Seriousness (Serious/Non-Serious)
Case Listedness (Listed / Unlisted / Unknown)	Case Causality (Related / Not Related)
Case Outcome (Died/Improving/…)	Leading Event/Diagnosis: Diagnosis (Yes/No)
Event Seriousness: (Yes/No)	Event Death: (Yes/No)

Event LT: (Yes/No)	Event Hospitalized: (Yes/No)
Event Disability: (Yes/No)	Event Congenital Anomaly: (Yes/No)
Event Medically Significant: (Yes/No)	Conservative Event Causality Conservative Event Causality (Derived *field* for the Study Drug)
Event Listedness Event Listedness (for the Administered/Blinded Drug and Datasheet with Name "IB")	Study Drug: (Investigational Products) Family Name Study Number Center Number
Administered Drug Family Name or "Blinded" <Drug> (Administered Drug or "Blinded")	Drug Type: (Suspect / Concomitant / Treatment)
Additional Products (only WHO Drugs) Chemical subgroup: ATC Code Pharmacological subgroup: ATC Code (ATC Text) <WHO Drug Name> (Preferred Term)	Blinding Status: Unblinded Status (Blinded / Broken by sponsor / Broken after study / Open Label Trial / Not Blinded)
Treatment Duration - Hours	Treatment Duration - Days
Treatment Duration - Weeks	Treatment Duration - Months
Treatment Duration - Years	Daily Dose Daily Dose
Route of Administration: Route of administration	Time to Onset from First Dose - Hours
Time to Onset from First Dose - Days	Time to Onset from First Dose - Weeks
Time to Onset from First Dose - Month	Time to Onset from First Dose - Years
Time to Onset from Last Dose - Hours	Time to Onset from Last Dose - Days
Time to Onset from Last Dose - Weeks	Time to Onset from Last Dose - Months
Time to Onset from Last Dose-Years	

Medical Analysis

You can generate the Medical Analysis standard cube only for Priority Drugs as configured by the administrator. The Medical Analysis Cube lets you explore these dimensions.

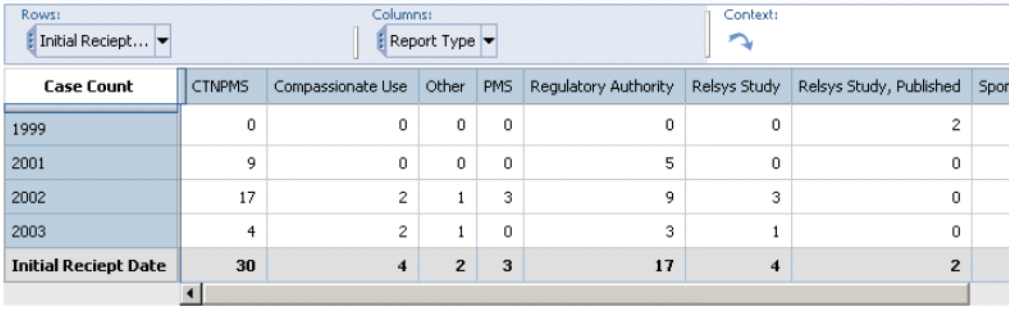


Initial Receipt Date Year (YYYY) Quarter (Q1, Q2, Q3, Q4) Month	Report Type (SR/LIT/CT/PMS- based on derivation rule)

Reporter Type (HCP/Non-HCP/Unknown)	Country of Incidence
Age Group	Gender
BMI (as per Derivation Rule)	Relevant History: Description PT
Events: (all events) SOC HLGT HLT PT LLT	Case Seriousness (Serious/Non-Serious)
Case Causality (Related / Not Related)	Case Outcome (Died/Improving/…) (Died is a derived value based on derivation rule)
*Dechallenge*Result (Pos/Neg/NA/Unk)	*Rechallenge*Result (Pos/Neg/NA/Unk)
Leading Event/Diagnosis: Diagnosis (Yes/No)	Event Seriousness: (Yes/No)
Event Death: (Yes/No)	Event LT: (Yes/No)
Event Hospitalized: (Yes/No)	Event Disability: (Yes/No)
Event Congenital Anomaly: (Yes/No)	Event Medically Significant: (Yes/No)
Conservative Event Causality: Conservative Event Causality	Event Listedness: BPI Event Listedness (for all Company suspect drugs and Datasheet with Name "BPI")
Company Product: Family Name Product Name	Drug Type: (Suspect / Concomitant / Treatment)
Additional Products (only WHO Drugs) Chemical subgroup: ATC Code Pharmacological subgroup: ATC Code (ATC Text) <WHO Drug Name> (Preferred Term)	Treatment Duration - Hours
Treatment Duration - Days	Treatment Duration - Weeks
Treatment Duration - Months	Treatment Duration - Years
Daily Dose: Daily Dose	Indication: (for Company Suspect Drugs) Indication (for Company Suspect Drugs)
Route of Administration: Route of administration	Time to Onset from First Dose - Hours
Time to Onset from First Dose - Days	Time to Onset from First Dose - Weeks
Time to Onset from First Dose - Month	Time to Onset from First Dose - Years
Time to Onset from Last Dose - Hours	Time to Onset from Last Dose - Days
Time to Onset from Last Dose - Weeks	Time to Onset from Last Dose - Months
Time to Onset from Last Dose - Years	

Overdose-Pregnancy-Interaction

The Overdose-Pregnancy-interaction standard cube can be generated only for cases where at least one of the following fields is mentioned: Overdose Interaction Pregnancy Lack of Efficiency.



Case Count	CTNPMS	Compassionate Use	Other	PMS	Regulatory Authority	Relsys Study	Relsys Study, Published	Spor
1999	0	0	0	0	0	0	2	
2001	9	0	0	0	5	0	0	
2002	17	2	1	3	9	3	0	
2003	4	2	1	0	3	1	0	
Initial Reciept Date	**30**	**4**	**2**	**3**	**17**	**4**	**2**	

The Overdose-Pregnancy-Interaction Cube lets you explore these dimensions.

Initial Receipt Date: Case Creation Date Year (YYYY) Quarter (Q1, Q2, Q3, Q4) Month	Age Group
Gender	BMI (As per Derivation Rule)
Relevant History	Events: (all events) SOC HLGT HLT PT LLT
Case Listedness: (Listed / Unlisted / Unknown)	Case Outcome: (Died/Improving/…)
Leading Event/Diagnosis: Diagnosis (Yes/No)	Event Seriousness: (Yes/No)
Event Death: (Yes/No)	Event LT: (Yes/No)
Event Hospitalized: (Yes/No)	Event *Disability*: (Yes/No)
Event Congenital Anomaly: (Yes/No)	Event Medically Significant: (Yes/No)
Event Outcome (Fatal/Improving/…)	· Event Listedness BPI Event Listedness (for all suspect drugs and Datasheet with Name "BPI")
Company Product Family Name Product Name	Drug Type: (Suspect / Concomitant / Treatment)
· Additional Products (only WHO Drugs) Chemical subgroup: ATC Code Pharmacological subgroup: ATC Code (ATC Text) <WHO Drug Name> (Preferred Term)	Daily Dose Daily Dose
Indication: (for Company Suspect Drugs) Indication (for Company Suspect Drugs)	Route of Administration: Route of administration
Time to Onset from First Dose - Hours	Time to Onset from First Dose - Days
Time to Onset from First Dose - Weeks	Time to Onset from First Dose - Month
Time to Onset from First Dose - Years	Time to Onset from Last Dose - Hours
Time to Onset from Last Dose - Days	Time to Onset from Last Dose - Weeks
Time to Onset from Last Dose - Months	Time to Onset from Last Dose - Years
Overdose (as per Derivation Rule)	Interaction (as per Derivation Rule)
Pregnancy (as per Derivation Rule)	Lack of Efficacy (as per Derivation Rule)

Working with Cubes

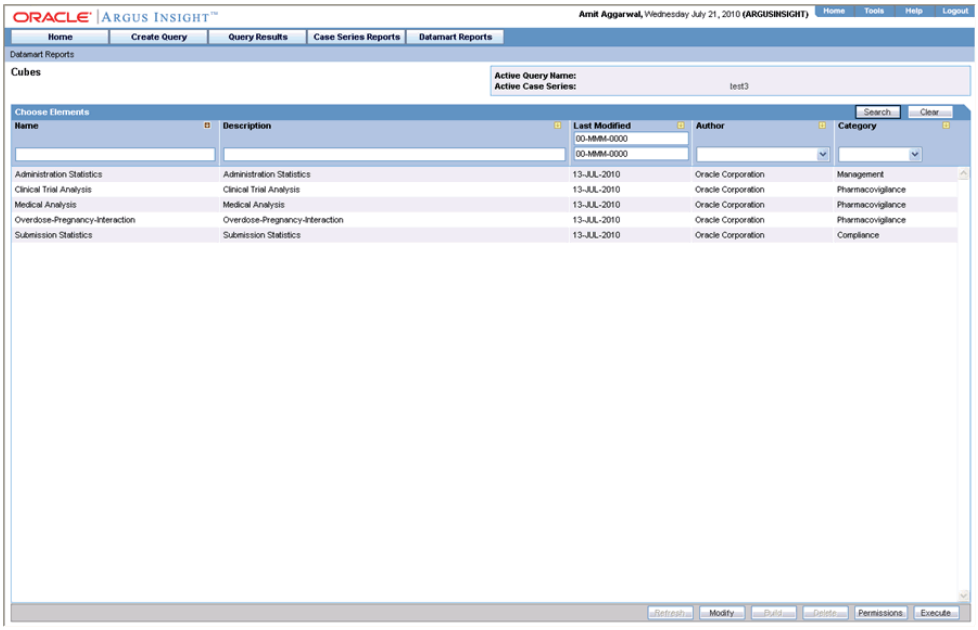
This section provides information about using and executing Cubes. Be aware, however, that this section only discusses the basic features of Standard and Demand Cubes. For detailed information, refer to the documentation supplied with the Cognos8 products.

Refer to the section onCreating Demand Cubesfor detailed information on creating Demand Cubes

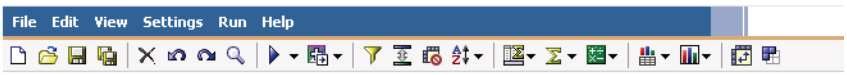
Executing a Cube

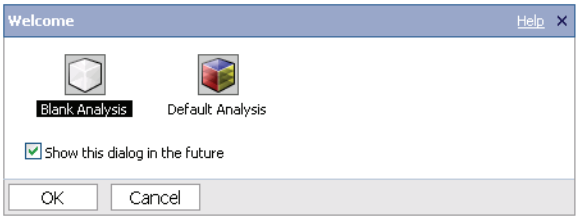
Use the following procedure to execute a Cube.

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.

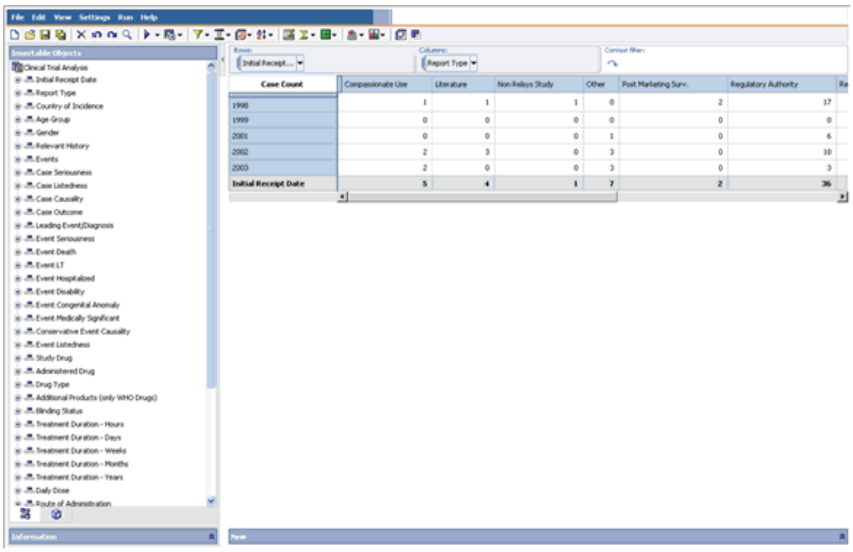


2. Select the Cube you wish to execute.
3. Click **Execute**. A separate Analysis Studio Explorer window displays the option to view the cube in either the **Default Analysis** or **Blank Analysis** state.





4. Select **Default Analysis** to view the Cube in the interface similar to the one shown in the following figure.



Tip: Alternatively you can select the **Blank Analysis** option. This is useful when you want to select the Cube dimensions and measures based on your analysis requirements.

The Default Analysis option is helpful when you need to perform Cube analysis on the default dimensions and measures displayed in the Cube.

The left frame of the Cognos Analysis Studio Web Explorer window displays the available dimension categories (reporting aspects) in a tree hierarchy.

The **Measures** 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. Use the following procedure 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.

The sections that follow explain the basic Analysis Studio Web Explorer options that let you work with Cubes.

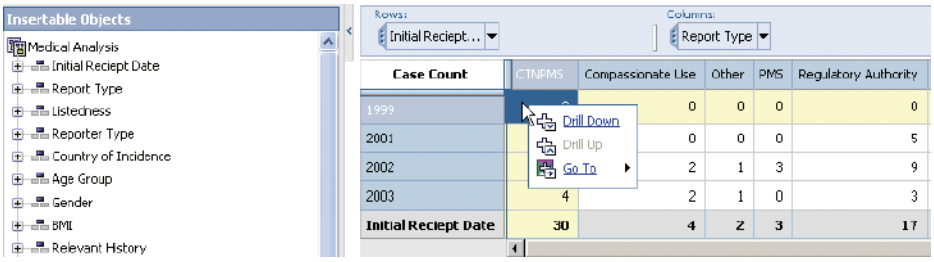
Performing Drill Operations

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. For example, in a Cube that shows years and quarters asgrouped dimensions, drilling down on a specific year removes the redundant years levels.

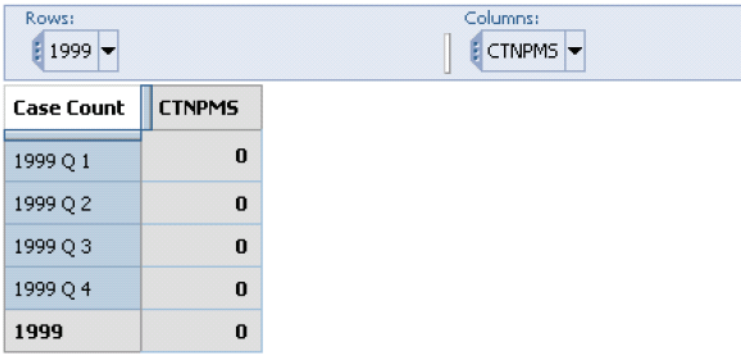
An example to demonstrate the drill functionality follows.

Use the following procedure to drill down to the next level in a hierarchical dimension, such as Product.

1. Click in the area between the top-left cell (measure cell) and the first header cell of the dimension row/column as shown in the following figure.



2. Click the **Down a Level** icon in the context menu that appears. The Cube output changes to display the data for all the next level dimensions.

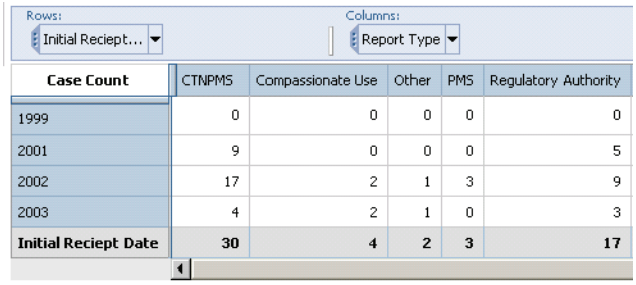


3. If the dimension has another lower level, you can drill down further by performing step 2.
4. While the above steps let you display the data for all the lower levels for all the products, you may change the reporting focus by only displaying the lower-level data for a specific product. Use the following procedure to do this, simply click on the dimension in the Cube output.

Filtering Data

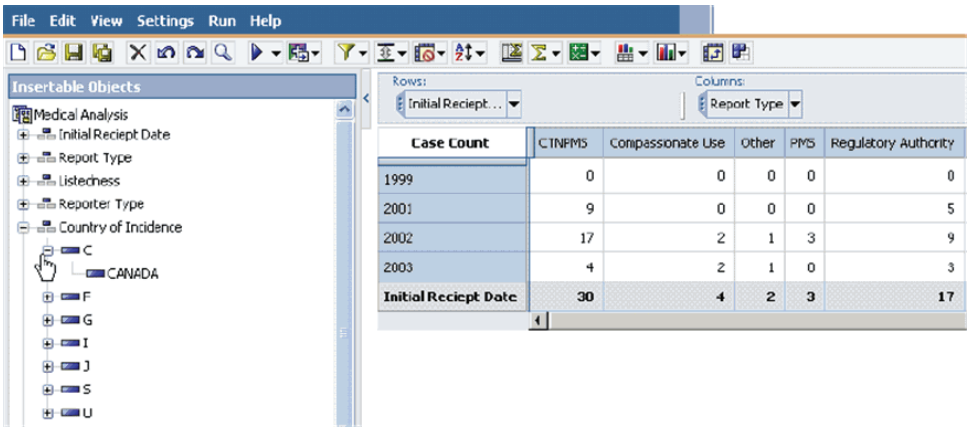
You can select a dimension to filter a Cube in order to reduce the data displayed in the Cube output. Unlike thedrilloperation, filtering does not change the existing Cube layout. Instead, it changes the measure values displayed in the Cube output according to the dimension you select as the filter.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

In the **Medical Analysis** Cube, the default row dimensions are from the **Initial Receipt Date** category and the default column dimensions are from the **Report Type** 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.



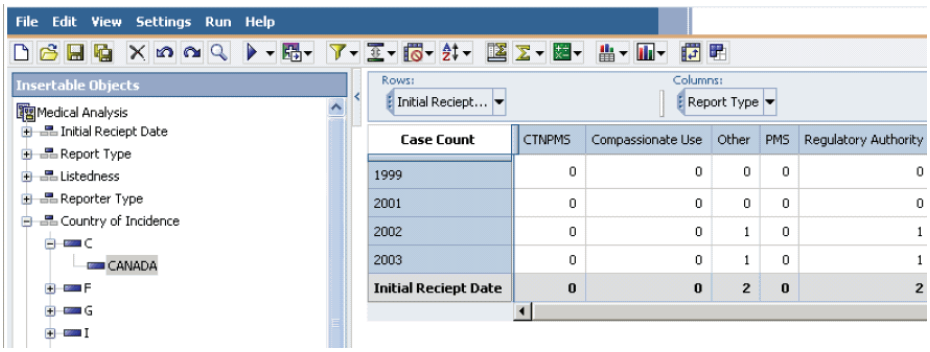
Case Count	CTNPMS	Compassionate Use	Other	PMS	Regulatory Authority
1999	0	0	0	0	0
2001	9	0	0	0	5
2002	17	2	1	3	9
2003	4	2	1	0	3
Initial Reciept Date	**30**	**4**	**2**	**3**	**17**

1. While the **Medical Analysis** Cube is open, the left panel in the Analysis Studio web browser window lists all the dimension categories available for the **Medical Analysis** cube.



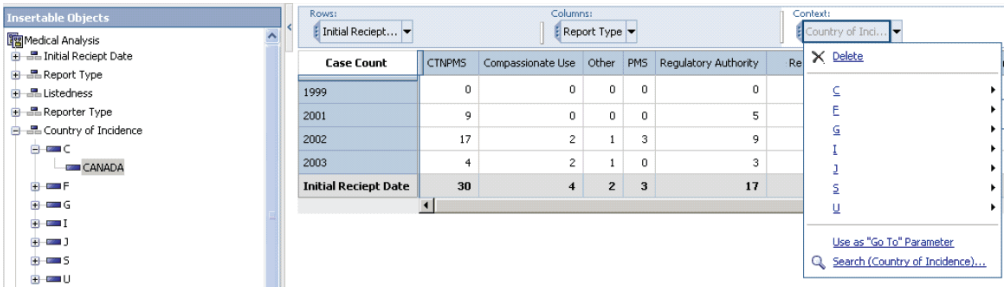
Case Count	CTNPMS	Compassionate Use	Other	PMS	Regulatory Authority
1999	0	0	0	0	0
2001	9	0	0	0	5
2002	17	2	1	3	9
2003	4	2	1	0	3
Initial Reciept Date	**30**	**4**	**2**	**3**	**17**

2. Drag and drop **Country of Incidence > Canada**, from the left-panel into the **Context** drop-down list as shown in the following figure.



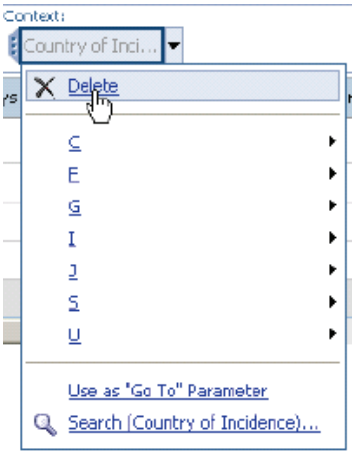
Case Count	CTNPMS	Compassionate Use	Other	PMS	Regulatory Authority
1999	0	0	0	0	0
2001	0	0	0	0	0
2002	0	0	1	0	1
2003	0	0	1	0	1
Initial Reciept Date	**0**	**0**	**2**	**0**	**2**

3. While the layout of the **Medical Analysis** Cube remains the same, the data in the Cube output changes to display the measure values specific to the selected country. Additionally, the **Context** drop-down displays **Canada** to indicate that the Cube output is filtered by the Canada dimension.
4. You can filter the output further by selecting another dimension as the filtering criterion.



Removing the Filter

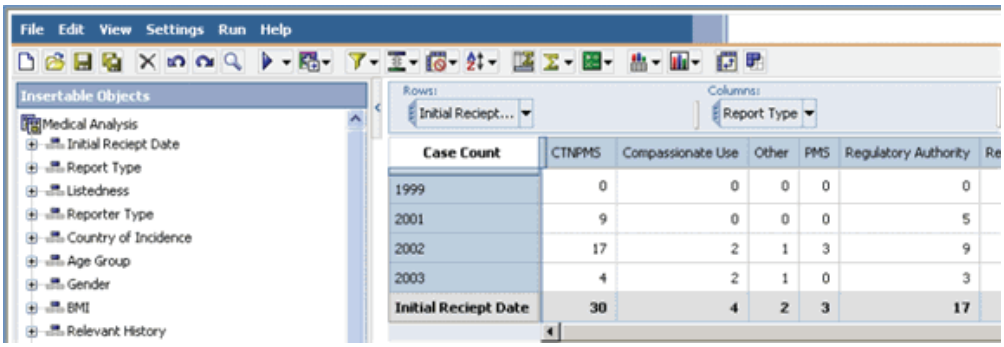
You can eitherresetthe Cube output or click the undo icon or in the Context drop-down list, right click to view the delete option. For example, to remove the filter described in the example above, select **Country of Incidence>Canada** in the Context drop-down and click **Delete**.



Replacing Rows and Columns

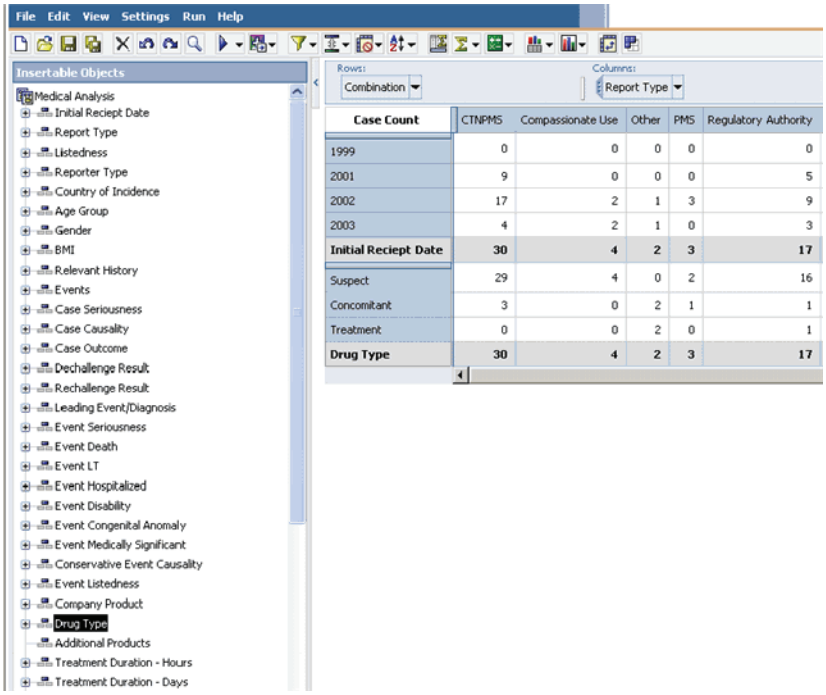
You may want to replace the existing row or column dimensions with dimensions from another category to observe the interaction between dimensions from different categories. Use the following procedure to do this, you can drag a category or a dimension from the left-panel of the Cognos Analysis Studio Web Explorer window into the middle of any header cell of the column or row you want to replace. An example follows.

In the **Medical Analysis** Cube, the default row dimensions are from the **Initial Receipt Date** category and the default column dimensions are from the **Report Type** category.



Use the following procedure to replace the existing row dimensions.

1. With the **Drug Type** dimensions , select and drag the **Drug Type** dimension from the left panel to the middle of any row header cell in the Cube.
2. The existing row dimensions in the Cube are replaced with the **Drug Type** dimension.



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 panel into the middle of a row/column header cell.

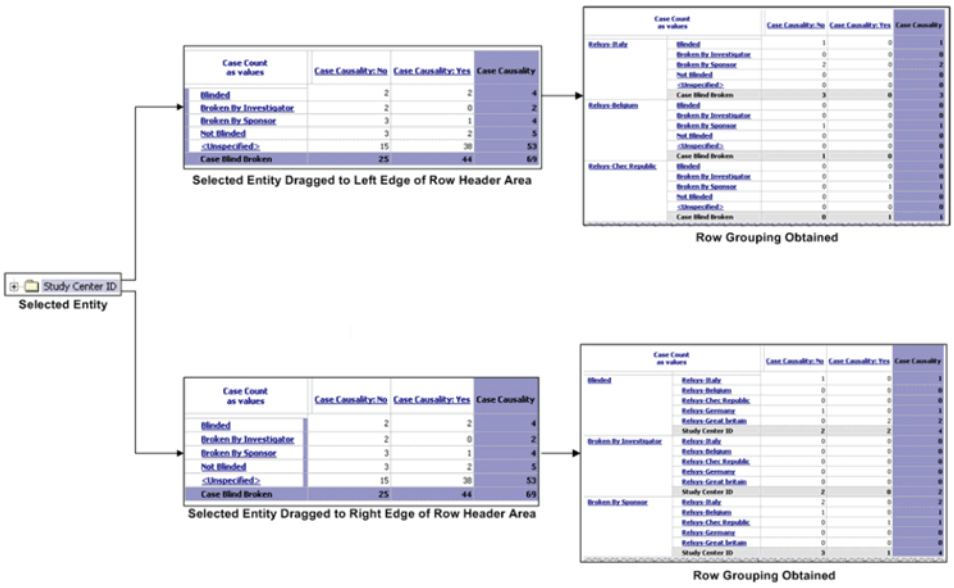
Grouping Multiple Rows and Columns by a Dimension or Category

You can have multiple rows and columns in a Cube by dragging additional entities (dimensions or categories) from the tree structure 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.

Obtaining a New Row Grouping

Select an entity from the tree structure in the left frame of the Analysis Studio Web Explorer window and drag it into the left or right edge of the row header area within the Cube.

The Cube output refreshes to show the grouping depending on the edge of the row header area where you dragged the new entity.



Obtaining a New Column Grouping

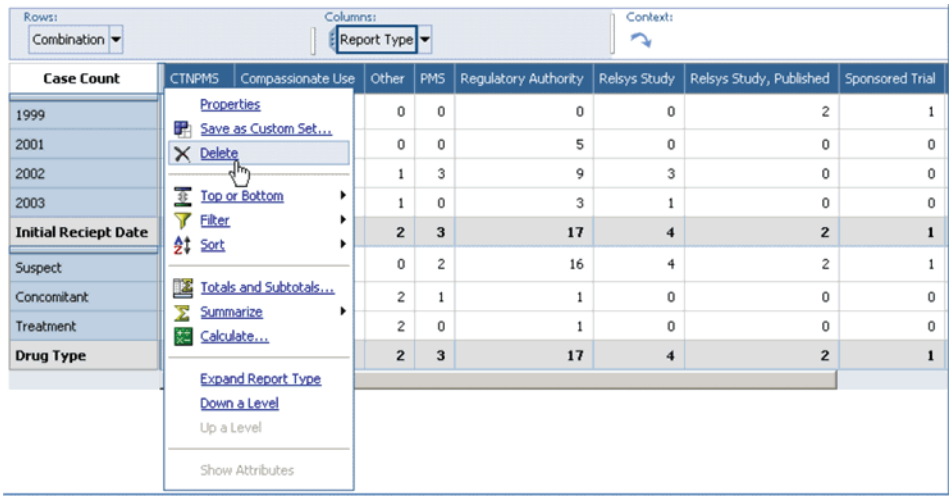
Use the following procedure to obtain a new column grouping.

1. Select an entity from the tree structure in the left frame of the Analysis Studio Web Explorer window.
2. Drag the entity to the upper or lower edge of the column header area in the Cube.
3. The Cube output refreshes to show the grouping depending on the edge of the column header area where you dragged the new entity.

Removing a Dimension Row from a Cube

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

1. Click in the white space between the top-left cell (measure cell) and the first header cell of the dimension row.



2. In the context menu that appears, click the **Delete** icon to delete the dimension row.

Removing a Dimension Column from a Cube 1.

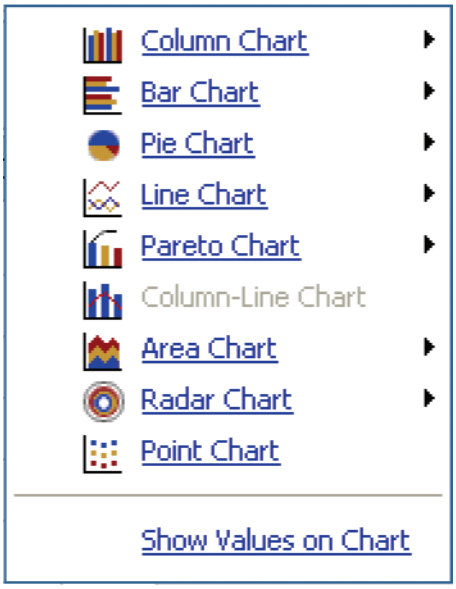
Click in the white space area between the top-left cell (measure cell) and the first header cell of the dimension column.

2. In the context menu that appears, click the **Delete** icon to delete the dimension column.

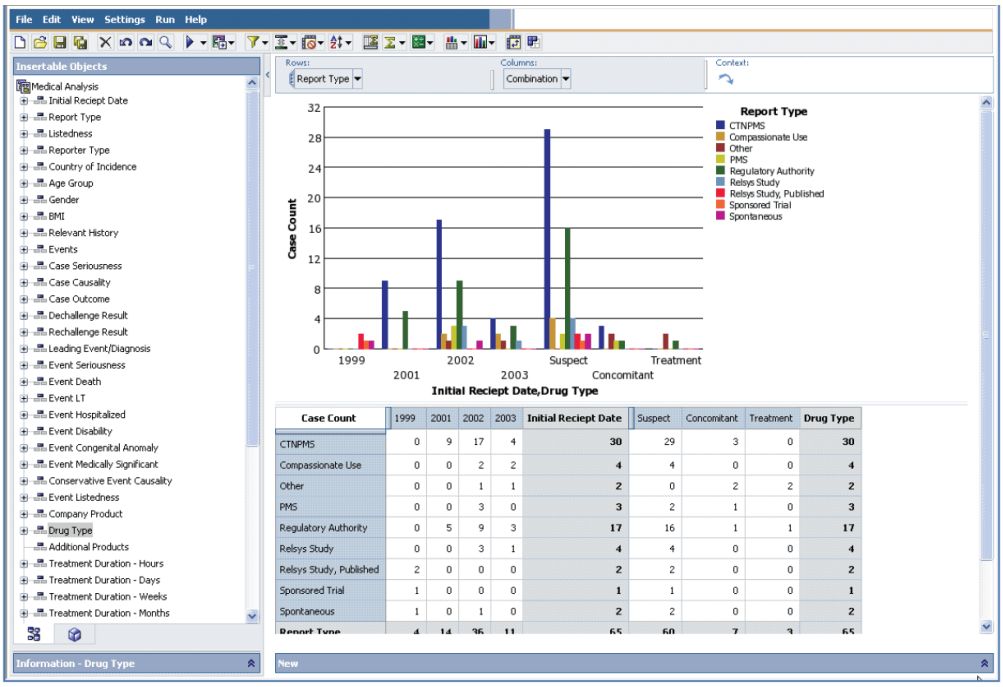
Creating Charts

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. Click the arrow next to the **Chart** icon on the Analysis Studio Web Explorer toolbar. A context menu displays the available chart types.



3. Select a chart type from the context menu, as appropriate. The report output refreshes; the chart is displayed.



Case Count	1999	2001	2002	2003	Initial Reciept Date	Suspect	Concomitant	Treatment	Drug Type
CTNPMS	0	9	17	4	**30**	29	3	0	**30**
Compassionate Use	0	0	2	2	**4**	4	0	0	**4**
Other	0	0	1	1	**2**	0	2	2	**2**
PMS	0	0	3	0	**3**	2	1	0	**3**
Regulatory Authority	0	5	9	3	**17**	16	1	1	**17**
Relsys Study	0	0	3	1	**4**	4	0	0	**4**
Relsys Study, Published	2	0	0	0	**2**	2	0	0	**2**
Sponsored Trial	1	0	0	0	**1**	1	0	0	**1**
Spontaneous	1	0	1	0	**2**	2	0	0	**2**
Report Type	**4**	**14**	**36**	**11**	**65**	**60**	**7**	**3**	**65**

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.

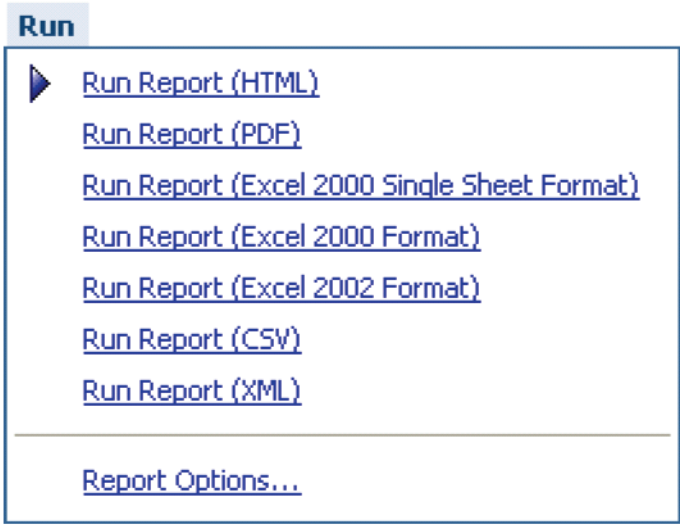
Use the following procedure to interchange rows and columns in a Cube, click the **Swap** icon on the Analysis Studio Web Explorer toolbar. If there are multiple/grouped rows or columns in the Cube, the outermost rows become the outermost columns, and the outermost columns become the outermost rows.

Exporting the Cube Output to Specific Formats

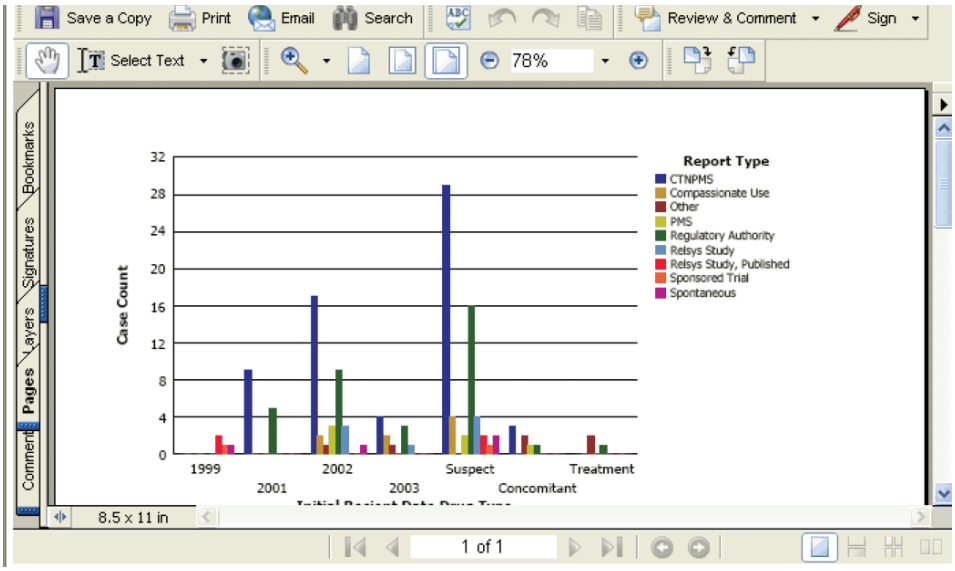
You can export the Cube output to formats, such as PDF, XLS, CSV and XML and save the file on the local machine.

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 **Run** in the Analysis Studio Web Explorer toolbar. A context menu displays the available export options.



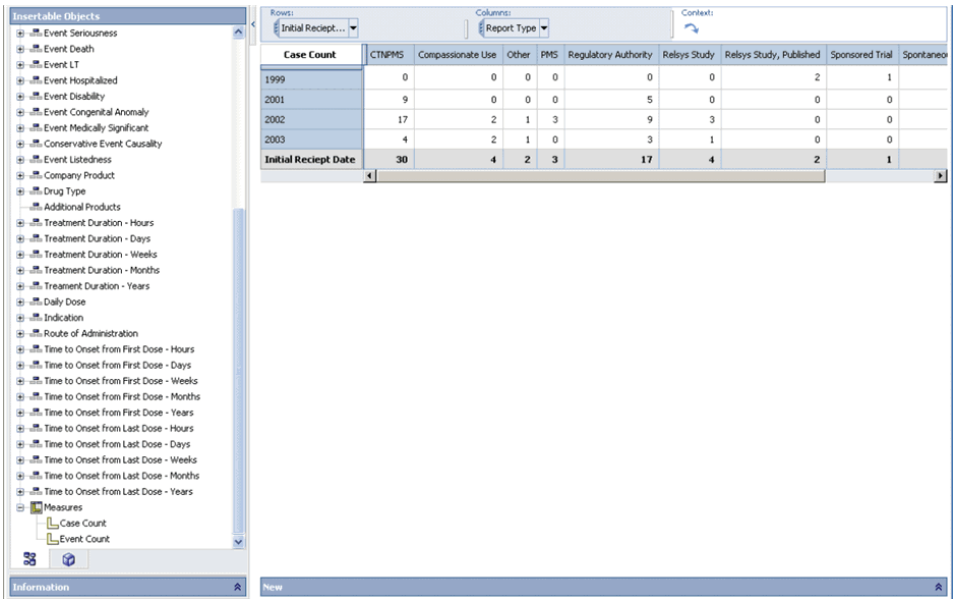
4. Select the desired run option. The file appears in the selected format in a new window.



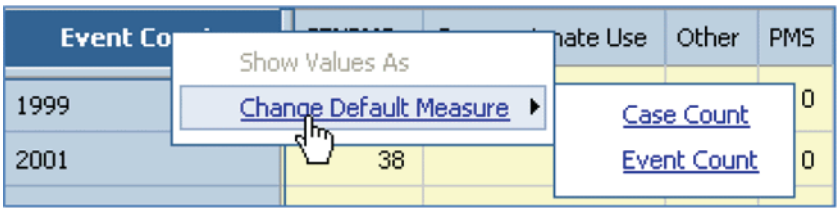
Changing Measures

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 both Case Count and Event Count as available measures. While the default measure displayed in these Cubes is Case Count, you can replace it with Event Count to change the reporting focus.

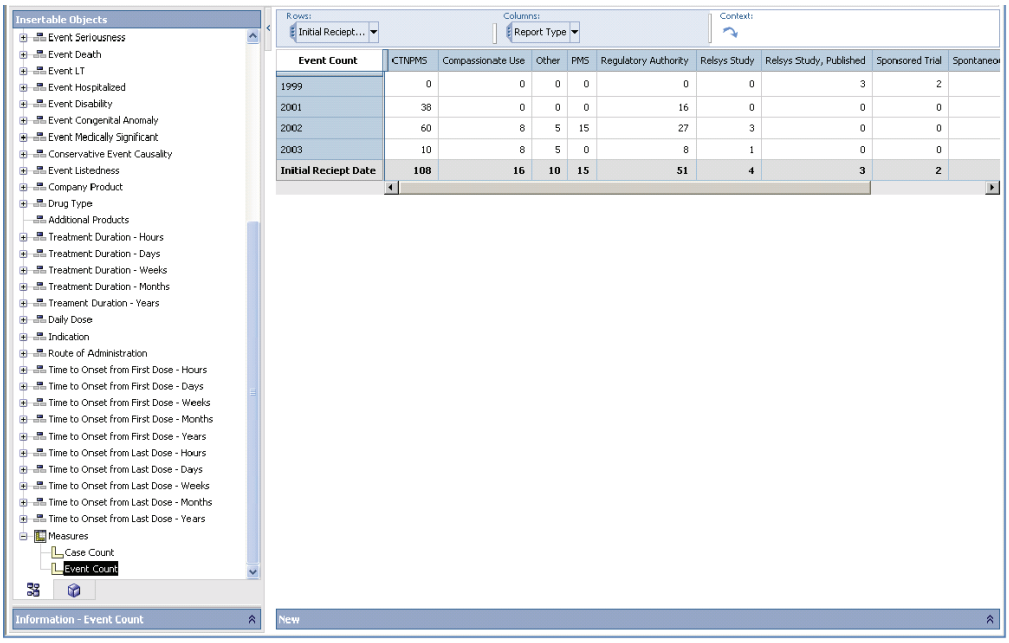
1. In the left panel displayed in the Analysis Studio Web Explorer window, select **Measures**. The measures available for the Cube are displayed.



2. Click and drag the category required under Measure. Alternatively you can also right-click the measure in the cross-tab output and select the required option.



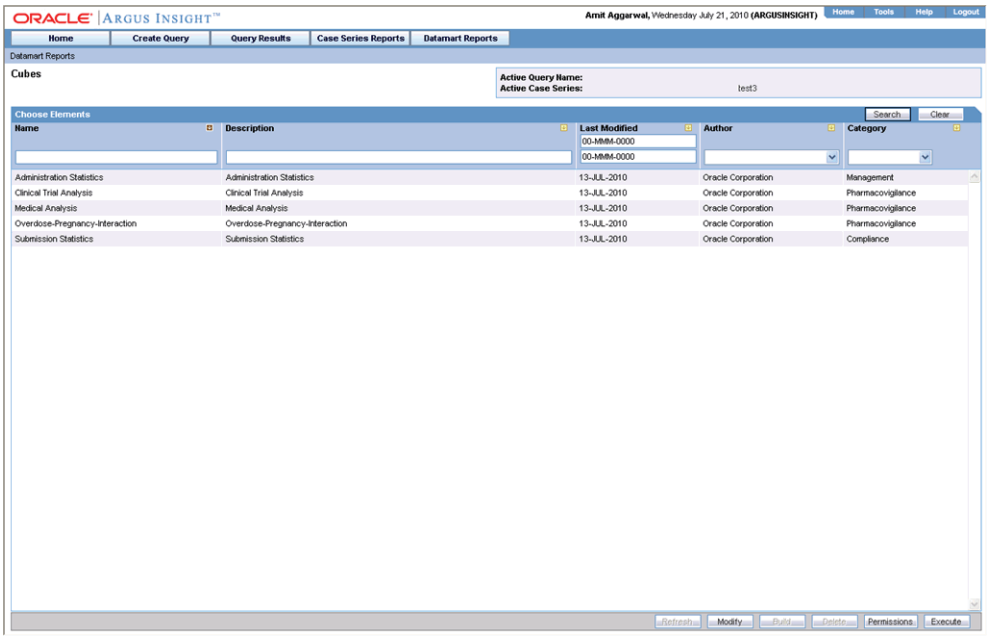
3. The crosstab output is refreshed; **Event Count** is the new measure added to the **Medical Analysis** Cube.



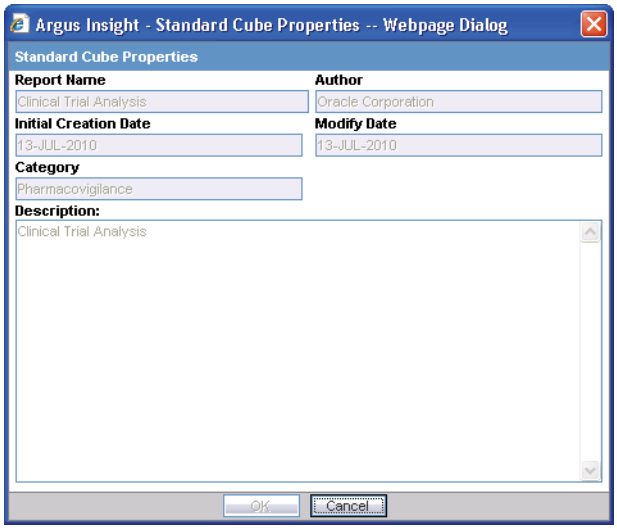
Modifying a Cube

Use the following procedure to modify 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 required Cube and click **Modify**.
3. The Modify cube interface appears. This interface helps you to capture information to modify the Demand 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.

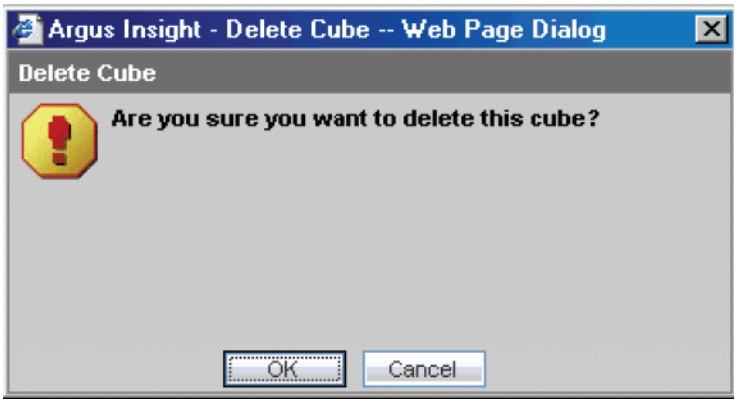
Deleting a Cube

Use the following procedure to delete 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.

   Note: Standard Cubes cannot be modified/deleted.

2. Select the required Cube and Click **Delete**.
3. The Delete cube confirmation dialogue 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 will be able to 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 Cubes 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 will be able to access the Case Series
Full Access	You can modify/delete/view the Cube

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

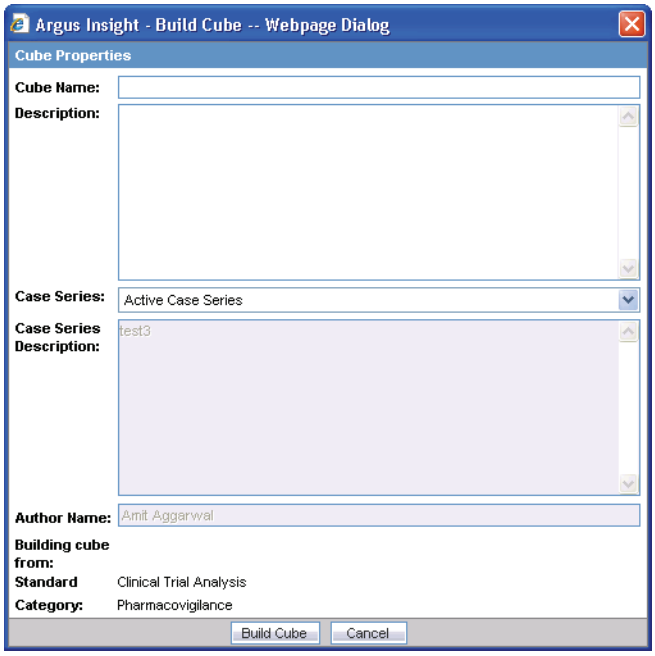
Creating Demand Cubes

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 onWorking with Cubes.

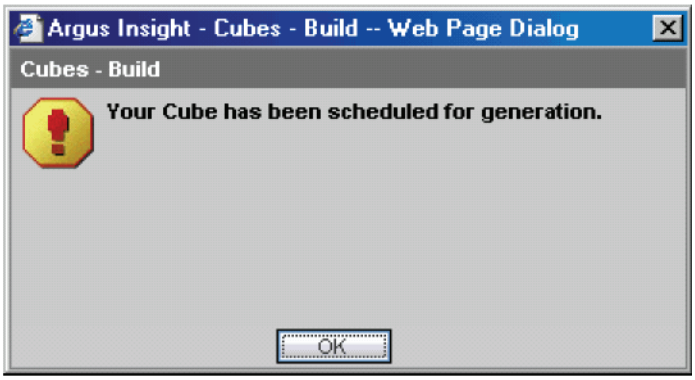
Demand Cubes are based on a specificCase Seriesinstead of the entire datamart. Therefore, you can use demand Cubes to analyze a reduced data set based on a specific Case Series and quickly obtain the desired reporting focus without having to

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.

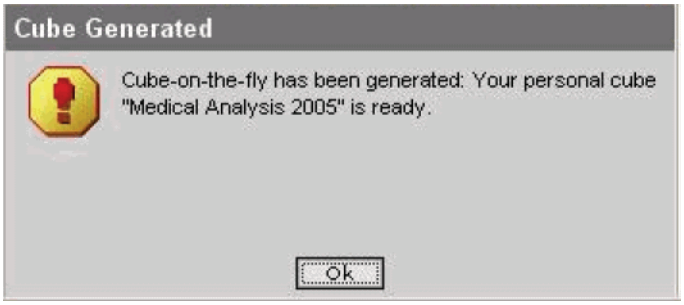
1. In Argus Insight, select **Datamart Reports >Cubes** > **All**. The **Cubes** page displays all the built-in Cubes in Argus Insight.
2. Select the standard Cube using which you wish to create the demand Cube. The Cube name is highlighted; the **Build** button becomes active.
3. Click **Build**. The **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 Cognos8 server.



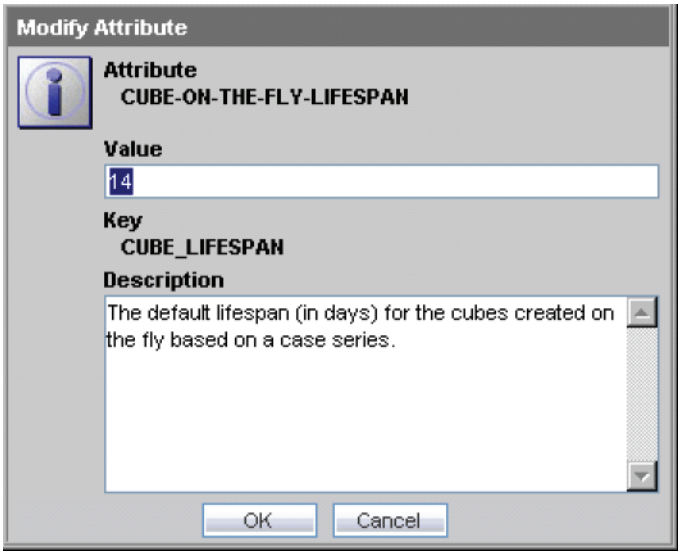
8. Click **OK**. The **Cubes** page displays the demand Cube name in grey.
9. When the Cognos8 server generates the demand Cube, the **Cubes Generated** dialog box notifies you. After the Cube is generated, you can execute it by selecting the Cube name and clicking **Execute**.



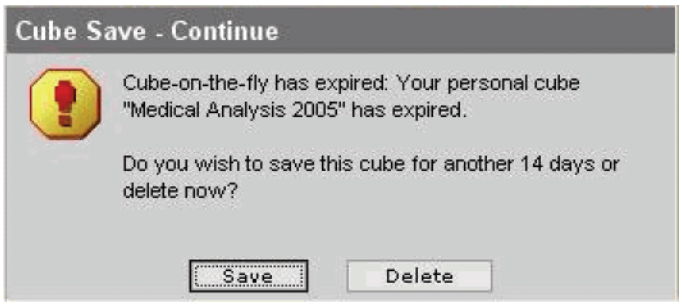
Note: The maximum number of cases for creating Demand Cubes is configured on the List Maintenance items.

Demand Cube Life Span

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. You can configure the Cube-on-the-fly Lifespan list maintenance item to set the expiration period.



When the demand Cube has reached the expiration date, the system notifies you through the following dialog box.



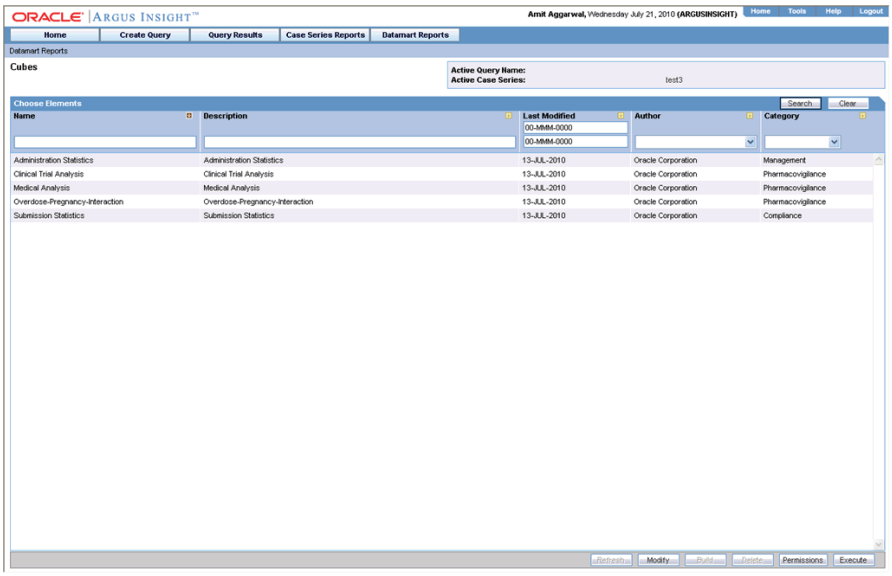
At this point, you can either delete the demand Cube or retain it for another 14 days (default).

Saving Cubes Views

This section describes the procedure to save Cube views (based on the drilled-down data).

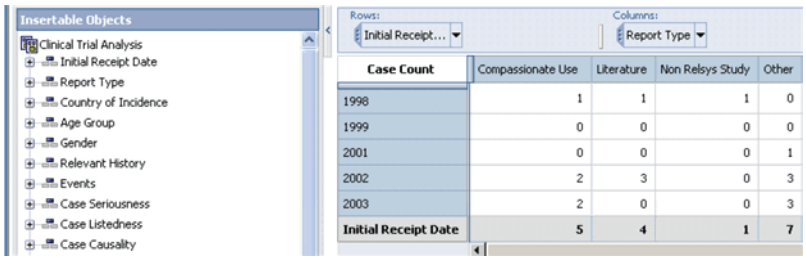
Use the following procedure to save Cube views.

1. Click **Datamart Reports->Cubes All** to view all the cubes

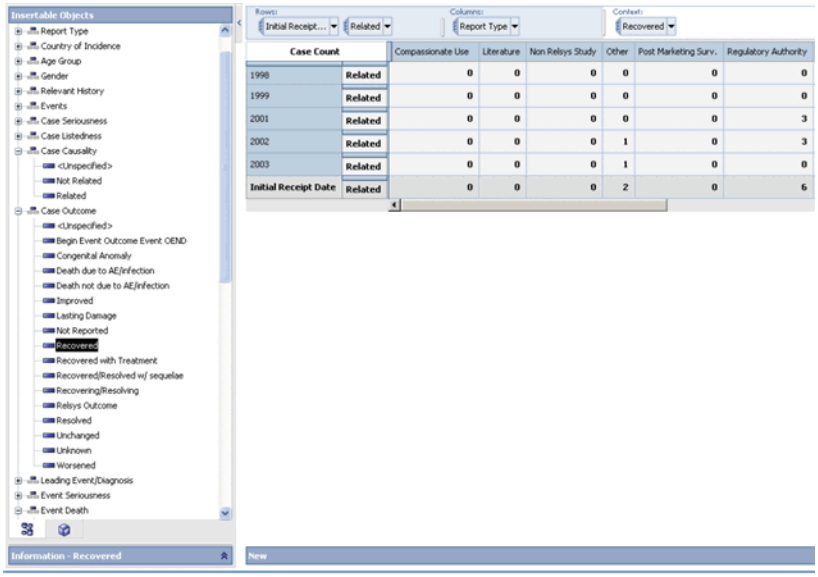


Tip: You can also search for specific Cubes by using any of the search options displayed on the screen.

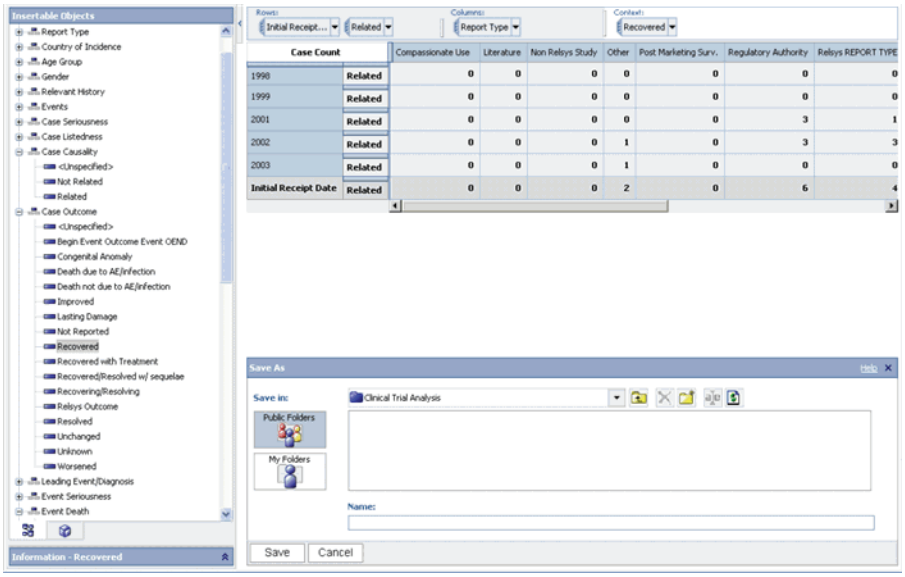
2. Select the Cube view that you want to save. The name of the cube is highlighted.
3. Click **Execute**. The Cognos Analysis Studio web explorer is displayed.



4. Perform the desired drill through operation. The cube view is displayed.



5. From the **File** menu, click **Save**. The **Save As** dialog appears.

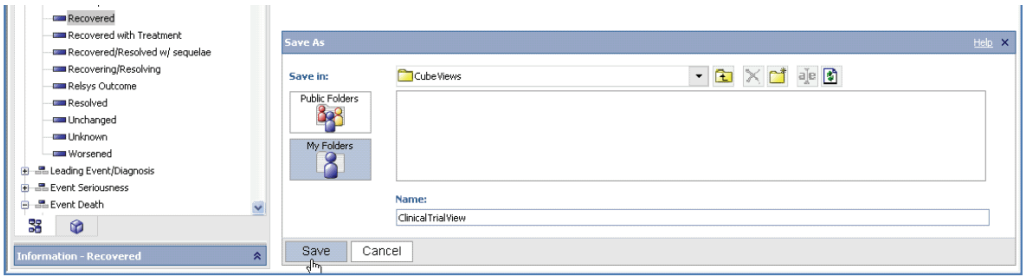


6. Select **My Folders>CubeViews** to save the cube view in the CubeViews folder.

Tip: If the CubeViews folder is not visible, create the CubeViews folder by clicking on the create new folder icon.

When naming the folder, do not leave a space between the letters.

7. Enter and save the **Name** of the Cube view. The Cube view is now saved.



Viewing Saved Cubes

Use the following procedure to view the saved Cube view.

1. Click on **Datamart Reports ->Cubes -> Library** option. 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 only be viewed by the owner or author of the Cube View.

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. Use 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 tasks:

- **Updates Cube data**- the data in the Cube is updated with the latest data from the datamart
- **Copies the updated Cubes in the backup folder**- the updated Cubes are copied into a backup folder that contains subfolders for each Cube; the backup folder path is: **<Argus Insight Installation path>\PowerReports\cognos\backup\PPESCubes**For example:**C:\Program Files \Relsys\PowerReports\Cognos\backup\PPESCubes**
- Copies the updated Cubes in the published folder - the updated Cubes are copied into the published folder at this location: <Argus Insight Installation path>\PowerReports\cognos\PPESCubes For example: C:\Program Files\Relsys\PowerReports\Cognos\PPESCubes

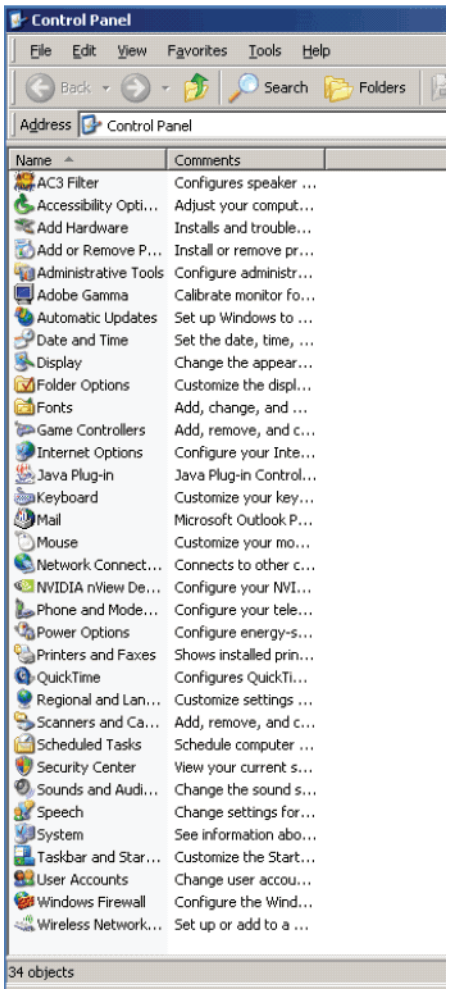
  Individual tasks need to be scheduled to update each Cube. Use the following procedure to improve the performance of the batch process, make sure that individual batch execution processes do not overlap with each other.

Note: Demand Cubes are refreshed sequentially.

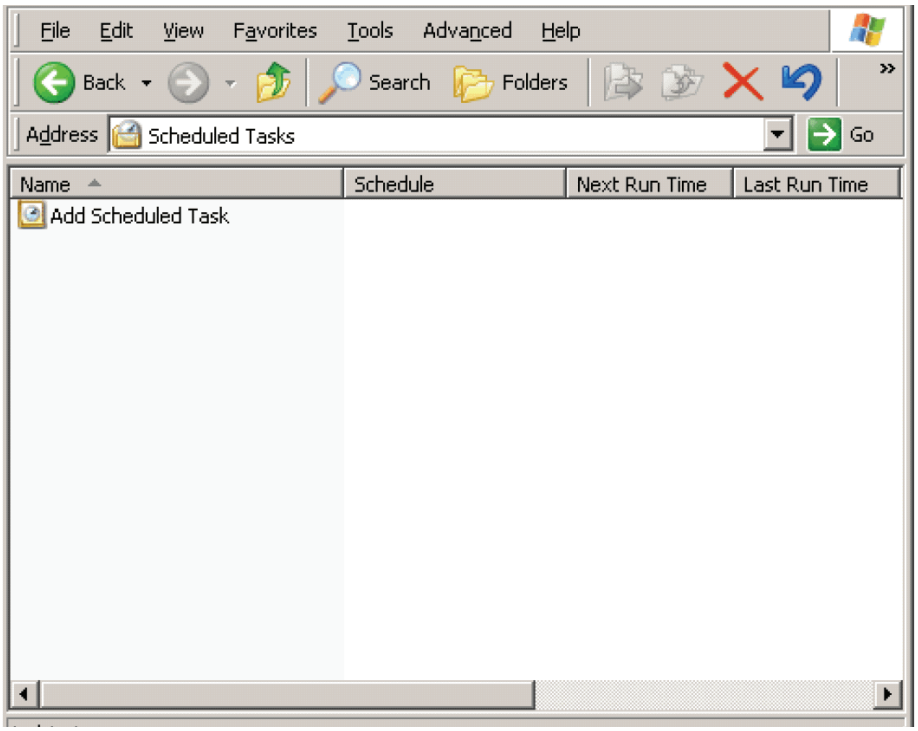
Setting up Batch Generation through Task Manager

This section provides instructions for scheduling batch generation using Windows Task Manager. You must perform this procedure for each of the five Cubes.

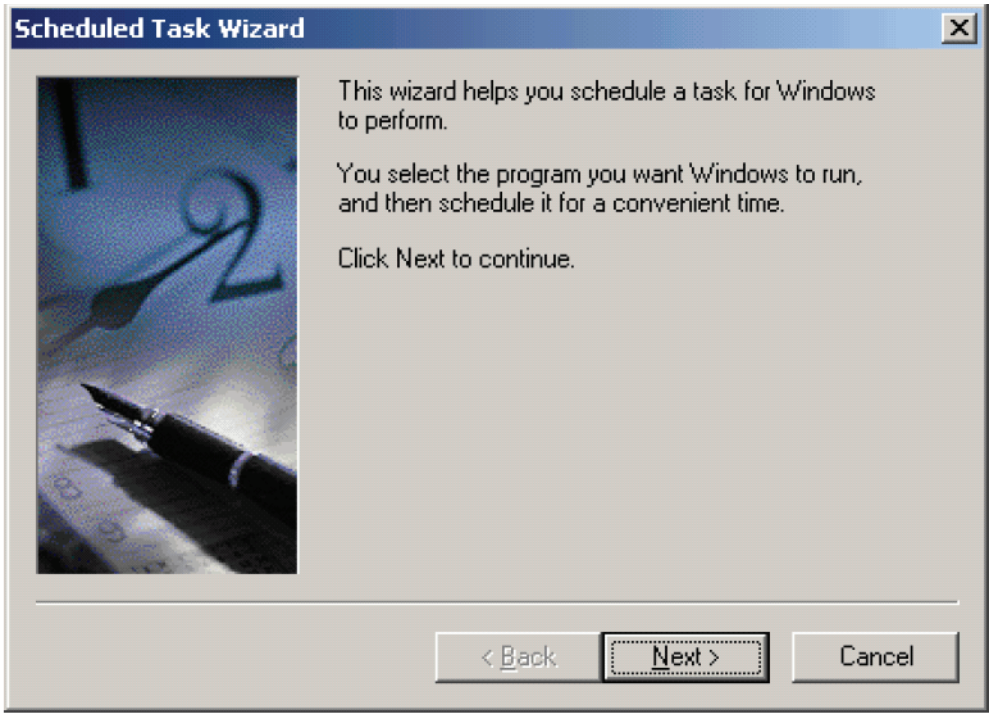
1. On the Cognos8 Server, select **Start > Settings > Control Panel**. The Control Panel window appears.



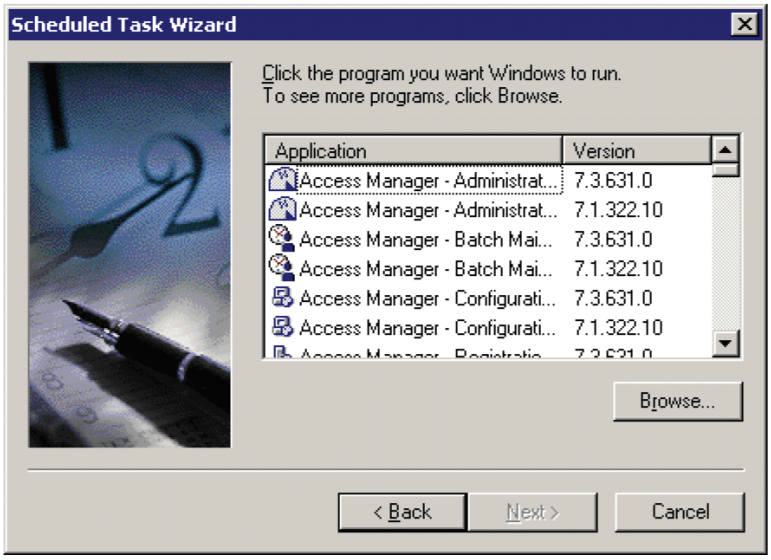
2. Double-click the **Scheduled Tasks** item. The **Scheduled Tasks** window opens.



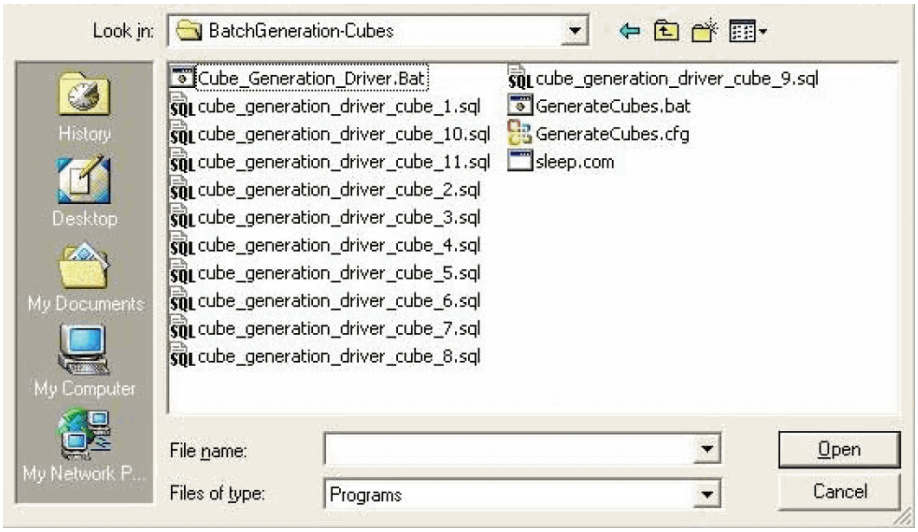
3. Double-click the **Add a Scheduled Task** item. The Scheduled Task Wizard starts.



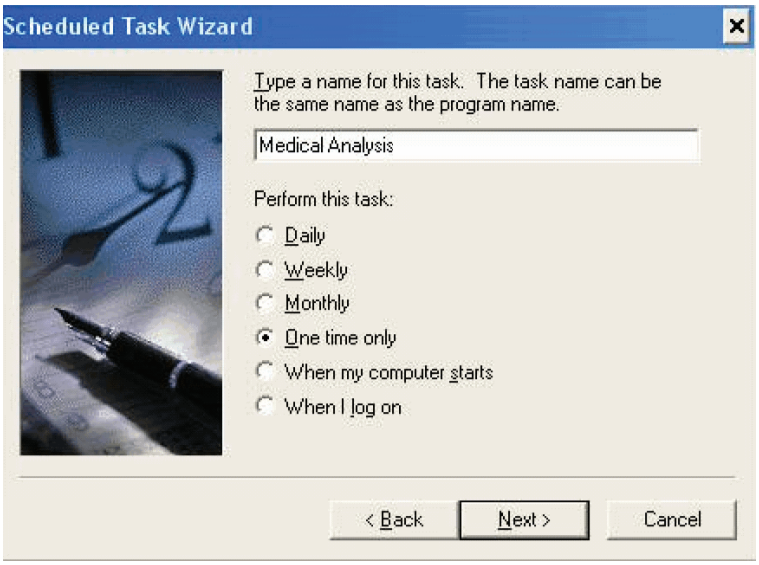
4. Click **Next**. The next screen of Scheduled Task Wizard appears.



5. Click **Browse**. The **Select Program to Schedule** dialog box appears.



6. Navigate to the following location: <Argus Insight Installation Path>\PowerReports\Cognos\Cubes\BatchGeneration-Cubes
7. Select the Cube_Generation_Driver.bat file.
8. Click **Open**. The next screen of Scheduled Task Wizard appears.

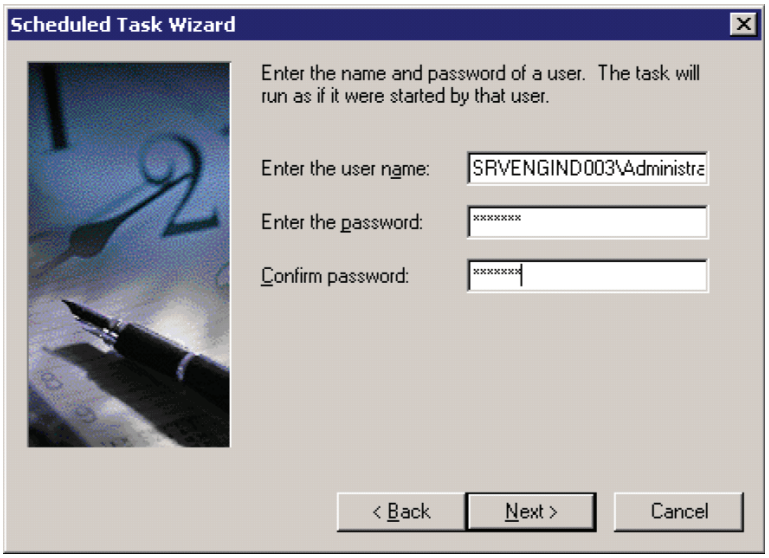


9. In the text box for entering the task name, type **Cube Generate 1**. The task name should be entered in the format **Cube Generate <Cube ID>**. The Cube IDs are listed in the table below.

Cube Name	Cube ID
Medical Analysis	7
Clinical Trial Analysis	8
Overdose-Pregnancy-Interaction	9
Submission Statistics	10
Administration Statistics	11

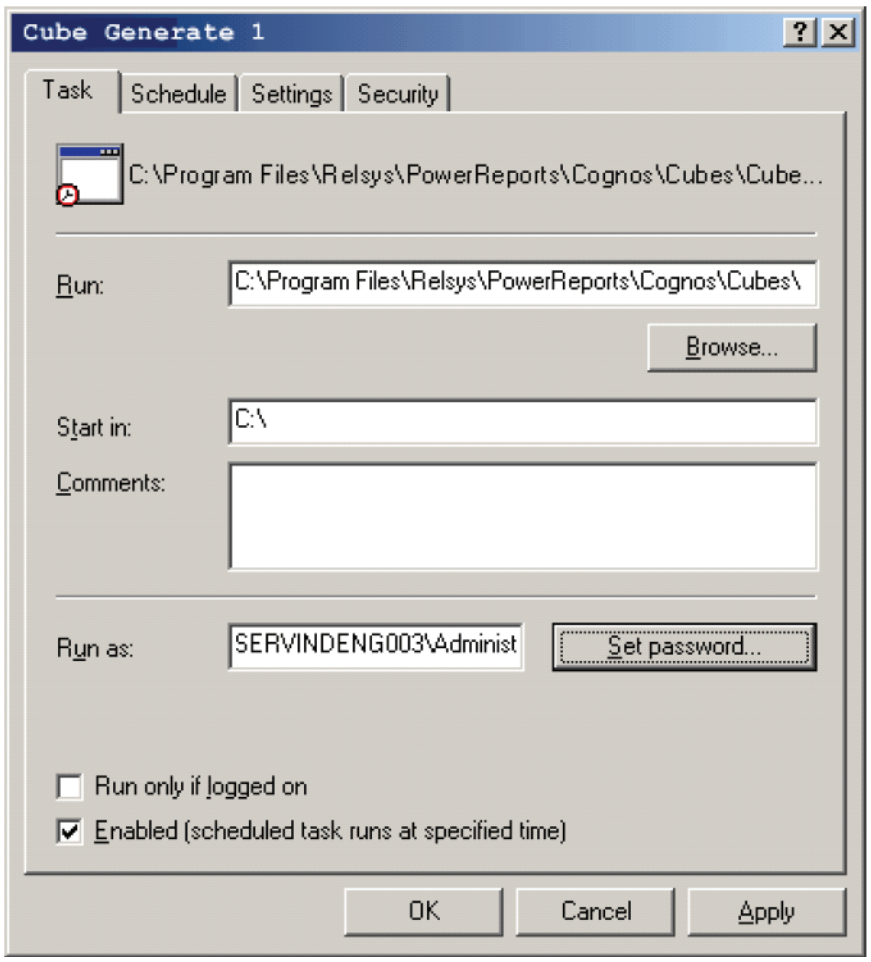
10. Use the **Perform this task** option button group to set the frequency of the task, as appropriate.
11. Click **Next**. The next screen of Scheduled Task Wizard appears.

12. Set the start time and day.
13. Click **Next**. The next screen of Scheduled Task Wizard appears.



14. Enter the user name and password of the user authorized to run this task.
15. Click **Next**. The next screen of Scheduled Task Wizard appears.

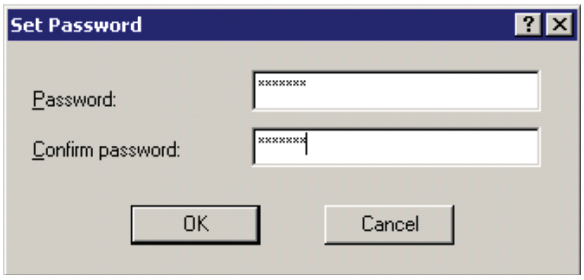
16. Check the Open advanced properties for this task when I click finish checkbox.
17. Click **Finish**. The dialog box for setting advanced properties for the task appears.



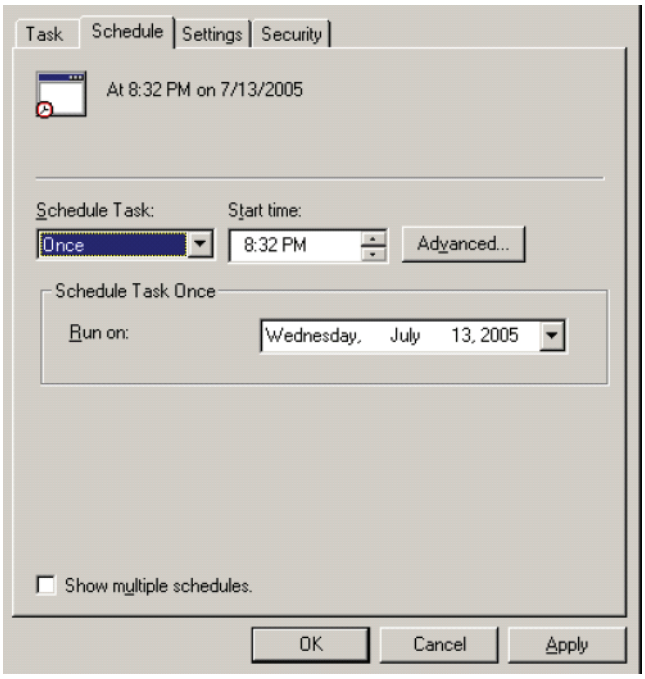
18. In the Run text box within the Task tab, enter the run-time parameter for this task in p[the following format: <Argus Insight Installation Path>\PowerReports\Cognos\Cubes\ BatchGeneration-Cubes\Cube_ Generation_Driver.bat" <Cube ID> <Cognos user name> <Cognos password> where CubeID is the ID of the Cube for which you are scheduling the batch generation, Cognos user name is the user name of the Cognos admin user, and Cognos password is the password for the Cognos admin user. Include the double quotation marks (" ") while entering the runtime parameter. The following table lists the Cube ID for each cube and provides examples of the run-time parameter to be entered.

> **Note:** The Cognos administrator password is blank in the following examples. To reset the Cognos login password, the administrator should log in to Argus Console, uncheck the LDAP authentication, reset the password, and save the change.

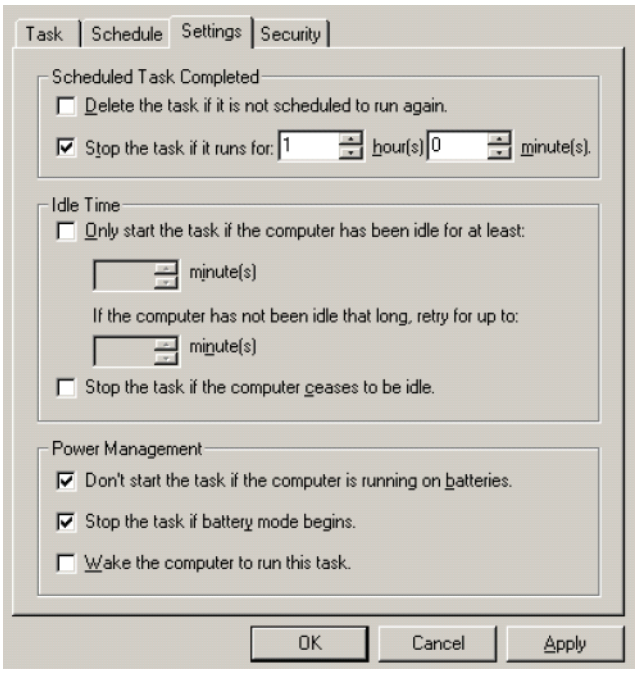
19. Click **Set Password**. The **Set Password** dialog box appears.



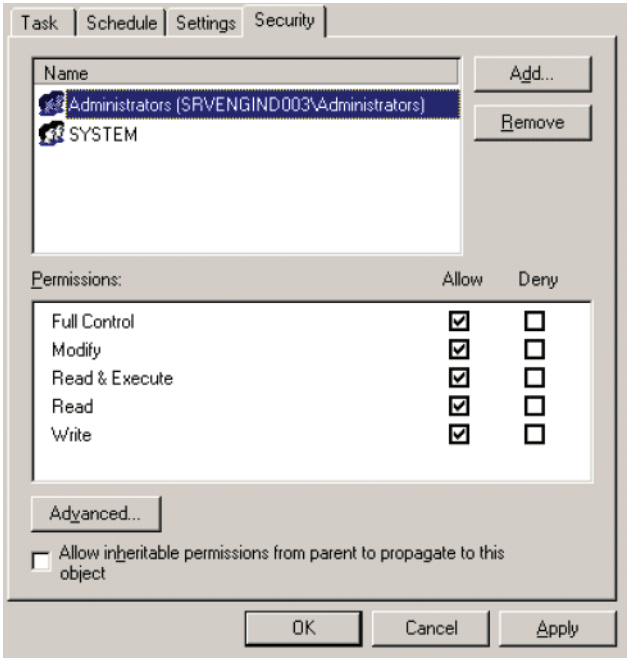
20. Enter the password for the Cognos8 Server admin user.
21. Click **OK**.
22. Select the **Schedule** tab. The **Schedule** tab page appears.



23. Set the schedule options, as appropriate.
24. Select the **Settings** tab. The **Settings** tab page appears.



25. In the **Scheduled Task Completed** and **Power Management** sections, set the options as shown in the figure above.
26. Select the **Security** tab. The **Security** tab page appears.



27. Verify that the user has full permissions assigned.
28. Click **OK**. The system creates the new scheduled task Cube Generation 1. Repeat the above steps to schedule batch generation for the remaining cubes.

9

Multi Tenancy

This chapter describes the Argus Insight features that are specifically applicable during multi-tenancy. These features have been listed and elaborated further in the following sections.

Assumptions and Constraints

This section lists the following assumptions and constrains with which the Argus Insight application works:

- Single Sign On: SSO needs to be enabled to have the capability to switch client context and to open Argus Insight application from the Application Access Portlet.
- Accessing Argus Insight directly via URL: It is expected that the customer will pass the internal Enterprise ID as a URL parameter for the Argus Insight application to open with the appropriate Enterprise context. If Enterprise ID is not passed, the user shall be validated against the default enterprise.
- Global User Management: In order to apply updates to the "Synchronizable" fields to all the enterprises in the system, a customer should maintain some administrative users with the Argus Insight 'Admin Tools' Security tab 'Groups' Group Administration: Administration: Users: Modify User Accounts access enabled for all enterprises in the system.
- User-Enterprise Association: When a user is copied from one enterprise to another, it is expected that the customer has set up the appropriate user groups in the target enterprise. Otherwise the user-association will fail with the appropriate error message.
- New User creation/association: Argus Insight allows same UserID to be used to create different users across multiple enterprises. It is recommended that this feature shall only be used if users are not expected to be shared across enterprises. Otherwise, if users are expected to be shared across multiple enterprises, then same UserID shall not be used to create different users across different enterprises. Instead of that, a user created in one enterprise shall be associated to other enterprises through Global User Management.
- New Enterprise Setup: It is expected that customer shall create and choose appropriate Enterprises with generic configuration data which can be used as source for copying the configuration data for creation of a new enterprises. The following is a list of items that the customer is recommended to ensure that the values being copied from the source enterprise are appropriate for the newly created enterprise:

    a. Power Queries used within any configuration item

b. Reports scheduling data

- The following is the list of items that are common for all enterprises:
  a. MedDRA and WHO dictionaries
  b. Common Profile Switches ' Enable/disable LDAP
  c. Common Profile Switches ' LDAP Server configuration
  d. Common Profile Switches ' Enable/disable SSO
  e. Common Profile Switches ' SSO Header Configuration
  f. Default Enterprise
- Pre-Database Upgrade Considerations for existing customers:
  a. It is required that Argus Safety be upgraded to 7.0 before starting the upgrade from Argus Insight 5.1 to 7.0.
- Post-Database Upgrade Considerations for existing customers:
  a. None.

Data Segregation

Having a system that can partition client data within a single, access-driven database significantly reduces operational and ownership costs for the client. Argus Insight achieves this objective through database segregation.

The entire Argus Insight application, including all its components and data, have been partitioned by an Enterprise ID. This ID is a unique, customer-specified identifier.

Module-wise Impact

The following table describes the modules in Argus Insight as per their data segregation status in Clinical Research Organization (CRO)-mode and hosting installations.

S. No.	Module	Data Segregation	Notes
1	Power Query	Yes	Displays QBEs, Filters, and Advanced Conditions only for one enterprise at a time, to the logged-in user. The type of display is based on the selected enterprise.
2	Case Series	Yes	It retrieves cases only from the logged-in Enterprise. The Case Series library displays the case series belonging to the logged-in enterprise only.
3	Standard Reports	Yes	All the standard reports are available to all the enterprises. An enterprise can configure reports from Admin Tools -> Security -> Group Access Rights tab of Argus Insight. An executed report retrieves cases from the logged-in Enterprise.
4	Custom Reports	Yes	It displays all the reports that are set up/created by a specific enterprise.

S. No.	Module	Data Segregation	Notes
5	Report Writer	Yes	The Report Writer module displays only those reports that are created by the logged-in user (irrespective of the enterprise). A report retrieves cases from the logged-in enterprise only.
6	Cubes	No	The Standard Cubes and demand cubes are not available in Insight 7.0 in CRO and Hosting mode. The Standard Cubes are available in single-tenant installations of Insight 7.0. The user can create demand cubes in single tenant installation of Insight 7.0 It is necessary that Cubes should not be configured in CRO and Hosting environment, because the Cubes functionality does not support data segregation.
7	Dashboards	No	The Dashboard function has been retired from the AI 7.0 application in CRO mode, as also from single-tenant installations.
8	MedDRA Dictionary and SMQ's	No	Each enterprise can configure a specific version of the MedDRA dictionary. A single copy of each version is to be shared by the enterprises.
9	WHO Dictionary	No	Each enterprise can configure a specific version of WHO Drug dictionaries (B2 as well as C formats). A single copy of each version is to be shared by the enterprises.
10	ETL	No	The ETL schedule is universal across all enterprises. The Admin users having access to this portlet can view/modify the schedule. When an enterprise is added to an existing CRO setup, the Initial ETL can also run for individual new enterprises. The Initial/Re-Initial/Incremental ETL cannot be run in parallel at any point of time in the application.
11	Cognos	No	A Single Cognos server supports all the enterprises. On logging in to Cognos directly, a user can see all the common objects as well as the enterprise-specific objects which are accessible to the user. When a report is executed, the user can only access the cases for a specific enterprise only. Any report that a user has access to, can be executed against any enterprise data for which the user has access.

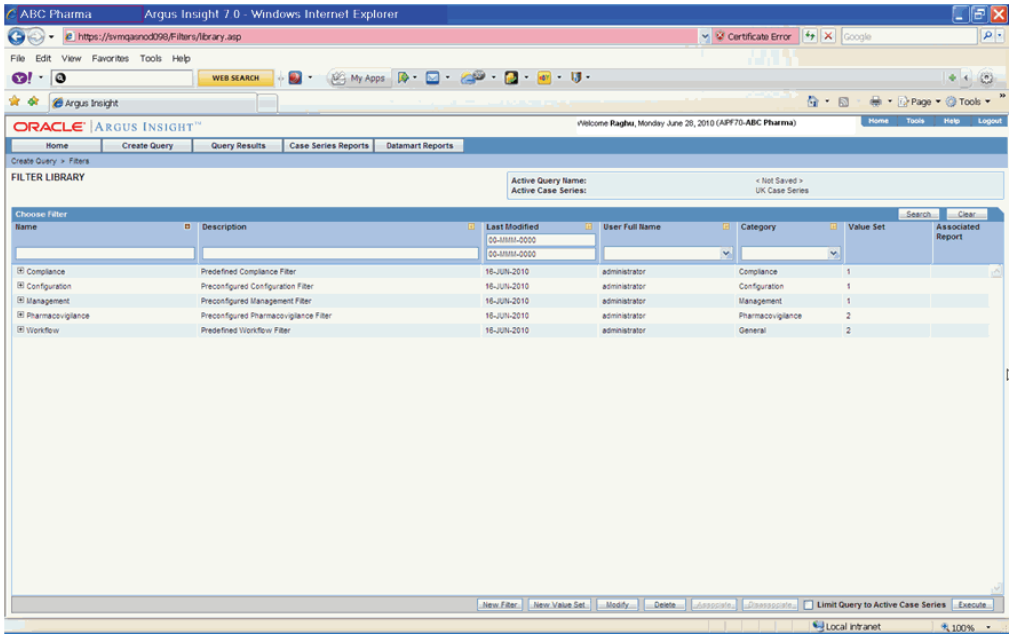
Enterprise Short Name in Argus Insight

All the screens in the entire Argus Insight application and its components display, if so configured by the customer, the Enterprise Short Name. This is a unique, abbreviated name of a client in the header of the application.

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

If this checkbox is not checked, the Enterprise Short Name is not displayed in the header of the Argus Insight application.

If this checkbox is checked, the Enterprise Short Name is displayed in the Argus Safety header along with database name (<DB Name> - < Enterprise Short Name>) where < Enterprise Short Name> is the unique short name of the enterprise.



The Enterprise Short Name is also displayed in the window bar of the Argus Insight application.

Single Sign On

With Single Sign On (SSO), users' log-in authentication is done using a centralized authentication system. With this, users do not need to enter their log-in credentials for each application they access, every single time.

When Argus Insight is configured for SSO, Cognos still uses the PowerReports namespace. This is the same implementation that already exists in the Argus Insight 6.0 application.

Login and Navigation

Clinical Research Organization (CRO) users can operate on only specific enterprises and not on all. User now have access to only certain Argus Insight modules.

Having a Single Sign On (SSO) login mechanism for the various modules that users have access to, and by providing navigation to these modules, simplifies the login, authentication and navigation process for a user.

The ability to switch enterprises within the same session also provides significant usability benefits to the user.

Description

- In multi-tenant installations, Global Homepage and Argus Insight application are two different applications that are available for end-users and CRO/Hosting administrators.
- Both these web applications have separate web URLs, which can be accessed independent of each other.
- When the user enters the URL of any of these web applications, the SSO module authenticates the user credentials and allows access to these applications without asking for any user credentials.
- In case of Global Homepage, if the SSO authentication fails for the user, it displays an appropriate error message returned by SSO module to the end user.
- In case of Argus Insight application, if the SSO authentication fails for the user, it displays an appropriate error message returned by SSO module to the end user on the regular Argus Insight login screen.
- Users can access the Argus Insight application through:
    - **a.** Global Homepage > Application Access Portlet or Insight link in Argus Safety. In this scenario, the Argus Insight application opens in a separate browser window for the enterprise selected by the user in the Application Access Portlet, or as per the enterprise selected by the user in the Safety application.
    - **b.** In this scenario, Argus Insight does not display Argus Safety buttons on the top navigation bar. This is because the user is expected to access these applications from the Application Access Portlet from the Global Homepage. These applications are available to be opened in separate windows.
    - **c.** If the user clicks the Logout button in Argus Insight application, it closes Argus Insight and its child windows after prompting for saving any unsaved changes. The Global Homepage window is not affected at all by Argus Insight logout.
    - **d.** If the user clicks the Close button in Global Homepage application, it closes only the Global Homepage. The Argus Insight application window is not affected at all by Global Homepage logout.
    - **e.** If Argus Insight is defined as the default application in Argus Console for a user, then when the user tries to log in to Argus Safety application via direct Safety link, the Argus Insight application shall open. It shall display the Argus Safety button on the top navigation bar, based on whether the user has logged-in via SSO and has access to Argus Safety.

- Enterprise Switching:
  a. Switching Enterprise context and opening Argus Insight application from Safety application or Application Access Portlet from the Global Homepage requires SSO to be enabled.
  b. The system allows a user to open the Argus Insight application in a separate window with the context set to a specific active Enterprise from Safety and Application Access Portlet from the Global Homepage.
  c. The user can switch the context to a different enterprise from the Global Homepage without logging out.
  d. When the Argus Insight application is already opened for an enterprise, and when the user switches to a different enterprise from the Application Access Portlet, a message is displayed before switching.
- Directly by using the Argus Insight application URL - Users can access Argus Insight directly by using the Argus Insight application URL. Argus Insight checks if Enterprise ID is already present in the request coming to it. If the Enterprise ID exists, it opens Argus Insight for that enterprise.

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

Changes to Power Queries and Case Series

The following changes have been made in the Argus Insight 7.0 release for Power Queries and Case Series. Power Queries include QBE's, Filters, Filter Value Sets, and Advance Conditions.

- A new Power Query/Case Series created and being saved stores the value of the Enterprise along with the other details:
  a. The value for the Enterprise is derived from the logged-in Enterprise.
  b. The Query and Case Series Libraries display only the Power Query/Case Series specific to the logged-in Enterprise.
  c. The 'Active' function retrieves the active Power Query/Case Series for the user within the enterprise.
- The Permissions on a Power Query/Case Series can be granted to the groups that belong to the currently logged-in Enterprise.
  a. The Permissions pop-up displays the User Groups that are associated with the logged-in Enterprise.
- The Power Query/Case Series created by users that are currently disabled or has been disassociated from the enterprise through which the Power Query/Case Series was created, are displayed in the respective library for users who have access to the respective Power Query/Case Series.
  a. The Power Query/Case Series created by the users are deleted when the user is deleted.
- When a Power Query is executed, it displays the cases from the currently logged-in enterprise only.
- All the library screens of Power Queries and Case series display the data pertaining to the logged-in enterprise only.

Importing a Case Series

- When a Case Series is imported, the system validates whether the cases being imported belong to the logged-in enterprise.
  - If the case does not belong to the current Enterprise, it is rejected and the log displays the value as 'Case Rejected' against the specific case number.
  - If the case belongs to the current Enterprise, the case series is imported into the system.

Modifying a Case Series

- When a Case Series is modified to add a new case number, the system validates whether the cases being added belong to the logged-in Enterprise.
  - If the case does not belong to the current Enterprise, the case is not added and the existing message 'Case Number does not exist' is displayed.
  - If the case belongs to the current Enterprise, the case is added into the case series.
  - There are no changes while deleting a case from the case series.
- Single Sign On: SSO needs to be enabled to have the capability to switch client context and to open Argus Insight application from the Application Access Portlet.
- Pre-Database Upgrade Considerations for existing customers:
  a. It is required that Argus Safety be upgraded to 7.0 before starting the upgrade from Argus Insight 5.1 to 7.0.
- Post-Database Upgrade Considerations for existing customers:
  a. None.

Exporting a Case Series

- Single Sign On: SSO needs to be enabled to have the capability to switch client context and to open Argus Insight application from the Application Access Portlet.
- Pre-Database Upgrade Considerations for existing customers:
  a. It is required that Argus Safety be upgraded to 7.0 before starting the upgrade from Argus Insight 5.1 to 7.0.
- Post-Database Upgrade Considerations for existing customers:
  a. None.

When a Case Series is exported to an excel document, the Enterprise is included as part of the export details.

- A new column named 'Enterprise' is added in a tab named 'Case Series Details'. The Enterprise Short name is displayed in this column value. The value for this column is derived from the currently logged in 'Enterprise'.
- The Enterprise short name is displayed in CRO, hosting and single tenant mode of installation.
- The Enterprise column and its value is not displayed when the value to display the enterprise short name is 'Unchecked' or 'No' for the 'Display Enterprise Short Name in Application Header' column for the logged-in Enterprise.

Importing a Case Series

When a Case Series is imported, the system validates whether the cases being imported belong to the logged-in enterprise.

If the case does not belong to the current Enterprise, it is rejected and the log displays the value as 'Case Rejected' against the specific case number.

If the case belongs to the current Enterprise, the case series is imported into the system.

Modifying a Case Series

When a Case Series is modified to add a new case number, the system validates whether the cases being added belong to the logged-in Enterprise.

If the case does not belong to the current Enterprise, the case series is not added and the message 'Case Number does not exist' is displayed.

If the case belongs to the current Enterprise, the case series is added into the case series.

There are no changes while deleting a case from the case series.

Exporting a Case Series

When a Case Series is exported to an excel document, the Enterprise is included as part of the export details.

A new column called 'Enterprise' is added in a tab named 'Case Series Details'. The Enterprise Short name is displayed in this column value. The value for this column is derived from the currently logged in 'Enterprise'.

The Enterprise short name is displayed in CRO, hosting and single tenant mode of installation.

The Enterprise column and its value is not displayed when the value to display the enterprise short name is 'Unchecked' or 'No' for the 'Display Enterprise Short Name in Application Header' column for the logged-in Enterprise.

Global Homepage

This release of Argus Insight provides a Global Homepage that can host multiple portlets. With this feature, CRO users can now access different views of their work items for Argus Safety.

A CRO can access the following modules from the Global Homepage:

Argus Insight application for different enterprises from the Application Access Portlet

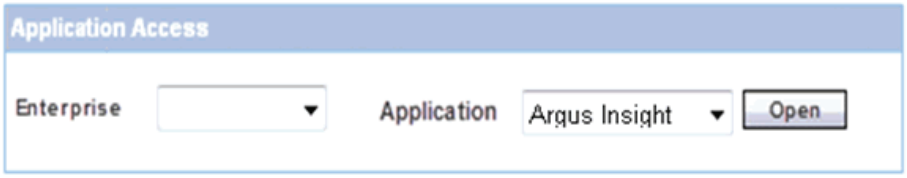
Global Enterprise Management

Global User Management

Application Access Portlet

The Applications Access Portlet within the Global Homepage allows users to launch the Argus applications for an enterprise that they can access.

If you have access to both Argus Safety and Argus Insight, this portlet displays a drop-down list from where you can select between Argus Safety and Argus Insight.



To access the application, select the required option(s) from the **Enterprise** and **Application** drop-down menus, and click **Open**, as shown above.

Global Enterprise Management Portlet

The Global Enterprise Management Portlet allows users to easily define and manage enterprises, as per the configuration of the already existing enterprises. This portlet is also part of the Global Homepage and is available only to those users who have been configured to access the Portlet.

This portlet allows you to do the following:

Copy the Enterprise created in Argus Safety to Argus Insight

Copy the Configuration data from an existing enterprise in Argus Insight

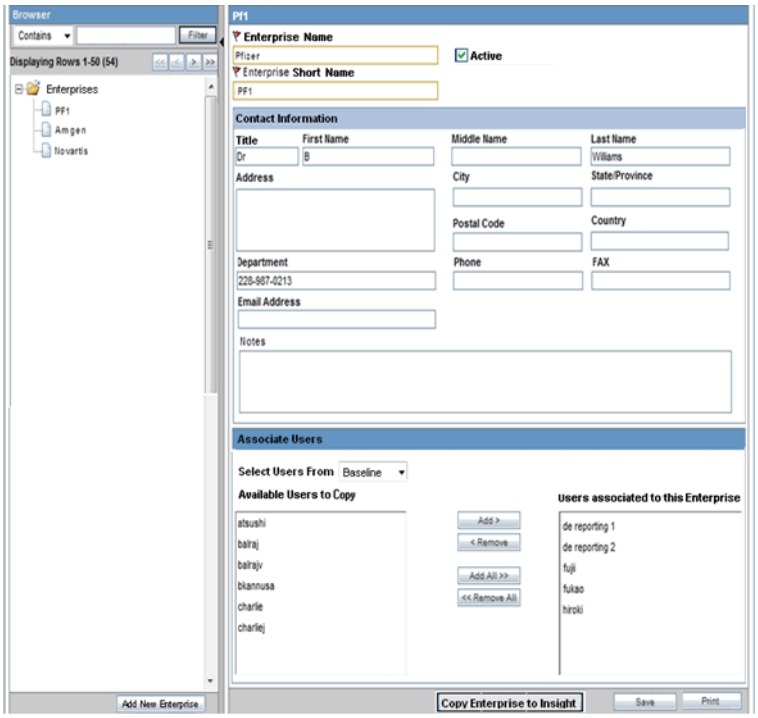
---

Note: The Argus Insight module in this portlet can be available only when the **Safety to Insight** database link is set up in the database.

If this link is not created, the **Copy Enterprise to Insight** button can not appear on the Global Enterprise Management screen.

It is recommended that on clicking 'Copy Enterprise to Insight', the same enterprise should be selected as the source enterprise, with which the Argus Safety enterprise has been created.

As shown in the following figure, the Global Enterprise Management portlet comprises two panes.



The left-hand pane lists all the enterprises of the portal user, in a tree-view structure. The right-hand pane is loaded, by default as blank, in disabled mode.

When an enterprise from the left-hand pane is clicked, its details are displayed in the right-hand pane.

The following features and actions are applicable to this page:

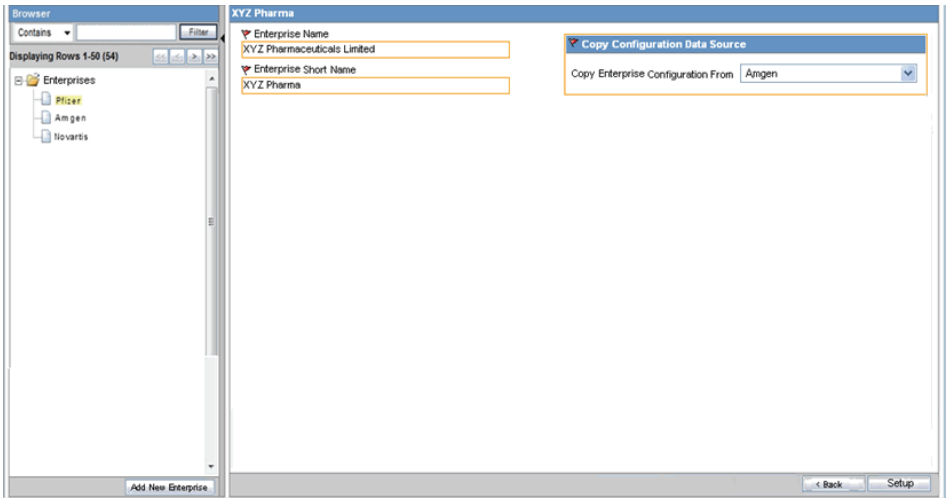
Add New Enterprise in Insight

Click **Add New Enterprise** from the left-hand pane to create a new enterprise in Insight.

> **Note:** A new enterprise can be created in Argus Insight only after the enterprise and its details are entered and saved in Argus Safety.

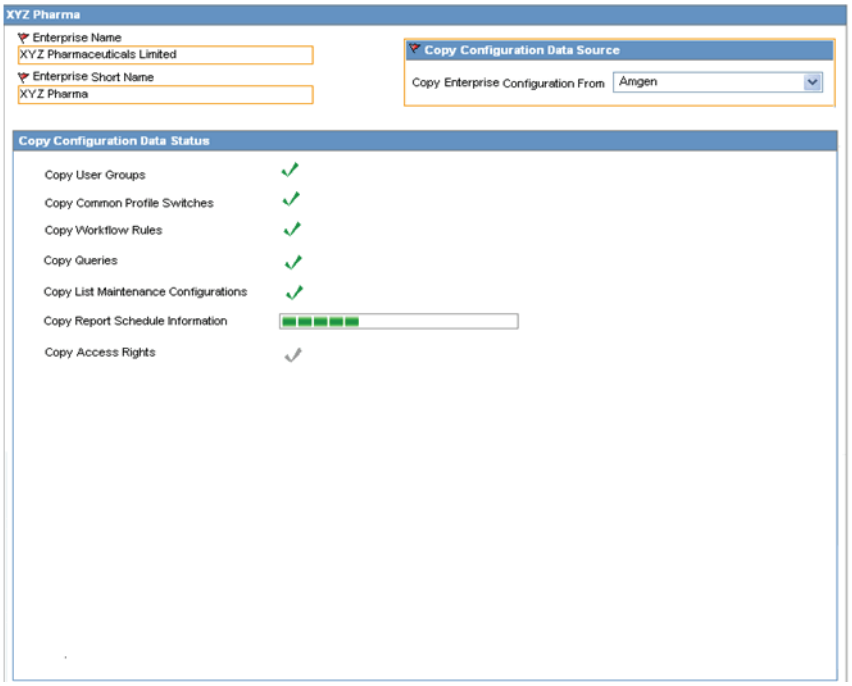
Copy Enterprise to Insight

On clicking the **Copy Enterprise to Insight** button, a new pop-up is displayed as shown below, that allows you to enter detailed information about the enterprise that is being copied. This button is disabled for the default enterprise.



When enterprise creation is completed for an enterprise, the **Copy Enterprise to Insight** button is disabled for that enterprise forever. This is because enterprise creation in Insight is a one-time operation.

The **Setup** button in this screen is enabled only after all the mandatory fields have been populated. This button copies all the configuration data from the enterprise selected from the drop-down list in the screen, under **Copy Configuration Data Source**.



Note: The Copy Enterprise to Insight button can be created in Argus Insight only after the enterprise and its details have been entered and saved in Argus Safety.

The details in the Enterprise Name and Enterprise Short Name fields appear in read-only mode.

Once all the configuration data has been successfully copied, the user who is setting up the new Enterprise, is associated as a new user an Enterprise Manager, to the newly created Enterprise partition.

The user attributes of the user get copied from the source Enterprise.

Refer to the Argus Safety Administrator's Guide for additional details about this portlet.

Global User Management Portlet

The Global User Management Portlet within the Global Homepage allows users to associate themselves to multiple enterprises, and also keep their user attributes consistent across all the enterprises.

All the Argus Insight users are created from Argus Safety Console only. Refer to the Argus Safety Administrator's Guide for additional details about this tab.

Common Profile Switches

None of the Cubes-related profile switch are available in the application for multi-tenant installation.

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

From Argus Insight 7.0 onwards, two new enterprise-level profile switches, called 'Cognos Enterprise Folder and Role Creation' and 'Populate Study Reconciliation Report Table Data' have been added.

To view or edit Profile Switches, log in to the Argus Insight application and select Admin Tools > List Maintenance tab > Profile Switches at the global (application) level or at the enterprise level, as mentioned in the table below:

S. No.	Profile Switch	Enterprise-Level Switch	Notes
1	POPULATE WHO Drug C DATA	Obsolete	Not required from 7.0 onwards.
2	POPULATE INTERCHANGE DATA	Yes	
3	POPULATE AFFILIATE DATA	Yes	
4	POPULATE BLOB DATA	No	
5	POPULATE INTERCHANGE CLOB DATA	No	
6	CUSTOM ROUTINE BEFORE INCREMENTAL ETL	No	
7	CUSTOM ROUTINE AFTER INCREMENTAL ETL	No	
8	POPULATE DLL SLL REPORTS TABLE DATA	Yes	

S. No.	Profile Switch	Enterprise-Level Switch	Notes
9	DOSE CATEGORY UNITS	No	Not required for Multi-tenant installation.
10	COGNOS NAMESPACE	No	
11	COGNOS USER ROLE NAME	No	
12	SINGLE SIGN ON ENABLED	Obsolete	The value should be consistent with the Argus Safety application.
13	SINGLE SIGN ON HTTP HEADER	Obsolete	The value should be consistent with the Argus Safety application.
14	POPULATE NARRATIVE LANGUAGES TABLES	Yes	
15	POPULATE DATA QUALITY INDICATOR	Yes	
16	POPULATE RPT_REG_ REPORTS COLUMNS	Yes	
17	LOGO IMAGE	Yes	
18	ALL CASES QUERY NAME	Yes	
19	MAXIMUM EMAIL ATTEMPTS	No	
20	COGNOS EXCEL VERSION	Yes	
21	SET REPORT PRE-FILTER POPULATION	Yes	
22	ETL DATA EXCLUSION	No	
23	CONFIDENTIALITY TEXT	Yes	
24	DAYS TO LOCK	Yes	
25	PASSWORD EXPIRATION	Obsolete	
26	RESET PASSWORD	Obsolete	
27	FOLLOW-UP ACTION CODE	Yes	
28	CAUSALITY ASSESSMENT. R	Yes	
29	CAUSALITY ASSESSMENT. C	Yes	
30	CAUSALITY ASSESSMENT. R+C	Yes	
31	CAUSALITY ASSESSMENT. UD FIELD	Yes	
32	COMPANY LOGO PATH	Yes	
33	CUBE-ON-THE-FLY-LIFESPAN	No	Not required for Multi-tenant installation.
34	DATASHEET PI	Yes	
35	DATASHEET IB	Yes	

S. No.	Profile Switch	Enterprise-Level Switch	Notes
36	DATASHEET EMEA	Yes	
37	DATASHEET BPI	Yes	
38	REPORT PROMPTS	Yes	
39	CIOMS MANUFACTURER	Yes	
40	MEDWATCH MANUFACTURER	Yes	
41	ALPHANUMERIC PASSWORD	Obsolete	
42	PASSWORD LENGTH	Obsolete	
43	CUSTOM HELP URL	Yes	
44	ARGUS INSIGHT SERVER	No	
45	DATASHEET FLAG	Yes	
46	MARKETED DATASHEET	Yes	
47	INVESTIGATIONAL DATASHEET	Yes	
48	DATE DIFFERENCE BAND	No	Not required for Multi-tenant installation.
49	REPORTING TOOL	No	
50	COGNOS CUBE PASSWORD	No	Not required for Multi-tenant installation.
51	COGNOS CUBE SERVER	No	Not required for Multi-tenant installation.
52	COGNOS ADMIN PASSWORD	Yes	
53	COGNOS SERVER	Yes	
54	COGNOS ADMIN USER	Yes	
55	COGNOS REPORT WRITER MODEL	Yes	
56	COGNOS CUBE USER	No	Not required for Multi-tenant installation.
57	COGNOS CUBE VERSION	No	Not required for Multi-tenant installation.
58	WHO DRUG BROWSER FORMAT	Obsolete	
59	ETL EMAIL SETUP	No	
60	ETL EMAIL SENDER ADDRESS	No	
61	ETL EMAIL RECEIVER ADDRESS	No	
62	CASE REFERENCE TYPE ID	Yes	
63	ENABLE COMPANY HOLIDAY	Yes	
64	PRODUCT LOGO PATH	Yes	

S. No.	Profile Switch	Enterprise-Level Switch	Notes
65	REPORT FOOTER LOGO PATH	Yes	
66	UDN Column for SUPPLIER NAME	Yes	
67	DELAY IDENTIFIER	Yes	
68	POPULATE CUBES FACT DATA	No	Not required for Multi-tenant installation.
69	POPULATE PERCEPTIVE DATA	Obsolete	Not required from 7.0 onwards.

ETL Scheduler

From Argus Insight 7.0 onwards, ETL Scheduler is a Role, added under Admin Tools > Security. It is available across all enterprises at a Global level.

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

Changes to Reports

This section lists the changes that are applicable from this release onwards, for Argus Insight reports.

Report Changes in the Argus Insight User Interface

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

The Argus Insight administrator can assign enterprise-specific access rights (by enabling or disabling report access) to standard reports. This can be done from **Admin Tools > Security > Group Access > Data Rights** tab.

On being executed, the reports now display the Enterprise Short Name, along with the User ID in the footer of the report output, in both PDF and Excel formats.

> **Note:** The Enterprise Short Name is not displayed if the value to display the enterprise short name is 'Unchecked' or is set as 'No' for the logged-in enterprise. The Enterprise Short Name will also not get displayed in the footer of the report output for CIOMS, CIOMS II Line Listing and Medwatch reports.

Report Changes in the Cognos Environment

Users can log into the Cognos environment after specifying an enterprise with their user credentials. If no enterprise is mentioned while logging in, the default enterprise is assigned to the user.

A set of standard reports are available in the 'Argus Insight' folder, which is common across all enterprises. Users have write-access to this folder.

On executing or running a report, it displays only the data that pertains to the logged-in enterprise.

Changes in Custom Reports

Custom Reports can be created as either specific to an enterprise or across all enterprises.

To make custom reports available across all enterprises:

- Add the report in the Argus Insight folder in Cognos. Cognos comprises category-specific folders such as Pharmacovigilance, Management, etc. under the enterprise folder, where the custom report can be saved.
- Any user can add custom reports in the Argus Insight/Category folder.

To create custom reports specific to a particular enterprise:

- Add the report in the enterprise/category-specific folder at the root level in Cognos. On doing so, the report cannot be viewed if you log in with a different enterprise.
- Argus Insight users can view the enterprise/category-specific Custom Reports created through Cognos report studio along with the other available standard reports in their respective report category in the report library, based on the logged-in enterprise.
- Custom Reports display data for only the logged-in enterprise.

Report Changes while Saving and Accessing Report Writer Reports through Cognos Query Studio and Argus Insight

The 'Enterprise' is not available as an object while creating a new report in the report writer.

The reports created through report writer can be saved in the user specific folder.

The data that is displayed, is fetched from only the logged-in enterprise.

Changes to Cubes

This section lists the changes that are applicable from this release onwards, for Argus Insight Cubes.

Changes in Standard Cubes and Demand Cubes

Standard and Demand cubes cannot be configured for any of the enterprises in the CRO mode or Hosting mode. This is because enterprise-specific data segregation is not supported in Cubes.

In CRO or Hosting mode, the Datamart Reports tab is not displayed. This tab and its menu items are available for single-tenant mode and not for multi-tenant mode.

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