Oracle® Argus Safety Japanese

User's Guide

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Preface

This document describes the steps for installing and configuring the components of the Argus Safety Solution application.

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About This Book

This manual contains following chapters:

Chapter 1, "Product Overview"

Provides an overview of the Argus Safety application.

Chapter 2, "Getting Started"

Provides information about how to begin using the Argus application.

Chapter 3, "Active Cases"

Provides information about how to access an active case.

Chapter 5, "Case Actions"

This chapter describes the lifecycle of a case: entering or importing a case, updating a case, and deleting a case.

Chapter 4, "Case Form"

Provides information about how to use the Argus Safety Case Form.

Chapter 5, "Case Actions"

Provides information about the following:

- Finding and opening cases
- Processing cases
- Closing, saving, copying, and deleting cases
- Using the medical and code review functions
- Using the print function and printing cases and medical summaries
- Viewing case revisions

Chapter 6, "Advanced Conditions"

Provides information about how to use Advanced Conditions.

Chapter 8, "MedDRA Browser"

Provides information about using the MedDRA Browser.

Chapter 9, "Argus Affiliate Module"

Provides information for using the Local Affiliate Module.

Chapter 10, "Argus Reports"

Provides information about Argus reports and how to create and use them.

Chapter 11, "Dashboards"

Provides information about using the Argus dashboards.

Chapter 12, "Utilities"

Provides information about how to use various Argus utilities.

Chapter 13, "About dsNavigator"

Provides information about using dsNavigator.

Conventions

The following text conventions are used in this document:

Convention	Meaning
boldface	Boldface type indicates graphical user interface elements associated with an action such as Buttons, Dialog boxes, Check boxes, Combo boxes, Drop-down lists, Labels, Option (Radio) buttons, Tabs, Text boxes, etc.
"between quotation marks"	Information that may appear as-is on screen, or information provided by the user.
NOTE	Information that should be noted before proceeding with the instructions.
IMPORTANT	Important information that must be noted to ensure accurate, reliable, or safe behavior of the system
TIP	Information that enables easier completion of the current task or helps in completing other tasks.
Bold Underline	Link indicating that additional "pop-down" information is available.
ALL CAPITALS	Keyboard keys
Initial Capitals	Names of user interface elements, modules, applications, proper nouns, etc.

1

Product Overview

Argus Safety/Argus Safety Japan is a complete pharmacovigilance software system designed to solve the pharmaceutical industry's toughest regulatory challenges. It provides the most comprehensive global Adverse Events (AE) case data management and regulatory reporting in the pharmaceutical industry. Argus Safety Japan brings the single global database for the Japanese market to include localization and regulation support.

Application Map

The Argus Safety suite of products support drug safety business processes from an easy-to -understand user interface. The application map includes the following:

- Argus Console
  - Code Lists
  - Business Configuration
  - Access Management
  - System Configuration
  - Tools
- Active Cases
  - Last Access Cases
- Worklist
  - New
  - Open
  - Action Items
  - Coding Action Items
  - Contacts
  - Reports
  - Bulk Transmit
  - Bulk Print
  - Bulk E2B Transmit
  - Local Labeling
  - Coding Status

  - Letters
  - Intake
  - Literature Intake (Japan only)
- Case Actions
  - Open
  - New
  - New Case from Image
  - Close
  - Save
  - Copy
  - Medical Review
  - Coding Review
  - Print
  - Delete
  - Case Revisions
- Reports
  - Compliance
  - Aggregate Reports
  - Periodic Reports
  - Bulk Reporting
  - E2B Pending
  - Processed E2B
- Utilities
  - Change Password
  - MedDRA Browser
  - User Login List
  - Logs
  - E2B
  - Case Undelete
  - Batch Reports
  - Blank Report Forms
  - End of Study
  - Clear Cache
  - Advanced Condition Library
- Dashboards
  - Open Case Summary
  - Open Action Items

- Quick Signal Reports
- Increased Frequency Wizard
- Expedited Report Status
- Workflow Status
- Reports Due Soon
- Personal Argus Status
- Case Workload

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Getting Started

This chapter discusses how to start working with the Argus application and access Help files. It also explains how to perform some generic operations in the application.

- Logging In
- About the Argus Home Page
- Basic Features

Logging In and Out

Ensure that before starting Argus Safety, the Argus Safety Administrator of your company has created an account for you and that you have the correct Username and Password for the system. Be aware of the following:

- If you enter an incorrect password three (3) consecutive times, the system disables the Login button and displays the following message:

  Your account has been locked due to 3 consecutive failed login attempts. Please contact your System Administrator.

  The number of times the user is permitted to enter an incorrect password is configurable. The default is 3. For information about configuring Argus Safety see the *Oracle Argus Administrator's Guide.*

- The Date/Time format reflect s the 24-hour format used by the Web server.
- When you click the name of an enabled/disabled module, the system opens the Oracle Web site pages to enable you to access information about the module in a new Internet Explorer window as follows:

  http://www.oracle.com/relsys/index.html

Logging into the Argus Application

Use the following procedure to log in to the Argus application.

To log in to the Argus application

Use the following procedure to login to the Argus application:

1. Open Microsoft Internet Explorer and enter the Uniform Resource Locator (URL) for Argus Safety Web in the Address bar.
2. When the Argus login screen opens,enter your username and password in the appropriate fields.

Note: Available modules appear in bold text on the log-in screen. Once the system authenticates your log-in information, you will be able to access these modules.

3. Select the appropriate database from the Database drop-down list and click Login.

Note: If you get an error message such "Unable to connect to the database," you may not have permissions to access the database. Please contact your database administrator for assistance.

4. Once the system authenticates your log in, you can access the modules whose names are in Bold text. For more information, click the following Single Signon link.

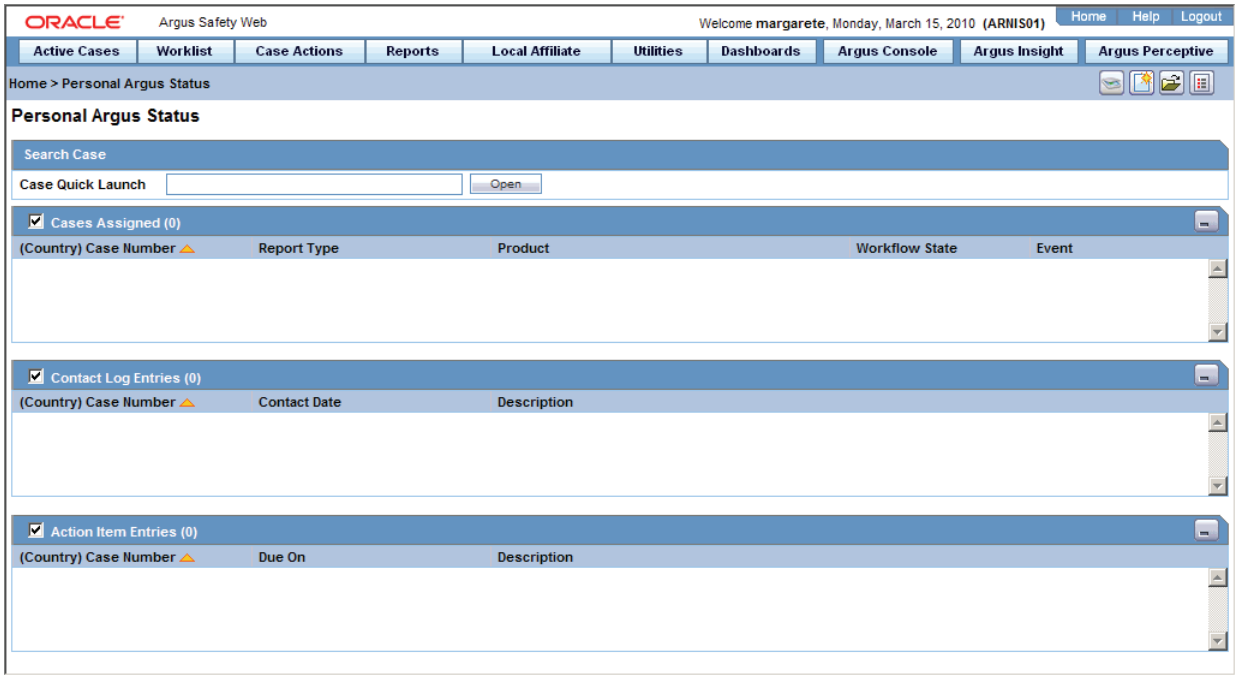
Note: If your login ID fails three times in a row, the system presents the following error message: "The log in button has been disabled due to 3 consecutive incorrect entries of Username or Password. Please refresh the page to enable the Login button."

To log out of the Argus application

Click Logout on the top-right frame of the window to log out of the application.

About the Argus Home Page

The Argus Safety application Home page odisplays a list of Cases Assigned, Contact Log Entries and Action Item Entries sections specifically for the logged-in user.



Home Page Sections and Fields

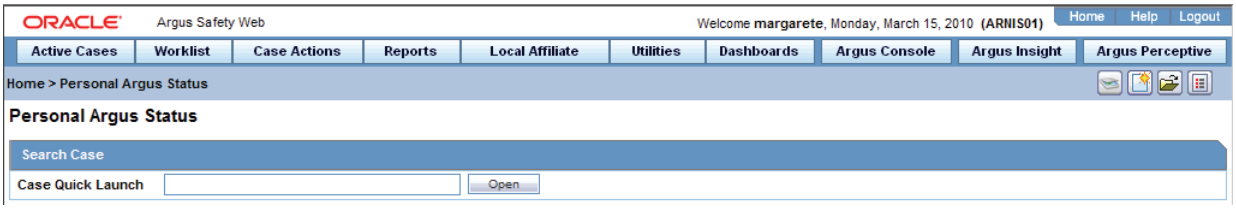
The following table lists and describes the section and the fields it contains.

Section Name	Field/ Control Name	Description
Search Case	Case Quick Launch	Enables you to enter number of a specific case to search for.
Cases Assigned	(Country) Case Number	Displays the name of the country the case belongs to. The Case Number is in brackets.
	Report Type	Displays the report type of the case.
	Product	Displays the product name.
	Workflow State	Displays the workflow state.
	Event	Displays the event name.
Contact Log Entries	(Country) Case Number	Displays the name of the country to which the case belongs, with the Case Number listed in brackets.
	Contact Date	Displays the contact date.
	Description	Displays the description of the case.

Action Item Entries	(Country) Case Number	Displays the name of the country the case belongs to. The Case Number is in brackets.
	Due On	Displays the date when the case is due.
	Description	Displays a description of the case.

Additional Tabs

The Argus Safety menu displays additional tabs, if you have permission to use the associated applications. The following is an illustration of additional tabs that may display.



Tab Name	Description
Argus Console	The system displays this tab if you have administrator permissions.
Argus Insight	The system displays this tab if you have permission to use Argus Insight.
Argus Perceptive	The system displays this tab if you have permission to access the Argus Perceptive application.

Quick Launch Toolbar

Quick Launch enables you to navigate through the application more quickly and more efficiently. Click the relevant

Quick Launch icons on the to perform different actions. The Quick Launch Toolbar is on the top right side of the screen.

To enable you to perform the quick launch, the menu bar also lists the quick launch shortcut keys in parentheses.

Note: Shortcut keys are driven off a combination of Common Profile switches and menu access rights. For example, the "Case Save" shortcut / icon is visible only to users who have been granted access to save the case in the group configuration. If the menu option is disabled in the group configuration for a user, the respective shortcut / icon will be removed as well. Certain shortcuts / icons such as Field Validation are enabled only through a common profile switch. These switches are described in the Common Profile Switch document. Shortcuts / icons that are driven through common profile switches are global to all users and are not controlled by group permissions.

Place the cursor over each icon to view the tool tip, which describes the role of each icon.The following table lists and describes the function of each icon and includes each associated shortcut key.

Icon	Tool Tip	Description	Shortcut Key
	New Case from Image	Displays a new case from an image.	CTRL+ALT+G
	New Case	Displays the **Initial Case Entry** dialog. This is similar to performing **Case Actions - New Case**.	CTRL+ALT+N
	Open Case	Displays the **Case Search** dialog. This is similar to performing **Case Actions - Open Case**.	CTRL+ALT+O
	Close Case	Performs the same functionality as **Case Actions - Close Case**.	CTRL+ALT+C
	Print Case	Displays the **Case Print** dialog. This is similar to performing **Case Actions - Print Case**.	CTRL+ALT+P
	Save Case	Saves the case with any changes made.	CTRL+ALT+S
	Forward Case	Displays the **Case Routing** dialog and enables you to forward the case.	CTRL+ALT+>

Icon	Tool Tip	Description	Shortcut Key
	Return Case	Displays the **Case Routing** dialog and enables you to return the case.	CTRL+ALT+<
	Worklist	Displays the **Worklist** dialog. This is similar to performing **Worklist - XXX** option. **Note:** XXX is defined within the User Configuration for the default Worklist option. If no default Worklist option is defined, then **Worklist - New** is displayed.	CTRL+ALT+W
	Lock Case	Displays the Case Lock or Case Unlock dialog. This is similar to performing Locking or Unlocking Cases in the Activities Tab.	CTRL+ALT+L
	Medical Review	Displays the **Medical Review** dialog. This is similar to performing **Case Actions - Medical Review**.	CTRL+ALT+M
	Coding Review	Displays the **Coding Review** dialog. This is similar to performing **Case Actions - Coding Review**.	CTRL+ALT+Q
	Draft Report	Displays the Report List of All the Expedited Reports. This is similar to selecting View Draft Report.	CTRL+ALT+R
	E2B Check	Performs the function that prints the E2B Report - DTD Length Check Warnings and E2B report - DTD Validation.	CTRL+ALT+E
	Validation Check	Performs case validation.	CTRL+ALT+V

Error Messages

The system displays error messages in pop-up boxes. Every popup box has a Copy link that enables you to copy the message text to the clipboard so that you can use it later.

Searching for a Case

You can search for the following:

- A specific case
- An existing case
- A duplicate case

To search for a specific case

1. Type the case number in the Case Quick Launch field of the Home page and click Open.

2. The system displays the case details

To search for an existing case

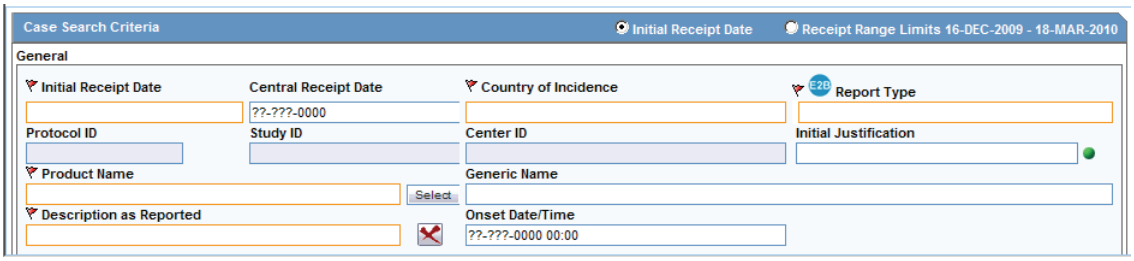
1. Select Case Actions --> Open.

2. Enter the case search criteria in the appropriate fields.
3. Click the link displaying a case number to view the case details. By default, each section and header column is sorted by Case Number in ascending order.
4. Select the checkbox for any of the headers to enable that section. The sections in which the checkbox is not selected display at the bottom of the screen.

To search for a duplicate case

1. Select Case Actions --> New.

2. Enter the case search criteria in the appropriate fields to determine whether a duplicate case is already in the system.



Sharing a Case Series

You can share a case series between Argus and Argus Insight as follows:

- Sharing a Case Series in Argus with Argus Insight
- Sharing a Case Series in Argus Insight with Argus

Sharing a Case Series in Argus with Argus Insight

In Argus, a case series can be made available through the Case Search dialog.

1. Search for and select a case in Argus.
2. Open Argus Insight.
3. The system writes case series belonging to the alert to the Argus case-sharing table.
4. Select Make Active from Argus to make the Case Search dialog case series active in Argus Insight.
5. If Argus Insight was already open, the Active Case series in Argus Insight is replaced with cases from Argus.

Sharing a Case Series in Argus Insight with Argus

A case series can be made available from Argus Insight through Active Case Series. To share a case series in Argus Insight with Argus

1. Go to Case Actions and then click Open.
2. Click Result from Argus Insight to create a search result with the same cases as the Active case series in Argus Insight.

Basic Features and User Actions

This section discusses the basic features and common user actions available throughout Argus Safety. These features can be used when working in different sections of the Argus application.

Common Icons. The icons shown below are common to all modules within Argus:

Icons	Description
	These icons help the user to traverse to the left or right side in a page. **Note:** These arrows will not be visible if there is no need to scroll the tabs.
	A standard **Notes** dialog is available. **Note:** If the notes are filled in, the dialog displays a Notepad icon. Otherwise, it is shown as empty by the icon, without any flags.

Icons	Description
	Re-arranges the entered items by moving them up or down.
	Depicts the column that is being sorted currently.
	Enter a justification for an optional field.
	Indicates that a field has been overwritten or that you can enter data in an initial justification field.

Sorting on Columns

The user can sort on all the columns by clicking the header column.

> **Tip:** Click the same column header again to toggle between ascending and descending order.

Configuring the Display View for a Case To configure the display view for a case

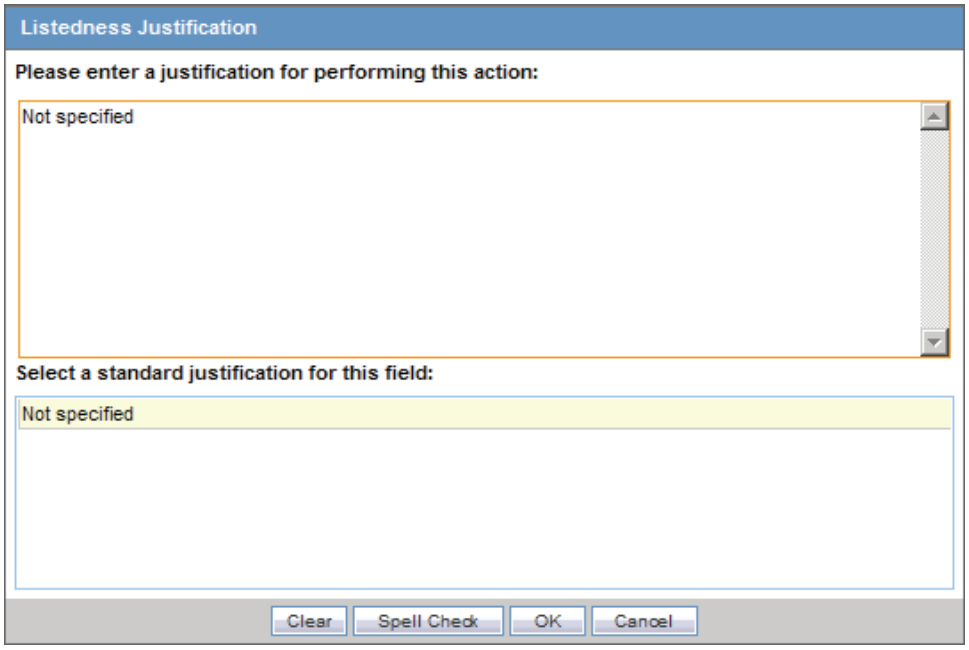
1. Click the Page-Size drop-down list to configure the number of cases to be displayed.
2. You can scroll through the pages by page increments as defined by the Page Size drop-down list.
3. You can also go directly to a range of cases from the Displaying Rows drop-down option.

> **Note:** By default, 100 cases appear on the page but the user can select up to 2000 cases to be displayed within one page.

Field Justifications The fields that display in the application are either required or optional. Each field type displays with a different colored icon:

- Required fields display with a red icon.
- Optional fields are displayed with a green icon.

Click the icon next to a field to view its corresponding Field Justification dialog. The image below shows the Field Justification Dialog:



This field warning justification dialog asks the user for a justification to perform the selected action. To overwrite the warning:

- Enter a specific reason
- Select a standard reason from the message box.

Enter a justification by doing one of the following:

4. Click OK to overwrite the field justification warning.
5. The orange icon changes to green.

Common Right Click Options

The following table lists and describes common right-click options.

Right-click option	Description
Re-arrange	Re-arranges all the information.
Copy	Copies all the information.
Delete	Deletes all the information entered in the tab.

Getting Help

Argus Safety provides you with two main sources of online help:

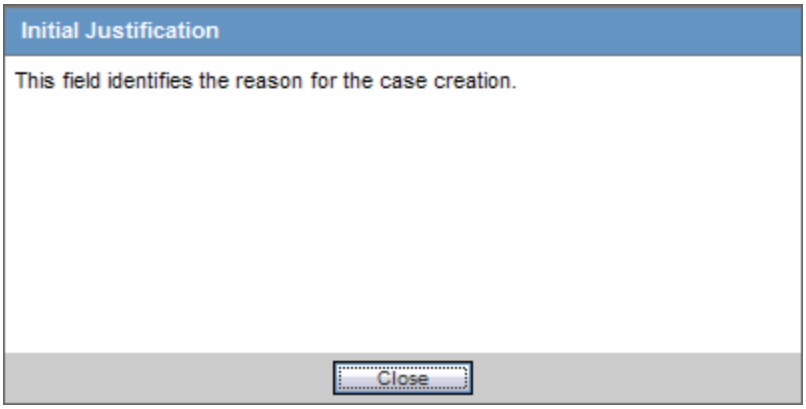
- Field-level Help
- Task-based Online Help

To get help performing a particular task:

- From the Help menu, select Online Help.
- When the Argus Safety Online Help opens use the Contents, Index, or Search tabs to locate the required information.

To get information about a particular field on the Case Form

Double-click the label associated with the field. For instance, on the Case Form, you can double-click the Country label to obtain information about this field



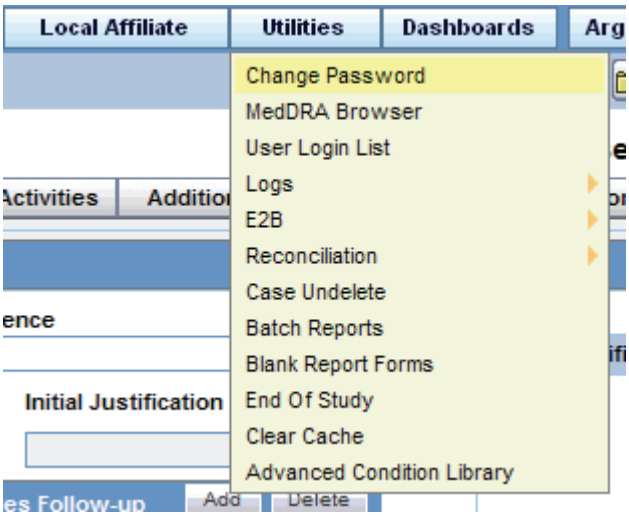
Changing Your Password

When you log on to the system for the first time, it change the password that has been assigned to you.

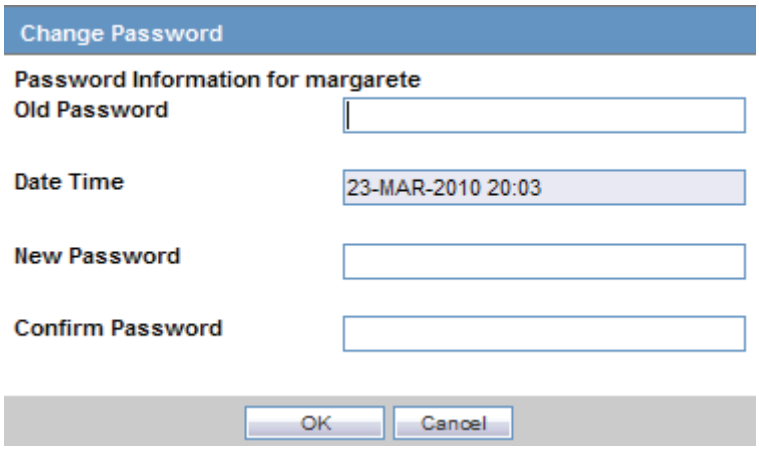
> **Note:** LDAP users cannot change their passwords.

To change your password

1. Select Change Password from the Utilities menu.



2. The Change Password dialog box opens.
3. Enter your current password in the Old Password field.



4. Enter the new password in the New Password field and confirm the new password by re-entering it.
5. Click OK to change your password. Your password has now been changed.

Entering Dates

Several fields in the Argus Safety user interface enable you to enter dates. Fields that accept full dates appear in the "dd-mmm-yyyy" format. You enter the month using numbers, or alphabetic characters.

Appropriate formats for entering English dates are as follows:

- DDMMMYYYY where MMM is the three-character abbreviation for the month (e.g., MAR, APR, JUN, etc.)
- DDMMMYY where MMM is the three-character abbreviation for the month and YY is the two-digit numeric value for the year (e.g. 09, 10, etc.)
- DDMMYYYY where MM is the two-digit value identifying the month (e.g., 01 = January, 02 = February, etc.) and YYYY is the four-digit value for the year.
- DDMMYY
- DD-MMM-YYYY
- DD-MMM-YY
- DD-MM-YYYY
- DD-MM-YY
- DD.MM.YY
- DD.MMM.YY
- DD.MM.YYYY
- DD.MM.YY
- DD/MMM/YYYY
- DD/MMM/YY
- DD/MM/YYYY
- DD/MM/YY

In English date fields, if the numbers entered for a month are appropriate, they are automatically converted to letters corresponding to that month (For example, entering "03" for the month will automatically convert month field to "MAR").

Some fields can also accept partial dates in case the exact date is not known. Fields that allow 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 of either a year, or a year and a month. A partial date that comprises of a day and the year, but not the month, is not accepted.

Tip: Ensure that the dates are displayed accurately in the date-month-year format by entering the date in the given format and wait till the entered dates get displayed in the field. To enter the current date in a field, press the '=' key on the keyboard and tab out of the field.

After you enter the date and tab out of the date field, the system verifies that the date you entered is valid for the year and month.

When entering dates in Argus J, the system converts dates to the following format YYYY/MM/DD (i.e., 2001/11/30). Appropriate formats for entering dates are as follows:

- YYMMDD
- YYYYMMDD
- YY-MM-DD
- YYYY-MM-DD
- YY.MM.DD
- YYYY.MM.DD
- YY/MM/DD
- YYYY/MM/DD

Using the Data Entry Abbreviation (DEA) to Enter Dates You can enter a year using the Date Entry Abbreviation function from the Code List Maintenance screen. The DEA indicates a particular year during the reign of a specific emperor. For example, H indicates Heisei and indicates the first year of his reign. When you enter following H1-01-08, the system converts the date to 1989/01/08 when you tab to the next field.

Acceptable formats for entering dates using the DEA are as follows:

- DEAYMMDD
- DEAYYMMDD
- DEAY-MM-DD
- DEAYY-MM-DD
- DEAY.MM.DD
- DEAYY.MM.DD
- DEAY/MM/DD
- DEAYY/MM/DD

Entering Multiple Language Text

Certain fields on the Case Form allow you to enter text in languages other than English. The non-English text that is entered in these fields can also appear on expedited reports.

To enter text in a language other than English:

1. Click the English language icon.
2. Use the pane associated with English to enter the English language text. Open the tab associated with the required language to enter text in that language.
3. After completing text entry, you can perform a spell-check for the text.
4. Once you enter text in another language, the icon associated with that language opens adjacent to the field on the Case Form.

Languages Supported in Argus Safety

The table below displays different icons representing different languages.

Icon	Language
	English
	German
	French
	Spanish
	Italian
	Japanese

3

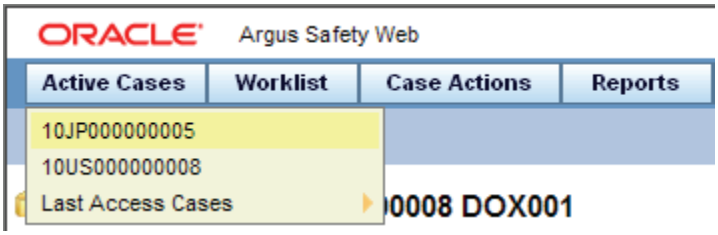
Active Cases

Active Cases are cases that have already been opened or are currently in use. The system logs any cases you view in the active case list.

Opening Active Cases

Follow these steps:

1. Log in to Argus.
2. When system opens the Home page, click Active Cases.
3. The system displays a list of the last 10 cases you accessed in the Last Accessed Cases drop-down list.
4. Click any of the links to select and open an active case



4

Case Form

The Case Form is the most important section of the Argus Safety user interface.

Case Form Functions

The **Case Form** enables you to do the following:

- Enter case-specific information
- Enter case-specific information
- Log preliminary information about cases

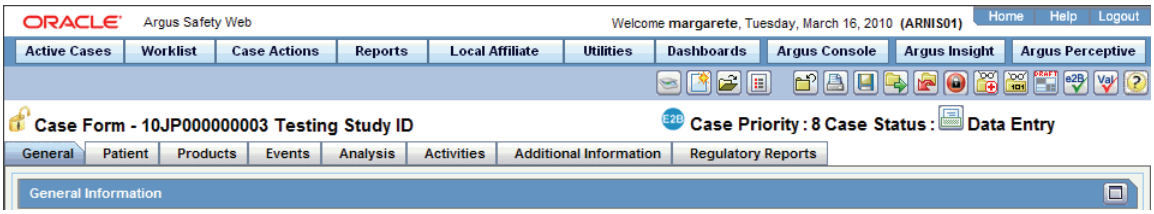
The Case Form has eight (8) tabs as follows:

- General Tab
- Patient Tab
- Products Tab
- Events Tab
- Analysis Tab
- Activities Tab
- Additional Info Tab
- Regulatory Reports Tab
- PMDA Tab

Each tab enables you to capture specific information about the case and is designed to capture similar information in each of its subsections.

> **Note:** Some sections in each tab enable you to make multiple entries. For example, you can have more than one reporter in the Reporter Information section of the General tab. Each individual entry is identified by another set of tabs in the section.

All tabs of the Case Form also display read-only information about case priority and status.



To access the Case Form

1. Search for an existing case.
2. When the application displays the search results, locate the appropriate case number and click the case number link.
3. The system opens the Case Form with information about the case.

Case Form Features

The case form provides features to help you use it more effectively.

General Case Form Usage Information

When using the Case Form, be aware of the following:

- The maximum number of Products and Events is 200 per case.
- The drop down values for elements such as Yes/No/Unk is not hard coded. The system retrieves the values from a look-up table. This affects the following:
  - Reporter Information | HCP
  - Device Information | Improper usage/Storage Field
- The system defaults to the first button on every message box pop up dialog. When the user clicks Enter or the space bar, the system validates the choices.
- The user can enter a hyperlink (e.g. http://www.oracle.com and https://www.oracle.com) in the Field Label Help for the Case Form Fields
- When the user clicks a hyperlink, the system opens the link in a new Internet Explorer browser window.
  - Contact Logs | Group and Users
  - Action Items | Groups and Users

  The following Case Form fields are type ahead fields:
- The WHO Drug browser displays the WHO Drug Version on the browser dialog. The browser dialog is configured in System Configuration | Case Form Configuration.
- Users can enter decimal numbers with up to three (3) decimal places in the UDF Number fields on all tabs. If the user does not enter a decimal, the system does not display trailing zeroes.

Using Password Acceptance Dialog Boxes

The system displays the User Name in read-only mode in following dialog boxes where the user must enter a password to start processing:

- Activities Tab: Case Lock/Unlock
- Activities Tab: Case Archive/Un-Archive

- General Tab: Unblind Case
- E2B Acceptance/Rejection for Initial, Follow-up, and Notification
- Affiliate Acceptance/Rejection of Events
- Case Actions: Delete/Undelete

Initial Case Entry

When using the BookIn dialog box, be aware of the following:

- You can enter the attachment classifications and their descriptions on the Initial Case entry dialog.
- The field labels are the same as those defined in the Field Labels and the Case Form
  - The lengths for the Classifications type ahead field and the Description field are the same as those on the Additional Info tab
  - The system filters classifications by user sites and the attachment classifications permissions.
  - When you select the URL Reference, the system hides the Classifications and Description fields.
- The system transfers the values the user enters in the Classifications and Description fields after the cases have been booked in.
- f the system does not find any cases during a duplicate search, it places the following message in the search results section: No cases found.
- When you try to book in a clinical trial case and select a study where the country of incidence value does not match the list of countries defined in the study configuration, the system displays the following warning message in the standard Argus Safety warning message dialog box:

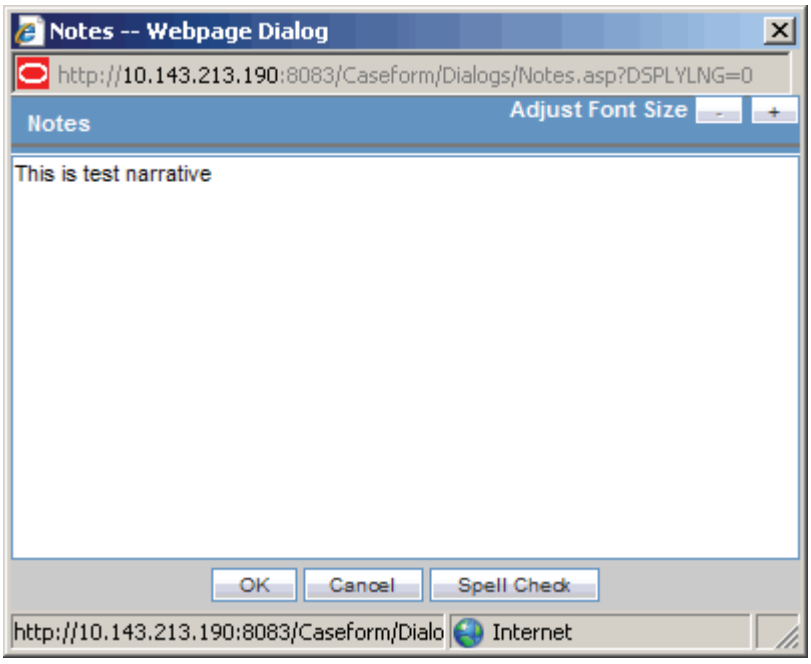
  The country of incidence does not match the country list specified for the selected study.
  - If no countries are specified in the study configuration for the selected study, the warning message does not display.
  - If the user selects the study before entering the COI, the system performs the validation
- The user can right click on the row and select the following:
  - Case Summary -- The system displays the Case Summary (Current functionality).
  - Medical Summary Report -- The system displays the Medical Summary report PDF only if the user has access to the Medical Review dialog box. If the user does not have access, the system hides the Medical Summary Report option.
  - Print -- The system launches the Case Form print dialog box. If the user has permission to access the Print Case dialog, the user can print the Case Form. If the user does not have access to the Case Form print dialog box, the system hides the Print Case option.

Zoom Function

The Zoom feature enables you to increase or decrease the font size of the text.

1. Click the Zoom icon across the Case Form tabs.

2. The Zoom dialog enables you to increase or decrease the Font Size of the text on the Zoom dialog.



3. Click Adjust Font Size to increase or decrease the font size.
   - Click + to increase the font size up to five (5) font sizes in one-size increments.
   - Click - to decrease the font size to the current by increments of 1.

This feature is available on the following dialogs:

- Reporter Notes
- Patient Notes
- Patient Other Relevant History Notes
- Patient Lab Data Notes
- Patient Relevant Test
- Parent Medical History
- Parent Other Relevant History Notes
- Product Notes
- Case Analysis: Narrative. This is also available on the Medical Review Dialog.
- Case Analysis: Abbreviated Narrative. This is also available on the Medical Review Dialog.
- Case Analysis: Company Comment. This is also available on the Medical Review Dialog.
- Case Analysis: Local Evaluator Comment. This is also available on the Medical Review Dialog.
- Case Analysis: Administrative Notes. This is also available on the Medical Review Dialog.

- Case Analysis: Evaluation in light of similar events in the past. This is also available on the Medical Review Dialog.
- AffSAPS: Future Actions.
- Activities: Contact Log Description.
- Activities: Action Item Description. This is also available on the Medical Review Dialog.
- Activities: Routing Comments
- Notes and Attachments: Description

Case Form Drop-down Options

The Case form for the following fields includes Type Ahead functionality. This feature automatically suggests possible options as term names as you are entering the text. If you double-click on the field, the system shows the standard drop-down values for the field.

The following is a list of fields with type ahead functionality:

- Accidental Exposure
- Action Taken
- Action Type
- Age Groups
- Age Units
- Anatomical Locations
- Attachment Classification
- Attachment Keywords
- Birth Type
- Case Classification
- Causality Category
- Condition Type
- Contact Type
- Delivery Types
- Device Preliminary Comments
- Device Subcomponents
- Device Type
- Dosage Frequency
- Dosage Units
- Ethnicity
- Evaluation Reason
- Event Frequency
- Event Intensity
- Event Outcome

- Fetal Outcome
- Formulation
- Gender
- Intermediary
- Lab Result Assessment Terms
- Lab Test Type
- Manufacturers
- Occupations
- Package Units
- Reference Type
- Report Media
- Report Type
- Reporter Type
- Routes of Administration
- Study Center

Argus Safety Case Form User Preferences

Argus Safety remembers your actions as you navigate through the Case Form.

The system can return to the same location on the tab after you tab to a different form. For example, you are on the 8th reporter in the Reporter Section on the General tab and move to another location in the application. When you return to the General tab, the system takes you directly to the 8th Reporter because it was the last Case Form location that you accessed before moving out of the Case Form.

User preferences are only applicable during the same session for a case, irrespective of the Case Status (read-only or editable). If you exit from the case and open a new case, the system resets the preferences.

Quick Navigation

Each page displays the navigation flow used to access the page. The following table lists shortcut keys to help you navigate more easily and quickly.

Shortcut Key	Output
CTRL+SHIFT+#	Goes to the tab indicated by the # entered. (1=General tab, 2=Patient tab, etc.)
ALT+SHIFT+#	Goes to the sub-tab as indicated by the # entered (= Product 1, Product 2, etc.)Note: The maximum # for the sub entities is 10 which pertains to ALT+SHIFT+1 for the first entity within the tab till ALT+SHIFT+0 for the 10th entity within the tab.

Argus Safety Japan Split Screen Feature

For Argus Safety Japan users, a split screen icon enables you to view both English and Japanese screens. By default, the system displays the Case Form screen in Japanese. When you choose to view the screen in both English and Japanese, place the mouse cursor over the split screen icon shown in the following illustration

When you place the mouse on the split screen icon, the system displays the split screen drop-down menu as shown in the following illustration.

The following table lists and describes the items on this menu.

Country	Choose this Icon	To:
		Splits the Japanese screen horizontally. The system places the Japanese text on top and the English text on the bottom. The Japanese text is editable but the English text is read-only.
		Splits the Japanese screen vertically. The system places the Japanese text on the left and the English text on the right. The Japanese text is editable, but the English text is read-only.
		Displays the full screen in Japanese.
		Splits the English screen horizontally. The system places the English text on top and the Japanese text on the bottom. The English text is editable but the Japanese text is read-only.
		Splits the English screen vertically. The system places the English text on the left and the Japanese text on the right. The English text is editable, but the Japanese text is read-only.
		Displays the full screen in English.

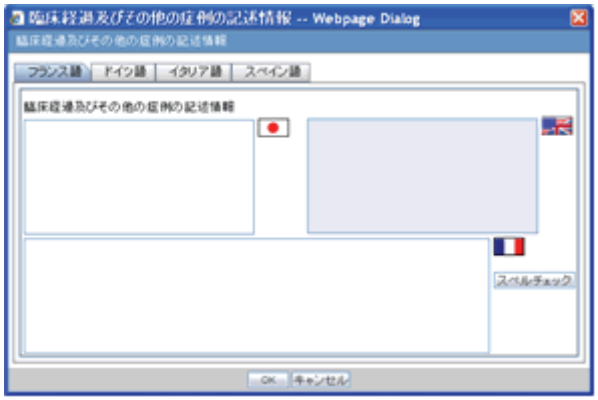
When using the split screen feature, be aware of the following:

- The scroll bar is available only in the editable part of the split screen. The enables the screens to scroll at the same time so you see the same portion of the screen in both English and Japanese.
- The split screen drop-down menu is also available on the following case for analysis tabs:
  - MedWatch Info
  - BfArM Info
  - PMDA
  - AFSSaPS Info

- If the case is first found outside Japan, the Argus Safety user enters the data. The Japanese case form window has all common field items enterby the English user in Japanese.
- If the case is first found in Japan, the English screen has the Equivalent English information enterdd in the common fields on the case form.
- If you use the minimize/maximize button on one of the split screens, the system also minimizes/maximizes the other screen to keep the same view between the editable and non-editable windows..

Multi-Lingual Text Box

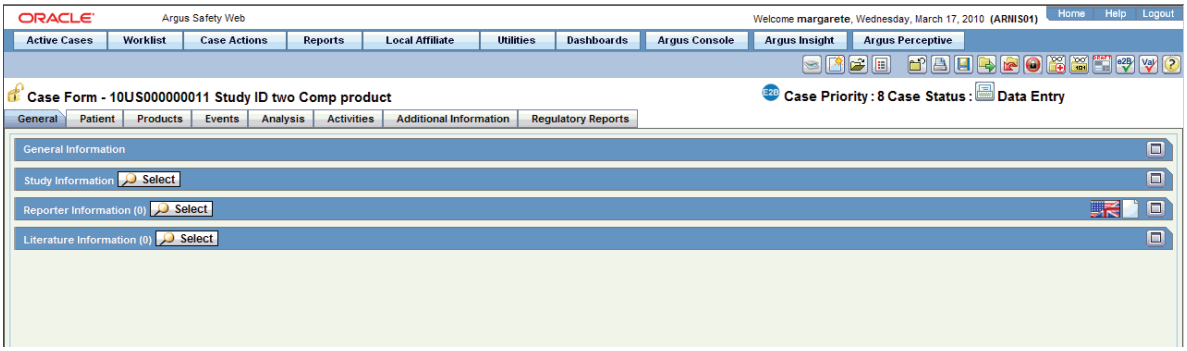
The system provides a multi-lingual text editor as shown in the following illustration.



You can only edit the Japanese text field; the English text field is read-only.

General Tab

The General tab is designed to capture case information in categorized sections that capture category-specific information. The General tab enables you to enter or view information such as type of report, literature information, and so forth. The following is an illustration of the **General** tab.



The **General** tab has four sections as described in the following table.

Section	Purpose
General Information	Contains information about the report type, receipt dates, etc.
Study Information	Contains information about clinical trial details, if appropriate.

Section	Purpose
Reporter Information	Contains information about Reporter details.
Literature Information	Contains information about Literature cases.

General Usage Information

When using the **General Tab** be aware of the following:

- The system saves all filtering criteria the user enters on the Reporter Look Up dialog as user preferences while it populates the reporter information on the General Tab.
  - If you have reporter information in the case, the system continues to display the reporter information in the **Reporter Lookup** dialog and automatically performs a search.
  - After performing the search the system retains the search criteria as user preferences. The next time you perform a search, the system displays these preferences.
  - When you log out, the system retains the user preferences and makes them available the next time you log in to the system
  - You can click Clear to clear all the values in the filtering elements.
  - If the system cannot find any reporters during a search, it displays the following message in the reporter look up dialog:

    No reporters found
- If a priority has not been assigned to a case, the system hides the **Case Priority** field label.
- If a case owner has been assigned to the case, the system displays the name of the case at the top of the **Case** form. If a case owner **has not** been assigned, the system hides the **Case Owner** label.
- The **Project ID** can be 40 characters long. Users can scroll in the field.
- The **Study Name** field can be 70 characters long.
- When the **Classifications** field is hidden, the system **does not** display the classification section on the Case Form.
- The mandatory fields identified in the E2B Mapping in the factory or custom profiles are identified with an icon on the Case Form fields on the Case From and Medical Review dialog boxes.
- All popup message boxes that had only an OK or Cancel button have a Clipboard button that enables you to copy the message content to the clipboard for later use.

Dynamic Workflow Indicators

Dynamic workflow indicators track the amount of elapsed time it takes to complete a workflow step.

- The first number represents the time left or exceeded for a given workflow step
- The second number indicates the time left till the reporting deadline.
- Time is expressed in days (d), hours (h), and minutes (m) respectively.

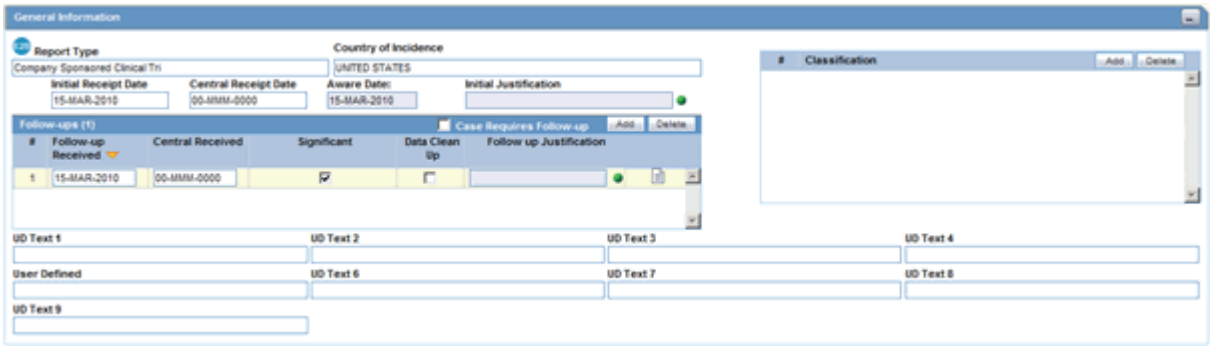
The icon changes based on the amount of elapsed time for the workflow step.

Icon	Denotes
Traffic Light	No status can be indicated, for example if no timing is defined in the workflow.
Red Traffic Light	The timing has been exceeded.
Yellow Traffic Light	The timing is in danger of being exceeded.
Green Traffic Light	The timing is in good standing.

If the time to complete the case process exceeds the allocated time, the system displays the value in **red** with the time displayed as a negative value. Only archived, locked cases **do not** display the dynamic workflow indicator.

General Tab: General Information Section

The following is an illustration of the General Information section on the General tab.



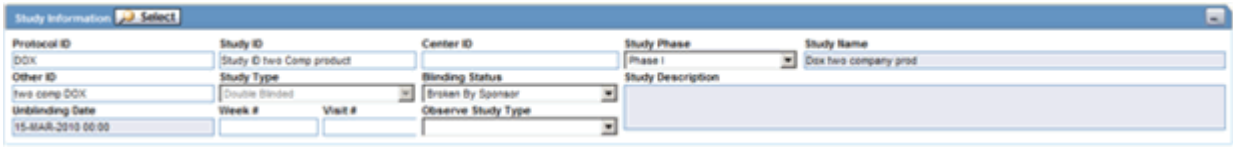
General Information Fields The following table lists and describes the fields in the **General Information** section.

Field/Control Name	Description
Report Type	Select the item that best describes the type of report. Choice of report type determines availability of fields relating to clinical studies and/or literature references. **Note:** Clinical study reports prompt the user for information relating to the study, and literature-based reports enable the user to select the journal and reference on which the case is based.
Country of Incidence	Select the country where the adverse event occurred. The E2B icon identifies fields required for E2B.
Initial Receipt Date	Enter the date your company became aware of the case. Argus Safety uses this date throughout all reports. **Note:** This date can be changed only prior to regulatory report submission.
Central Receipt Date	Enter the date on which this information was received by Central Safety.
Initial Justification	Enables you to enter the initial justification reason. The entry in this field is displayed as per the reason entered when the case is being booked in.
Aware Date	This item is read-only. It displays the most recent significant follow-up when such follow-up information was specified. If not, the initial receipt date is displayed.

Field/Control Name	Description
Follow-up (#)	Follow-up number automatically increments based on updates to the Follow-up Received field. The figure displayed within "()" denotes the number of follow-ups added to the case. **Note:** The order of the Follow up dates is maintained. For instance, on sorting the Follow-up, the serial number still displays the order of entering the follow-ups. The Follow-up headers can be sorted by the Follow-up Received and Follow-up Safety Received Columns. Click on the header to sort in ascending order or to sort in descending order. By default, the sorting is in descending order of the Follow-up Received Date.
Follow-up Received	Click **Add** to enter the date on which follow-up information was received by your company. You can select whether the case has significant follow-up information. **Note:** If you select **Yes**, the **Significant** check box is selected. When sorting on follow-ups, by default, the dates are sorted in descending order of the Follow-up Received Date.
Central Received	Enter the date on which follow-up information was received by Central Safety.
Significant	Click the checkbox if the follow-up is significant.
Data Clean up	Click the checkbox to mark the Follow up as a Data Clean up version. This version is used in the Data Lock Point for Case Versioning in and System Reports.
Follow-up Justification	Enables you to select a pre-defined justification for Follow-up. Click the icon to view the standard justifications dialog. You can select a pre-defined justification from this dialog or enter a new justification. Refer to the screen shot given below the table.
Classification	Select up to 50 case classifications used to categorize a case. Click **Add** to enter additional case classifications.
Case Requires Follow-up	Select this check box if the case requires follow-up information.

General Tab: Study Information Section

The Study Information section enables you to enter information about case studies.



Study Information Fields and Field Descriptions The following table lists and describes the fields in the **Study Information** section.

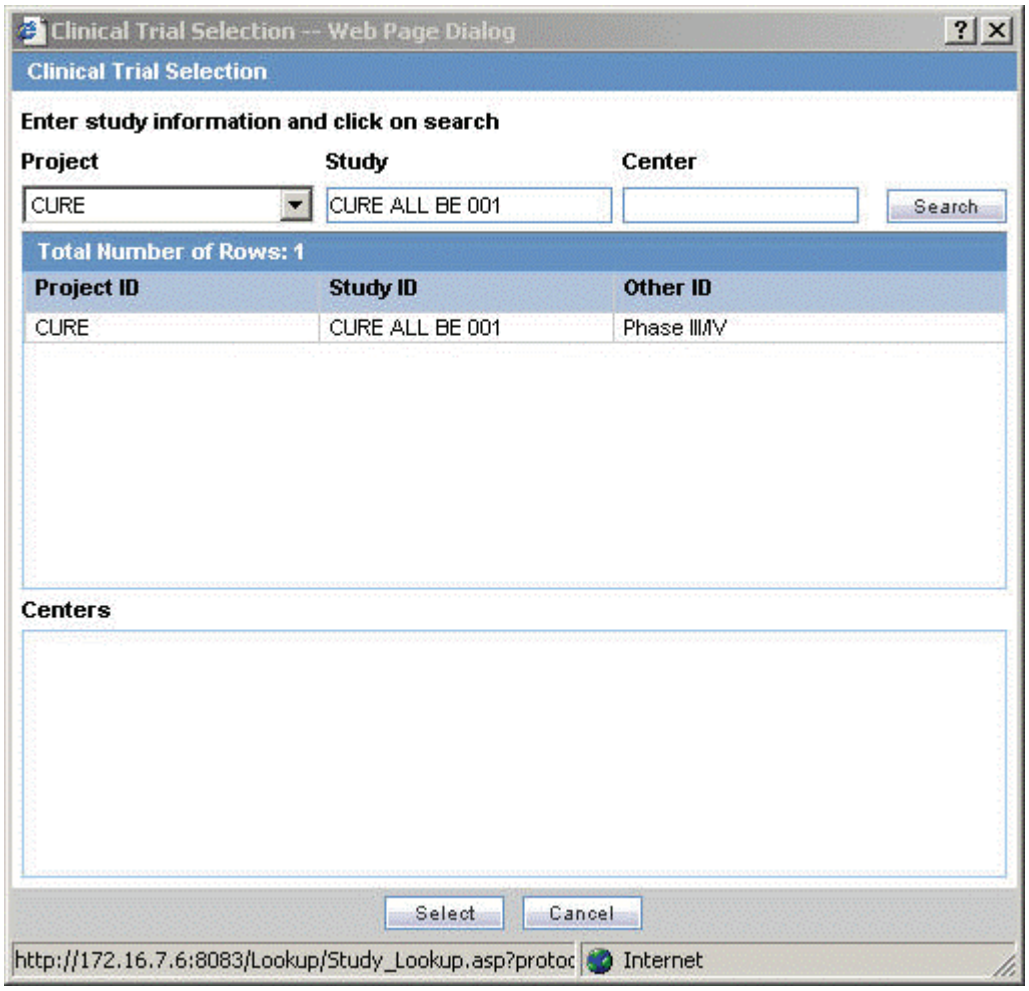
Field/Control Name	Description
Project ID	Enter the Project ID, or select one from the list. Selecting a Project ID automatically creates items in the **Study ID** list.
Center ID	Select the appropriate center ID from the list.
Study Phase	Enables you to enter the Study Phase for the configured study. **Note:** This field is pre-populated if you select a Study with an already-configured Study Phase.

Field/Control Name	Description
Study Name	The study name is entered automatically based on the study that is selected.
Study Type	The study type is entered automatically based on the study that is selected.
Week #	Enter the week number of the study during which the adverse event occurred.
Visit #	Enter the visit number of the study during which the adverse event occurred.
Blinding Status	Depending on the type of study, this item is entered automatically by the system. You need special access rights to use any of the **Broken By** entries. **Note:** The **Unblind Case** dialog appears when you try to unblind a study. For **Not Blinded** studies, saving the case or generating a report, you can enter the actual drug (vs. placebo) given to the patient.
Study Description	The study description is entered automatically based on the study that is selected.
Observe Study Type	The value selected from this drop-down list is populated in the Case Form Study Section when the Clinical Study is selected.
Unblinding Date	This item is automatically entered by the system. If you double-click the date in this item, the **Unblind Case** dialog is displayed. If the date of unblinding is more recent than the date for the most significant follow-up information, an automatic follow-up is generated.

Study Restrictions To enter pre-defined Study Information

1. Click Select to choose from the already available list of study information.
2. When the Clinical Trial Selection dialog opens, enter Project, Study, and Center information as appropriate.

   The **Clinical Trial Selection** dialog allows you to select a clinical trial from the list configured by the Administrator.



3. Click Search to generate the search results.

   Tip: To broaden the search results, enter as little information as possible. Select the required clinical study and study center and click **Select**.

4. Choose the appropriate study information from the list and click **Select**.
5. The details of the selected Study Information are added to each field in the **Study Information** section

General Tab: Reporter Information

The **Reporter Information** section enables you to enter information about the person providing the case-related information. The following is an illustration of the Reporter Information section.

When using this section, be aware of the following:

- The Reporter Rearrangement dialog also shows the number of Reporters present in the case. It displays the First Name and Last Name, followed by the Reporter Type in brackets, as entered in the reporter information dialog.
- You can also view all the Reporters by clicking the Quick Launch icon.
- Click any Reporter Name to view the details of the selected Reporter tab.
- Click the **New** tab to add a new reporter anytime. You can add a maximum of 100 reporters.
- The Primary Reporter is identified by the Reporter icon on the Reporter Information tab.

Reporter Information Fields

The following table lists and describes the fields in the **Reported Information** section.

Field/Control Name	Description
Notes	Click this button to enter free text notes relating to this reporter. **Note:** This field supports multiple language entry. You can click on a flag, select the language tab, and enter information.
Sal.	Enter the reporter's salutation.
First Name	Enter the reporter's first name.
Middle Name	Enter the reporter's middle name.
Last Name	Enter the reporter's last name. The **Select** button displays the Reporter Selection dialog. If you select a reporter from this dialog, the system automatically completes the case form reporter fields.
Suffix	Enter the reporter's suffix; for example, HR, or MED.
Health Care Professional	Select **Yes**, **No**, or **Unk** (Unknown) to indicate whether the reporter is a health-care professional.
Occupation	Select the reporter's occupation from the list.
Address	Enter the reporter's address.
Institution	Enter the reporter's institution.
Department	Enter the reporter's department.
City	Enter the reporter's city.
State/Province	Enter the reporter's state, province, or county.
Postal Code	Enter the reporter's postal code.
Country	Select the country name. The Administrator maintains this list.

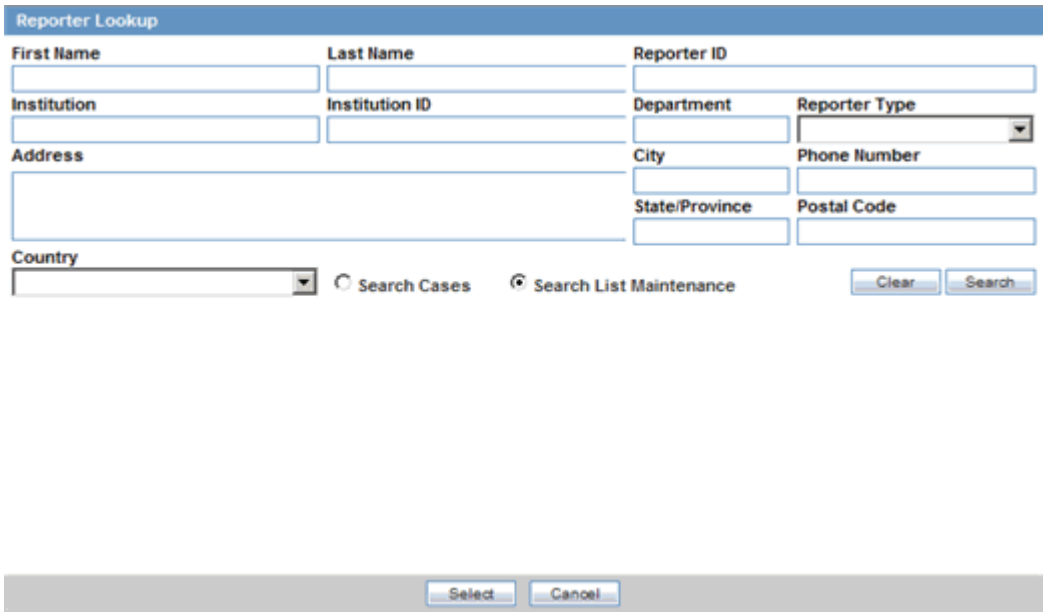
Field/Control Name	Description
Phone Number	Enter the reporter's telephone number.
Alternate Phone	Enter another telephone number for the reporter, if available.
FAX Number	Enter the reporter's fax number.
Reporter ID	If known, enter the Reporter ID. This automatically completes the Case Form reporter fields.
Reporter's Reference #	Enter the Reporter's Reference # for the case.
Email Address	Enter the reporter's email address.
Reporter Type	Select the Reporter Type. The Administrator maintains this list.
Report Media	Select the medium of the report. The Administrator maintains this list.
Intermediary	If appropriate, select the type of intermediary. The Administrator maintains this list.
Report sent to Regulatory Authority by Reporter?	Make a selection, as appropriate to the case.
Protect Confidentiality	If this check box is selected, the name and address of the reporter do not appear on regulatory reports and the reporter's information displays "NAME AND ADDRESS WITHHELD".
Primary Reporter	Identifies the primary reporter. Only one primary reporter is permitted per case. The primary reporter is the reporter whose name appears on the regulatory reports. The tab that identifies the primary reporter is displayed in blue as compared to the other reporter tabs.
Correspondence Contact	If this check box is selected for a reporter, the reporter's address information is used in letters. You can select more than one reporter as the correspondence contacts for the case.
(New) Tab	Creates details for a new reporter.

Adding Reporter Information You can add reporter information by clicking the **Select** button and entering data in the **Reporter Lookup** dialog box.

To add reporter information

1. Click Select in the Reporter Information section.
2. When the system opens the **Reporter Lookup** dialog box, enter the required search criteria in the fields and click **Search.**

> **Tip:** You can choose to search either by Search Cases or by Search List Maintenance.



3. The Search results for the entered search are displayed.
4. When the system displays the search results, choose the appropriate reporter information from the list and click **Select**.
5. The system adds the selected, pre-defined information to the fields in the **Reporter Information** section.

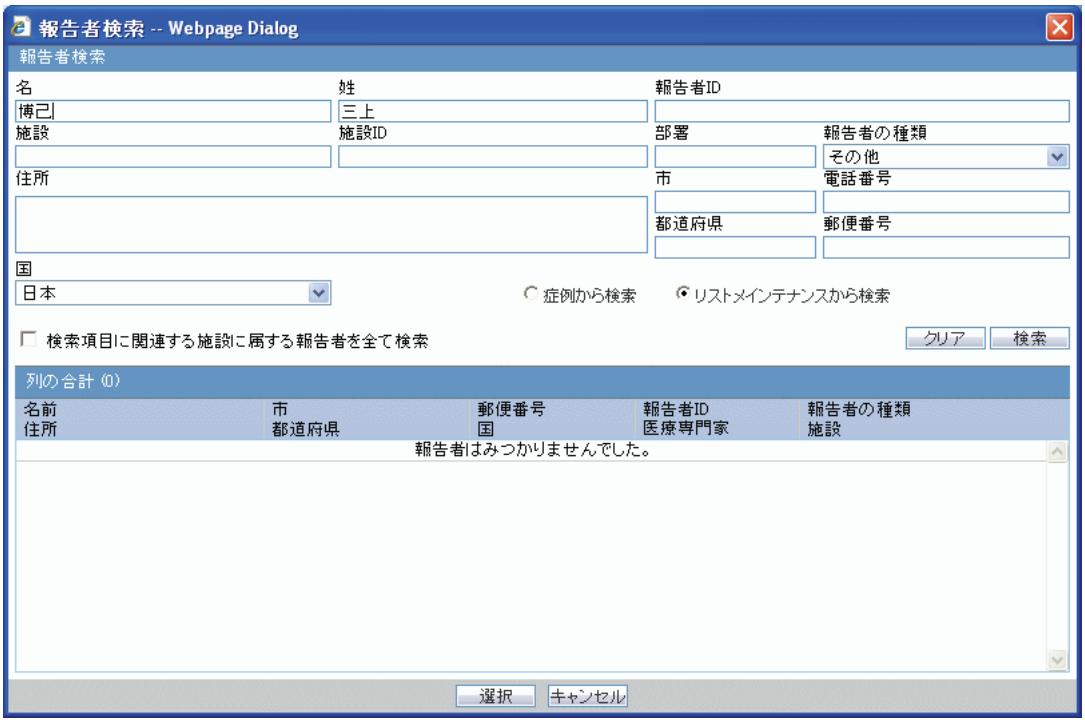
Reporter Lookup Dialog Box Fields The following table lists and describes the fields in the **Reporter Lookup** dialog box.

Field/Control Name	Description
First Name	Enter the first name of the reporter.
Last Name	Enter the last name of the reporter.
ID	Enter the ID of the reporter.
Institution	Enter the institution of the reporter.
MR	Select this button if the reporter is a Medical Representative (MR).
Physician	Select this button if the reporter is a Healthcare Physician.
Department	Enter the department of the reporter.
Reporter Type	Enter the reporter type.
Address	Enter the address of the reporter.
City	Enter the city of the reporter.
State/Province	Enter the state/province of the reporter.
Postal Code	Enter the postal code of the reporter.
Phone Number	Enter the phone number of the reporter.
Country	Enter the country of the reporter.
Search Cases	Click this button to search for cases that match the specified search criteria.

Field/Control Name	Description
Search List Maintenance	Click this button to search the list maintenance for the specified criteria.

J Reporter Lookup Dialog Box

The following table lists and describes the fields in the J Reporter Lookup dialog box shown in the following illustration.



Field/Control Name	Description
First Name	Enter the first name of the reporter.
Last Name	Enter the last name of the reporter
Reporter ID	Enter the reporter's ID
Institution	Enter of select the institution.
Institution ID	The unique value that identifies the institution.
Reporter Type	Enables you to select the reporter type from the drop-down list.
Address	Enter the address of the reporter.
City	Enter the city of the reporter.
State/Province	Enter the state/province of the reporter.
Postal Code	Enter the postal code of the reporter.
Phone Number	Enter the phone number of the reporter.
Country	Enables you to select the reporter's country.

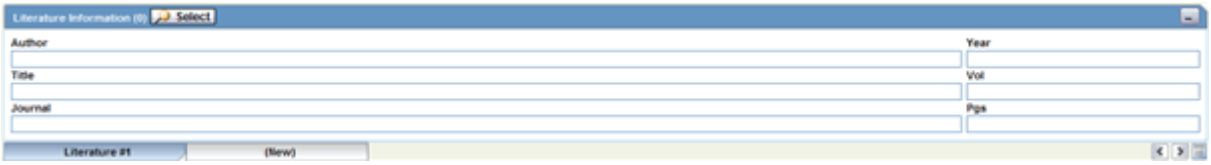
Field/Control Name	Description
Search Cases	Click this button to search for cases that match the specified search criteria.
Search List Maintenance	Click this button to search the list maintenance for the specified criteria.
Search all the reporters who belong to the institution found from the current serch item	When checked, enables you to search for all reporters linked to the specified institution. The result list shows all the reporters belonging to the institution When you click this checkbox the system does the following: ■ Searches for all reporters matching the specified criteria. ■ Retrieves a list of all institutions the reporter's results belong to. ■ Searches for additional reporters and adds them to the results set when the institution is the only search parameter.

When using the Reporter Lookup dialog box, be aware of the following:

- The "Search all the reporters who belong to the institution found from the current search item" checkbox is enabled only when the "Search List Maintenance" radio button is selected.
- You can select multiple reporters in the search results table. Hold down the Shift key and click each item to select it.
- When this option is enable, the system places the multiple reporter informtion in the Case Form when you click Select.
- When you click Select, and one or more rporters are already in the Case Form, the system adds these reporters on the Case Form.
- When you select multiple reporters, the information replaces the current tb and adds a new tab for each additional report.

General Tab: Literature Information Section

This section enables you to enter a literature reference for the case. You can enter the information manually or you can enter pre-defined literature information by click the **Select** button and selecting from the list of pre-defined references.



Click the Quick Launch **icon**to view all the items present in the case. This information appears in the format: (Journal Name Yea Vol: Pages)

Literature Information Fields and Field Descriptions The following table lists and describes the fields in the **Literature Information** section.

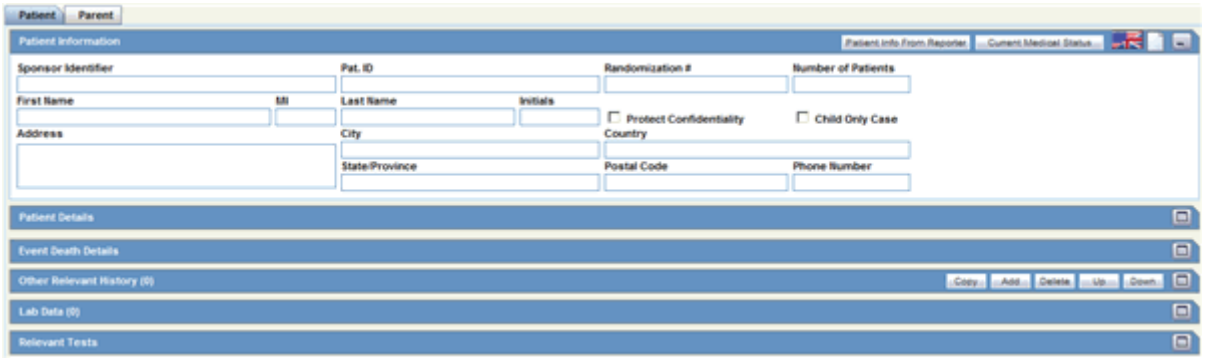
Field/Control Name	Description
Select	Selects a literature reference directly from the list of literature articles entered by the Administrator. **Note:** If the required literature article is not present in the list, details of the article can be entered by using the remaining fields in the section.
Journal	Enter the name of the journal in which the article appeared. This value gets displayed in italics.
Author	Enter the name(s) of the author(s) of the article.
Title	Enter the title of the article.
Volume	Enter the volume of the particular journal.
Year	Enter the year in which the article was published.
Pgs	Enter the journal page numbers in which the article appears.

To enter pre-defined literature information

1. Click **Select** to choose from the already available list of literature information.
2. When the **Literature Reference** dialog opens, locate and select the appropriate reference in the list and click **Select.**
3. The details of the selected literature information are added to each field in **Literature Information**.

Patient Tab

This section of the Case Form helps you to enter patient information such as the patient's past medical history and current conditions, and laboratory tests and test results. The medical information entered here could be very useful to the person analyzing the event. For example, if the adverse event was a rash that developed after applying a topical product, the knowledge that the patient has a history of allergic reactions could be relevant.



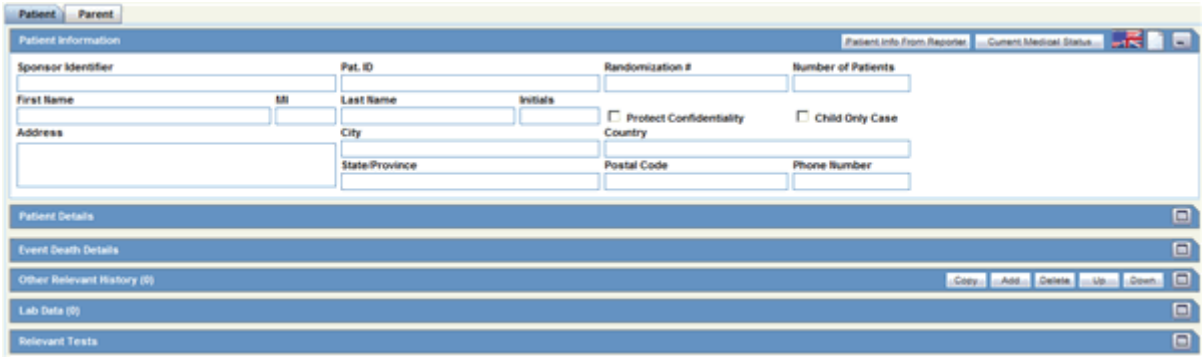
The **Patient** tab includes the following tabs: Patient and Parent.

- Patient Tab
- Parent Tab

Patient Tab: Patient Information

The **Patient** tab includes the following sections:

- Patient Information
- Patient Details
- Other Relevant History
- Event Death Details
- Lab Data
- Relevant Tests



Patient Information Fields The following table lists and describes the function of each field.

Field/Control Name	Description
Patient Info From Reporter button	Copies name and address information from the **Reporter** section of the General Tab into the **Patient Information** section.
Current Medical Status Button	Captures details about the history and the current condition of the patient from the dialog. **Note:** The items that appear in the Current Medical Status dialog automatically map to the fields for the German BfArM tab on the **Analysis** tab. Changing the values on the BfArM tab does not affect these items.
Sponsor Identifier	Enter the Sponsor Identifier of the patient. **Note:** This field appears for clinical trial cases only. **Tip:** This field can be used while searching for cases in the Case Selection dialog.
Pat. ID	Enter the Patient Identifier number. **Note:** This field appears for clinical trial cases only. **Tip:** This field can be used while searching for cases in the Case Selection dialog.
Randomization #	Determines which drug was administered to the patient during the course of the study. **Note:** This field appears for clinical trial cases only. **Tip:** This field can be used while searching for cases in the Case Selection dialog.
Number of Patients	Enter the number of patients involved in the adverse event.

Field/Control Name	Description
First Name	Enter the first name of the patient. **Note:** During book-in, the system transfers the appropriate patient name to the relevant name and initials fields. If the Patient Name or Initials are three characters or less, this is transferred to the Initials field.
MI	Enter the middle initial of the patient.
Last Name	Enter the last name of the patient.
Initials	Enter the patient's initials. Existence of the patient's first, middle, or last name automatically populates this field.
Protect Confidentiality	If this check box is selected, the patient's name and address will not appear on any of the regulatory reports and the patient's information will show the word PRIVACY.
Child only Case	If this check box is selected, then the pregnancy [Detail] button is accessible from the Parent information tab only and no longer through the Patient tab directly.
Address	This field and the following four fields allow you to enter the patient's address.
City	Enter the patient's city.
State/Province	Enter the patient's state, province, or county.
Country	Select the country. The Administrator can adjust this list.
Postal Code	Enter the patient's postal code.
Phone Number	Enables you to enter the phone number of the patient.

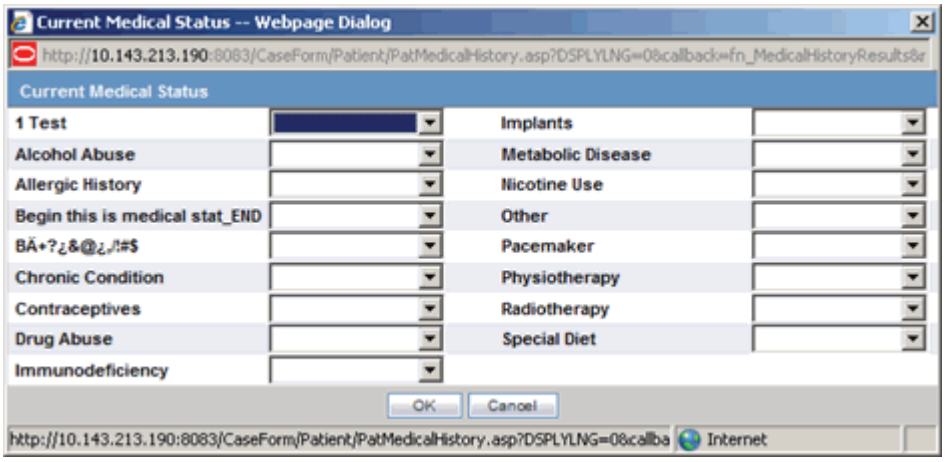
Neonate Information Section When using the Neonate Information section, be aware of the following:

- You can delete neonate information by right clicking the neonate and selecting the **Delete** option.
- The system tracks changes to the neonate information in the audit log.

Pregnancy Information The Pregnancy Information section enables you to enter data about a pregnancy. When using this section be aware of the following new fields: Gravida and Para. These fields enable you to capture numerical gravida and para information.

Entering Current Medical Status Use the following procedure to enter information about the patient's current medical status.

1. Click Current Medical Status in the Patient tab of the Case Form.
2. The Current Medical Status form opens as a pop-up.



3. Select the choices that apply to the patient from the items in the form.

   If you don't know whether a particular condition applies for the patient, select **Unk**.

4. Click **OK** to save the current medical status.

Copying Patient Information from Reporter Information If the patient and the reporter are the same person, the reporter information entered in the **General** tab can be copied to the Patient tab.

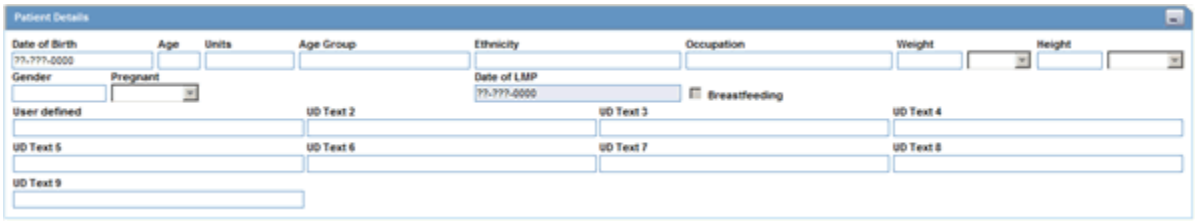
Reporter Information

If the patient and the reporter are the same person, the reporter information entered in the **General** tab can be copied to the Patient tab.

Click **Patient Info From Reporter** in the **Patient** tab to copy the reporter information. The reporter information is copied.

Patient Details Section

The Patient Details section enables you to enter information, including pregnancy data, about a patient. The following is an illustration of the Patient Details section.



Patient Details Fields and Field Descriptions The following table lists and describes the fields in the **Patient Details** section.

Field/Control Name	Description
Date of Birth	Enter the patient's date of birth. You can enter a partial date if the actual date is unavailable.

Field/Control Name	Description
Age	Calculates the patient's age, from the date of birth and earliest event onset date, if both full dates are available; otherwise, you can enter the age manually.
Units	Select the age units. (i.e., days, weeks, months, years) **Note:** If both the date of birth and event onset date are available, the Age Units field is automatically calculated. The Administrator can adjust this list.
Age Group	Select an age group. If the age group is entered manually, the Age and Age Units fields are disabled. The Administrator can adjust this list. **Note:** This field is automatically filled in when the Age and Age Units fields are both entered.
Ethnicity	Select the patient's ethnicity. The Administrator can adjust this list.
Occupation	Select the patient's occupation. The Administrator can adjust this list.
Weight	Enter the patient's weight.
Weight Units	Select the appropriate weight unit.
Height	Enter the patient's height.
Height Units	Select the appropriate height unit.
Gender	Select the patient's gender. **Note:** If the patient is male, the system automatically disables the **Pregnancy** field. When the Gender is set to Female, the Pregnancy drop down is enabled and set to **Unknown**.
Pregnant	Make the appropriate selection. **Note:** If **Yes** is selected, a **Details** button will appear. Click **Details** to enter pregnancy information.
Date of LMP	Enter the date of the Last Menstrual Period, if applicable. A partial date can also be entered.
Breastfeeding	Select the checkbox, if applicable.
User Defined	Enables the user to enter information about the patient.
UD Text 2 -- UD Text 9	Enables users to enter information about the patient.

Entering Pregnancy Information Use the following procedure to enter pregnancy information.

1. Select **Yes** from the **Pregnant** drop-down list, if applicable.

   This field is shown as active only after the **Gender** field in this section is selected as **Female**.

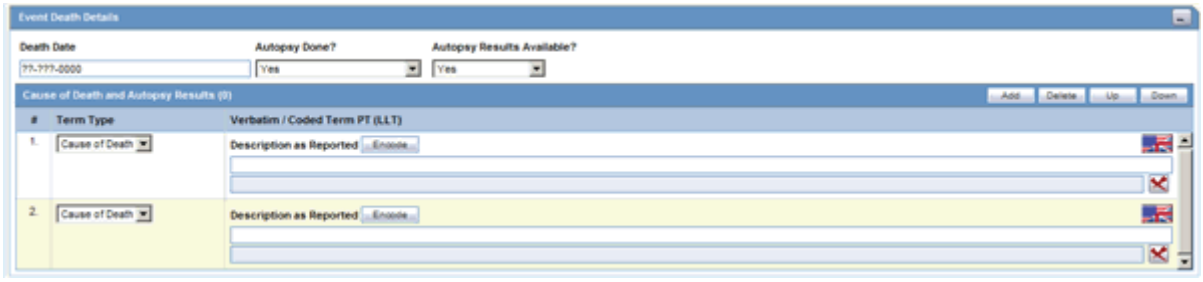
   The **Pregnancy Information** section is displayed.
2. Enter the available pregnancy information in the form.
3. Click **OK** to save the pregnancy information.

The following lists and describes the fields on the Pregnancy Information form.

Field/Control Name Name	Description
Due Date	Enter a due date or an approximate due date, if known.
Weeks at Onset	Enter the number of weeks of pregnancy at the time the event occurred, if known. The maximum entry allowed in this field is 50.
Prospective/Retrospective	Select if the information was Prospective or Retrospective. **Note:** A prospective information is one where the company hears of the case *before* the baby is born to the patient who took the drug. In a retrospective case, a company gets to know *after* the baby is born.
Weeks at Exposure	Enter the number of weeks of pregnancy at the time of exposure, if known. The maximum entry allowed in this field is 50.
Trimester of Exposure	Make the appropriate selection.
Number of Fetus	This tab allows entry of data for a baby who is born to the patient. Click **New** to make an additional entry.
Delivery Date	Enter the date of the delivery.
Weight	Enter the birth weight
Weight Units	Select the appropriate weight units.
Delivery Type	Select the delivery type from the list. The Administrator can adjust this list.
Birth Type	Select the birth type from the list.
Fetal Outcome	Select the fetal outcome from the list.
APGAR Score	Enter the APGAR scores-up to three per neonate.
Delivery Notes	Enter notes on the case.

Event Death Details

The Event Death Details section enables you to enter information about the death of a patient.



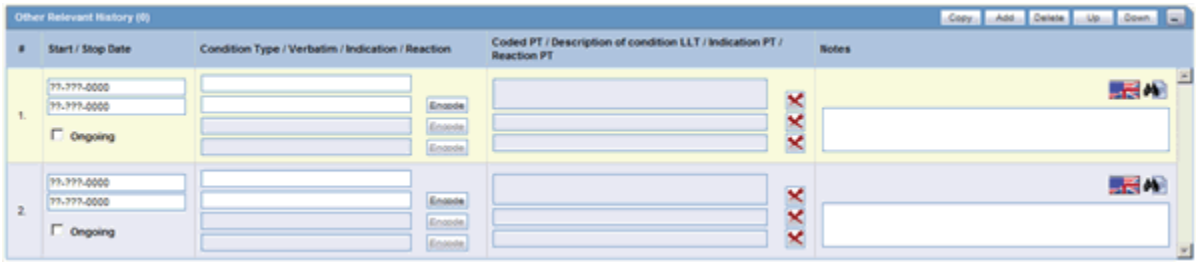
The following table lists and describes the fields in the Event Death Details section.

Field/Control Name	Description
Date of Death	Enter the date of death
Autopsy Done?	Select whether autopsy was done. Note: If Autopsy Done is set to No or Unknown, the Autopsy Results Available is shown as No.

Field/Control Name	Description
Autopsy Results Available?	Select if autopsy results are available. **Note:** The **Autopsy Results Available?** field is enabled only if the **Autopsy Done?** field is marked as **Yes**. However, if A**utopsy Results Available** is changed to **No** and **Autopsy Result** rows exist, you will be asked to delete the rows first. Click **Yes** to delete the data.
Add	Click this button to add a Cause of Death and Autopsy Results row. **Note:** A user can add multiple records, up to 50 entries.
Delete	Enables you to delete a highlighted row.
Up/Down	Click Up to move the record up and click Down to move the record down. **Note:** Ordering reflected on the case form displays the same ordering as displayed in the E2B report repeatable tags.
Cause of Death	Describes the cause of death.
Description as Reported	Displays the description reported by the reporter.
Autopsy Result	Describes the autopsy results.
Encode	Encodes the event reported by the reporter.

Other Relevant History Section

The Other Relevant History section enables you to enter information that might be useful. The system enables you to copy the Other Relevant History rows by selecting the row and clicking Copy. The following is an illustration of the Other Relevant History section.



Other Relevant History Fields and Field Descriptions The following table lists and describes the fields in the **Other Relevant History** section.

Field/Control Name	Description
Start Date	Enter the start date of the condition. You can enter a partial date if the actual date is not available. You can also choose not to enter a date. **Note:** If you click **Add** but do not enter a date, the **Date** column is removed. Once the date is entered and there is a test associated with the date, you cannot clear the date but can only modify it. To remove the date column, individually delete all the cells in that **Date** column.
Stop Date	Enter the stop date of the condition. You can enter a partial date if the actual date is not available. You can also choose not to enter a date.
Ongoing	If the condition is ongoing, select the **Ongoing** check box.

Field/Control Name	Description
Condition Type/Verbatim/Indication/Reaction	Select a condition type from the list. The Administrator can adjust this list. **Note:** If the **Condition Type** value is **Medical History Episode** and the term is not encoded, the value entered in the **Description** field is appended to the **Patient Notes** value. However, if the **Condition Type** value is **Other Relevant Therapy** and the term specified in the **Description** field is not encoded, then this record is not transmitted at all.
Encode	Click this button to encode the term. **Note:** To view the complete MEDDRA hierarchy for the encoded term, click the encoding status icon.
Coded PT/Description of condition LLT/Indication PT/Reaction PT	Enter a term to describe the condition. You can either manually encode or auto-encode, if you have been so configured by the Administrator. In manual mode, type the description (for example, Fever). In Auto-encode mode, enter a partial description and press ENTER or TAB. The appropriate coding dialog appears. In either mode, you can click **Encode** and modify the encoding. If the condition type is historical drug, the encoding will be done with WHO drugs. **Note:** To view the complete MEDDRA hierarchy for the encoded term, click the encoding status icon.
Indication PT	Enter a term to describe the indication. **Note:** This field is visible on the case form only if the condition type selected in the List maintenance is **Patient Other Relevant Therapy**.
Reaction PT	Enter a term to describe the reaction. **Note:** This field is visible on the case form only if the condition type selected in the List maintenance is **Patient Other Relevant Therapy**.
Notes	Enter any notes that are relevant to the condition.
Copy	Enables you to copy a row. After you copy the row, the focus will be on the newly copied row.
Add	Enables you to add a row to the relevant history. After you add the row, the focus will be on the new row.
Delete	Enables you to delete a row from the relevant history.
Up	Enables you to move up a row in the relevant history.
Down	Enables you to move down a row in the relevant history.

Lab Data Section

The Lab Data section provides data about lab test and test results. The maximum number of lab test data on the Case Form is 2000. The following is an illustration of the Lab Data section.

Lab Data Fields and Field Descriptions The following table lists and describes the fields in the **Lab Data** section.

Field/Control Name Name	Description
Lab Data Section	
Date	Enter the date the test was carried out. Partial dates are allowed for in this field.
Test Name/Assessment	Enter a lab test name, or select from the list. Also select the assessment from the list below the **Test Name**.
Select Lab Test Group	Enables you to select one or more lab test groups.
Result/Units	Enter the test result, including the appropriate units and select a term to describe the qualitative assessment of the results. The Administrator can modify the list of possible assessments.
Norm Low/Norm High	The **Test Name** list can retrieve details of the normal range for the test selected (if the Administrator has entered the normal range into the list). Otherwise, enter the values manually.
Encode	Click this button to encode the term. **Note:** To view the complete MedDRA hierarchy for the encoded term, click the encoding status icon.
Notes	Enter notes pertinent to this case.

Using the Lab Data Section When using the **Lab Data** section, be aware of the following:

- A single, vertical scroll bar has been placed beneath the header and date information in the Lab Data section. This enables the date to be seen at all times.
  - To keep all the rows together, all rows in the **Lab Data Test as Reported "** and **Results/Units** use this scroll bar.
  - A maximum of three (3) rows is visible at all times.

You can perform several different actions in the Lab Data section as follows:

To enter a Lab Test Name

1. Click **Add Test**.
2. Enter a partial description of the lab test in the Lab Test Name dialog.
3. Click **Search**. Select the required lab test from the search results.

Selecting a Lab Test Group

The system enables you to select a lab test group from the dialog box shown in the following illustration.

When selecting a lab test group, be aware of the following:

- When you click Select, the system popultes the Lab Test Group with a list of lab tests that match the selected lab test group.
- If lab test data is already on the Case form, the system appends the lab test group after the last lab test.
- The Import/Export buttons enable you to import/export lab test data.
  - When you click Import the system opens a dialog box to enable you to enter the name of the file to import.
  - You can copy the lab test results to the English field. When you check this check box, the system copies all test results to the English case form fields. The default is checked.
  - The system does not commit imported data until you save the case.
  - When there are multiple same dates for the same thes, the system sorts the data by sequence number.
  - If data is alread in the lab data field of the case form, the system displays the following message: "Data already exists in the case form field. If you continue, the data will be overwritten. Do you want to proceed?"
  - The system validates the fields before mapping the data to the case form.
  - If there are errors, the system provides error information.
  - If the system encounters an error, it displays the following message: "There are errors in the import data. Click Detail to check the error detail."
  - When imported data exceed the maximum field length, the system returns the following message: "Imported data exceeds the maximum length. The import cannot continue."
  - When all the data is mapped, the system displays the following message: "Import completed successfully."

Arranging Entries in a Specific Order

Click the **Order** icons to arrange entries in a specific order.

Adding Additional Rows

Click the **Add** button to add more rows.

Deleting Entries

Click the button, to highlight the row for removal.

Sorting the Entries

The Lab data can be sorted in chronological order by Date of the Test and alphabetically by the Test Name.

If there are partial dates entered, the date is displayed at the beginning of the month, and year for the date entered.

Copying or Pasting Rows in Lab Data

Click the icon to highlight the row to be copied or pasted to an empty cell after a Test Date has been added. You can also use the right-click functionality to copy or paste data.

Viewing the Hierarchy of the Event Term

1. Click the icon to view the entire hierarchy of the Event Term.
2. Click outside the MedDRA hierarchy dialog to close this hierarchy listing.

Viewing Notes

Click the icon to view display the Notes in a Zoom dialog.

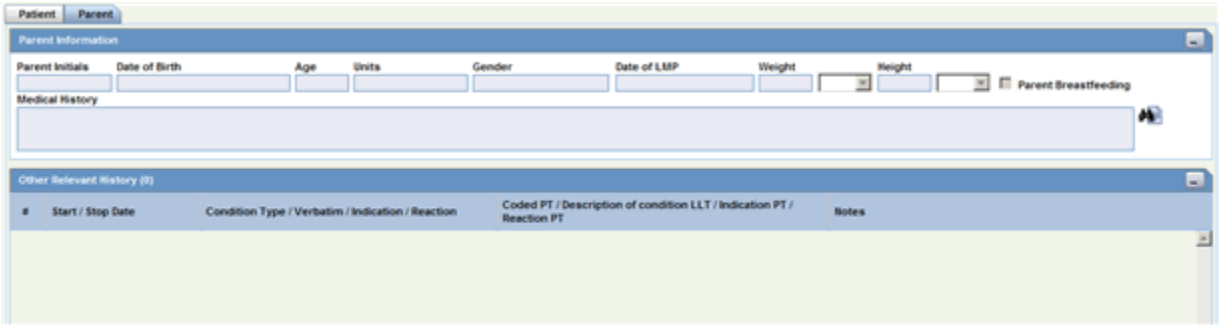
Arranging the Lab Test data Click the arrow button to arrange the Lab Test to the right Lab Test. This shall only be available when the Lab Test has been entered for the same date.

Click the arrow button to arrange the Lab Test to the Left Lab Test. This shall only be available when the Lab Test has been entered for the same date.

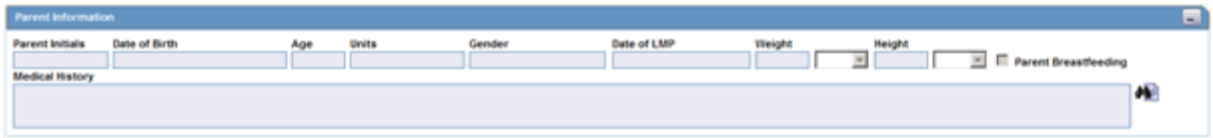
Relevant Tests Section This section enables you to enter additional information about any relevant tests, such as toxicology. The following is an illustration of this section.

Patient Tab: Parent Information

The following is an illustration of the Parent tab.



Parent Information Section The following is an illustration of the Parent Information section on the Parent tab.



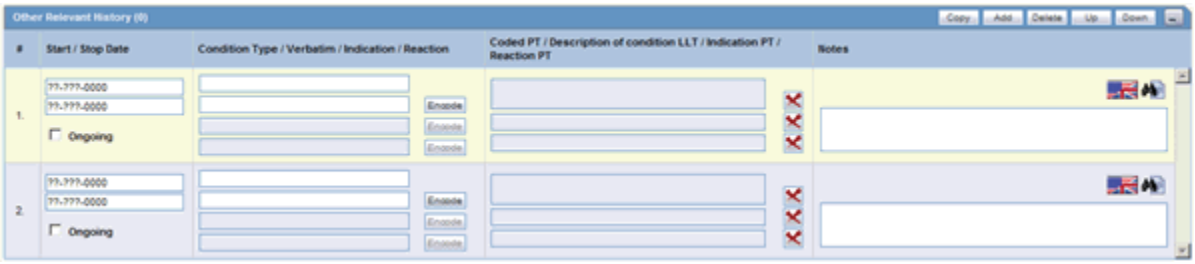
Parent Tab Fields and Field Descriptions

The following table lists and describes the fields on the **Parent** tab.

Field/Control Name Name	Description
Parent Initials	Enter initials about the parent.

Field/Control Name Name	Description
Date of Birth	Enter the parent's date of birth. You can enter a partial date if the actual date is unavailable.
Age	Calculates the parent's age, from the date of birth and earliest event onset date, if both full dates are available; otherwise, you can enter the age manually.
Units	Select the age units. **Note:** If both the date of birth and event onset date are available, age units field is automatically calculated. The Administrator can adjust this list.
Gender	Select the parent's gender. **Note:** If the parent is male, the system automatically disables the **Pregnancy** field. When the Gender is set to Female, the **Pregnancy** drop down is enabled and set to **Unknown**.
Date of LMP	Enter the date of the Last Menstrual Period, if applicable. A partial date can also be entered.
Weight	Enter the parent's weight.
Weight Units	Select the appropriate weight unit.
Height	Enter the parent's height.
Height Units	Select the appropriate height unit.
Parent Breastfeeding	Select the check box, if applicable.
Medical History	Captures information about the parent's medical history.

Other Relevant History Section The Other Relevant History section enables you to enter information that might be useful. The system enables you to copy the Other Relevant History rows by selecting the row and clicking Copy. The following is an illustration of the Other Relevant History section.



Other Relevant History Fields and Field Descriptions

The following table lists and describes the fields in the **Other Relevant History** section.

Field/Control Name	Description
Start Date	Enter the start date of the condition. You can enter a partial date if the actual date is not available. You can also choose not to enter a date. **Note:** If you click **Add** but do not enter a date, the **Date** column is removed. Once the date is entered and there is a test associated with the date, you cannot clear the date but can only modify it. To remove the date column, individually delete all the cells in that **Date** column.
Stop Date	Enter the stop date of the condition. You can enter a partial date if the actual date is not available. You can also choose not to enter a date.
Ongoing	If the condition is ongoing, select the **Ongoing** check box.
Condition Type/Verbatim/Indication/Reaction	Select a condition type from the list. The Administrator can adjust this list. **Note:** If the **Condition Type** value is **Medical History Episode** and the term is not encoded, the value entered in the **Description** field is appended to the **Patient Notes** value. However, if the **Condition Type** value is **Other Relevant Therapy** and the term specified in the **Description** field is not encoded, then this record is not transmitted at all.
Encode	Click this button to encode the term. **Note:** To view the complete MEDDRA hierarchy for the encoded term, click the encoding status icon.
Coded PT/Description of condition LLT/Indication PT/Reaction PT	Enter a term to describe the condition. You can either manually encode or auto-encode, if you have been so configured by the Administrator. In manual mode, type the description (for example, Fever). In Auto-encode mode, enter a partial description and press ENTER or TAB. The appropriate coding dialog appears. In either mode, you can click **Encode** and modify the encoding. If the condition type is historical drug, the encoding will be done with WHO drugs. **Note:** To view the complete MEDDRA hierarchy for the encoded term, click the encoding status icon.
Indication PT	Enter a term to describe the indication. **Note:** This field is visible on the case form only if the condition type selected in the List maintenance is **Patient Other Relevant Therapy**.
Reaction PT	Enter a term to describe the reaction. **Note:** This field is visible on the case form only if the condition type selected in the List maintenance is **Patient Other Relevant Therapy**.
Notes	Enter any notes that are relevant to the condition.
Copy	Enables you to copy a row. After you copy the row, the focus will be on the newly copied row.
Add	Enables you to add a row to the relevant history. After you add the row, the focus will be on the new row.
Delete	Enables you to delete a row from the relevant history.
Up	Enables you to move up a row in the relevant history.
Down	Enables you to move down a row in the relevant history.

Products Tab

The **Products** tab enables you to enter and view details about products and dosage regimens. The **Products** tab contains the name of the drug that has been entered within that tab. For Blinded Studies, the Blinded Product Name gets displayed in the tab.

When a user has no access to view unblinded information on the Case Form, the following fields are hidden:

- Drug Code
- Study Drug
- Formulation
- Concentration
- Outside Therapeutic Range
- Dose
- Dose Description
- Daily Dosage
- Regimen Dosage
- Patient Route of Administration
- Parent Route of Administration
- Package ID
- Pack Units
- Batch\Lot
- Expiration Date
- Total Dosage Units
- Total Dose to Primary Event

General Usage Information

When using the **Products** tab, be aware of the following:

If the study has been unblinded and a study drug had been selected, the selected Study Drug Name is displayed. You **cannot** view unblinded information and the tab continues to show the Blinded Product Name.

You can enter details of more than one product and more than one dosage regimen for a company product for which multiple licenses exist (for example, drug and vaccine, or drug and device).

Depending on the type of license (drug, vaccine, or device), different views are available in the Products tab. If the selected item is not a company product or if a license for a company product does not exist, all three views are always available.

Time Measurement Fields You can enter seconds in the following fields:

- Argus > Case Actions > Open > (Select a Case) > Event tab > Event sub tab > {event description} sub tab > Event Information section (middle of screen)
  - Onset From Last Dose field
  - Duration field
  - Onset Latency field

- Argus > Case Actions > Open > (Select a Case) > Products tab > Product sub tab > {Product Name} sub-sub tab (drug) > Dosage Regimen section (lower 1/3 of screen)
  - Duration of Regimen
- Argus > Case Actions > Open > (Select a Case) > Products tab > Product sub tab > {Product Name} sub-sub tab (drug) > Product Details section (lower 1/3 of screen
  - Duration of Administration
  - Time between First Dose/Primary Event
  - Time between First Dose/Primary Event
- Any number following by the letter "s" defaults to "#sec."
- The system interprets the seconds the user enters in the following formats where:

  # is a number from 0 to 9

  #s -- The system automatically changes the format to # sec.

  # s -- The system automatically changes the format to # sec.

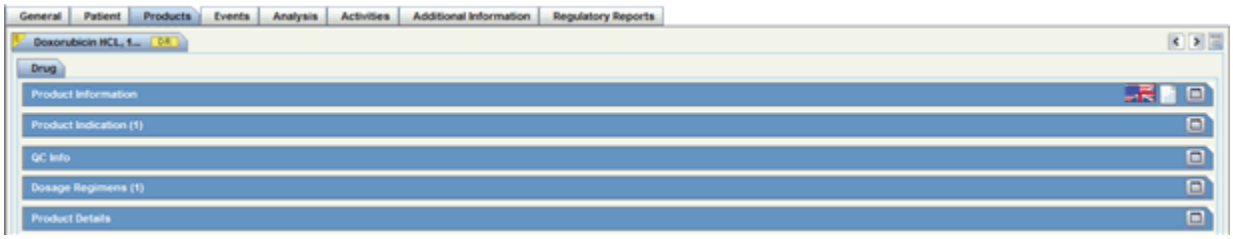
  # sxx

  where:

  x is other letters -- The system automatically changes the format to # sec
- The Temporal View and the Case Form printout display the seconds.
- The E2B import and export case functions support seconds and M2 Validation for the defined fields.

Date of Mfr Field You can enter a partial date in the **Date of Mfr** field. The MedWatch (Device) and EU Device Reports print the partial dates entered in the field.

The **Products** tab includes three tabs: Drug, Device, and Vaccine.



Products Tab: Drug Tab

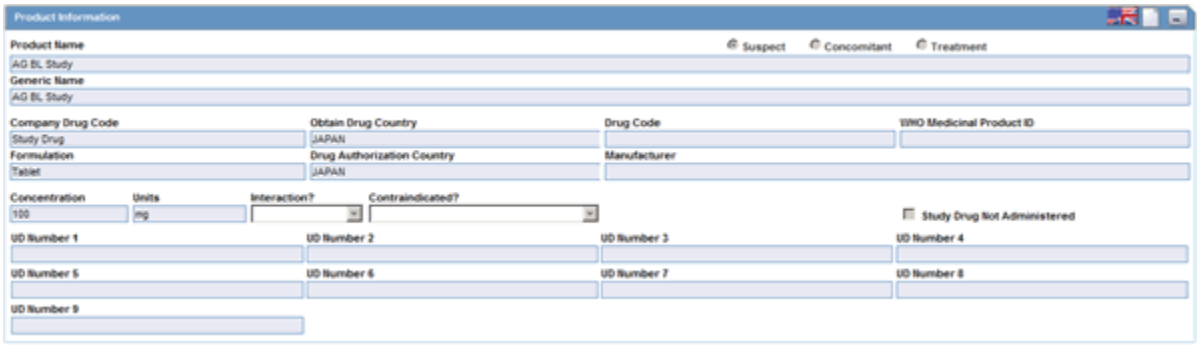
The **Products** tab displays the **Drug** section by default as shown in the following illustration.

The Drug tab includes the following sections:

- Product Information

- Product Indication
- Dosage Regimens
- QC Info
- Product Details

Product Information Section The Products Information section enables you to enter information about the drug being used for the case. The following is an illustration of the Product Information section.



Product Information Fields and Field Descriptions

The following table lists and describes the fields and controls in the Product Information section.

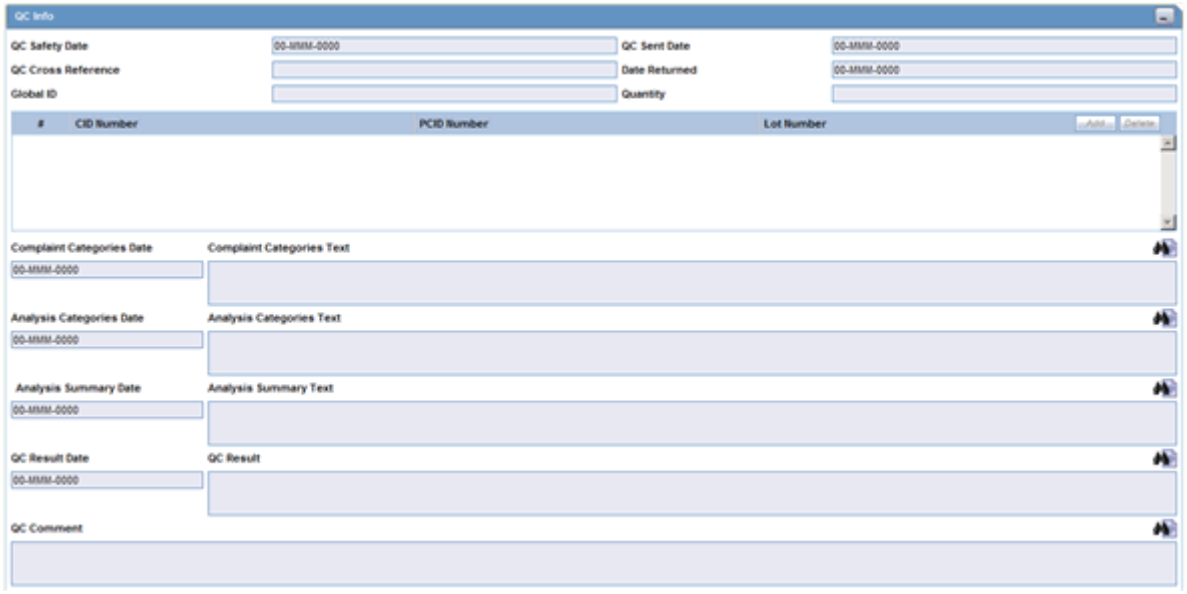
Field/Control Name	Description
Suspect Concomitant Treatment	Indicates whether the drug
Product Name	The name of the product associated with the adverse event.
Generic Name	The generic name of the product
Company Drug Code	The unique value the company uses to identify the drug.
Obtain Drug Country	The name of the country where the drug was obtained.
Drug Code	The unique value that identifies the drug.
WHO Medicinal Product ID	The WHO Drug code used to identify the drug
Formulation	The form in which the drug was administered (liquid, tablet, capsule, etc.)
Drug Authorization Country	The country where the drug was authorized for use.
Manufacturer	The company that manufactured the drug.
Concentration	The amount of the drug that was administered.
Unit	The drug unit (i.e., mg, tsp, etc.)
Interaction	Identifies the drug interaction, if any.
Contraindicated?	
Study Drug Not Administered	Check this box if this is a study drug and was not administered.

Field/Control Name	Description
UD Number 1 -- UD Number 9	

Product Indication Section The Product Indication section enables you to enter information about the indicator of the adverse event. It includes two fields: Reported Indication and Coded Indication

Reported indication is the reported reaction and Coded Indication is the code for the reaction. The two values may be the same, but they may also be different.

QC Info The QC Info section enables you to enter quality control information. The following is an illustration of the



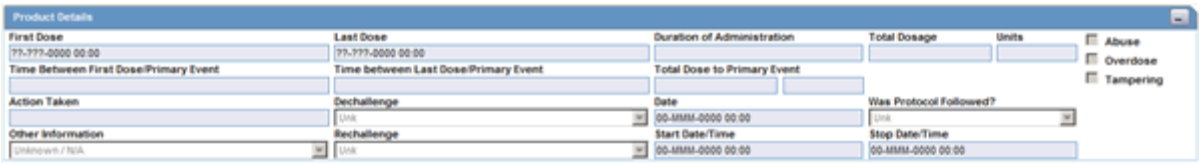
QC Info Fields and Controls

The following table lists and describes the fields in the QC Info section.

Field/Control Name	Description
QC Safety Date	Enter the QC department reference number for the analysis.
QC Sent Date	Enter the sent date.
QC Cross Reference	Enter the QC department reference number for the analysis.
Date Returned	Enter the date returned.
Global ID	Enter the global number.
Quantity	Enter the quantity.
# CID Number	Enter the Control Identification Number.
PCID Number	Enter the Product Control Identification Number.
Lot Number	Enter the lot number. If the Lot Number entered is incorrect, a Lot Number Lookup dialog is displayed, that allows you to enter select from the existing lot numbers.

Field/Control Name	Description
Complaint Categories Date	Enter a date for complaint categories.
Complaint Categories Text	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
Analysis Categories Date	Enter a date for analysis categories.
Analysis Categories Text	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
Analysis Summary Date	Enter a date for an analysis summary.
Analysis Summary Text	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
QC Result Date	Enter the date the result of the analysis was received by the QC department.
QC Result	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
QC Comment	Enter any comment relating to the analysis.

Product Details Section The **Product Details** section enables you to enter information about the drugs being used for the case. The following is an illustration of the Product Details section



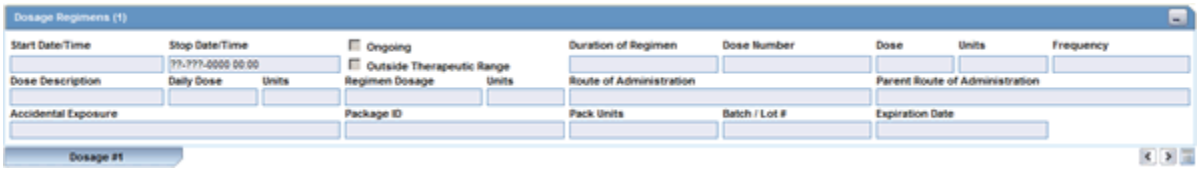
Product Details Fields and Field Descriptions

The following lists and describes the fields in the **Product Details** section.

Field/Control Name	Description
First Dose	This date is defined as the earliest regimen start date and is entered automatically.
Last Dose	This date is defined as the latest regimen stop date and is entered automatically. If the **Ongoing** check box is selected, this field will not be filled in.
Duration of Administration	This field is calculated automatically if full dates are available for first and last doses. It is the difference between the first and last dose for all dosage regimens. **Note:** If the duration is five days or more, the duration displays in number of days. If less than five days, it displays in days and hours.
Total Dosage	This field is calculated automatically based on daily dose, duration, and frequency. If each regimen is associated with different dosage units, this field is not calculated automatically.
Total Dosage Units	This field is calculated automatically based on daily dose, duration and frequency. If different regimens have different dosage units, this field is not calculated automatically.
Time between First Dose/Primary Event	Enter the time from the first dose to the onset of the primary event.

Field/Control Name	Description
Time between Last Dose/Primary Event	Enter the time from the last dose to the onset of the primary event.
Total Dose to Primary Event	Enter the total dose of drug given before the onset of the primary event.
Action Taken	Select the appropriate item from the list. If no change or dose increased is selected, the **Dechallenge Results** and **Rechallenge Results** sections below are not available. The Administrator can adjust the values in this list.
Abuse	Select this check box if the patient abused the product (For example: Painkillers taken without pain).
Overdose	Select this check box if the patient took an overdose of the product.
Tampering	Select this check box if the product appeared to have been tampered with before it was used.
Taken Previously / Tolerated	Select the appropriate response from the list.
Was Protocol Followed?	Click the appropriate button to indicate whether the protocol was followed during the study. **Note:** This item is only available for study products.
Dechallenge	Make the appropriate selection depending on whether the drug was stopped. If you select **Neg** or **Pos** or **Unk**, the Dechallenge Date is enabled. Select **N/A** to disable the Dechallenge date.
Date	Enter the date when the dechallenge was carried out.
Rechallenge Results	Make the appropriate selection depending on whether the drug was taken again. If **Pos** or **Neg** or **UNK** is selected for the Rechallenge field, the **Rechallenge Start Date/Time, Rechallenge Stop Date/Time, and the Rechallenge Outcome** fields are enabled.
Start Date/Time	Enter the date and/or time when the rechallenge was started.
Stop Date/Time	Enter the date and/or time when the rechallenge was stopped.
Additional Product Tabs	Click the additional product tabs to switch views. The products may have one or two letter icons next to it. The following are the icon names, and what they mean: VC- Vaccine view selected DR- Drug view selected DV- Device view selected **S**- Suspect Product **C** - Concomitant Product
(New) Tab	Enter information about a new product.

Dosage Regimens Section The **Dosage Regimens** section enables you to enter information about the size and frequency of drug doses being given to a patient. The following is an illustration of the Dosage Regimens section.



Dosage Regimens Fields and Field Descriptions

The following lists and describes the fields in the Dosage Regimens section of the Drug tab.

Field/Control Name	Description
Start Date/Time	Enter the start date and time of the dosage. Entry of time information is optional, and you can enter partial dates.
Stop Date/Time	Enter the stop date and time of the dosage. Entry of time information is optional, and you can enter partial dates. **Note:** If no Stop Date is entered, Onset from Last Dose is calculated automatically from the Event Onset Date and the most recent Stop Date or the most recent Start Date.
Ongoing	Select this check box if the drug treatment is ongoing. The **Stop Date**, **Duration of Regimen**, and **Last Dose** fields are removed if this check box is selected.
Outside Therapeutic Range	Select this check box if 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.
Duration of Regimen	This value is calculated automatically, based on regimen start and stop dates (if full dates are entered for the start and stop dates). If the value is entered manually, the duration units (for example: minutes, hours, days, months, or years) must also be entered along with the actual duration. **Note:** The Administrator can set the duration to be inclusive or exclusive. In Inclusive mode, the starting day counts in the calculation of the duration; in Exclusive mode, it does not.
Dose #	Enter the drug dose number.
Dose	Enter the dose received by the patient.
Dose Units	Select the dose unit. The Administrator can adjust this list.
Frequency	Select the frequency. The Administrator can adjust this list.
Dose Description	This value is automatically entered by using the values from **Dose**, **Dose Units**, and **Frequency**. If necessary, you can change this value. However, if Dose, Units, or Frequency information is changed, this value will be recalculated.
Daily Dose	This value is calculated automatically depending on the dose and frequency. It can be manually overwritten. If either the dose or the frequency fields are blank, this field is not calculated automatically.
Daily Dose Units	This value is derived automatically from the dose unit.
Regimen Dosage	This value is calculated automatically depending on the daily dose, duration, and frequency. This total can be overridden. If the daily dose is blank or the frequency fields are 0, this field is not calculated automatically.
Regimen Dosage Unit	This value is derived depending on the **Daily Dose Units**.

Field/Control Name	Description
Route of Administration	Select the route of administration. The Administrator can adjust this list.
Parent Route of Administration	Select the route of administration for the parent. The Administrator can adjust this list.
Accidental Exposure	Select the type of Accidental Exposure from the list. A non-modifiable list of items is provided for this list.
Package ID	Enter the package ID.
Pack Units	Select the package presentation information of the product. The Administrator can adjust this list.
Batch/Lot #	Enter the batch and/or lot number(s).
Expiration Date	Enter the expiration date. Enter a partial date if the full date is not known.
(New) Tab	Click this tab to create a new dosage regimen entry.

Study Drug Information You can enter a Study Drug for a Non-Configured Study entered in a case and mark a current product as a study drug.

To mark a product as a study drug

1. Right click on any suspect product in the case.
2. Select **Make Study Drug** to mark the current product as a study drug.

Be aware of the following:

- The system disables the drug type to make the product a **Concomitant** or **Treatment** option.
- **Study Drug** is a read-only field that contains the product name selected by the user.
- For non-configured studies in the case, the system displays the following for all study drugs in the case:

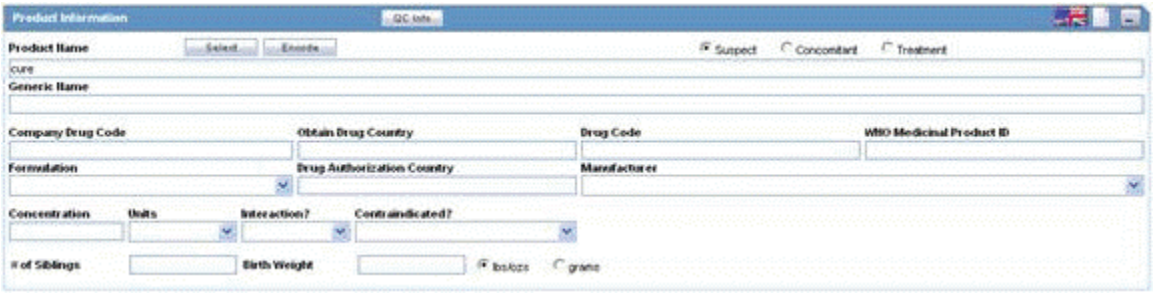
  Study Drug Not Administered.

Products Tab: Device Tab

The **Device** tab enables you to enter information about devices being used for a particular case. It has the following subsections:

- Product Informationi
- Product Indication
- Product Delivered by Device
- Device Information

Product Information Section The following is an illustration of the **Product Information** section of the **Device** tab.



Fields and Field Descriptions

The following table lists and describes the fields in the section.

Field/Control Name	Description
QC Info	Click **QC Info** to enter quality control information in the **Quality Control** dialog box.
Multiple Language Text	Click Multiple Language Text to open the Multiple Language Text dialog box.
Notes	Click the **Notes** icon to enter notes related to the product.
Select	Displays the product selection dialog. Select a product from the list of company products click **Select**. The relevant fields are added to the Case Form.
Encode	Click **Encode** to retrieve the code.
Suspect/ Concomitant/ Treatment	Make the appropriate selection for the product you are entering. The drug types indicate the involvement of the product with the adverse event(s) reported for the case. **Suspect** indicates that the product may have caused the adverse event(s). **Concomitant** indicates drugs that are taken with the suspect drug. **Treatment** is the drug taken to treat the adverse event.
Product Name	Enter the name of the product using the **Select** button or by entering a partial product name. Type a partial product name and press TAB. This displays the **Product Selection** dialog. If only one product is found, this information is entered without showing the dialog. If no match is found in the company product list, the WHO Drug Dictionary is searched for a possible match through the WHO Drug Dictionary Dialog. If a match is still not found, the text you initially typed in, is used as is. **Note:** If the study is blinded, the **Blinded Name** of the clinical study is displayed in this field. If a user has access, the selected **Study Product Name** for Unblinded cases is shown.
Generic Name	Enter the generic name of the drug in a manner similar to the **Product Name**. If the study is blinded, the **Generic Name** is replaced with the **Study Name** of the product. **Note:** This name is entered automatically depending on the chosen company product.
Company Drug Code	Displays the licensed country for the selected company product.
Obtain Drug Country	Country the drug is licensed in.
Drug Code	Enter the WHO-DRUG code.
WHO Medicinal Product ID	Displays the Medicinal ID associated with the selected WHO drug. **Note:** This ID is populated only if a WHO-drug is selected.

Field/Control Name	Description
Device Type	Indicates the type of device being used for this case.
Formulation	Select the formulation of the product. The Administrator can adjust this list. **Note:** This field is entered automatically depending on the product.
Drug Authorization Country	Enter the company drug code. **Note:** This name is entered automatically depending on the chosen company product.
Manufacturer	A different Manufacturer can be selected from the drop-down list and can still be kept as a company product.
Concentration	After a drug and formulation have been entered, select the concentration from the list, or enter the concentration. If this information is changed manually, the product is marked as a non-company product. **Note:** This field is entered automatically depending on the chosen product. The concentration cannot be modified for a Study drug.
Units	Select a concentration unit. The Administrator can adjust this list.
Interaction?	Indicates whether the case involves a drug interaction
Contraindicated?	Indicates whether the drug was administered contrary to its indication. Make the appropriate selection to indicate whether the drug was contraindicated in this case.
Study Drug	Select the study treatment the patient received from the list. If the study is Blinded, this field is disabled. The Administrator can adjust the information in this list. Drugs listed here are dependent on the Study ID selected for the **General** tab. **Note:** This field is applicable for Unblinded or not blinded clinical trial cases only.

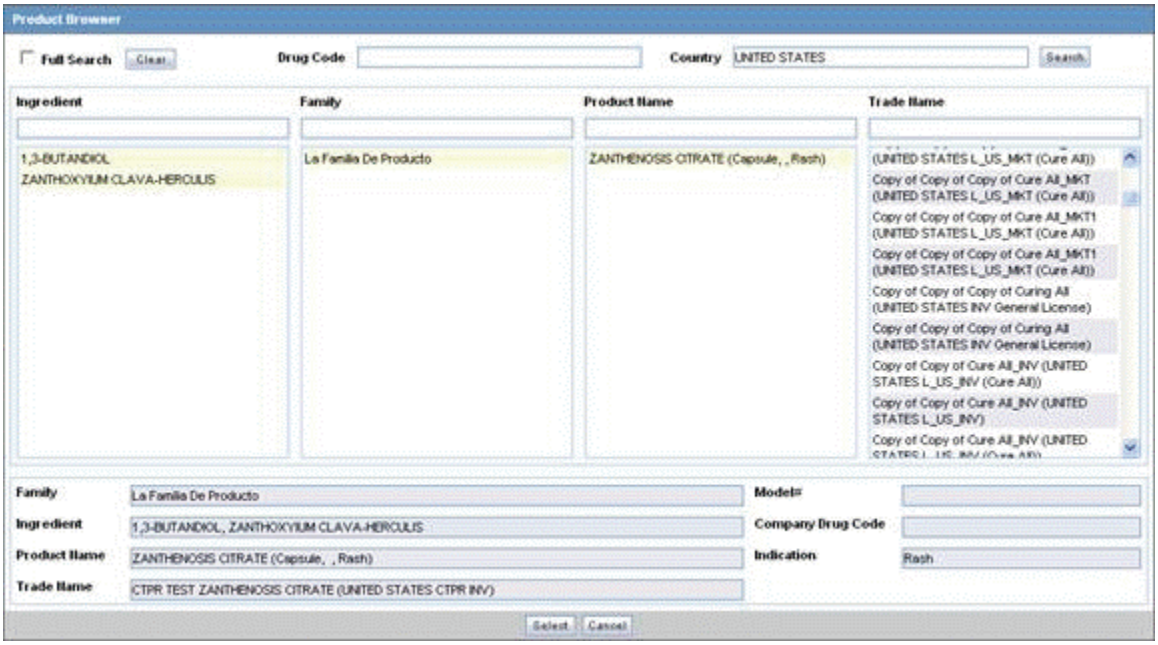
Searching for Products You can perform two types of searches in the section:

- Product Browser Search
- WHO Drug Coding Search

Product Browser Search

To search for a product

1. Click **Select** in the **Products** tab.
2. The **Product Browser** dialog is displayed.



3. Click **Select** to start searching.
4. When the system opens the **Product Browser** dialog box, Click the entities displayed in the dialog.

   The hierarchy above and below the entity being searched is also displayed. For example, if Product Name is searched, it displays the Product Name as well as the Family Name and Trade Name.
5. Search for Products based on the following criteria:
   - Ingredient
   - Family
   - Product Name
   - Trade Name - Searches the License Trade Name
6. Click the **Full Search** check box to select all these criteria when searching.
7. Click **Select**.
8. The results based on the search criteria are displayed and the user can select the Product.
9. Click **Clear** to remove the entered search criteria.

WHO Drug Browser Search

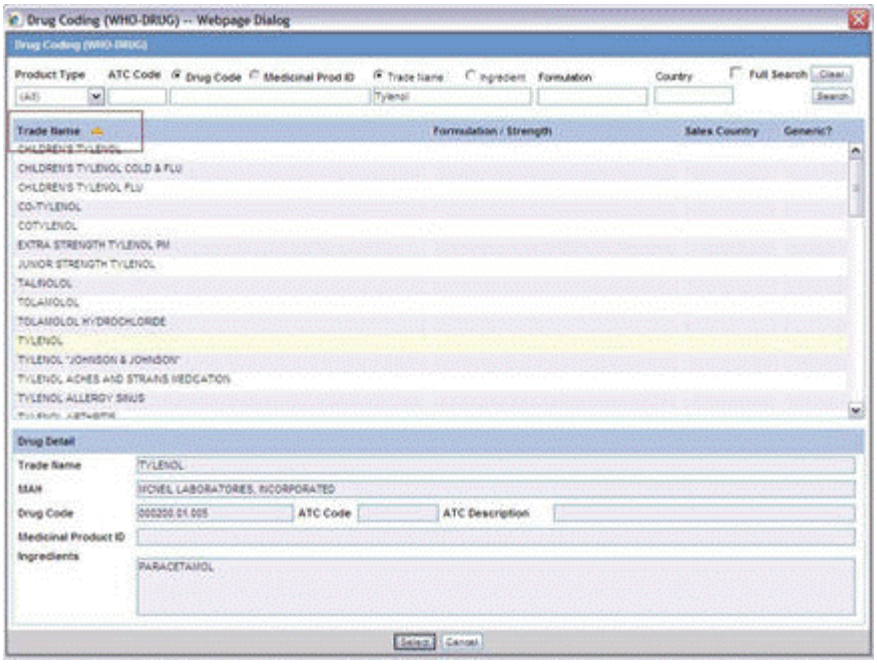
Be aware of the following when using the WHO Drug Browser search function:

- The system enables you to perform a full search from the WHO Drug browser when you select the Full Search option.
  - By default, the system performs a like search (e.g., CUREALL%)
  - You can use the percent (%) sign to perform wildcard searches
  - If you click Full Search, the system performs a full search (e.g., %CUREALL%)

- The system also enables you to search for drug formulation and country. However, this is available only if you select the WHO Drug C format. Otherwise, the option is disabled.
- When you click Clear, the system clears the search criteria you entered.
- After the system performs the search, you can sort the results on all the fields.

To perform a WHO Drug Browser Search

1. Select the **Encode** button to open the **WHO Drug Coding** dialog.



2. You can use both the WHO Drug B Format as well as the WHO Drug C Format using the same browser.

   Select either the WHO Drug B format or the WHO Drug C format from the Case Form Configuration dialog where the Dictionaries are chosen for encoding.

3. Enter your search criteria in these fields and click **Search** to display the product attributes that match the given search criteria:
   - Trade Name - the trade name of the product
   - Formulation / Strength - the Formulation / Strength (sequence 3 and sequence 4) of the product.
   - Country - The Sales Country Code of the Product as defined in the WHO Dictionary
   - Generic - Whether Generic - Yes or No.

     The following criteria are not available for display or searching in the WHO Drug B Format:

     – Formulation
     – Strength
     – Generic
     – Medicinal Product ID

  - Product Type

4. Click Select to copy the selected drug to the Product tab.
5. Click Cancel to close the selection dialog without making any updates to the Product tab.

The WHO Drug Coding Dialog has the following fields:

Field	Description
Product Type	Select the type of product from the drop-down list. Note: All is displayed as the Product Type by default.
ATC Code	Enter the ATC Code up to a maximum of 10 characters.
Drug Code / Medicinal Prod ID	Searches on either criterion as per the radio button selected for the search. By default, the **Drug Code** option is selected.
Trade Name / Ingredient	Searches on either criterion as per the radio button selected for the search. By default, the **Trade Name** option is selected.
Formulation	Enables you to search based on the drug formulation.
Country	Enables you to search for a drug based on the country where the drug was sold.

J Drug Browser

When using the J Drug browser, be aware of the following:

- Clicking Enclode enables the Drug Coding (J-Drug) dialog box.
- The system store both the WHO and the J codes.
- The system uses the WHO drug code in the English screen for global cases.
- You can search for a product by typing the product name in the Description field and/or entering the drug code in the Code field and clicking Search.
- The system searchs the J Diction and returns a list of products in Japanese character order.
- The system places a list of prodcts from J Drug in the "Proprietary J-Drug" list box. Scroll through the list and click a product to select it. Click Select to choose the product used for the case.
- When you click Select, the system closes this screen and populates the following fields in the Case Form:
  - Product Name
  - Generic Name
  - J Drug Code

Entering Quality Control Information You can enter quality control information by clicking the **QC Info** button and entering the appropriate information in the Quality Control dialog box. Click the following link to see an illustration of the Quality Control dialog box and information about the fields in it.

About the Quality Control Dialog Box

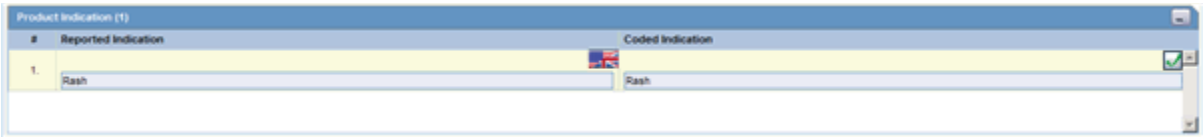
The following is an illustration of the Quality Control dialog box.

The following table lists and describes the fields in the Quality Control dialog box.

Field	Description
QC Safety Date	Enter the QC department reference number for the analysis.
QC Sent Date	Enter the sent date.
QC Cross Reference	Enter the QC department reference number for the analysis.
Date Returned	Enter the date returned.
Global ID	Enter the global number.
Quantity	Enter the quantity.
# CID Number	Enter the Control Identification Number.
PCID Number	Enter the Product Control Identification Number.
Lot Number	Enter the lot number. If the Lot Number entered is incorrect, a Lot Number Lookup dialog is displayed, that allows you to enter select from the existing lot numbers.
Complaint Categories Date	Enter a date for complaint categories.
Complaint Categories Text	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
Analysis Categories Date	Enter a date for analysis categories.
Analysis Categories Text	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
Analysis Summary Date	Enter a date for an analysis summary.
Analysis Summary Text	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
QC Result Date	Enter the date the result of the analysis was received by the QC department.

Field	Description
QC Result	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
QC Comment	Enter any comment relating to the analysis.

Product Indication Section The following is an illustration of the **Product Indication** section of the Device tab.



Product Indication Fields and Field Descriptions

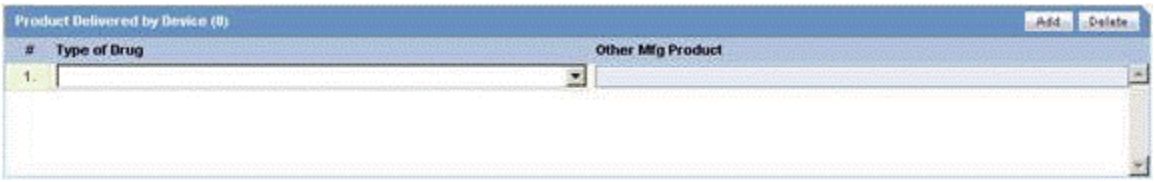
The following table lists and describes the fields in the **Product Indication** section.

Field/Control Name	Description
Reported Indication	By default, the value of this field is populated with the Product Indication from the Product Configuration, if set up by the user. If not, you can enter a term into the Reported Indication field. **Note:** Argus Safety automatically encodes this information. You can also click **Encode** to open the coding dictionary dialog.
Coded Indication	This field is populated with the encoded term when the user enters data in the reported indication field and tabs out.
Encode (Indication)	Opens the MedDRA Browser with the term already populated from the **Coded Indication** field. **Note:** To view the complete MEDDRA hierarchy for the encoded term, click the **Encoding Status** icon.
Add	Adds a new Indication row. **Note:** Only two indications are visible at a time
Delete	Click this button to delete the selected Indication row.
M/W Info	The MW Info dialog allows you to enter the following device information: ▪ Usage of Device: Make the appropriate selection to indicate whether the use of the suspect medical device was the initial use, reuse, or unknown. ▪ Is this a single-use device that was reprocessed and reused on a patient?: Indicate whether the device was labeled for single use. If the question is not relevant to the device being reported (for example, an X-ray machine), leave the select box cleared. ▪ Single Use Device: This field will be populated by information on the form. ▪ Name and Address of Reprocessor: Enter the name and address of the reprocessor.

Field/Control Name	Description
	■ Device Evaluated by Mfr: Select the **Not returned to mfr.** check box if an evaluation could not be made because the device was not returned to or made available to the manufacturer. Select **Yes** if an evaluation was made for the suspect medical device. You can attach a summary of the evaluation and select the **Yes,Summary Attached**. If an evaluation of a returned suspect or related medical device was not conducted, select the **No** check box and attach an explanation or provide an appropriate code from the coding manual (Part II, Subpart A). ■ If no, provide reason: If the Device Evaluated by Mfr is "No," then select a reason from the drop down. ■ Type of Follow-up Report: Select the appropriate check boxes that most accurately describe the nature of the follow-up (supplemental) report as follows: ■ **Correction** - Changes to previously submitted information.**Additional information** - Information concerning the event that was not provided in the initial report because it was not known/available when the report was originally submitted.**Response to FDA request** - Additional information requested by FDA concerning the device/event.**Device evaluation** - Evaluation/analysis of device. ■ Evaluation Codes: Click **Select** to enter the applicable codes from the categories listed. Follow the instructions in the dialog to enter the evaluation codes. Conclusion codes must be entered even if the device was not evaluated. ■ USC 360i(f) correction/removal reporting number: Enter the number that the FDA assigned to the corrective action. If the FDA has not yet assigned a number, the internal number assigned to the action by the company is used. ■ If remedial action indicated, check type: Select the applicable actions. If other, specify the type of action in the space provided (for further reference, see 21 U.S.C. 360h and 21 CFR part 803). ■ Additional manufacturer narrative: Select the check box (if applicable) and enter any additional information, evaluation, or clarification of data presented in previous sections. ■ Corrected Data: Select the check box if corrected data. ■ Select if the device was an Adverse Event or a Product Problem.

Field/Control Name	Description
EU / CA Device	The EU/CA Device dialog allows you to enter the device information. Fields are marked by either an EU flag or a Canadian flag to indicate which entity is mapped to the field. The following list describes each field in detail: ■ Accessories Associated Devices: Enter associated devices and/or accessories involved in the incident. ■ Software Version: Enter relevant software version. ■ Incident or Near incident: Select the appropriate incidence type. ■ Identification of notified body involved in Conformity Assessment: Enter identification number of the Notified Body involved in the conformity assessment procedure (if any) and the date(s) of the attestation(s). ■ Was the device labeled sterile?: Select the appropriate choice. ■ Reporting firm is aware of other similar incidents having an impact on the current report: Select the appropriate choice. ■ If yes, to which countries: Enter appropriate countries. ■ Device distributed within the following EEA Countries: Enter appropriate countries. ■ Current location of device: Enter the present location of the device that was involved in the incident. ■ Where was the device purchased: Enter the establishment where the device was purchased. ■ Address: Enter the address of the location where the device was purchased. ■ Expected date of follow-up report: Enter the expected date of follow-up report. ■ Importer: Enter the name, address, telephone, and fax of the importer. ■ Initial Corrective Action: Enter corrective action for the Initial report. ■ Initial Project Timing: Enter projected timing for the Initial report. ■ Final Corrective Action: Enter corrective action for the Final report. ■ Final Project Timing: Enter projected timing for the Final report. ■ Investigation Result: Enter the results of investigation from the follow-up. ■ Further Investigation: Enter the details of further investigation from the follow-up.
CID Number	Enter the Control Identification Number.
Global ID	Enter the Global Identification number. When you add a second device product to a case that already contains a device product with a Global ID number, the same number populates the new device added. Changing the Global ID number for the new product updates all products in the case to have the same Global ID number.
Device Subcomponent Name	Select the sub-component of the device.
Device Subcomponent Lot#	Enter the lot number for the sub-component of the device.

Product Delivered by Device Section The following is an illustration of the **Product Delivered by Device** section



Product Delivered by Device Fields and Field Descriptions The following table lists and describes the fields in the **Product Delivered by Device** section.

Field/Control Name	Description
Type of Drug	Select the type of drug from the drop-down list.
Other Mfg Product	Displays the Other Manufacturing Product.
Add	Adds another row.
Delete	Deletes the highlighted row.

Device Information Section This section enables you to enter information about the device being used. The following is an illustration of the section.

Device Information Fields and Field Descriptions When using the Device Information section, be aware of the following:

- You can enter up to 20,000 characters in the **Additional Manufacturer Narrative** field.
- The device evaluation codes have been updated to reflect FDA standards. Go to the following link for more information: `http://www.fda.gov/cdrh/mdr/373_appdxb.html`.
- The evaluation method is available is the following site: `http://www.fda.gov/cdrh/mdr/373.html`.
- The evaluation results are available at the following site: `http://www.fda.gov/cdrh/mdr/373_appdxd.html`.

The following table lists and describes the fields in the **Device Information Section**

Field/Control Name	Description
Lot #	Enter the lot number of the device.
Expiration Date	Enter the expiration date. Enter a partial date or no date if the full date is not available.
Date of Mfg	Enter the month and year of manufacture of the suspect medical device.

Field/Control Name	Description
Device Age (Approx.)	Enter the age of the device.
Model #	Enter the model number of the device.
Serial #	Enter the serial number of the device.
Catalog #	Under Catalog#, enter the exact catalog number as it appears in the manufacturer's catalog, device labeling, or accompanying packaging.
Other #	Under Other #, enter any other applicable identification number (for example: component number, product number, part number, bar-coded product ID).
Date Implanted	If the device is implantable, enter the date of the implant. Enter a partial date if the full date is not available.
Date Explanted	If the device is implantable, enter the date of the explant, if any. Enter a partial date if the full date is not available.
Improper Use/Storage	Indicate if the device was improperly used or stored.
Operator of Device	Select the type of person operating or using the suspect medical device on the patient at the time of the event. For instance, Health Professional applies to a physician, nurse, or respiratory therapist. Lay User applies to the person being treated, a parent, or a spouse. Other applies to a nurse's assistant, or orderly.
If other	If the operator of the device is other, enter the operator of the device.
Trained User	Indicate if the operator of the devices was trained to use the device.
Device Available for Evaluation	Indicate whether the device is available for evaluation. Also, indicate whether the device was returned to the manufacturer and if so, the date of the return.
Preliminary Comments	Enter or select preliminary comments.
Malfunction	Indicate if the devices malfunctioned.
Malfunction Type	Make the appropriate selection to indicate the type of reportable event. For an event associated with a malfunction, the FDA refers users to applicable sections in 21 CFR Part 803 reporting guidelines.
Manufacturer/Importer Awareness Date	Enter the date when the manufacturer became aware of the event
Return Date	Enter the Device Return Date.

EU/CA Device Dialog Fields and Field Descriptions

The **EU/CADevice Fields** dialog includes the following fields:

- NCA Reference Number
- Identify to what other NCA's this report was also sent
- Number of Patients Involved
- Number of Devices Involved
- User facility reference number
- Remedial Action by HC Facility
- Usage of Medical Device
- Other

- Update to Initial Report (Follow-up Report)
- Final Report

The following table provides attribute information for the device fields

Field/Control Name Name	Field Length	Field Type
NCA Reference Number	100 characters	Alphanumeric
Identify to what other NCA's this report was also sent	2000 characters	Alphanumeric
Number of Patients Involved	3 characters	Numeric
Number of Devices	3 characters	Numeric
User facility reference number	20 characters	Alphanumeric
Remedial Action by HC Facility	1000 characters	Alphanumeric
Usage of Medical Device	N/A	Check box
Other	15 characters	Alphanumeric
Update to Initial Report (Follow-up Report)	N/A	Check box
Final Report	N/A	Check box

When you select the **EU/CA Device** option, the system prints the fields on the Case form. The system tracks the fields and any updates in the audit log.

Products Tab: Vaccine Tab

The **Vaccine** section of the **Products** tab enables you to enter information about a vaccine. The Vaccine tab includes the following sections:

- Product Information
- Product Indication
- Vaccine Information

Product Information Section

The following is an illustration of the section on the **Vaccine** tab.

Fields and Field Descriptions

The following table lists and describes the fields in the **Product Information** section.

Field/Control Name	Description
Notes	Enter notes related to the product.
WHO Medicinal Product ID	Displays the Medicinal ID associated with the selected WHO drug. **Note:** This ID is populated only if a WHO-drug is selected.
Obtain Drug Country	Enter the country where the drug was purchased.
Drug Authorization Country	Displays the licensed country for the selected company product.

Field/Control Name	Description
Product Name	Enter the name of the product using the **Select** button or by entering a partial product name. Type a partial product name and press TAB. This displays the **Product Selection** dialog. If only one product is found, this information is entered without showing the dialog. If no match is found in the company product list, the WHO Drug Dictionary is searched for a possible match through the WHO Drug Dictionary Dialog. If a match is still not found, the text you initially typed in, is used as is. **Note:** If the study is blinded, the **Blinded Name** of the clinical study is displayed in this field. If a user has access, the selected **Study Product Name** for Unblinded cases is shown.
Select	Displays the product selection dialog. Select a product from the list of company products click **Select**. The relevant fields are added to the Case Form.
Drug Code	Enter the WHO-DRUG code.
Encode	Click **Encode** to retrieve the code.
Suspect/Concomitant/Treatment	Make the appropriate selection for the product you are entering. The drug types indicate the involvement of the product with the adverse event(s) reported for the case. **Suspect** indicates that the product may have caused the adverse event(s). **Concomitant** indicates drugs that are taken with the suspect drug. **Treatment** is the drug taken to treat the adverse event.
Generic Name	Enter the generic name of the drug in a manner similar to the **Product Name**. If the study is blinded, the **Generic Name** is replaced with the **Study Name** of the product. **Note:** This name is entered automatically depending on the chosen company product.
Company Drug Code	Enter the company drug code. **Note:** This name is entered automatically depending on the chosen company product.
Manufacturer	A different Manufacturer can be selected from the drop-down list and can still be kept as a company product.
Study Drug	Select the study treatment the patient received from the list. If the study is Blinded, this field is disabled. The Administrator can adjust the information in this list. Drugs listed here are dependent on the Study ID selected for the **General** tab. **Note:** This field is applicable for Unblinded or not blinded clinical trial cases only.
Formulation	Select the formulation of the product. The Administrator can adjust this list. **Note:** This field is entered automatically depending on the product.
Interaction?	Indicates whether the case involves a drug interaction
Contraindicated?	Indicates whether the drug was administered contrary to its indication. Make the appropriate selection to indicate whether the drug was contraindicated in this case.

Field/Control Name	Description
Concentration	After a drug and formulation have been entered, select the concentration from the list, or enter the concentration. If this information is changed manually, the product is marked as a non-company product. **Note:** This field is entered automatically depending on the chosen product. The concentration cannot be modified for a Study drug.
Units	Select a concentration unit. The Administrator can adjust this list.

Searching for Products You can perform two types of searches in the section:

- Product Browser Search
- WHO Drug Coding Search

To perform a search in the Product Browser dialog box 1.Click **Select** in the **Products** tab.

2. The **Product Browser** dialog is displayed.
3. Click **Select** to start searching.
4. When the system opens the **Product Browser** dialog box, Click the entities displayed in the dialog.

   The hierarchy above and below the entity being searched is also displayed. For example, if Product Name is searched, it displays the Product Name as well as the Family Name and Trade Name.
5. Search for Products based on the following criteria:
   - Ingredient
   - Family
   - Product Name
   - Trade Name - Searches the License Trade Name
6. Click the **Full Search** check box to select all these criteria when searching.
7. Click **Select**.
8. The results based on the search criteria are displayed and the user can select the Product.
9. Click **Clear** to remove the entered search criteria.

WHO Drug Browser Search Be aware of the following when using the WHO Drug Browser search function:

- The system enables you to perform a full search from the WHO Drug browser when you select the Full Search option.
  - By default, the system performs a like search (e.g., CUREALL%)
  - You can use the percent (%) sign to perform wildcard searches
  - If you click Full Search, the system performs a full search (e.g., %CUREALL%)
- The system also enables you to search for drug formulation and country. However, this is available only if you select the WHO Drug C format. Otherwise, the option is disabled.
- When you click Clear, the system clears the search criteria you entered.

- After the system performs the search, you can sort the results on all the fields.

To perform a WHO Drug Browser Search

1. Select the **Encode** button to open the **WHO Drug Coding** dialog.
2. You can use both the WHO Drug B Format as well as the WHO Drug C Format using the same browser.

   Select either the WHO Drug B format or the WHO Drug C format from the Case Form Configuration dialog where the Dictionaries are chosen for encoding.

   The WHO Drug Coding Dialog has the following fields:

Field/Control Name	Description
Product Type	Select the type of product from the drop-down list. Note: All is displayed as the Product Type by default.
ATC Code	Enter the ATC Code up to a maximum of 10 characters.
Drug Code / Medicinal Prod ID	Searches on either criterion as per the radio button selected for the search. By default, the **Drug Code** option is selected.
Trade Name / Ingredient	Searches on either criterion as per the radio button selected for the search. By default, the **Trade Name** option is selected.
Formulation	Enables you to search based on the drug formulation.
Country	Enables you to search for a drug based on the country where the drug was sold.

3. Enter your search criteria in these fields and click **Search** to didisplay the product attributes that match the given search criteria:
   - Trade Name -- the trade name of the product
   - Formulation / Strength -- the Formulation / Strength (sequence 3 and sequence 4) of the product.
   - Country -- The Sales Country Code of the Product as defined in the WHO Dictionary
   - Generic - Whether Generic - Yes or No.

     The following criteria are not available for display or searching in the WHO Drug B Format:

     – Formulation
     – Strength
     – Generic
     – Medicinal Product ID
     – Product Type
4. Click **Select** to copy the selected drug to the Product tab.
5. Click **Cancel** to close the selection dialog without making any updates to the Product tab.

Entering Quality Control Information You can enter quality control information by clicking the **QC Info** button and entering the appropriate information in the Quality Control dialog box. Click the following link to see an illustration of the Quality Control dialog box and information about the fields in it.

About the Quality Control Dialog Box

The following is an illustration of the Quality Control dialog box.

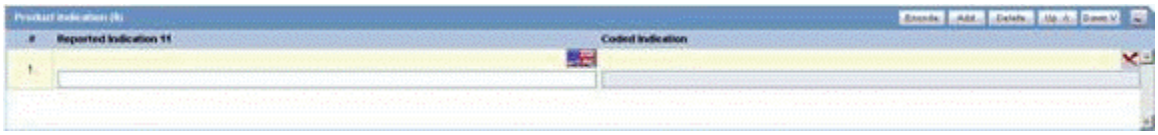
The following table lists and describes the fields in the Quality Control dialog box.

Field/Control Name	Description
QC Safety Date	Enter the QC department reference number for the analysis.
QC Sent Date	Enter the sent date.
QC Cross Reference	Enter the QC department reference number for the analysis.
Date Returned	Enter the date returned.
Global ID	Enter the global number.
Quantity	Enter the quantity.
# CID Number	Enter the Control Identification Number.
PCID Number	Enter the Product Control Identification Number.
Lot Number	Enter the lot number. If the Lot Number entered is incorrect, a Lot Number Lookup dialog is displayed, that allows you to enter select from the existing lot numbers.
Complaint Categories Date	Enter a date for complaint categories.
Complaint Categories Text	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
Analysis Categories Date	Enter a date for analysis categories.
Analysis Categories Text	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
Analysis Summary Date	Enter a date for an analysis summary.
Analysis Summary Text	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.

Field/Control Name	Description
QC Result Date	Enter the date the result of the analysis was received by the QC department.
QC Result	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.
QC Comment	Enter any comment relating to the analysis.

Product Indication Section

The following is an illustration of the fields in the **Product Indication** section of the **Vaccine** tab.



Product Indication Fields and Field Descriptions

The following table lists and describes the fields in the **Product Indication** section.

Field/Control Name	Description
Product Indication Section	
Reported Indication	By default, the value of this field is populated with the Product Indication from the Product Configuration, if set up by the user. If not, you can enter a term into the Reported Indication field. **Note:** Argus Safety automatically encodes this information. You can also click **Encode** to open the coding dictionary dialog.
Coded Indication	This field is populated with the encoded term when the user enters data in the reported indication field and tabs out.
Encode (Indication)	Opens the MedDRA Browser with the term already populated from the **Coded Indication** field. **Note:** To view the complete MEDDRA hierarchy for the encoded term, click the **Encoding Status** icon
# of Siblings	Enter the number of siblings for patients who are children under the age of five.
Birth Weight	For patients who are children under the age of five, enter the birth weight. For example: 3260g, 3.26kg, or 7lb 4oz. If a number without units is entered, the following units are assumed: < 32 - Pounds 32-200 - Ounces >200 - Grams
Birth Weight Units	Select the appropriate weight units.
Add	Adds a new Indication row. **Note:** Only two indications are visible at a time
Delete	Click this button to delete the selected Indication row.
Order	Allows the user to move an indication up and down.
Obtain Drug Country	Enter the country where the drug was purchased.
Interaction	Indicates whether the case involves a drug interaction
Contraindicated?	Indicates whether the drug was administered contrary to its indication. Make the appropriate selection to indicate whether the drug was contraindicated in this case.

Product Details Section

The following is an illustration of the **Product Details** section.

Product Details Fields and Field Descriptions

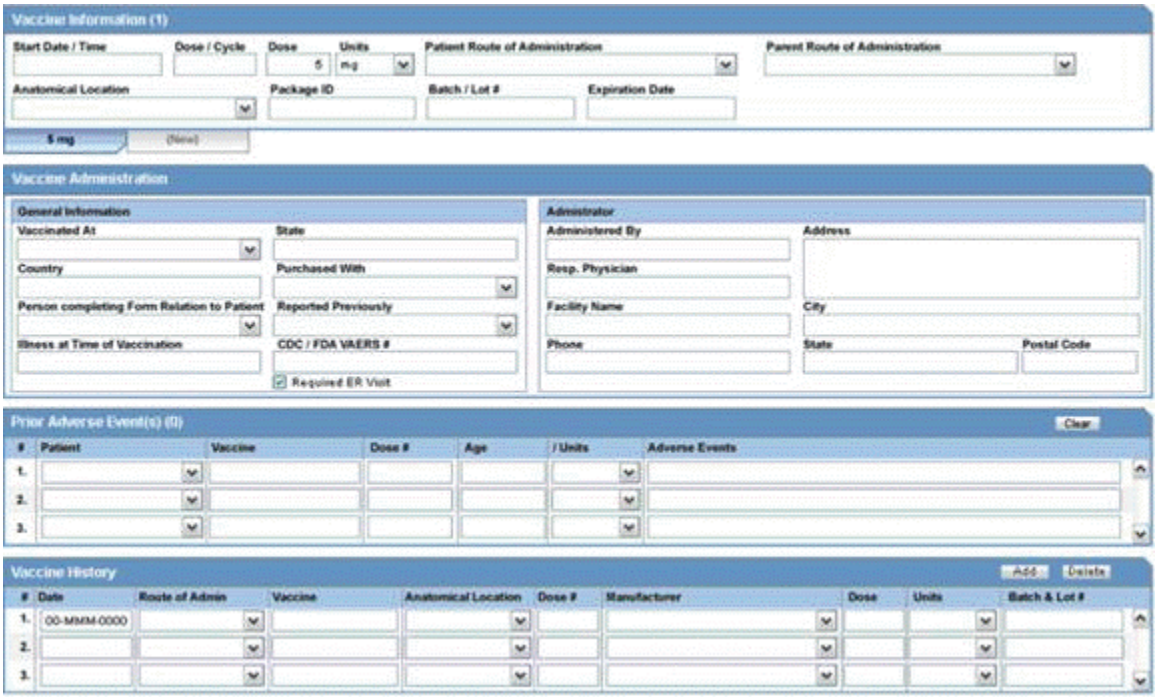
The following table lists and describes the fields in the **Product Details** section.

Field/Control Name	Description
Product Details Section	
Action Taken	Select the appropriate term. If you select Dose Increased or No change, the dechallenge and rechallenge fields are disabled. The Administrator can adjust this list.
Dechallenge Results	Indicates the drug stopped for the purpose of determining if it was the drug that caused the adverse event. Click the appropriate button
Date	Enter the date the dechallenge was carried out
Taken Previously / Tolerated	Select the appropriate response from the list.
Rechallenge Results	Make the appropriate selection depending on whether the drug was taken again. If **Pos** or **Neg** or **UNK** is selected for the Rechallenge field, the **Rechallenge Start Date/Time, Rechallenge Stop Date/Time, and the Rechallenge Outcome** fields are enabled.
Start Date/Time	Enter the date and/or time when the rechallenge was started.
Stop Date/Time	Enter the date and/or time when the rechallenge was stopped.
Abuse	Select this check box if the patient abused the product (For example: Painkillers taken without pain).
Overdose	Select this check box if the patient took an overdose of the product.
Tampering	Select this check box if the product appeared to have been tampered with before it was used.

Vaccine Information Section

The following is an illustration of the **Vaccine Information** section. It has the following sections:

- Vaccine Information
- Vaccine Administration
- Prior Adverse Events
- Vaccine History



Vaccine Information Fields and Field Descriptions

The following table lists and describes the fields in the **Vaccine Information** section.

Field/Control Name	Description
Start Date/Time	Enter the vaccination date. Enter a partial date if the full date is not available.
Dose Number	Enter the vaccine dose number.
Dose	Enter the vaccine dose.
Units	Select the dose unit. The Administrator can adjust this list.
Patient Route of Administration	Enter the route of administration or a short code for the route of administration. The system automatically decodes your entry. The Administrator can adjust this list.
Parent Route of Administration	Enter the route of administration or a short code for the route of administration. The system automatically decodes your entry. The Administrator can adjust this list.
Anatomical Location	Select the anatomical location of the vaccination. The Administrator can adjust this list.
Package ID	Enter the package ID.
Batch / Lot #	Enter the batch and/or lot number(s).
Expiration Date	Enter the expiration date. Enter a partial date or no date if the full date is not available.
Vaccine Administration	Enter the **Vaccine Information**. Items entered here are used to complete the VAERS form.
Prior Adverse Events	Enter the Prior Adverse Events.
Vaccine History	Enter the vaccine history.

Entering Vaccine Administration Information The following is an illustration of the **Vaccine Administration** form.

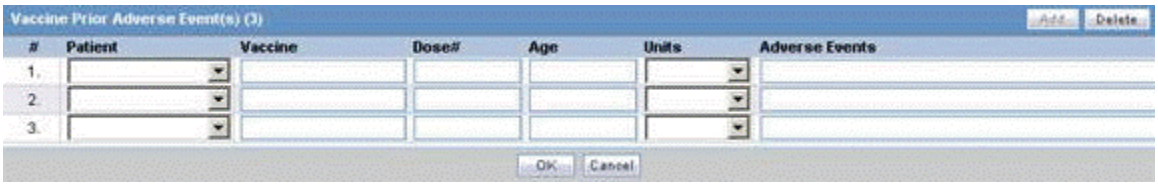
To enter vaccination information

1. Enter the relevant vaccination information items in the form.
2. Click **OK** to save the entered vaccine information.

The following table lists and describes the fields in the **Vaccine Administration** form.

Field/Control Name	Description
General Information	
Vaccinated At	Select the most appropriate item from the list to describe where the patient was vaccinated.
State	Enter the state where the patient was vaccinated.
County	Enter the county where the patient was vaccinated.
Purchased With	Select the most appropriate item from the list to describe how the vaccine was purchased.
Person Completing Form Relationship to Patient	Select an appropriate item from the list.
Reported Previously	Select an appropriate item from the list.
Illness at time of Vaccination	Enter the illness, if known.
CDC/FDA VAERS #	Enter the verification number.
Required ER Visit	Select this check box if the event required a visit to the emergency room or doctor.
Administrator	
Administered By	Enter the name of the person who administered the vaccine.
Resp. Physician	Enter the name of the physician responsible for the patient.
Facility name	Enter the name of the facility where the vaccine was administered.
Address	Enter the address of the facility where the responsible physician works.
City	Enter the city of the facility where the responsible physician works.
State	Enter the state of the facility where the responsible physician works.
Postal Code	Enter the postal code of the facility where the responsible physician works.
Phone	Enter the telephone number of the facility where the responsible physician works.

Entering Prior Adverse Events Information The following is an illustration of the **VaccinePrior Adverse Events** form.



To enter prior adverse events information

1. Enter the relevant vaccination information items in the form.
2. Click **OK** to save the entered prior vaccination adverse event information.

The following table lists and describes the fields in the **Vaccine Prior Adverse Events** form.

Field/Control Name	Description
Patient	Select whether the details refer to the patient or to a sibling.
Vaccine	Enter the name of the vaccine.
Dose #	Enter the dose number of the vaccine.
Age	Enter the patient's age at onset of the event.
Age Units	Select the appropriate age unit from the list.
Adverse Events	Enter a term that describes the adverse event.

Vaccine History Section

The following is an illustration of the **Vaccine History** section of the screen.

Vaccine History Fields and Field Descriptions

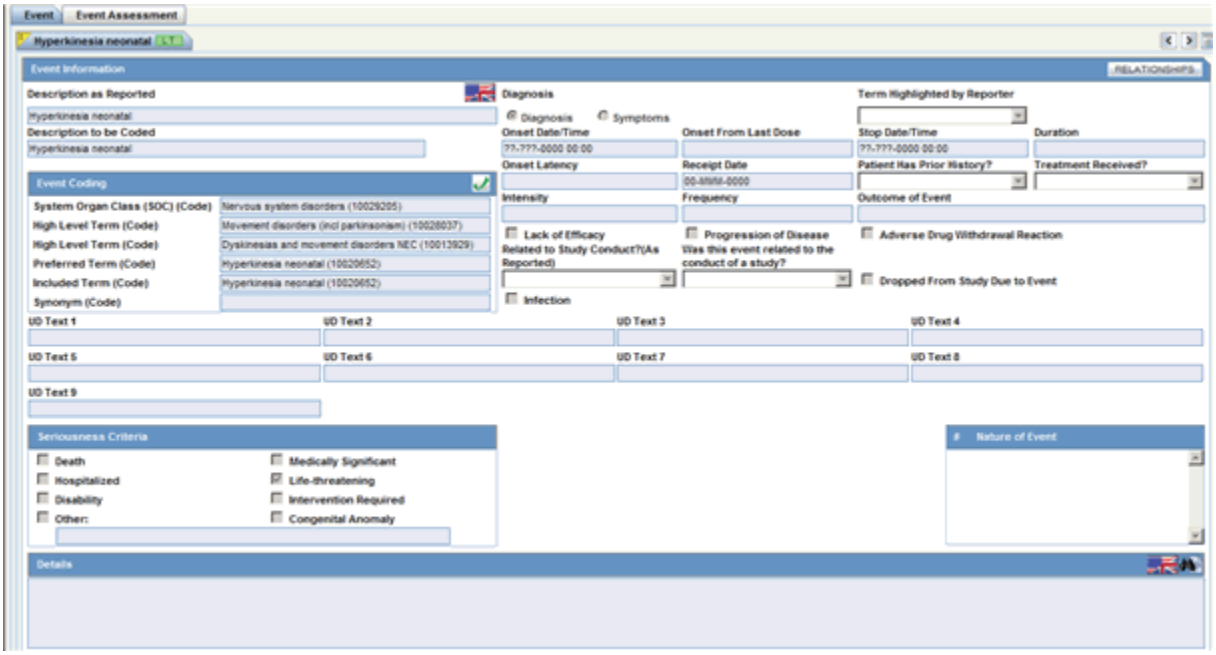
The following table lists and describes the fields in the **Vaccine History** section.

Field/Control Name	Description
Date	Enter the date of vaccination. Enter a partial date if the full date is not available.
Route of Admin	Enter the route of administration or a short code for the route of administration. The system automatically decodes your entry. The Administrator can adjust this list.
Vaccine	Enter the name of the vaccine.
Anatomical Location	Select the anatomical location of the vaccination. The Administrator can adjust this list.
Dose #	Enter the vaccine dose number.
Manufacturer	Enter the vaccine manufacturer or select a manufacturer. The Administrator can adjust this list.

Field/Control Name	Description
Dose	Enter the vaccine dose.
Units	Select the dose unit. The Administrator can adjust this list.
Batch & Lot #	Enter the batch and/or lot number(s).
Add	Adds a new Indication row. **Note:** Only two indications are visible at a time.
Delete	Click this button to delete the selected Indication row.

Events Tab

The **Events** tab enables you to enter or view details for adverse events associated with a case. The following is an illustration of the **Events** tab.



General Usage Information

When using the **Events** tab, be aware of the following:

- You **can** change the listedness for a drug at the individual level.
- This limitation also applies to the Medical Review and Local Labeling dialogs.

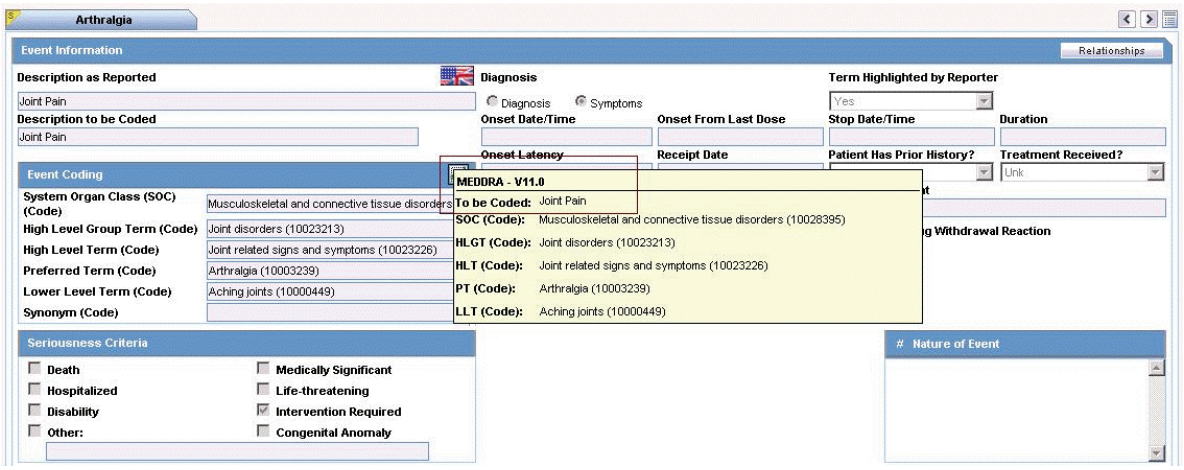
- The field labels for the **Event Assessment** tab are updated and configured on the **Argus Console**
- When you modify the Event outcome on the Events Tab, and the event outcome and case outcome don't match, the system displays the following message:

  Case Outcome may no longer match events.

- If the **Death Seriousness** criteria on the **Event** tab are unchecked, the event outcome reverts to empty and **is not** set to fatal.
- On the **Death Details** screen, the **Autopsy Results** field defaults to blank instead of No. If the value is incorrectly set, the system sets it to null during the upgrade.

- On the **Event Assessment** tab, the system displays the **Notes** icon beside the event term if the preferred term has associated notes on the datasheet.
- If the datasheet **does not** have notes for the preferred term, the system **does not** display the **Notes** icon.
- This is also true for the **Medical Summary** and the **Local Labeling** dialog
- When you click the **Notes** icon, the system displays the notes in read-only mode.
- The system populates the "To be coded" value on the MedDRA popup dialog box when you click the green checkbox for the MedDRA hierarchy. This applies to the following area where the MedDRA dialog box appears.
  - Patient Tab: Other Relevant History: Description
  - Patient Tab: Other Relevant History: Reaction
  - Patient Tab: Other Relevant History: Indication
  - Patient Tab: lab Tests
  - Product Tab: Product Indications
  - Event Tab: Event Coding
  - Analysis Tab: Company Diagnosis Syndrome
  - Console: Business Configuration: Products: Datasheets
  - Console Business Configuration: Products: Product Indications
  - Console: Codelists: Lab Tests
  - Console: Codelists: Always Serious Term List
- The Event to Exclude from Report Field enables you to identify information not to include in a PMDA expedited report.
  - The default for this check box is unchecked.
  - When this check box is checked, you are required to enter a justification for this action in the Reason to Exclude from Report dialog box.
  - After you enter the justsification, the system places a symbol to the right of the field.
  - You must have at least one event in a report. If you try to exclude all events from the report, the system presents the following message: "All the events are excluded from reports. If you want to report, at least one event is necessary. Proceed?"
  - The system does not retrieve evenst that are excluded from a report as part of CSPSR (Clinical Study Periodic Safety Report) unless it has been configured to include them in such a report.

The following is an illustration of the MedDRA dialog box.



When you click the Recalculate button, the system **does not** recalculate listedness where the Event Assessment Listedness already has a case justification (generated automatically or manually overwritten).

Field Properties for Help Text/Default Labels The following table describes the field properties for the **Help Text/Default Labels**.

Default Field Label	Default Help Text
Onset from First Dose	This date is defined as the earliest regimen start date to Onset and is completed automatically. The Date calculation is based on the Case Form Calculation for Inclusive or Exclusive
Onset from Last Dose	This date is defined as the latest regimen stop date to Onset and is completed automatically. The Date calculation is based on the Case Form Calculation for Inclusive or Exclusive.
Total Dose to Event	The system calculates this value based on daily dose and duration.
Units	The system provides this value based on the dosage units entered.
Action Taken	Select the appropriate term from the drop-down list (e.g., Dose Increased, Withdrawn, etc.). The Administrator may adjust the values in this list.
Other	The value can only be entered when the Action Taken is "Other."
Dechallenge Results	Select the appropriate option.
Rechallenge Results	Select the appropriate option.
Event occurred as consequence of	Select the appropriate option.
Term	Select the appropriate option.
Most Important Diagnosis?	Select the appropriate option.
Event more specific/severe than PT?	Select the appropriate option.

Field Calculations

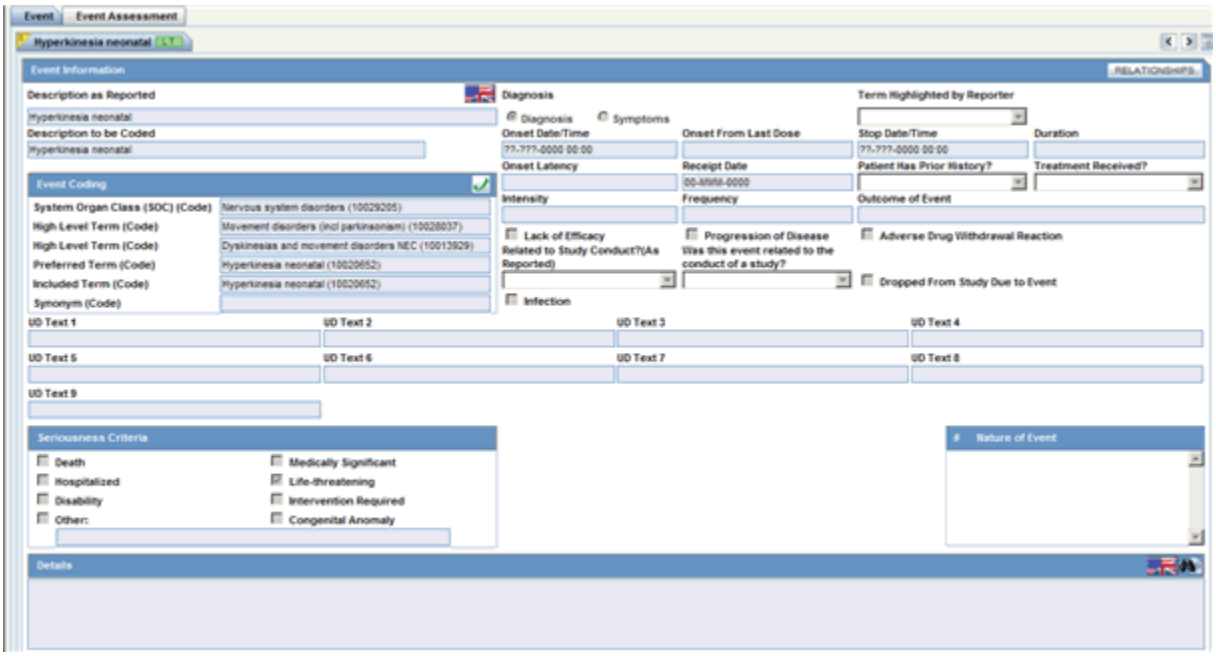
The following table describes the calculations the system uses for each field.

Field	Calculation
Total Dosage	The sum of all Total Regimen Dosages.
First Dose to Onset	The system calculates this value based on the first dose stop date and the event onset date, if present. If any regimen start date is null, the system sets the First Dose to Onset is to null. The system **does not** automatically use partial date entries for the Regimen Start and Stop Date/Time fields to calculate First Dose to Onset. The user can overwrite this field.
Last Dose to Onset	The system calculates this value based on the last dose stop date and the even onset date, if present. If the regimen start date is null, the system sets the Last Dose to Onset is to null. The system **does not** automatically use partial date entries for regimen Start and Stop Date/Time fields to calculate the Last Dose to Onset. The user can overwrite this field.

Events Tab: Event Tab

The **Event** information tab enables you to encode adverse events, record the criteria for the seriousness of each event, and display the results of automated assessments to determine whether events are listed in data sheets. It also lists the licenses for the data sheets. The **Event** information tab includes the following sections:

- Event Information
- Event Coding
- Seriousness Criteria
- Nature of Event
- Details



Event Information Section The **Event Information** section enables you to enter information about the event information including diagnosis, patient history, intensity, and so forth.

Event Information Fields and Field Descriptions

The following table lists and describes the fields in the **Event Information** section.

Field/Control Name	Description
Description as Reported	Enter the verbatim term used by the reporter, or patient, to describe the adverse event. As you type, the term is automatically copied under **Description to be Coded**. Verbatim English translations of foreign languages may also be entered here.
Relationships	Click the **Relationships**button to view the Diagnosis-Event Relationships dialog. This allows you to group symptoms and signs with diagnoses. This requires at least two events and a diagnosis.
Encode	Click this button to search for the term entered under **Event Description**. The entered term is checked in the MedDRA dictionary.
Term Highlighted by Reporter	Make the appropriate selection to indicate whether the person reporting the event considered it to be serious. **Note:** Selecting **Yes** does not mark this case as **Serious** automatically.
Diagnosis	Make the appropriate selection to indicate whether the event is a diagnosis.
Description to be Coded	If necessary, the verbatim term can be modified in this field. For example, the original term may need to be split, or enhanced with an anatomical location. The Administrator can prevent manual encoding of the description. If automatic encoding is enabled, the term can be auto-encoded to the included term level.
Patient Has Prior History?	Make the appropriate selection to indicate whether the patient has had a prior history or has suffered from the same event in the past.
Onset Date/Time	Enter the date/time when the event started. Enter a partial date if the full date is not available.
Onset from Last Dose	This field is calculated automatically from the event onset date and most recent stop date listed in the dosage regimen details of the suspect drug(s). You can also enter or modify the field manually. This field is removed if the dosage regimen is ongoing.
Stop Date/Time	Enter the date/time when the event stopped.
Duration	This field is calculated automatically from the event start and stop dates. You can also enter or modify the duration manually.
Onset Latency	This field is calculated automatically from the earliest first dose date of the suspect drug(s) to onset date. You can also enter or modify the duration manually.**Note:** Onset Latency = Onset Date - First Dose.
Intensity	Select the category of severity of the event. The Administrator can adjust this list.
Frequency	Select the frequency of the event from the list. The Administrator can adjust this list.
Was this event related to the conduct of a study?	For clinical trial cases only. Make the appropriate selection to indicate whether the event was associated with the conduct of a study. Consult your Administrator for further company-specific information on completing this field.
Associated with Rechallenge?	Only available if a suspect drug was rechallenged. Make the appropriate selection.

Field/Control Name	Description
Product	Only available if event is associated with rechallenge. A list of all suspect products that were rechallenged is displayed. Select the product associated with this event from the list. You can identify multiple products to be associated with a single event.
Dropped from Study due to Event	For clinical trial cases only. Select this check box if the subject was dropped from the study due to this adverse event.
Treatment Received?	Make the appropriate selection to indicate whether the event required treatment.
Outcome of Event	Select the outcome of the event. The Administrator can adjust this list. If **Fatal** is selected, **Death** is selected in the list of seriousness criteria. **Note:** If the **Death** check box is subsequently cleared, the outcome still remains fatal.
Receipt Date	Enter the date on which information about this event was received by your company.
Lack of Efficacy	Select this check box, if appropriate.
Progression of Disease	Select this check box, if appropriate.
Adverse Drug Withdrawal Reaction	Select this check box, if appropriate.
Infection	Select this check box, if an infection has occurred.

Understanding the Diagnosis-Event Relationship Argus Safety allows you to group events in a case, and/or to associate them with particular diagnoses. These determinations can be made by your company or simply as reported to your company. This feature aids significantly in the interpretation and review of individual case reports. It is also useful in summary reports as it enables the reporting of diagnoses only, while retaining database records of individual event terms.

Click the **Relationships** button in the **Event Information** section of the Eventstab to open the Diagnosis-Event relationship dialog.

> **Note:** To use this feature, the case must contain at least two events and, at a minimum, one diagnosis. The events related to a diagnosis are listed on top in this dialog and the symptoms are indented with respect to the diagnoses. You can group events together and associate them with individual diagnoses.

Associating a symptom with a diagnosis Click the up or down arrows to associate a selected symptom with a diagnosis. In Argus Safety Web, select the symptom and click Move Up or Move Down.

Example:

Such Adverse Events (AE) might be entered into the database as follows:

This example demonstrates how defining a diagnosis-event relationship can clarify an adverse event report. Suppose an initial case report describes a patient suffering from "Somnolence," "Sore Throat," and "Fever."

AE # Diagnosis AE Term (Associated AEs)

1 Somnolence

2 Sore Throat

3 Fever

For reports on all events, they would appear on a CIOMS-I form as:

- Somnolence [SEDATION]
- Sore Throat [SORE THROAT NOS]
- Fever [PYREXIA]

Suppose a follow-up report then supplies information that the patient also had neutropenia, and had been diagnosed as suffering from agranulocytosis (the cause of the sore throat and fever). The somnolence was considered to be co-incidental, and unrelated to any other adverse events.

Neutropenia and agranulocytosis would be entered onto the system, and a diagnosis-event relationship established as follows:

AE #	Diagnosis AE Term (Associated AEs)
1	Yes agranulocytosis
2	(sore throat)
3	(fever)
4	(neutropenia)
5	Somnolence

These events would appear on a CIOMS I form as:

- AGRANULOCYTOSIS
- [AGRANULOCYTOSIS] ([SORE THROAT],
- [PYREXIA NOS], [NEUTROPENIA])
- Somnolence [SEDATION]
- This immediately gives a clear clinical picture of the case.

Using the MedDRA Browser The MedDRA application searches the term dictionary for a match at the Lower level term or at the Synonym level. If a match is found, the following fields are automatically populated: **Term code, Preferred Term, Included Term, High Level Term, Group Term** and **Body System/SOC**.

Click the icon to view the **MedDRA Browser**.

Configuring Regulatory Reporting Rules The regulatory reporting rules can be configured to look at any type of criteria but are mainly configured to look at Seriousness, Listedness, Causality, and Outcome. Out of these, Listedness and Causality can be captured and controlled (using the event assessment section) down to an individual license basis.

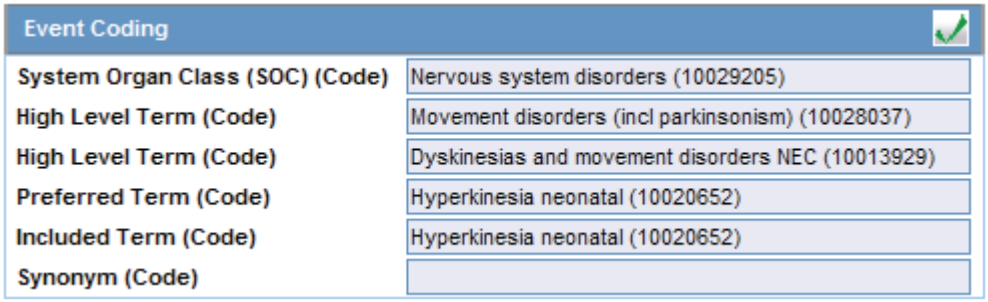
This granularity allows individual license holders to override the normal listedness and causality assessment to control the need for submissions to their local regulatory authority. Each affiliate could either suppress the need for a report by demoting the criteria, or add the requirement for a report by promoting the listedness or causality.

This serves to promote the global reporting automation while maintaining the level of individual local affiliate control that is often needed.

Note: To obtain an assessment of the adverse event, the product must be in the company's suspect product and the event must be encoded.

Event Coding Section

The **Event Coding** section enables you to enter information about the event. The following is an illustration of the **Event Coding** section.



The following table lists and describes the fields in the **Event Coding** section.

Field/Control Name	Description
Body System/SOC	Displays the body system or System Organ Class. This item is automatically entered from the event dictionary that is used and it cannot be edited.
Lower Level Term	Displays the ART code. If you have appropriate access rights, click **Encode** to view the associated coding dialog.
Preferred Term	Displays the preferred term. This item is automatically entered from the event dictionary that is used and it cannot be edited.
Preferred Term Code	Displays the preferred term code. This item is automatically entered from the event dictionary that is used and it cannot be edited.
High Level Term	Displays the High Level Term when the MedDRA coding dictionary is used. This item is not displayed when event encoding is done using the WHO-ART dictionary. This field cannot be edited.
High Level Group Term	Displays the high-level group term when using the MedDRA coding dictionary. This field is not shown when coding with WHO-ART. This field cannot be edited.

When the following fields are encoded, the system enables you to copy either the PT or the LLT based on the "Description as Reported" common profile swith. When the application cannot find match Japanese data, it automatically copies the English term in the Japanese "Description as Reported" field. The following rule applies to all Argus J applications:

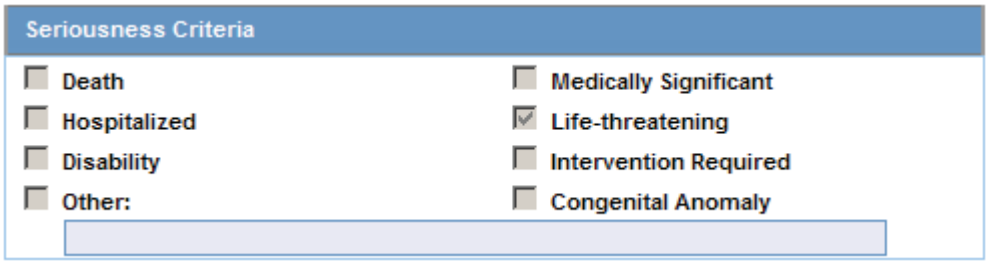
When Japanese to English code is executed and the system cannot find matching data, you must enter a manual Engish translation in the English split window in the "Description as Reported" field as follows:

- Patient Tab: Patient Lab Data
- Patient Tab: Other Relevant History Indication
- Patient Tab: Other Relevant History Reaction

- Parent Tab: Other Relevant History Indication
- Parent Tab: Other Relevant History Reaction
- Product Tab: Product Indication
- Event Tab: Event Verbatim
- Event Tab: Cause of Death
- Event Tab: Autopsy Results
- Analysis Tab: Company Diagnosis/Syndrome

Seriousness Criteria Section

The **Seriousness Criteria** section enables you to identify how serious the event was. For example, did the result in death or was it life threatening. The following is an illustration of the **Seriousness Criteria** section.



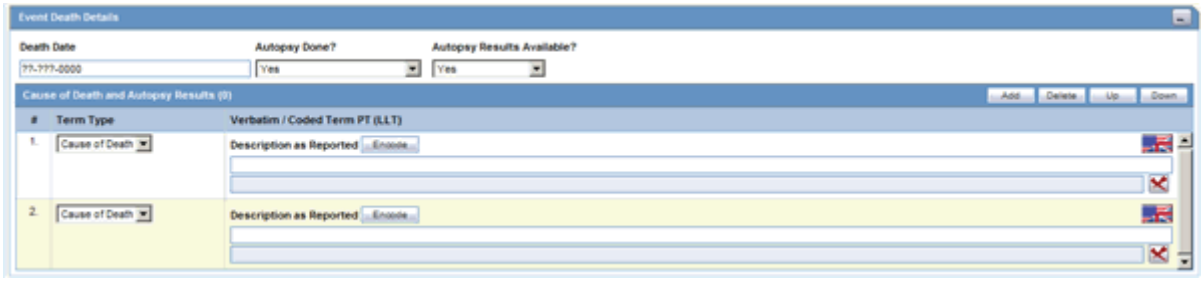
Seriousness Criteria Fields and Field Descriptions

The following table lists and describes the options in the **Seriousness Criteria** section.

Field/Control Name	Description
Death	Displays the **Death Details** dialog **Note:** If you un-check the **Death** option in the **Seriousness Criteria**, you are required to confirm the deletion of the death details.
Hospitalized	Displays the **Event Hospitalization** dialog.
Medically Significant	Select this check box to display the seriousness as medically significant.
Life-threatening	Select this check box to display the seriousness as life-threatening.
Disability	Select this check box to display the seriousness as a disability.
Intervention Required	Select this check box to display the seriousness as requiring intervention.
Congenital Anomaly	Select this check box to display the seriousness as a congenital anomaly.
Other	Select this check box to enter explanatory text. It is mandatory to enter text, specifying the **Other** Seriousness Criteria.

Entering Death Details Use the following procedure to enter details about a death.

1. Select the **Death** check box under **Seriousness Criteria**.
2. The form for **EventDeath Details** appears



3. Enter information for the items in the form.
4. Click **OK** to save the entered Death Details.

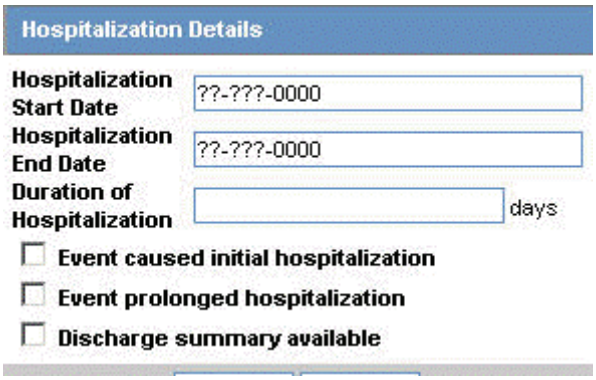
The following table lists and describes the fields in the **Event Death Details** section.

Field/Control Name	Description
Date	Enter the date of death. You can enter a partial date if the exact date is unavailable.
Autopsy Done?	Make the appropriate selection.
Cause of Death	Enter a term to describe the cause of death. Click **Encode** to display the associated encoding dialog.
Autopsy Results Available?	Make the appropriate selection.
Autopsy Results	Enter Information about the autopsy results.

Entering Hospitalization Details Use the following procedure to fill out the **Hospitalization Details** form.

To complete the Hospitalization Details form

1. Select the Hospitalized check box under Seriousness Criteria.
2. The form for **Hospitalization Details** appears.

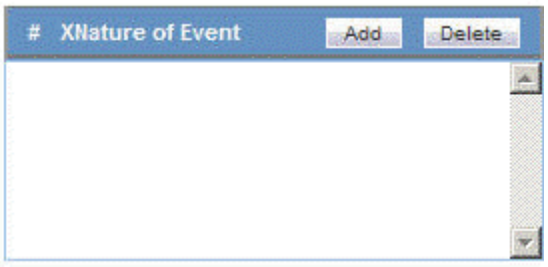


3. Enter information for the items in the form.
4. Click **OK** to save the entered Hospitalization Details.

The following tables lists and describes the fields in the **Hospitalization Details** form.

Field/Control Name	Description
Hospitalization Start Date	Enter the first date of the patient's hospitalization associated with this adverse event. If the exact date is not available, you can enter a partial date in this field.
Hospitalization End Date	Enter the last date of the patient's hospitalization associated with this adverse event. If the exact date is not available, you can enter a partial date in this field.
Duration of Hospitalization	This field is automatically calculated by the system, based on the start and end dates entered. This field is calculated using 24-hour increments. You can also manually enter the number of days the patient was hospitalized.
Event caused initial hospitalization	Select this check box if the event is associated with the initial hospitalization of the patient.
Event caused prolonged hospitalization	Select this check box if the event prolonged hospitalization.
Discharge summary available	Select this check box if a discharge summary is available.

Nature of Event Section The **Nature of Event** section enables you to identify the nature of the event from the drop-down list. You can add a maximum of 50 such Nature of Event rows.



Details Section This section enables you to enter notes related to the event. If **Reported Causality** is entered when the case is booked-in, the system automatically transfers it to this field. The following is an illustration of the **Details** section.

Events Tab: Event Assessment Tab

The **Event Assessment** tab enables you to capture causality and listedness information for a case. All encoded events in the case are compared with the listed events for company products (agents) associated with the case. The following is an illustration of the **Event Assessment** tab.

Event Assessment Tab Fields and Field Descriptions

The following table lists and describes the fields on the Event Assessment tab.

Field/Control Name	Description
Recalculate	Refreshes the Event Assessment section with the newly entered data if new suspect products or events are entered, or the Event Relationship is modified.
Product	This field is populated when events are entered in the Products tab and is displayed in the following format: ■ First Line - Product Name ■ Second Line - Generic Name
Causality Source	This field defines the source of causality calculation.
Causality as Partner	This field stores the Partner Level Causality defined within the cases.
Causality as Reported	Indicates the degree of reported causality.
Causality as Determined	This field is populated automatically, along with the information entered in the Reported Causality field.
Event	This field is populated when events are encoded and are displayed in the following format: ■ First Line - Event PT (Verbatim) ■ Second Line - LLT
D/S	Displays the Diagnosis/Symptom details by D or S in line with the Events.
Seriousness Severity Duration	Displays the Seriousness, Severity and the Duration of the Event.
Datasheet	Displays the datasheet(s) for the agent.
License	Displays the license(s) for the agent.
Listedness	Indicates whether the system found the event on the datasheet for this product.

Filtering in the Event Assessment Tab The following table lists and describes how the system filters each field on the **Event Assessment** tab.

Field/Control Name	Description
Product	The product filter drop down list contains all products listed in the event assessment. The user can filter on all the products which are present in the Event Assessment dialog.
Event	Contains a drop down of values of distinct Event PT. The user can filter on all the products which are present in the Event Assessment dialog.
D/S	Contains a drop down values of D for Diagnosis or S for Symptoms.
Datasheet	Contains a drop down of values of distinct Datasheets.
Licenses	Contains a drop down of values of distinct Countries of the Licenses.

Note: Only the assessment rows that match the selected criteria display in the filtering results.

User Actions on the Event Assessment Tab The following table list user actions and the results of those actions.

User Action	Result
Click **Datasheet** column's icon	The system does the following: ■ Displays the license view ■ Displays the datasheet view ■ Displays the License column ■ Enables the icon for the License column
Click Product Name link	Displays the for the selected product
Click Event Description link	Displays the Event Information for the selected event
Click License Description link	Displays the as defined in the License Configuration
Click Datasheet Description link	Displays all the configured terms in the datasheet

The Event to Exclude from Report Field enables you to identify information not to include in a PMDA expedited report.

- The default for this check box is unchecked.
- When this check box is checked, you are required to enter a justification for this action in the Reason to Exclude from Report dialog box.
- After you enter the justification, the system places a symbol to the right of the field.
- You must have at least one event in a report. If you try to exclude all events from the report, the system presents the following message: "All the events are excluded from reports. If you want to report, at least one event is necessary. Proceed?"
- The system does not retrieve events that are excluded from a report as part of CSPSR (Clinical Study Periodic Safety Report) unless it has been configured to include them in such a report.

Events Tab: Product -- Event Details Tab

The **Product -- Event Details** tab enables you to enter information for an adverse event related to a specific product. The following is an illustration of the **Product -- Event Details** tab.

Product -- Event Details Tab Fields and Field Descriptions

You can enter data in the following fields at a **Product Event** combination level:

- Most important diagnosis?
- Event more specific/severe than PT?
- Action taken
- Other text
- Onset from First Dose
- Onset from Last Dose

- Total Dose to Event
- Units
- De-challenge Results
- Re-challenge Results
- Event Occurred as a Consequence of
- Term

Be aware of the following:

- By default, all the new fields are hidden in the **Event Assessment**. If **all** the fields are hidden, the system also hides the **Product-Event** details tab.
- You can enter data in the **Event Occurred as Consequence of** field from the type ahead.
  - When you select the **Event Occurred as Consequence of** field, the list of corresponding values configured in the Argus Console is available for the user to select from the **Term** list.
  - You can add or delete elements in the **Event Occurred as Consequence of** fields.
  - You can enter a maximum of 20 entities in the **Event Occurred as Consequence of** field. After the user enters 20 entities, the system disables the **Add** button.
- **Filtering for Product.** The product **Filter** drop-down list contains all products listed in the event assessment.
  - You can filter on products on the **Event Assessment** dialog.
  - By default, the system displays all the products with the **<ALL>** option.
  - When filtering, the system displays only the assessment rows that match the product you selected.
- **Filtering for Event.** The **Event Filter** contains a drop-down list of values of distinct events.
  - You can filter on events in the **Event Assessment** dialog.
  - By default, the system displays all events with the **<ALL>** option.
  - When filtering, the system displays only the assessment rows that match the events you selected.
- The **Product Event** details are tied to the **Event Assessment** section. You can access these details only if your user group permissions give them access.
- The system tracks case updates in the **audit log.**
- The system prints the additional fields on the Case Form print out. The additional fields are linked to the **Event Assessment** section of the case form printout.

The following table lists and describes the fields on the **Product -- Event Details** tab.

Field/Control Name	Description
Product	Enables you to select a product whose event details you want to review.

Field/Control Name	Description
As Reported Causality/As Determined Event PT (Description)/LLT	Enables you to view details about a specific adverse event if more than one is associated with this product.
Most Important Diagnosis?	Enables you specify whether this is the most important diagnosis.
Event More specific/severe that PT?	Enables you to indicate whether treatment more serious than PT was required for this adverse event.
Onset from First Dose	The amount of time from the first dose was taken until the time the adverse event occurred.
Onset from Last Dose	The amount of time from the last dose was taken until the time the adverse event occurred.
Total Dose to Event	The total number of doses until the event occurred.
Units	The amount of each dose given to the patient.
Action Taken	Enables you to enter the action take when the adverse event occurred.
Other	Other information related to the adverse event.
Dechallenge Results	~
Rechallenge Results	~
Event Occurred as a Consequence of	The cause of the adverse event.
Term	~
Add	Click **Add** to add another row.
Delete	Click **Delete** to delete a specific row.

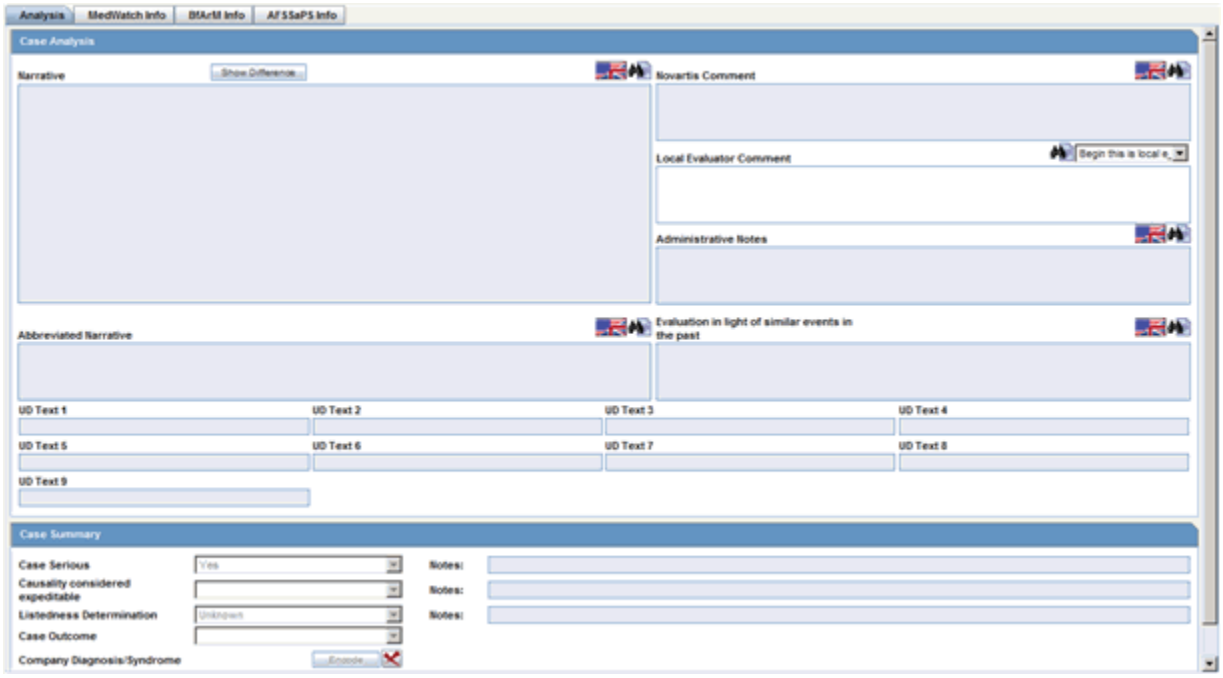
Analysis Tab

The Analysis tab enables you to generate or view a narrative description of the case, together with other notes. In addition, it also enables you to enter information required for generating the **MedWatch 3500A**, **BfArM**, and **AFSSaPS** reports.

The typical users of this tab are responsible for:

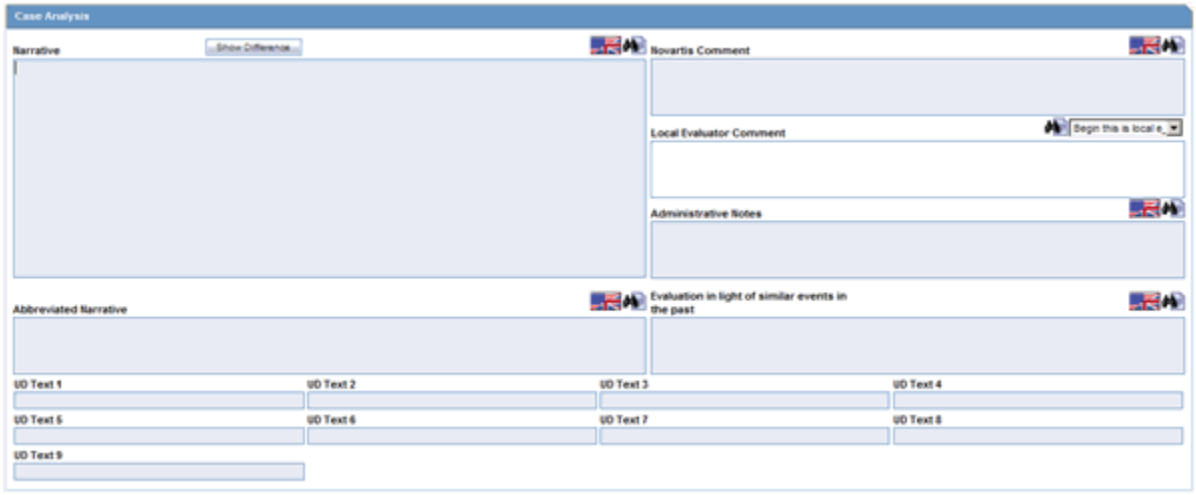
- Making a medical assessment of the case
- Approving the case for completeness and accuracy.

The following is an illustration of the **Analysis** tab.



Case Analysis Section

The **Case Analysis** section of the **Case Analysis** tab enables you to enter narrative information about the adverse event. The following is an illustration of the **Case Analysis** section.



Case Analysis Fields and Field Descriptions

The following table lists and describes the fields in the **Case Analysis** section of the **Case Analysis** tab.

Field/Control Name	Description
Narrative	Click **Generate** to generate an auto narrative. This feature is configured by the Administrator. If you are not utilizing the auto narrative feature, enter the narrative here. The narrative is printed on expedited reports.
Case Comment	You can enter comments in this area. If you are not permitted to edit the auto narrative, you can use this field to provide additional details important to the interpretation of the case. Comments appear on certain expedited reports.
Abbreviated Narrative	Enter brief comments in this field. This item maps only to the PSUR report.
Company Comment	Enter comments in this area. This information does not appear on expedited reports.
Evaluation Comment	Enter an evaluation comment that takes in to consideration similar events that have occurred in the past.

Using Auto Narrative Templates

You can select an Auto Narrative template for the Narrative, Case Comment, Abbreviated Narrative, Company Comment, and Evaluation in light of similar events in the past.

To generate or add narrative templates

1. Click the button to view the **Custom Auto Narrative Templates** dialog.
2. Select the required **Autonarrative** from the list.
3. Click **Append** to append this Autonarrative to the existing narrative.
4. Click **Append** if this is the first narrative being added to the text area.
5. Click **Replace** to replace the existing narrative with the selected narrative.

> **Note:** You **cannot** modify the Autonarrative text if the Administrator has configured the system to prevent modification of the Autonarrative.
>
> If an Autonarrative template has been configured in multiple languages, icons representing the languages display above the text area.

Viewing Differences in Case Narratives The system enables you to view the differences in case comments from previously locked versions of the case. To view these differences, click the **Show Difference** button in the **Case Comments** section of the Analysis Tab.

When you choose to view the differences in the two narratives, the system does the following:

- Displays the differences in red with a strike out and a yellow highlight.
- Displays additions to the narrative in black with green highlights.
- The Narrative is read-only and you **cannot** modify it.
- Use the zoom dialog to adjust the font size.

- The system displays the last revision number of the case and date and time stamp in the following format:
- (Last revision # X as of YYYY MMMM)

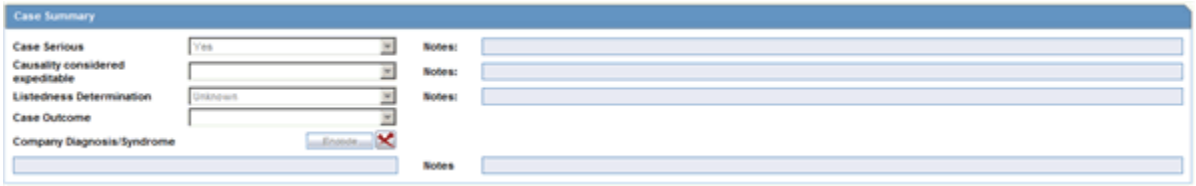
  where:

X	Is the revision number of the last case
YYYY	Is the date the case was locked
MMMM	Is the time the case was locked in 24-hour format.

- The system disables the button if there is no previously locked version of the case.
- This function is also available on the **Medical Review** dialog.

Case Summary Section

The **Case Summary** section of the **Case Analysis** tab enables you to enter summary information about the adverse event. The following is an illustration of the **Case Summary** section.



Case Summary Section Fields and Field Descriptions

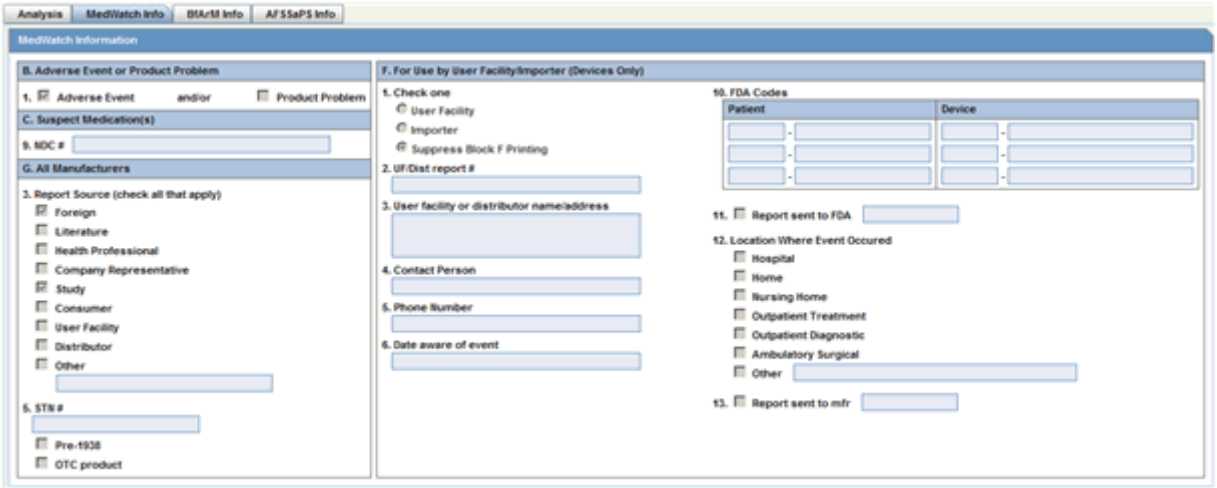
The following table lists and describes the fields in the **Case Summary** section of the **Case Analysis** tab.

Field/Control Name	Description
Case Serious	This list indicates whether the overall adverse event case is serious or non-serious. This assessment is automatically performed by the system from the **Seriousness Criteria** of the **Events** tab. If any of the Seriousness Criteria was selected for any event in the Event tab, **Yes** is selected automatically in the list. **No** is selected if the Seriousness Criteria is cleared for all events in the Events tab. You can modify the selection after entering a justification, if you have the access rights to do so.
Serious Notes	A justification for overriding the system determination will be displayed in the Notes area. A green dot will appear adjacent to the Notes area. Click the green dot to revert to the automatic calculation for seriousness or to view the overriding notes.
Case Causal	The system automatically determines this value from the As Reported and As Determined causalities in the **Event Assessment** section. This field is displayed as **Yes** if the As Determined causality is **Yes** and vice versa. If the **As Determined** causality is **Unknown**, this field will be **Yes**.
Case Causal Notes	A justification for overriding the system determination is displayed in the **Notes** area. A green dot is displayed next to the **Notes** area. Click the green dot to revert to the automatic calculation for seriousness or to view the overriding notes.

Field/Control Name	Description
Listedness Determination	The value for this field is calculated from the **Event Assessment** section in the **Events** tab. If any row there shows **Unlisted** under the **Listed** column, this value is set to unlisted.
Listedness Determination Notes	A justification for overriding the system determination is displayed in the **Notes** area. A green dot appears adjacent to the **Notes** area. Click the green dot to revert to the automatic calculation for seriousness or to view the overriding notes.
Case Outcome	The value for this field is also calculated from the **Events** tab. If the outcome for any event is **Fatal**, the case outcome is set to **Fatal**. If the case outcome is changed here, that change is not made to the event outcome in the **Events** tab.
Company Diagnosis/Syndrome	The company diagnosis or syndrome is entered in this field.
Notes	A justification for overriding the system determination is displayed in the **Notes** area. A green dot is displayed adjacent to the **Notes** area. Click the green dot to revert to the automatic calculation for seriousness or to view the overriding notes.

Analysis Tab: MedWatch Info Tab

The **MedWatch Info** tab enables you to enter additional details required for the MedWatch 3500A Drug Report. The following is an illustration of the MedWatch Info tab.



MedWatch Info Tab Fields and Field Descriptions

The following table lists and describes the fields on the **MedWatch Info** tab. Be aware that the values in the Form section column refer to specific sections of the MedWatch 3500A Drug Report form.

Form Section	Field Description
B1. Adverse Event / Product Problem	Select the applicable check boxes. Select **Adverse Event** when a product is suspected to have caused an adverse outcome in a patient. Select **Product Problem** when the defect or malfunction in the product could lead to a death or serious injury. Select both check boxes if a malfunction or product problem caused a death or serious injury.

Form Section	Field Description
C9. Suspect Medications (NDC#)	Enter the National Drug Code if you have selected the Product Problem check box.
F1. User Facility or Distributor	Indicate whether this report is from a user facility or a distributor. You can suppress printing of Block F of the MedWatch 3500A report by selecting **Suppress Block F Printing**.
F2. UF/Dist report number	Enter the complete number of the report exactly as entered in the upper right corner of the front screen.
F3. User facility or distributor name/address	Enter the full name and address of the user facility or distributor reporting site.
F4. Contact person	Enter the full name of the medical device reporting (MDR) contact person. This is the person who is designated as the device user facility/distributor contact for this requirement. The FDA will conduct its MDR correspondence with this individual. The contact person may or may not be an employee of the facility. However, the facility and its responsible officials will remain the parties ultimately responsible for compliance with MDR reporting requirements.
F5. Phone number	Enter the phone number of the medical device reporting (MDR) contact person.
F6. Date aware of event	Enter the date that the user facility's medical personnel or the distributor became aware that the device may have caused or contributed to the reported event.
F10. FDA codes Patient FDA Device Codes	Click the first row and column of the FDA Patient and Device Codes section and then click **Select**. You can enter up to six FDA Patient Codes. If the entered code is not present in the FDA Codes list, it is erased.
F11. Report sent to FDA	Select this check box if a report has been sent to the FDA. If you select it, enter the date when the report was sent to FDA.
F12. Location where event occurred	Select the location of the actual occurrence of the event.
F13. Report sent to mfr?	Select this check box if a report has been sent to the manufacturer. If you select it, enter the date when the report is sent to manufacturer.
G3. Report Source	Select the Report Source check boxes as applicable, to match all report sources specified with the Reporter Type. See the following guidelines for selecting the check boxes.
G5. PLA# Pre-1938 / OTC Product	Enter the PLA number. If the product pre-dates 1938, select **Pre-1938**. If the product is an over-the-counter product, select **OTC product**.

Guidelines to Selecting G3 Report Source Check Boxes The following table provides information about the conditions that govern when a specific check box should be selected.

If this condition is true	Select the following check box
Country of Incidence is not USA	Foreign
Report Case type is configured to contain cases from **Literature**	Literature

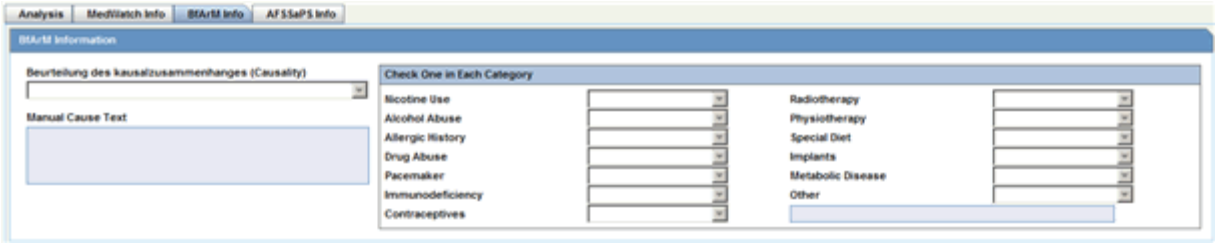
If this condition is true	Select the following check box
Report Case Type is configured to contain cases from **Clinical Trials**	Study
Any Reporter Type is selected as **Consumer** AND none of the reporters is identified as **Health Care Professional**	Health Professional
Any Reporter Type is selected as **Company Representative**	Company Representative
Any Reporter (Primary or Other) exists in a case with a Reporter Type of **Other**, If the selected Report Type is a **Regulatory Authority** (text value) within the Argus Case, the **Other** check box should be checked and the text "Regulatory Authority" should be entered in the text box.	Other
Case contains a Consumer Reporter AND also does not contain any Health Care Professional reporters.	Consumer

Note: The User Facility and Distributor check boxes must be checked manually.

Enter the appropriate text if you have selected **Other** as a report source.

Analysis Tab: BfArM Info Tab

Use the **BfArM Info** tab to enter information required for the BfArm Report. The following is an illustration of the **BfArM Info** tab.



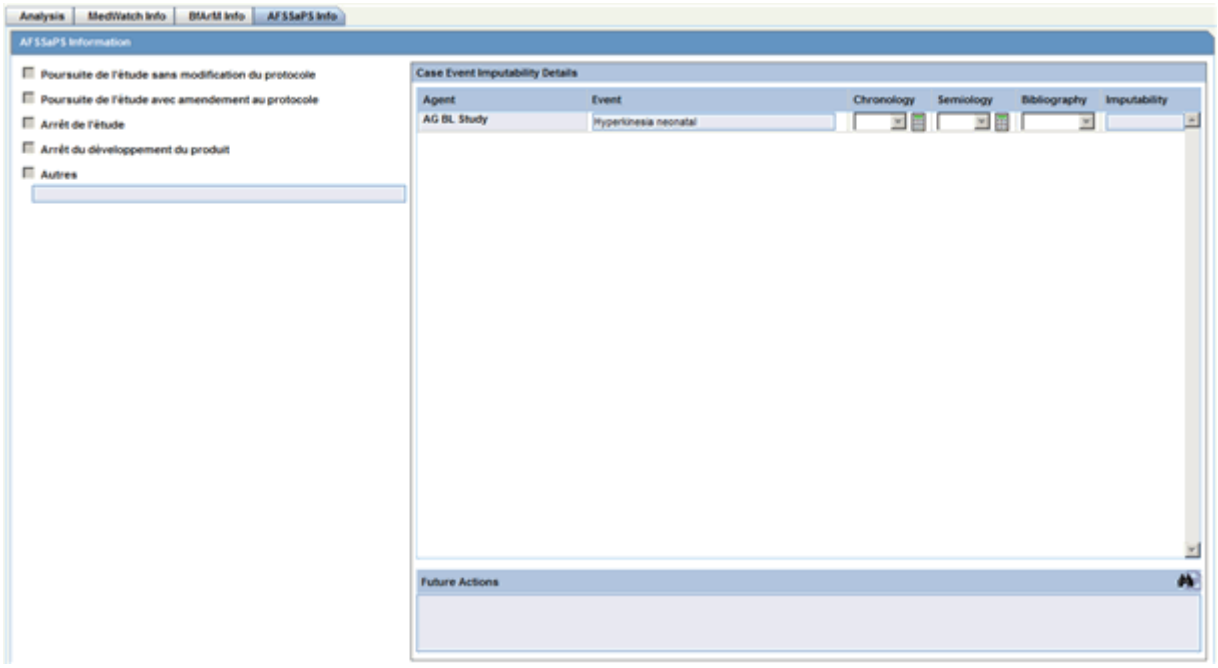
To enter data for the BfArM report

1. Open the **BfArM Info** tab.
2. Select the choices that apply to the patient from the items in the form.
3. If you do not know if a particular condition applies for the patient, select **Unk**.

Note: If any of the relevant items are entered in the Current Medical Status form in the Patient tab, the system automatically enters them here. If you change any of those items in the BfArM Info tab, the system will not enter the data in the Patient tab.

Analysis Tab: AFSSaPS Info Tab

Use the **AFSSaPS Info** tab to enter the imputability assessment information for the suspect product along with the Adverse Events. The following is an illustration of the **AFSSaPS Info** tab.



AFSSaPS Info Tab Fields and Field Descriptions

The following table lists and describes the fields on the **AFSSaPS Info** tab.

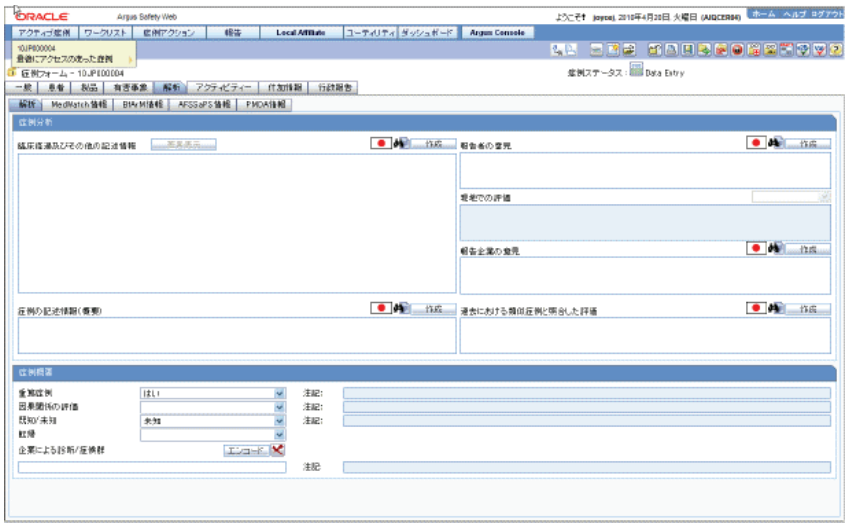
Field/Control Name	Description
Event	Displays included terms for all events.
Product	Enter the suspect product. You cannot enter a concomitant product.
Chronology	Select a Chronology code. The fixed set of values is C0, C1, C2, and C3. Click the icon to select the **Time to onset, Readministration** and **Drug Stopped Values**. The user's selection auto-calculates the Chronology for the Product - Event combination.
Semiology	Select a Semiology code. The fixed set of values is S1, S2, and S3. Click the icon to select the Semiology Outcome, Complementary Test, and Other Explanation. The user's selection auto-calculates the Semiology for the Product - Event combination.
Bibliography	Select a Bibliography code. The fixed set of values is B0, B1, B2, and B3.
Imputability	Imputability Calculation:

Field/Control Name	Description
~	Select from one or more of the following checkboxes: ■ Poursuite de l'étude sans modification du protocole ■ Poursuite de l'étude avec amendement au protocole ■ Arrêt de l'étude ■ Arrêt du développement du produit ■ Autres The text box after Autres supports fifty characters. If the Autres checkbox is not checked, the field is disabled. You can click **Copy to Local Evaluator Comment** to copy imputability values to the Local Evaluator Comment field and place the imputability text-equivalent at the beginning of the text that currently exists in the field. Copy to Local Evaluator Comment is visible only if the language for the "Local Evaluator Comment" field is French.
Future Actions	Enter a text description for future actions.

Analysis Tab: PMDA Tab

The PMDA tab enables you to enter information required for generating PMDA reports and includes the following tabs:

- General Tab
- Comments Tab



PMDA General Tab

The PMDA General tab has several sections as follows:

- Keyword Search Product Assessment
- Reason for Research Report

General Tab: Keyword Search Product Assessment

The PMDA General tab is used to collect product information in an assessment table. It collects this information when:

- The case is a foreign case
- One or more non-company products have been used in the case and are marked as "Suspects."
- The suspected company product has an equivalent Japanese license.

When using the PMDA General tab, be aware of the following:

- If a non-company suspected drug is in a foreign case, the system uses the product trade name and the generic name for the matching check with keywords from the Reportable Product Keyword screen.
- The system uses the keyword to find the related company product family the suspected product belongs to.
- The system matches the keyword with either the product name or the generic name fields on the case form.
- If the system finds a keyword match, the system assesses the Japanese license for the product family on the PMDA tab. If there are multiple Japanese licenses, the system lists all of them on the PMDA tab.
- In this section, Listedness is always "Unknown."
- This table enables the user to assess product reportability.
- The system automatically minimizes this section if any of the following are true:
  - The case is a Japanese COI case
  - The case is a foreign COI case that does not include non-company suspected products.
  - The case is a foreign COI case without non-company suspect products, but none of the keyword match the Product Trade Name or the Generic name.

PMDA General Tab Fields

The following table lists and describes the fields on the PMDA General Tab.

Field/Control Name Name	User Display
Product	Company products found based on the on the J Reportable keyword
Event PT (Description)/LLT	Case events
D/S	Read-only D/S information
Seriousness Severity Duration	Read-only event information
Reported Causality	Reported Causality. This is a type-ahead drop-down list.
Determined Causality	Determined Causality. This is a type-ahead drop-down list.
Product	Company products found based on the on the J Reportable keyword
Event PT (Description)/LLT	Case events
D/S	Read-only D/S information
Seriousness Severity Duration	Read-only event information

Field/Control Name Name	User Display
Reported Causality	Reported Causality. This is a type-ahead drop-down list.
Determined Causality	Determined Causality. This is a type-ahead drop-down list.
Product	Company products found based on the on the J Reportable keyword

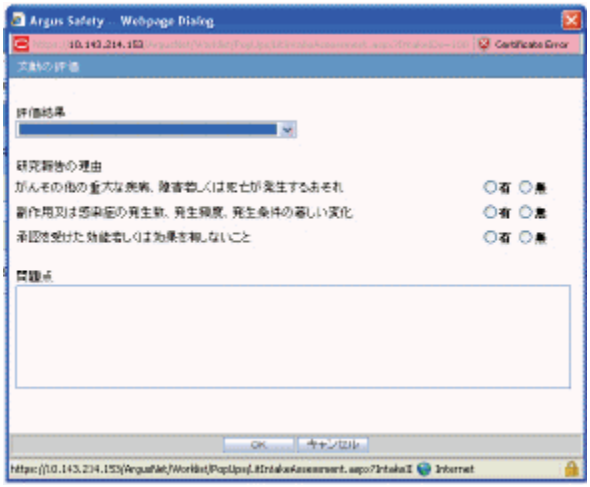
Information Tab: Reason for the Research Report

When the user selects Research Report on the PMDA Information tab, the system opens the Reason for subject of the Research Report dialog box to enable you to enter the reason for the research report. However, be aware that the dialog box opens only when any suspected drug license table has one of the following reporting categories selected:

- Reporting Category
- Research/Infection Report (Marketed Drug)
- Research/ADR Report (Market Drug)
- Research/Infection Report (Investigational Drug)
- Research/ADR Report (Investigational Drug)
- Research Report (Quasi Drug)
- Research Report (Cosmetics)

Justification Dialog Box Fields

The following table lists and describes the fields in the Justification dialog box.



Field/Control Name Name	Description
Reason of Research Report	Title of the UI

Field/Control Name Name	Description
Assessment Result	Read-only field that contains the value from the Literature intake assessment or the reporting category selected on the PMDA General tab. The value in this field can be one of the following: ■ Not Necessary ■ AE Case (Reporting Category A, B, C, D, H, I, J, K) ■ Research/Infection Report -- Marketed Drug (Reporting Category E) ■ Research/ADR Report -- Market Drug (Research Category F) ■ Research/Infection Report -- Investigational Drug (Reporting Category L) ■ Research/ADR Report -- Investigational Drug (Reporting Category M) ■ Research Report -- Quasi Drug (Reporting Category 0) ■ Research Report -- Cosmetics (Reporting Category P) ■ Measures in foreign countries including discontinuation of manufacture, recall and withdrawn -- Marketed Drug (Reporting Category G) ■ Measures in foreign countries including discontinuation of manufacture, recall and withdrawn -- Investigational Drug (Reporting Category N)
Reason of Research Report	Section Title
Possibility of occurrence of serious disease such as cancer, disorder, or death	Choose Yes or No to indicate whether the possibility exists or not
Significant change on event or infection occurrence number, frequency, and condition	Choose Yes or No to indicate whether there has been a significant change.
It doesn't have acknowledged effectiveness	Choose Yes or No to indicate whether the drug is considered effective.
Problems	Enter a description of any problems with the drug. You can enter a maximum of 20,000 characters in this field.

PMDA Tab: Field Label Rules, User Defined Fields, and Help

The PMDA Information tab supports the use of user-defined fields.

PMDA Comments Tab

The Comments tab captures narrative data for various elements reported in the E2B reports submitted to PMDA.

The following table lists and describes the fields on the Comments tab.

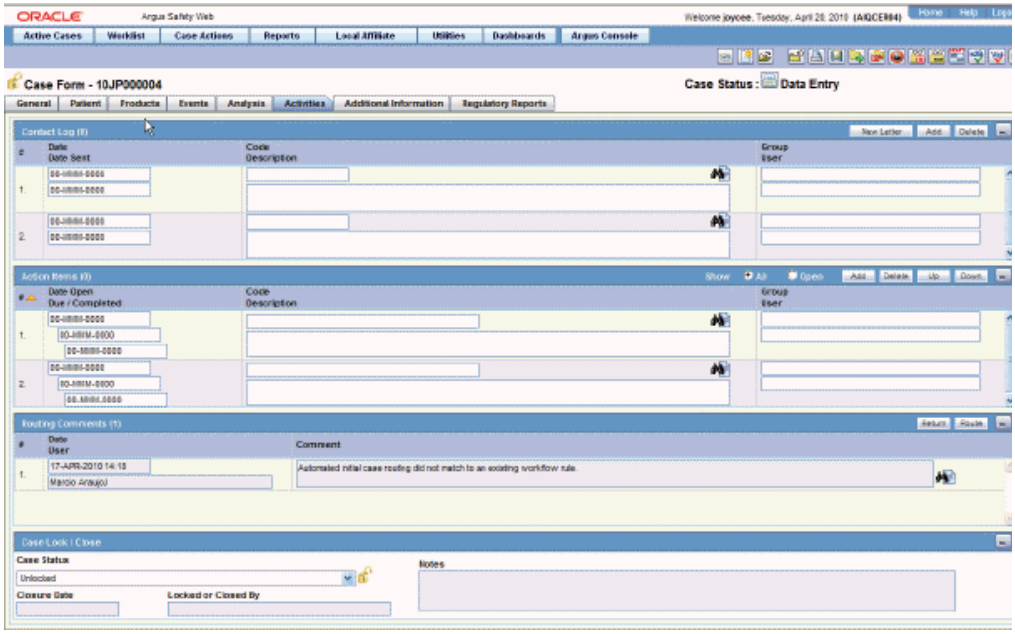
Field/Control Name	Description
Product License No.	Enables you to select a specific product from the drop-down list to apply the comments to.

Field/Control Name	Description
Comment on Incomplete	Enables you to enter information about an incomplete report.
E.G. Cure all MKT	A sample license for which the narratives are being written All narratives written in the various text boxes apply to this license.
Countermeasure for the future	Enables you to enter information about future countermeasures based on an evaluation made by the reporting company about the adverse effect (i.e., infection, etc.). For a foreign case, you can enter the countermeasures taken by the Japanese reporting company, but not the foreign company.
Other Reference	Enables you to enter additional information.
Comment of Sender	Enables you to enter the sender's comment.
Remarks 1 -- 4	Enables you to enter additional comments.
Copy the comments in this tab to other reporting licenses	Click this button to copy all the comments to other licenses in the list. The button is disabled when there is a single product.
Generate	When clicked, the system populates the text fields using the Japanese narrative template.

Activities Tab

The **Activities** tab presents detailed information about the contact log, routing comments, action items, and Case Lock/Closure.

The following is an illustration of the **Activities** tab.



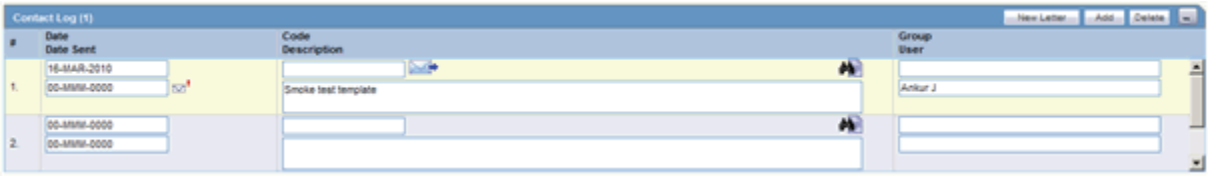
Activities Tab: Contact Log Section

The **Contact Log** section of the **Activities** tab enables you to:

Track correspondence related to individual cases.

Display scheduled letters

The following is an illustration of the **Contact Log** section of the **Activities** tab.



Contact Log Fields and Field Descriptions

When using the **Contact Log** section, be aware of the following:

The number displayed in parenthesis in the header of each section - Contact Log, Action Item, Routing Comments, Case Lock/Archive - displays the total number of entities within the section.

You can choose to view **All Action Items** or only **Open Action Items**, which shall display all the Open Action items within the case. By default, **All Action Items** are displayed.

You can sort Action Items by clicking on the column headers.

The system remembers the sort order on for the duration of the case.

The following table lists and describes the fields in the **Contact Log** section of the **Activities** tab.

Field/Control Name	Description
Date	The date is automatically inserted by the system when a letter is scheduled or generated through the **Letters** menu. You can enter the date on which the letter is manually scheduled or generated. Click the letter icon to open the **Letter Preview** dialog. This allows you to view a letter or to modify it if it has not been sent already.
Code	Select from a list of values to set the contact code for this entry. The Administrator can adjust the information in this list.
e-mail button	Click to send an e-mail message.
Description	Enter a brief explanation for the letter, for example, "Initial Letter," or the details of a phone conversation.
New Letter button	Click this button to generate a new letter
Group/User	Select a group responsible for the Contact item. From the list below, select a user from the selected group who will be responsible for the action. The Contact Item will appear in the Worklist for selected user. If "Any" is chosen as the group, the Action Item appears in all the users' Worklist. The Administrator can adjust the information in these lists.
Date Sent	The date is automatically inserted when a letter is sent through the letter menu. You can also manually enter the date the letter was sent. If this field is completed, the letter will become read-only.

Generating Letters You can generate letters from the **Contact Log** section. When generating letters, be aware of the following:

- The placeholders for the original letter template can be replaced by information that is specific to the current case.
- A letter is only added to a search if the **Correspondent** check box is checked.

- The Administrator can configure the system to generate letters automatically and to schedule them for a specific number of days after receiving details of an adverse event. For example, the system might schedule an Initial Response Letter to be sent the day after an adverse event is received. Auto letter scheduling is triggered when a case is initially saved.
- Letters cannot be auto-generated unless the "Date" [contact log date] is reached, to ensure that the latest information for the case has been updated to the letter.
- If the Primary Reporter is marked as a correspondence contact, the system sends Auto-scheduled letters are sent to the Primary Reporter. Otherwise, the letter is sent to the first correspondence contact.
- Auto-scheduled letters appear in the **Contact Log** section of the Case Form. You can view or print them by double clicking the letter icon. You can also edit letters that have not been sent. The system **does not** automatically send letters. You must send or remove letters manually.
- In addition to auto-scheduling letter, you can also configure auto action items, which prompt you to follow-up with a correspondent after a letter has been scheduled and sent. Auto action item scheduling is triggered once the sent date has been entered for a letter. Auto action items appear in the **Action Items** section on the Case Form and in the **Action Items** tab of the Worklist.
- The system uses the following naming convention to when saving letters in the **Uploaded** letters folder:

  XXXX_YYYY.RTF

  where:

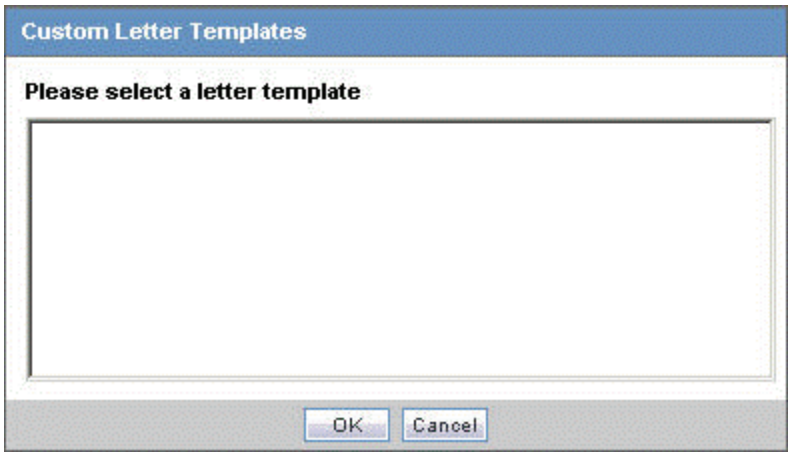
XXXX	Is the current case number
YYYY	Is the current letter numbering format (i.e., date and time the letter was generated)

- The system replaces all special characters in the case number with an underscore (_) character.
- The **CFG_PLACEHOLDER** SQL limit is 4000 characters rather than 1000.

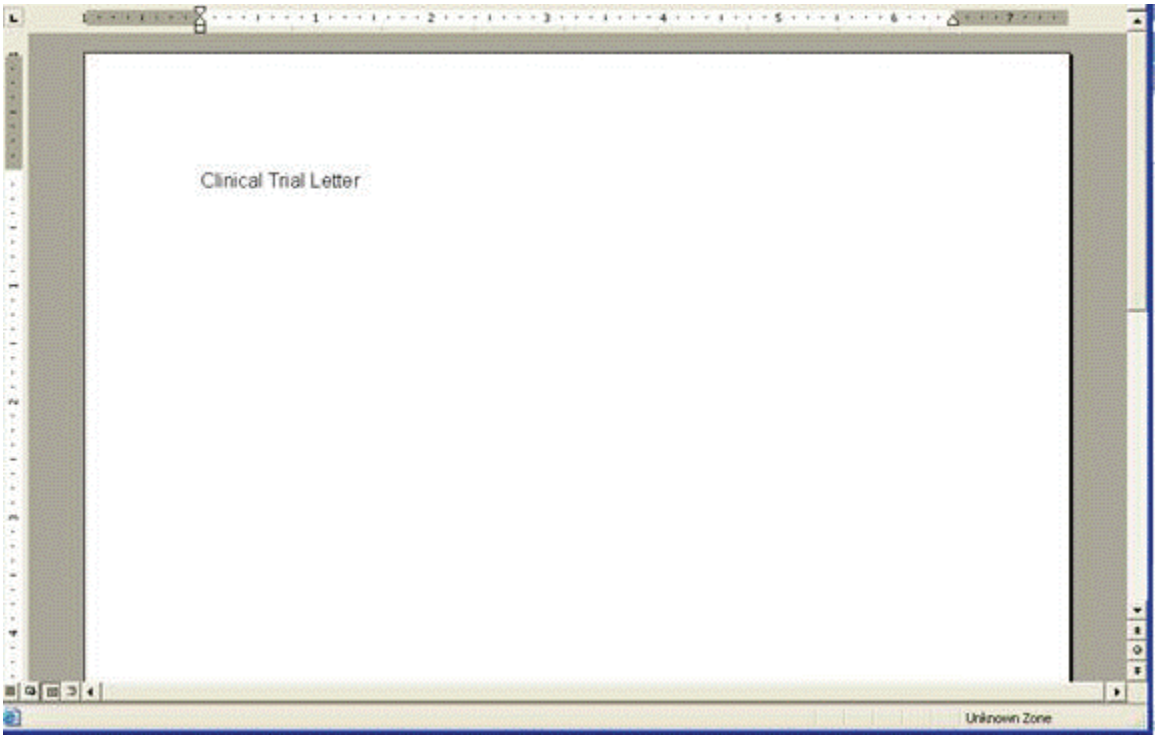
Use the following procedure to generate a letter.

To generate a letter

1. Go to **Contact Log** in the **Activities** tab and click **New Letter**.
2. The Custom Letter Templates dialog opens.



3. Select the required letter template from the list and click **OK** to open the letter in a separate window.



4. Make the necessary changes to the letter text.
5. Select **File-->Save** to save the changes.
6. If you modified the letter, select **Yes**.

   This attaches the letter to the Case Form by browsing to the location where you saved the changes.
7. After saving the letter, the system displays it in the **Contact Log** section of the **Activities** tab.
8. The system creates an action item for following-up on this letter in the **Action Items** section of the **Activities** tab.

Scheduling Action Items for Letters When specifying or changing the **Date Sent** field in a letter, you can schedule an action item if you wish to do so.

- If an action item is not specified, the field is blank.
- Any Action Item can be updated on the screen immediately after a case has been saved.
- Unless the Action Item has already been marked as completed, each time the **Date Sent** field is changed for a letter, the corresponding action item (if one exists) is also updated with a new Due Date of **Date Sent** of the Letter and the number of days specified for the **Action** in the Letter configuration

Opening a Message Editor To open a message editor

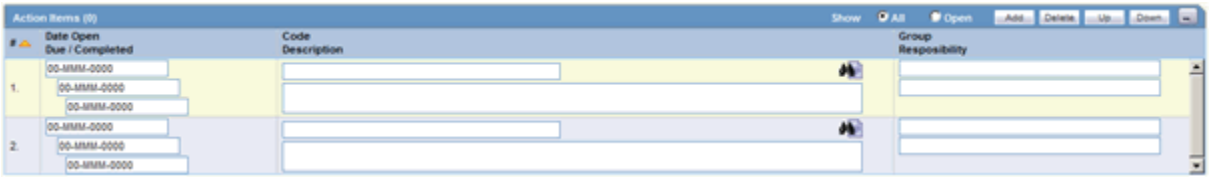
1. Click the letter icon to open the message editor.
2. The system opens the message editor.

The following table lists and describes the fields in the dialog box

Field/Control Name	Description
To	Displays the e-mail address specified for the **Primary Reporter** in the Case Form. You can edit this field.
From	Displays the email address specified in the Return Email Address in Argus Console>Code Lists>Letter Configuration. You can edit this field also.
Subject	Displays the Case Number and the Description of the Contact log. You can edit this field.
Send	Enables you to send the e-mail to the intended recipient.

Activities Tab: Action Items Section

The **Action Items** section enables you to view or enter details of action items for the case and to assign responsibilities for actions. The following is an illustration of the **Action Items** section.



Action Items Fields and Field Descriptions The following lists and describes the fields in the **Action Items** section.

Field/Control Name	Description
Date Open	Enter the date the action item was created. Open action items appear in the Worklist of the user who is responsible for the action item. They also appear in the Open Action Items Report.
Code	Select an Action Item code from the drop-down list. This will display the description of the selected Action Item Code. The Administrator can adjust this list.

Field/Control Name	Description
Description	Selecting an Action Item code automatically enters information into this field. The text can be modified as required. The Administrator can adjust this list.
Group/User	Select a group responsible for the Action Item from the given drop-down list. From the drop-down list below this, select a user from the selected group who will be responsible for the action. The Action Item will appear in the Worklist for the selected user. If "Any" is chosen as the group, the Action Item appears in all the users' Worklist. The Administrator can adjust these lists.
Due	Enter the date on which the action item is to be completed.
Completed	Enter the date on which the action item was completed. A red border indicates a completed action item while a green border indicates an incomplete action item.

Activities Tab: Routing Comments Section

The **Routing Comments** section displays workflow routing information and comments for the case. It also contains a read-only sub-section on Case Locking/Closure. The following is an illustration of the **Routing Comments** section.

Routing Comments Fields and Field Descriptions

The following table lists and describes the fields in the **Routing Comments** section.

Field/Control Name	Description
Date	Displays the date the case was routed to a new workflow state. This field is automatically generated when a case is routed.
User	Displays the name of the user who routed the case. This field is automatically generated when case is routed.
Comment	Displays the routing comment.
Route button	Routes the cases.
Return button	Returns the case to the previous state.

Routing Cases If the case meets the routing rules specified by the Administrator, you can use the **Case Routing** dialog box to route a case to the next workflow state. When using the **Routing Forward Cases** function, be aware of the following:

- Non-Enterprise Workflow managers **cannot** view **all** the Workflow States below the line if the Workflow States are assigned to Sites in the Workflow Configuration.
- Only Enterprise Workflow managers have access to **all** sites for routing cases ahead in the Workflow.
- If the Workflow state **does not** have defined site, **all** workflow managers can see it.

To route a case

1. Click **Route** in the **Activities** tab of the Case Form to open the **Case Routing** dialog box.
2. From the **Route to Next State** drop-down list, select the state to which you would like to route the case.

   If only one workflow state can be selected for the Next Route state, that state can be selected by default in the **Route to Next State** field.
3. From the **Route to User** drop-down list, select the user or user group to route the case to.
4. Enter the routing comments in the **Comments** field

   OR

   Click **Select** to select a comment from a list of pre-defined routing justifications.

To select text from the pre-define list of routing justifications

1. Click on the **Select** button in the Case Routing dialog to open the Routing Justification dialog box.
2. Select the required justification from the justification list displayed under **Select a standard justification for this field**. The system highlights the selected row.
3. Click **OK.**
4. The system closes the Routing Justification dialog box and displays the selected justification text in the **Comments** field in the **Case Routing** dialog box.
5. Click **OK** to route the case.

> **Note:** The system displays disabled users in the user drop-down list in alphabetical order with an asterisk (*) at the end. You can view the total number of times the case has been routed in the header section, excluding the blank rows.

Returning Cases If necessary, you can return a case to its previous workflow state.

To return a case to its previous workflow state

1. Open the case.
2. Click the **Return** button in the **Activities** tab of the Case Form.
3. When the system opens the **Case Routing** dialog box, enter your password in the **Password** field.
4. From the **Route to User** drop-down list, select the user or group the case needs to be returned to.
5. Enter any routing comments in the **Comments** field.
6. Click **OK** to return the case to its previous workflow state.

Activities Tab: Case Lock/Close Section

The **Case Lock/Close** section enables you to lock a case, unlock a locked case, and formally close a case. You must lock the case before you can generate a report. The following is an illustration of the **Case Lock/Close** section on the **Activities** tab.

When closing a case, be aware of the following:

- If the **Auto-schedule Later** checkbox for expedited reports is checked and you try to archive a case, the system displays the following message:

  Case xxxx cannot be closed while Auto Schedule Later is checked. Please uncheck the option for the Auto Schedule Later option on the Regulatory Reports tab or wait for the Report Scheduling to complete before attempting to archive the case.

- The system displays this same message when you close single or multiple cases from the New/Open dialog on the Worklist.

Case Lock/Close Fields and Field Descriptions

The following table lists and describes the fields in the **Case Lock/Close** section of the **Activities** tab.

Field/Control Name	Description
Case Status	Enables you to unlock, lock, or close a case after entering the appropriate user information. ▪ Unlock -- Enables you to unlock a case if you have the appropriate permissions. To unlock a case, enter the password you use to log on to Argus Safety. ▪ Lock -- Enables you to lock a case if you have the appropriate permissions. The current date will be used for the lock date. To lock the case, enter the password you use to log on to Argus Safety in the **Case Locking** dialog box. ▪ Close -- Enables you to close a case if you have the appropriate permissions. To close the case, enter the password you use to log on to Argus Safety in the **Case Closure** dialog box.
Closure Date	Date on which the case was locked or closed. If a locked case is being viewed by a user, any other user who tries to access the same case will have read-only access to the case. ▪ Cases should be closed only after all action items for the case are complete, all expedited regulatory reports have been submitted, and all the expected follow-up information has been received. If a closed case that is closed requires modification, the case must be re-opened by using the password. ▪ A case may be either locked or closed, but not both. A locked case will be moved from the locked state to the closed state without having to unlock first. ▪ **Note:** Case closure should not be confused with closing the Case Form. Closing of the Case Form refers to removing the current Case Form from the screen.
Lock or Closed By	Displays the name of the user who locked or closed the case.
Notes	Displays relevant information about the case lock or closure.

Locking a Case To lock a case

1. In the **Case Lock/Close** section of the **Activities** tab, click **Lock**.
2. The system opens the **Case Locking** dialog box.

3. Enter your Argus Safety password in the **Password** field.
4. Enter any notes in the **Notes** field.
5. Click **OK**.
6. The system displays the locking notes in the **Notes** field of the **Case Lock/Close**

> **Note:** To unlock a case from the Locked/Archived state, select the **Unlocked** value from the **Case Status** drop-down list. This will display the Archived Case or Case Lock dialog. The dialog box requires you to specify your password and the reason for unlocking the case. The case is unlocked/archived after you enter this information.

Unlocking a Case Use the following procedure to unlock a case.

To unlock a case

1. In the **Case Lock/Close** section, select **Unlocked** from the **Case Status** drop-down list.
2. When the system opens the **Locked Case** dialog box:
    1. Type your password in the **Password** field.
    2. Type any relevant information in the **Notes** field.
    3. Click OK.
3. When the system opens the **Case Unlock** dialog box, click one of the following:
    - Significant F/U
    - Non-significant F/U
    - Other

Setting the Focus for a Follow-up Event After unlocking a case, the system sets the focus for significant/non-significant follow-up events as follows:

1. When you click the **Significant F/U** button on the **Case Unlock** dialog, the system automatically displays the case **General** tab, checks the **Significant** check box for both drugs and devices (if enabled by the profile switch), and sets the focus on the **Follow-up Received Date**.

    Screen: Argus > Case Actions > Open > (Select a Case) > General Tab > General Information Section > Follow-ups sub-section (middle of screen).

    - The system checks to determine whether the **Significant** check box is checked.
    - The system sets the focus on the **Follow-up Received Date**.
2. When a case is unlocked and you select the **Non-Significant F/U** button from the case unlock pop-up dialog, the system automatically displays the case General tab and sets focus on the Follow-up Received Date.

    Argus > Case Actions > Open > (Select a Case) > General Tab > General Information Section > Follow-ups sub-section (middle of screen)

    - The **Significant** check box **is not** checked.
    - Focus is on the Follow-up-Received Date.
    - You can add multiple follow-ups.

Argus > Case Actions > Open > (Select a Case) > General Tab > General Information Section > Follow-ups sub-section (middle of screen)

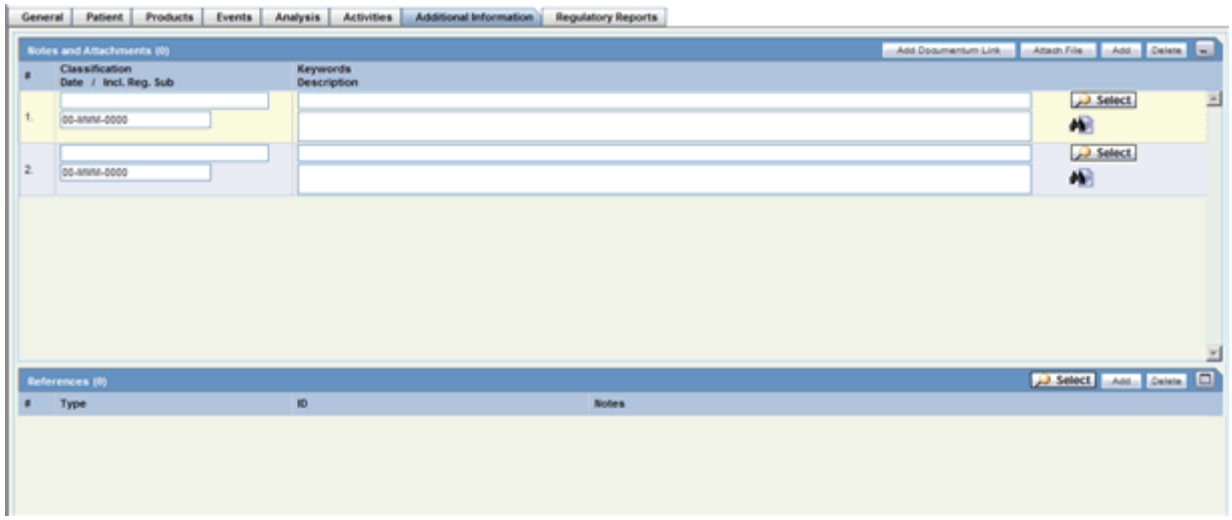
  - If you add a single follow-up, the **Add** button remains available for the user to add additional follow-ups.
  - Currently, the Add button disappears after the user adds a single follow-up. The user must save, close and reopen the case before he/she can add an additional follow-up.

- A hyperlink in the follow-ups section enables you to open the link in a different dialog box.

Additional Information Tab

The **Additional Information** tab enables you to attach notes and other items to the case. For example, you could attach a fax message that came in as part of the case and needs to be scanned and attached or an electronic file received by e-mail. It also enables you to set up cross-references to other cases such as links between cases referring to mothers and children. The total number of attachments and references attached to a case display in the header.

The following is an illustration of the **Additional Information** tab.



When using the **Additional Information** tab, be aware of the following:

- The system shrinks the main widow up to 60% and opens the attachments from the Notes and Attachments dialog in a new browser window.
- The system opens any hyperlinks that appear on the Additional Info tab in a new Internet Explorer window if the selected reference is HTTP/URL Reference.
- When you click the hyperlink and a reference case is present, the system opens a case number irrespective of the selected reference type when you clicked the hyperlink.
- If no sites are defined for the attachments classification, the system permits **all** users to view the attachments on the **Additional Info** tab.
- The system only permits users who belong to the site defined on the attachment classifications to view the attachments.

- The system filters the attachment classifications based on the sites a user has permission to access.
- The Case Form/Case Listing reports printout hides the row.
- The system permits **Workflow Enterprise** to view **all** attachments across **all** sites

Additional Info Tab Fields and Field Descriptions

The following table lists and describes the fields on the **Additional Info** tab.

Field/Control Name	Description
Notes and Attachments	
Classification	Select a classification that describes the attachment. The Administrator can adjust this list. If any attachment classification has the E2B Additional Report checked and the attachment is an file in either .XLS, .TXT, .TIF, .DOC/.RTF, >PNG, >JPG or >BMP formats, the selected attachment is converted to a PDF file. This PDF file is then merged into a single PDF file, which comprises text converted to PDF from all the attachments present in the case. The single merged PDF comprises each attachment as a link by the classification name provided for the attached file.
Date	The current date is automatically entered in this field. You can also enter a date manually.
Incl. Reg. Sub	Select this checkbox to merge PDF attachments within the case form. The Incl. Reg. checkbox identifies the attachments to be included as an appendix to the Expedited Reports. On selecting this checkbox, the Expedited Reports - CIOMS I, CIOMS I (Local), US FDA MedWatch 3500 Drug and 3500 A Device print an appendix page before each attachment. This is added to the case, and marked as Inc. Reg. Sub checked. **Note:** The checkbox is available only if a PDF is selected as an attachment.
Keywords	Enter keywords related to the case or click **Select**.
Description	Enter a description of the attachment.
Attach File	Inserts a file attachment into the case. Maximum file size is 4 GB.
Add	Inserts a row for an additional attachment.
Delete	Deletes the selected row.
Attach Documentum Link	This option is visible only if Documentum is available. Click **Searching for Documentum** to search for and attach Documentum.
References Type	Select a reference type from the list, for example, a parent-child link. The Administrator can adjust this list.
ID #	Enter the case number of the case that is to be referenced. **Note:** Click **Select** to search for the case that is to be referenced. You can also use this field to record the reference number for external cases.
Notes	Notes can be entered here for reference.
Select	Opens the Case Selection dialog for the selected ID.
Add	Inserts a row for an additional attachment.

Searching for Documentum Links

To search for Documentum links

1. Click the **Attach Documentum Link** button to open the **Documentum Lookup** screen.
2. Enter the desired search criteria as per **Type Name**, **Attribute Name** and **Search String**, and click **Search**.
3. Select the desired link from the row displaying the search results.
4. Click **Select** to select the link from the list.

Attaching Files to a Case

You can attach from 1 to 99 files to a case.

To attach files to a case In the **Notes and Attachments** section of the **Additional Info** tab, click **Attach File** to open the **Attachment** dialog box.

1. Click **Browse** to locate a file attachment.
2. Select the file and click **OK**

> **Note:** To view an attachment, click the icon associated with the attachment

Entering Keywords

You can associate keywords with a case in the **Notes and Attachments** section.

To attach keywords to a case

1. Go to the **Notes and Attachments** section and click **Select**.
2. When the system opens the **Attachment Keywords** dialog box:
   - Select a keyword from the **Select a keyword to add to the list** drop-down list.
   - The system displays the selected keywords in the **Keywords** field.
3. Click **OK**

Attaching References to a Case

To add a reference to a case

1. Locate the **References** section and click **Select**.
2. When the system opens the **Case Search Criteria** dialog box, enter the appropriate search parameters and click **Search.**
3. When the system displays the search results in the **Total Number of Rows** section, select the desired search criteria from the list and click **Select** to view details about the selected case.

Regulatory Reports Tab

The **Regulatory Reports** tab enables you to:

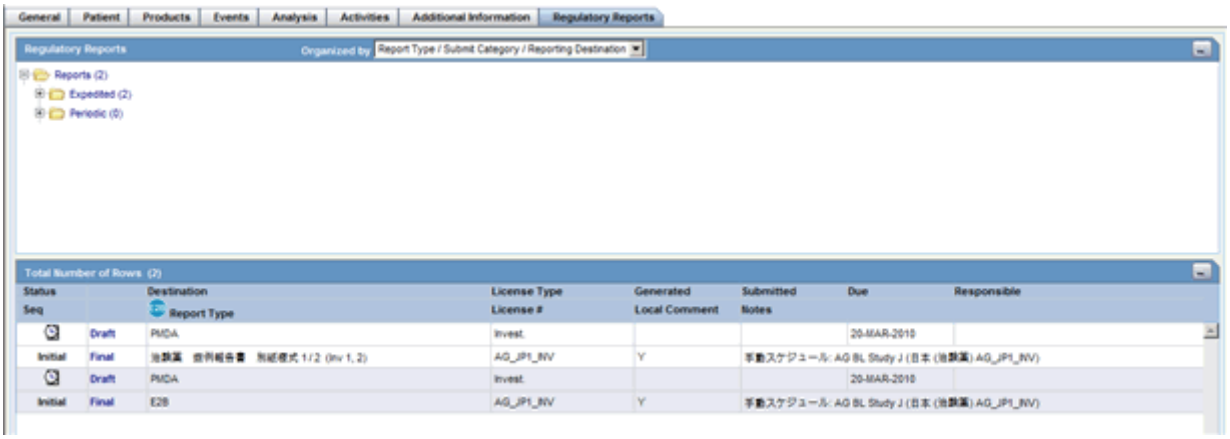
- View all scheduled reports

- Schedule new reports

When a new case is created, there are no reports associated with it. As data is entered and the case is saved, the regulatory report scheduling algorithm determines which reports, if any, will be required for that case.

The reports determined to be necessary appear in the Regulatory Reports tab. You can manually schedule reports via the Reports menu or by clicking the Regulatory Reports Tab. You can also add comments to the existing reports. The comment section can also be updated to enter the notes for the report even after the report has been submitted.

The following is an illustration of the **Regulatory Reports** tab.



General Usage Information

When using the **Regulatory Reports** tab, be aware of the following:

- The case submission date must be **on or after** the initial receipt date for the case. If the submission date is **before** the initial receipt date, the system displays the following message:

  Please enter the Submitted Date greater than the Initial Receipt Date of the Case

- The system displays the time component for the date generated on the **Case Form | Regulatory Reports** tab using the IE offset of the client machine for the display.
- The system displays the time component for the date generated on the **Report Details** using the IE offset of the client machine for the display.
- When you manually schedule an expedited report, the system places the word, Manual, in the **Notes** field along with the current notes information.
- When you manually schedule a report, the system enables you to check "Blind Product Study" on the Schedule New Expedited Report dialog box to blind the study products if they are in the case.

Regulatory Report Tab Fields and Field Descriptions

The following table lists and describes the fields on the **Regulatory Reports** tab.

Field/Control Name	Description
Status	The notification log provides a list of reports which have been scheduled, generated, or submitted. The following report status are available indicated by the icons in the regulatory reports tab: ■ Report has been routed and approved by a user. ■ Report has been routed and disapproved by a user. ■ Report has been scheduled but not saved. ■ Report has been scheduled and saved. ■ Report has been scheduled and generated. ■ Report has been scheduled/generated and it is past its due date of submission. ■ Report has been scheduled/generated and submitted. ■ Report has been marked as submission not required by a user.
Seq	Displays the sequence (Initial, Follow-up, etc.)
Destination	Displays regulatory authority to which the report is to be submitted.
Report Type	Displays the type of regulatory report like US IND Summary, BfARM Form 643, etc.
License Type	Displays license information.
License #	Displays the license number.
Generated	Displays the date when the regulatory report was generated (if applicable). The system date on which it is generated is used as the default value.
Local Comment	Displays a local comment, if it exists.
Submitted	Displays the date the regulatory report was submitted (if applicable). The system date on which it is generated is used as the default value. This date does not initially appear on the Case Form when submitted. It is displayed when the case is re-opened.
Notes	Displays notes entered when the report was created.
Due	Displays the date the regulatory report is due for submission to the regulatory authority (if applicable). This field is auto-calculated based on the initial receipt date or on the basis of the most recent significant follow-up date. It can also be specified manually by entering the date in the Due Date section.
Responsible	Displays the name of the user responsible for the report.
Auto Schedule button	Initiates Auto-Scheduling of expedited reports according to the configuration for this feature, for example, Always, Significant, Manual, or None.
Auto Schedule Device button	Schedules regulatory reports, using the Device rules.
Schedule New Report button	Schedules a new expedited report.
Auto Schedule Later	This item appears if the system is configured for auto-schedule of expedited reports using Argus Safety Service. Select this check box when the system is about to run the auto-scheduling against this case after the case is locked.
Auto Schedule Device Later	Select this check box to run the auto-scheduling for only devices.

Grouping Regulatory Reports

You can group reports by selecting the appropriate grouping structure from the **Organized by** drop-down list. You can group reports as follows:

- Report Type/Submit Category/Reporting Destination
- Report Type/Reporting Destination
- Report Type/Reporting Group

The numbers in parentheses next to each folder indicate the number of reports in the folder.

The following are definitions of the terms used in the reporting structure.

- **Report Type** -- Can be either **Expedited** or **Periodic** reports. The system generates a folder for each type.
- **Reporting Destination** contains all defined code list items for Reporting Destinations that have at least one report scheduled within the case.

If no reports are scheduled for a defined reporting destination, no folder will be created for this destination. All the folders which are the reporting destinations under each folder are sorted alphabetically.

- **Pending Reports** -- Reports that have not been submitted or are marked as non-submitted.
- **Submitted Reports** --All submitted reports.
- **Marked as Non-Submit** --Reports that **have not** been submitted.
- **Reporting Group** -- Contains all user groups assigned to the scheduled expedited or scheduled in the case

Grouping by Report Type/Submit Category/Reporting Destination The **Expedited** folder contains the following:

- Pending Reports by Destination
- Submitted Reports by Destination
- Non-Submitted Reports by Destination

The **Periodic** folder contains single case report forms (MedWatch, VAERS or CIOMS) that were generated as part of a Periodic Report.

- Pending Reports by Destination
- Submitted Reports by Destination
- Non-Submitted Reports by Destination

Grouping by Report Type/Reporting Destination The **Expedited** folder contains a sub-folder for reporting destinations that have at least one scheduled report.

The **Periodic** folder contains the single case report form (MedWatch, VAERS or CIOMS) generated as part of a Periodic Report are listed in the Periodic section. If no report was generated, the system does not create sub-folders.

Grouping by Report Type/Reporting Group The **Expedited** and **Periodic** folders contain sub-folders for each group that has generated a report. If a group has not generated a report, the system **does not** create a sub-folder.

5

Case Actions

This chapter discusses the actions that can be performed on the existing cases.

Working with Cases

This section provides information about actions that can be performed on existing cases. It includes discussions of the following:

- Finding and Opening Existing Cases
- Creating a New Case
- Processing a Case
- Closing a Case
- Saving a Case
- Copying a Case
- Performing a Medical Review
- Performing a Coding Review
- Printing Cases
- Printing Medical Summaries
- Deleting a Case
- Revising a Case

Finding and Opening Existing Cases

You can find and open a case from the **Case Open** form shown in the following illustration.

To find and open an existing case

1. Select **Case Actions --> Open** to view the **Case Open** form.
2. Enter or select the appropriate search criteria in the form fields and click **Search.**
3. When the system displays the **search results**, locate the appropriate case in the list.
4. Click the **link** associated with the **Case ID**.
5. The system opens the **Case Form** for the selected case.
6. You can now review the case details and enter further information in the Case Form.

Note: You can open the 10 most recently-accessed cases without going through the preceding process. These cases appear under Active Cases.

General Usage Information

When using the **Case Open** dialog box, be aware of the following:

- You can print **all** the cases in the current view from the **Case Actions | Open** dialog.
- If you search for a case that has been deleted, the system displays the following message:

  The case number being searched is deleted in the system. Please reactivate the case to allow processing of the case from Utilities | Case Reactivate Option.
- This message appears across the application where you use the case number to search for a case as follows:
  - Worklist -- All dialogs
  - Last Accessed Cases from the Menu
  - Person Argus Status
- Case Search while adding the Case as a reference
  - If a blinded user views the case information from the **Case Summary**, the system displays the **Blind** name instead of the **Study Drug** name in the product information.
  - When you view the case details, the system displays the same folder structure on **the Regulatory Reports** tab. This enables you to view the expedited and periodic in an organized tree structure.

Case Open Form Fields and Field Descriptions

The following table lists and describes the fields on the **Case Open** form.

Field/Control	Description
Search For	Select the criteria by which the case must be searched for and enter an appropriate search item, if applicable. **Note:** You can search for cases based on multiple study identifiers. The option, "Pri/Stdy/Othr/Cntr/Rptr/Pat" supports entry of Project ID, Study ID, Other ID, Center ID, Reporter ID, and Patient ID values separated by the "/" (forward slash) character. Any or all fields may be present.
Full Search	Select this check box, if necessary. Full search is best explained with an example. If the full search option is not used and the item that is entered under **Search for** is "AB", then a string such as "ABCESS" will match "AB", but a string such as "LABOR" will not. If the full search option is used, both these items will match "AB". Also, items whose first few letters sound similar (like "TIM" and "TIN") will also appear in the search results.
Product Family	Select the **Product Family** that the case belongs to, if applicable.

Field/Control	Description
Date Range	Select a relevant **Date Range**, if applicable. **Tip:** To enter a customized date range, select **Custom Date Range** from the list. ■ Enter an appropriate date range in the custom date range dialog and click **OK**. ■ Select the **Follow-up** radio button to search on Follow-up Dates, including the Significant and Non-Significant Follow-ups.
Advanced Condition	Select an **advanced condition** for the case, if applicable. **Note:** Click **AC** to create a new advanced condition.
Result from Argus Insight	Enables you to create a search result with the same cases as the Active Case Series in Argus Insight.
Search	Click Search to display the list of cases that match the search criteria.

Search Results Contents

The Search Results under **Total Number of Rows** display a list of cases as specified in the Search Criteria (Default Criteria is Date Range of Last 30 days). The previous search results are displayed if a search was performed by the user during the same session without logging out.

The following table lists and describes the **Search Results** columns and contents.

Column	Description
Total Number of Rows	Displays the total number of results found to match the search criteria. ■ **Displaying Rows.** The number of rows being displays. ■ **Page Size.** The number of rows that display on each page. ■ **<< >>.** Click to scroll through the search results.
Lock State	Displays the Lock Status - whether the case is locked or unlocked. Click the icon displaying the lock status for more information.
Case Number	Displays the unique Case Number of each case. Click the case number link to open the case.
Date	Displays the date when the case was opened.
Product	Displays the Product related to the case.
State	Displays the State that the case belongs to.

Sharing a Case Series

You can share a case series from:

- Argus to Argus Insight
- Argus Insight to Argus

To share a case series from Argus to Argus Insight

1. Click the **[Argus Insight]** option to automatically activate the same case series in the search result.
2. **Argus Insight** automatically makes the same case series active that is present in the search result of the **Case Search** dialog in Argus.

Note: : If Argus Insight is already open, the system replaces the active case series in Argus Insight with cases from Argus.

To share a case series from Argus Insight to Argus

Click the **Result from Argus Insight** button in **Case Search** to create a search result with the same cases as the **Active Case Series** in **Argus Insight**.

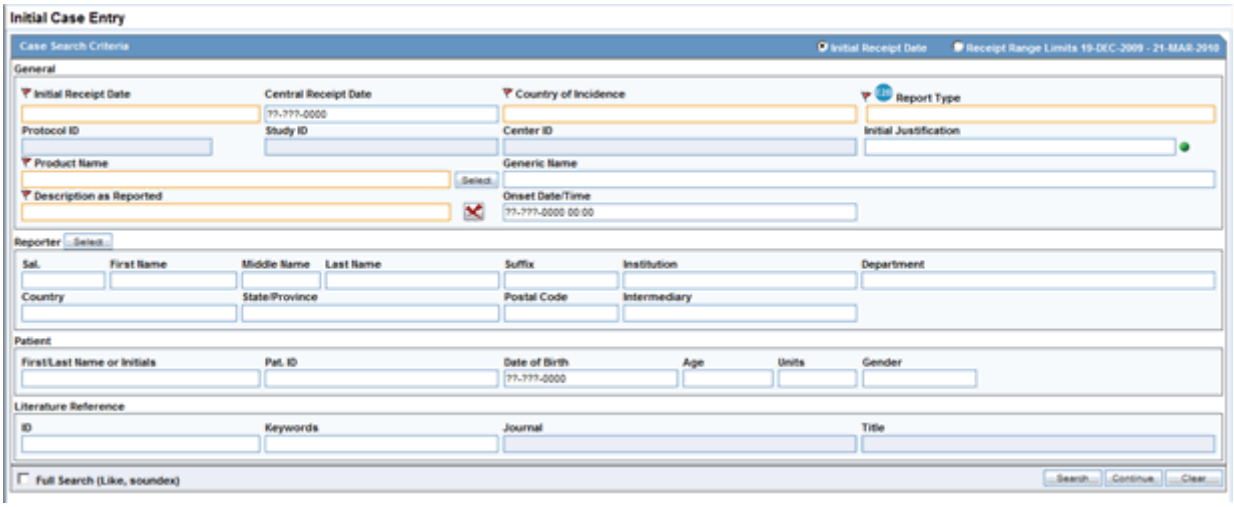
Be aware of the following:

- If there are no cases in the **Active Case Series in Argus Insight** or no **Active Case Series** exists, the system generates an "empty" search result.
- If there are cases in the **Argus Insight** Case series that no longer exist in Argus, they are excluded from the case series in Argus.
- You can also make the Case Search dialog case series active from within **Argus Insight** through the Case Series menu option **Make Active from Argus** in **Argus Insight**.
- A case is excluded from the case series, if a case series from Argus contains cases that are not present in the data mart.

Processing a Case

When your company receives initial case information you enter this information on the **Initial Case Entry** form. After entering this information, it must be verified, or checked for duplicates (possibly by another user) to ensure that duplicate information is not entered in the database. Once the information is verified, you can book in the case or enter additional case data.

The following is an illustration of the **Initial Case Entry** form.



Initial Case Entry Fields and Field Descriptions

The following table lists and describes the fields in the **Initial Case Entry** form.

Field	Description
Initial Receipt Date	Enter the date on which your company became aware of the case. The Receipt Date cannot be entered as a partial date.

Field	Description
Central Receipt Date	Enter the date on which this information was received by Central Safety.
Country	Enter the country where the adverse event occurred. You can select the appropriate country from the list. **Note:** This may or may not be the reporter's or the patient's country of residence.
Report Type	Select the item that best describes the type of report. This determines the fields that are made available for entering case information. **Note:** The report type also impacts the duplicate search. For example, selecting **Sponsored Trial** makes the **Study ID** and **Protocol ID** fields available. The Administrator can adjust the information in this list.
Project ID	Enter the Project ID of the case.
Study ID	This item is applicable to clinical trial cases only. Enter the study ID. Click **Select** to choose the study ID from the **Clinical Trial Selection dialog**.
Center ID	This item is applicable to clinical trial cases only. Click **Select** to choose the **Center ID** from the **Clinical Trial Selection dialog**.
Initial Justification	The values of this field are configurable through the standard Argus Justifications dialog. This field is reflected in the General tab of the Case Form and is also available for duplicate searching for cases. Click the green dot to view and select justifications from the Argus Justification dialog.
Product Name	Enter the name of the product associated with the case. If the adverse event(s) are associated with more than one product, each additional product can be added from the Case Form. **Note:** Enter the most suspect product here. Click **Select** to search for a product from the **Trade Name Product Lookup** dialog. Several items are automatically entered on the Case Form based on the product selected here.
Generic Name	This field can be used to enter the generic name of the product. This field will be automatically entered when a product is selected from the **Trade Name Product Lookup** dialog.
Description as Reported	Enter a brief verbatim description from the reporter that describes the event that is most clinically important in the case. The icon denotes that the event is encoded. Click the icon to populate the MedDRA hierarchy dialog.
Onset Date/Time	Enter the date/time for the onset of adverse event symptoms.
Sal. First Name Middle Name Last Name	Enter the reporter's salutation, first name, middle name and last name.
Suffix	Enter the reporter's name suffix, if applicable.
Country	Enter the reporter's country.
State/Province	Enter the reporter's state/province or county.
Postal Code	Enter the postal code or zip code.
Intermediary	Enter the type of intermediary for the case, if applicable.
Patient Name or Initials	Enter the patient's name or initials. The system can search for cases on initials, first name, and last name.
Pat. ID	Enter the patient's ID.

Field	Description
DOB	Enter the patient's Date of Birth (dd-MON-yyyy). **Note:** When entering the month, enter 1 for JAN, 2 for FEB, 3 for MAR and so on.
Age	Enter the patient's age. When searching for duplicates, the system will retrieve all ages that begin with the number that was entered for the search. For example, searching for "5," will retrieve patients aged 5, and 50 through 59.
Units	Enter the age units (days, months, or years).
Gender	Select the patient's gender from the list. The Administrator can adjust the information in this list.
ID	Enter the value to search for a Reporter Reference number, Case Reference, and Case number.
Keyword	Enter a keyword when searching for duplicates. Keywords are only used for searching for cases.
Journal Title	These items are applicable to literature cases only. Click **Select** to choose a journal and title from the **Literature Reference** dialog. The Administrator can adjust this list.
Full Search (Like Soundex)	Check the **Full Search (Like, Soundex)** check box to perform a full search, including Soundex search for cases. **Tip**: Soundex enables you to search for cases with similar phonetics.

Booking in Cases and Entering Initial Case Information

From the **Initial Case Entry** form, you can decide to book-in a case before entering further case information in the Case Form.

Note: You can configure the number of cases that display in the Bookin dialog in the Page Size drop-down list. By default, 100 cases appear on the page. You can choose to display up to 2000 cases on a single page.

To enter initial case information

1. Select Case Actions --> New to open the Initial Case Entry form.
2. Enter preliminary case information in the form.
3. Click **Search** to determine whether information related to this case has already been entered.
4. A list of cases that match the criteria you entered on the form is displayed. Inspect the search results for a duplicate case.

Note: Fields displayed with a red flag are required fields and must contain a value.

Note: : If a duplicate case exists, open the case to enter further information (if any) related to the existing case. Click the link associated with the case

5. If a duplicate case does not appear, click **Continue** in the Initial Case Entry form to display the **BookIn** and **Attachments and References** sections.
6. Enter the relevant information in sections like Causality, Seriousness, Attachments and References.
   - Under **Reported Causality**, select the reporter's assessment of causality. The causality relationship is the causal relationship between the clinically most important event and the suspect drug that is entered in the Initial Case Entry form.
   - For **Seriousness Criteria**, select the appropriate check boxes to indicate the seriousness of the case, as appropriate.

   Note:
   - Select only the criteria that applies to the clinically most important adverse event.
   - If you select the **Death** check box, you can enter the death details from the dialog that automatically appears. If you select the **Hospitalized** check box, you can enter hospitalization details from the dialog that automatically opens.
   - Either a seriousness criterion or a non-serious criterion must be entered before a case can be booked in.
   - When a Duplicate Search is performed, the system will remember the results until the user logs out of the system or performs a duplicate search again. When the Bookin screen is opened, the search results from the last search are displayed again.
7. If the case is not serious, select the appropriate check box under **Case is Non-Serious**. The Non Serious Section of the Initial Case Entry dialog is differentiated by a | between the Serious criteria and the Non Serious Criteria.
8. Click **Add** to add an attachment
9. Select **File Attachment** or **URL Reference**, as appropriate.

To insert a file attachment

1. Select **File Attachment** from the list and click **Browse**.
2. Click the **New Case from Image** button - is the first button (from left) in the Quick Launch bar. This button opens the **Windows Open** dialog, which helps you to browse to the default location from where the file(s) can be attached.

   Note: This location is configured can be configured by the administrator in Argus Console under **System Configuration > Common Profile Switches > Case Processing**.

To insert a URL Reference

1. To insert a URL Reference, select **URL Reference** from the list.
2. Enter the URL after "http://".

To search for and insert a document

1. Select **Documentum Link** and click **Add**.
2. The **Document Lookup** dialog is displayed.
3. You can search for a document from the database by specifying a search criterion in this dialog.
4. Click **BookIn.**

> **Note:** Once you click the Bookin button, it is hidden from the screen. The button is enabled only if the Save operation fails or when the case is booked in successfully. Mandatory fields are denoted by an orange border across the field in the Bookin dialog.

5. If the Administrator has configured the system for automatic numbering of cases, the automatically assigned case number opens. If the numbering of cases is manual, you can enter the appropriate case number.

> **Note:**
>
> - When a case is booked in, the case may be assigned to a specific user and it will be given a particular state, depending on the configuration set up by the Administrator.
> - The case can not be booked in without these fields populated: Product, Event, Receipt Date, Report Type, Country of Incidence and Seriousness.
> - These are noted by an orange border across the field label and identified by an orange flag to indicate that these are required fields.

Tip: When you book-in a case, a dialog that prompts you to open the newly created case is displayed.

Click **Yes** to open the case.

Checking for Duplicates

To check for duplicates

1. Check whether the case information that is being entered in the **Initial Case Entry** form has been entered previously (possibly by another user).
2. Enter the information related to the case in the Initial Case Entry form.
3. Select the **Receipt Range Limits** radio button to check for duplicates based on the dates entered in the form. Click **Search**. A list of cases that match the criteria entered in the form opens.
4. Inspect the list to determine if any case contains duplicate information.

Understanding Receipt Range Limits

The following table provides information about using **Receipt Ranges**.

Field	Description
No date	90 days before System Date and 2 days after System Date.
Full Onset Date	10 days before Onset date and 90 days after Onset Date.
Full Initial Receipt Date	60 days before Initial Receipt Date and 60 days after Initial Receipt Date. **Note:** This default date range for searching on Initial Receipt Date can be disabled by un-checking the **Receipt Range Limits** radio button on the **Initial Case Entry** dialog.
Partial Onset Date	Based on the Full Date Range - if only the year is entered, the date range becomes: 10 days before the end of the previous year and 90 days after end of the year.
Partial Initial Receipt Date	Based on Full Date Range - if only a year is entered, the date range becomes: 60 days before end of previous year and 60 days after the end of the year.

Note:

- If an **Initial Receipt Date** is not entered but an **Event Onset Date** has been entered, the search will default to look for cases with Initial Receipt Dates 10 days before and 90 days after the event onset date. This feature can also be disabled directly on the dialog by un-checking the **Receipt Range Limits** check box. If you do not check anything, the default date range shall be 90 days before and 2 days after the current date.
- The Duplicate Search permits you to sort in ascending or descending order in the duplicate search results. You can also use wild card searches on all text fields in the BookIn dialog.

Closing a Case

This section provides information about how to close a case. Once a case is closed, you can do the following:

- You can view a closed case in the Case Form in read-only mode.
- View reports generated for the case
- Preview new drafts
- View report details
- View drafts of reports that haven't been generated

You **cannot** create expedited reports for cases that have been formally closed. For that reason, you cannot close a case that has pending scheduled reports.

To close a case

1. Select Case Actions --> Close.
2. When the system opens the **Save Case** dialog box:

   Click **Yes** to save and close the case

   OR

   Click **No** to close the case without saving it.

After you close a case, the system does the following:

1. Opens the next active case, if you have active cases that you are working on. If there are no active cases, the system displays the default **Worklist**.
2. Displays the Personal Argus Status if the default Worklist option is **<None>.**

Saving a Case

This menu option enables you to save a case.

To save a case

1. Click the **Case Number** of the case you want to save.
2. When the system opens the **Case Form**, select **Case Actions --> Save**.
3. When the system opens the **Case Form Saving** dialog box, click **OK**.

Copying a Case

Argus enables you to save all or part of a case and stores the copy in the database as a separate case. When copying cases, be aware of the following:

- Clicking the case reference in any copied case opens the original case.
- You can select specific sections of the case to copy.
- If your system is configured for manual case numbering, the system prompts you to enter a new Case ID. Otherwise, the system automatically assigns a new Case ID. The following is an illustration of the Case ID Number dialog box.

To copy a case

1. Select Case Actions --> Copy.
2. When the system opens the **Case Copy -- Webpage** dialog box, enter the number of copies you want to make and click **Yes** to copy the case.
3. When the system displays the **Case Copy** dialog box, click the appropriate check boxes to select the portions of the case you want to copy

   OR

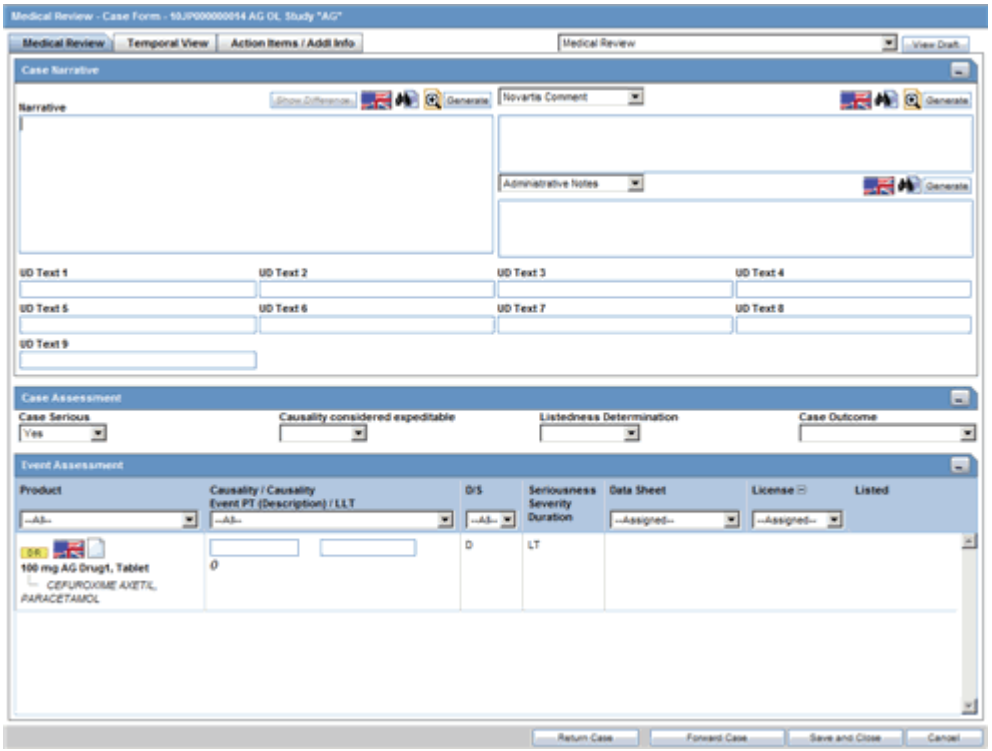
   Click **Select All** to copy the entire case.
4. Click **Copy**.
5. The system saves and opens a copy of the case with a new case number and presents a message. Click OK.

Note: Depending on whether the system is configured for automatic case numbering, the system either generates a case ID or enables you to enter the case ID for this case.

Using the Medical Review Function

Use the **Medical Review** function to quickly and efficiently add important information to a case. The **Medical Review** form has three (3) tabs as follows:

- Medical Review Tab
- Temporal View Tab
- Action Items/Addl Info Tab



To access Medical Review

1. Select Case Actions --> Medical Review.
2. The system opens the Medical Review form.
3. Click on the appropriate tab.

Common Actions

The following table lists and describes the actions you can perform from all Medical Review tabs.

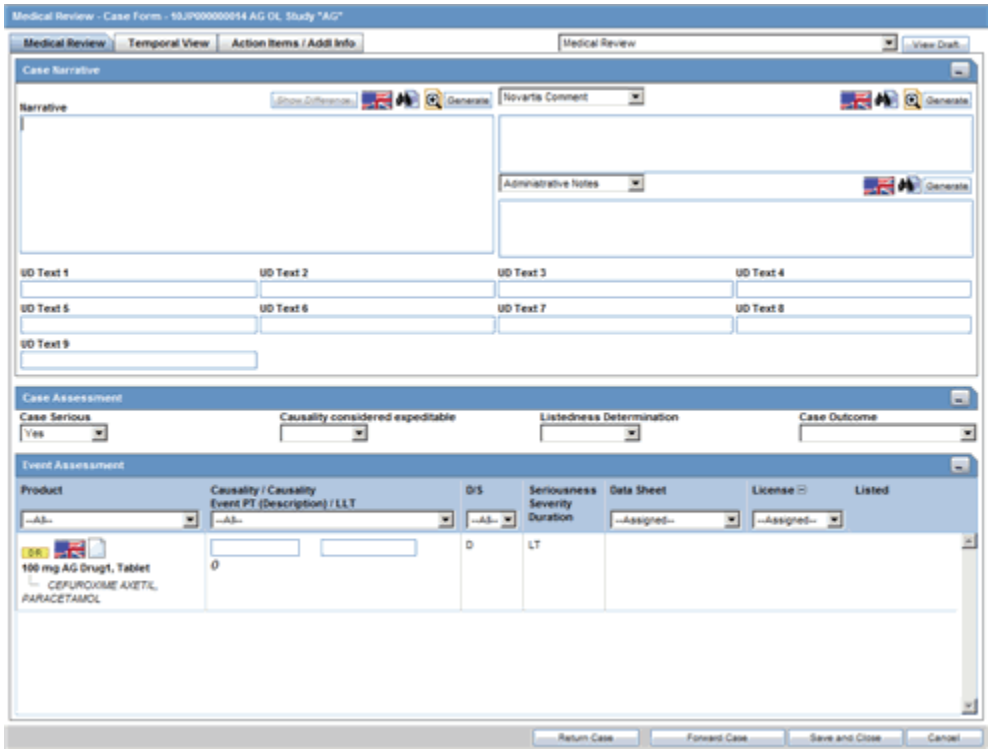
Field	Description
View Draft	Select a report from the drop-down list and click **View Draft** to generate a draft version of the report based on the open case. **Note:** This report form type is saved as a default and the next time the user opens the Medical Review for another case, this is defaulted to the Report Form selected previously. The Draft report does not display all the changes made to the Case until the case has been saved in the database.
Zoom/Unzoom	Click the zoom icon to view the selected dialog on a much bigger scale. Click Un-Zoom icon to revert back to the earlier view.
Return Case	Click **Return Case** to open the return route dialog and save the information.
Forward Case	Click **Forward Case** to open the forward route dialog and save the information. When the case has been routed and the form is closed, you cannot route from the case form **Activities** tab till the case has been closed and re-opened.

Field	Description
Save and Close	Click **Save and Close** to save and close the case.

Using the Medical Review Tab

The **Medical Review** tab has three sections as shown in the following illustration:

- Case Narrative
- Case Assessment
- Event Assessment



The system displays the user-defined fields in the Medical Review dialog box, if they if been enabled on the Case Form Analysis tab. If they have not been enabled, they do not display on the tab.

Enter information in the Case Narrative, Case Assessment and Event Assessment sections.

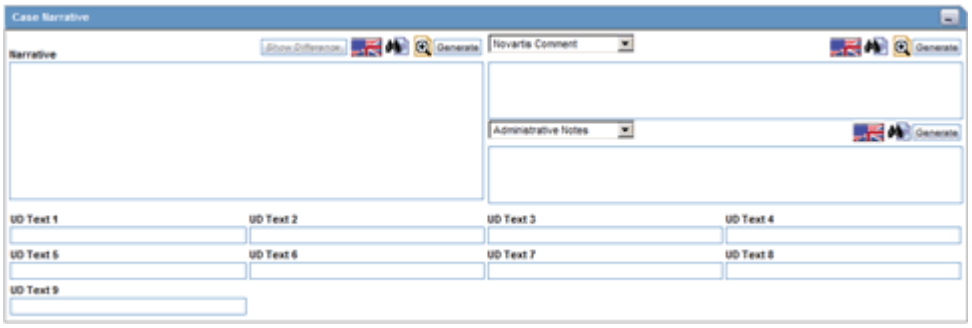
Note:

- An (S) is displayed for Serious events.
- An (F) is displayed for Fatal events.
- An (LT) is displayed for Life Threatening events.
- An (H) is displayed for Hospitalized events.

About the Case Narrative Section The **Case Narrative** section is fixed and cannot be changed. However, you can choose from the drop-down options associate with the

fields to view any of the other narrative fields. The system saves the view as a default and uses it when you open the Medical Review for another case.

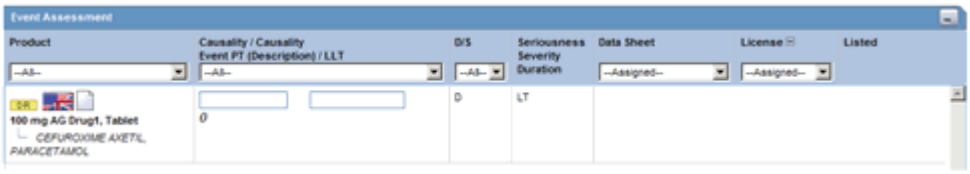
You cannot choose the same Narrative field in from the drop-down lists. For example, the first selected narrative field you selected is disabled in the second drop-down list. The following is an illustration of the **Case Narrative** section.



About the Case Assessment Section The **Case Assessment** section enables you to provide information about case details. The following is an illustration of the **Case Assessment** section.

Select whether the case is serious or not from the Case Serious drop-down list. In a similar manner, select relevant information about Company Agent Causal, Listedness, and Case Outcome from the drop-down lists.

About the Event Assessment Section The **Event Assessment** section allows you to understand more about the events. The following is an illustration of the **Event Assessment** section.



Event Assessment Fields and Field Descriptions

The following table lists and describes the fields in the **Event Assessment** section.

Field	Description
Product	This field is populated when events are entered in the **Products** tab and is displayed in the following format: ▪ First Line - Product Name ▪ Second Line - Generic Name

Field	Description
Causality as Reported/ Causality as Determined	**Causality as Reported** -- Indicates the degree of reported causality. **Causality as Determined** -- This field is populated with information entered in the Reported Causality field.
Event PT /Description/LLT	**Event PT/Description/LLT** -- This field is populated when events are entered in the **Events** tab and displays in the following format: ■ First Line - Event PT ■ Second Line - Verbatim ■ Third Line - LLT
D/S	Displays the Diagnosis/Symptom details by **D** or **S** in line with the Events.
Seriousness Severity Duration	Display the Seriousness, Severity and the Duration of the Event.
Data Sheet	Displays the data sheets for the agent.
License	Displays the licenses for the agent.
As Determined Listedness	Indicates whether the system found the event on the datasheet for this product.

Filtering in the Event Assessment Section

The following table describes how the each field of the **Event Assessment** section is filtered:

Field	Description
Product	The product filter drop down list contains all products listed in the event assessment. The user can filter on all the products which are present in the Event Assessment dialog.
Event	Contains a drop down of values of distinct Event PT. The user can filter on all the products which are present in the Event Assessment dialog.
Diagnosis	Contains a drop down values of D for Diagnosis or S for Symptoms.
Data Sheet	Contains a drop down of values of distinct data sheets. All the blank data sheets display as a single row of <Unspecified>.
Licenses	Contains a drop down of values of distinct Countries of the Licenses. All the Licenses which are not associated to a data sheet displays under <Unspecified> or are aligned with the data sheet view.

Note: Only the assessment rows that match the selected criteria are displayed in the filtering results.

User Actions within Event Assessment

The following table lists user actions and their result.

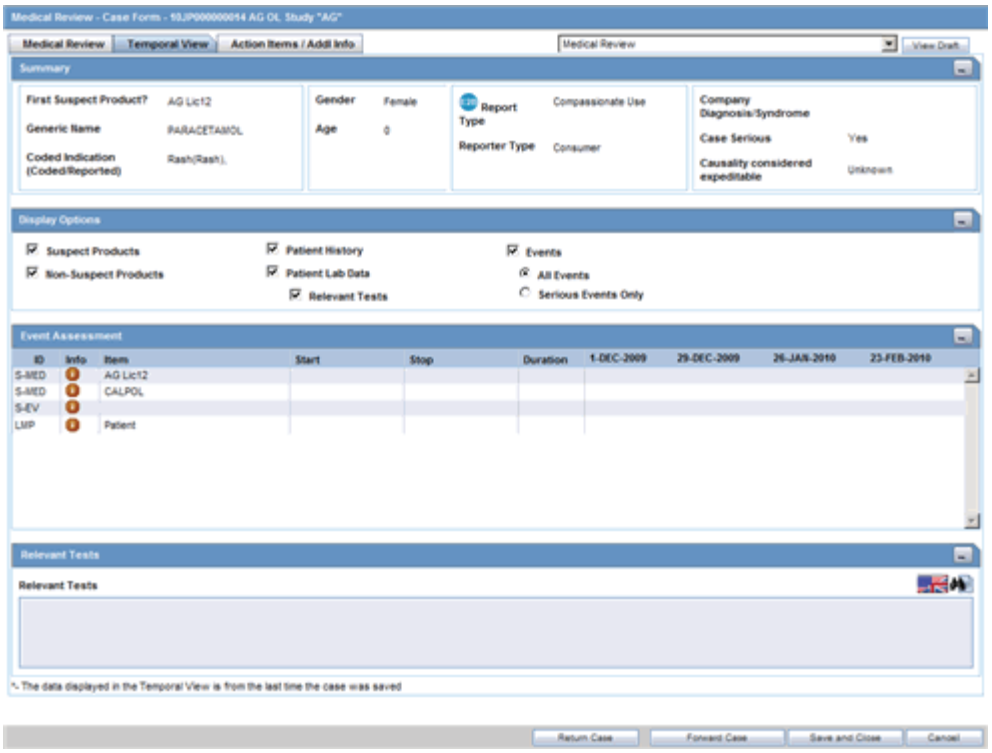
User Action	Result
Click **Datasheet** column's "plus" icon	Displays the license and data sheet views and displays the License Column and enable the "-" for the License Column.
Click Product Name	Displays the Product Information dialog for the selected product

User Action	Result
Click Event Description	Displays the Event Information dialog for the selected event
Click License Description	Displays the Product Information as defined in the License Configuration.
Click Datasheet Description	Displays all the configured terms in the data sheet.

Attaching Cases from the Medical Review Screen

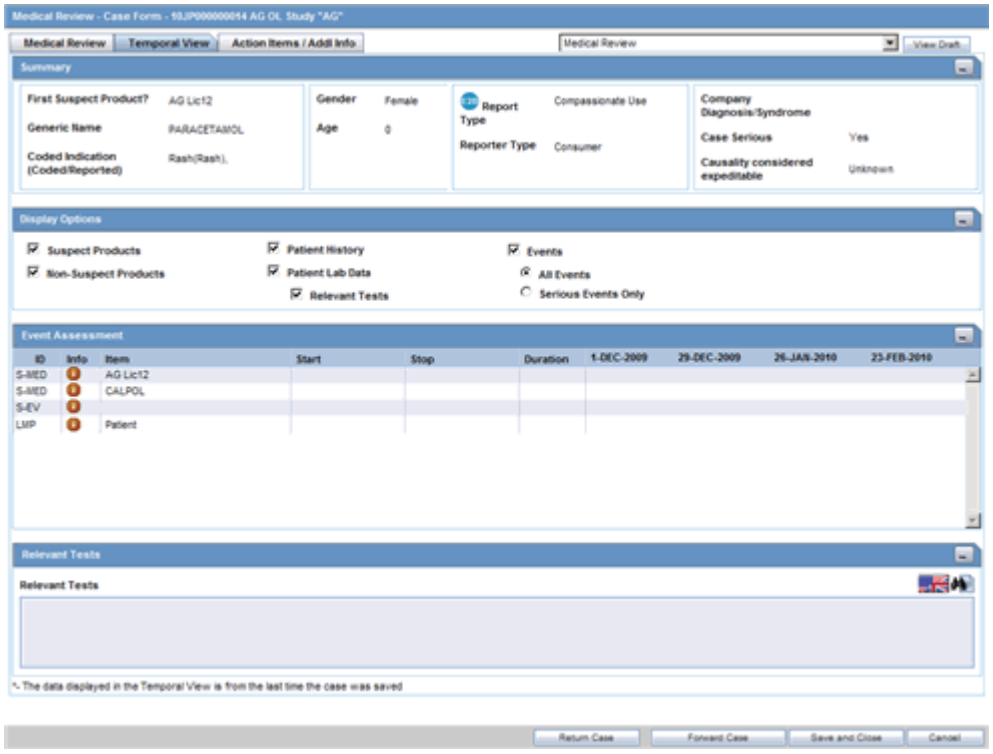
Notes and Attachments and Contact Log sections appear on the Case Form Addition Info tab to the Medical Review screen as follows:

- The new functions appear on the **Action Items/Addl Info** tab.
- The performance of the **Medical Review** dialog remains the same while initially loading the dialog.
- The system displays user-defined fields in the **Medical Review** dialog box if they have been enabled on the Case Form Analysis tab.



Using Temporal View Tab

Click **Temporal View** tab to view a read-only version of the case before routing. The following is an illustration of the **Temporal View** tab.



The information displayed in the Temporal View tab is taken from the information entered in the **Case Form** section. Click the following links for information about each section on the **Temporal View** tab.

About the Summary Section The **Summary** section provides read-only summary information about the case.

The following table lists and describes each field in the **Summary** section.

Field	Description
First Suspect Product	Displays the name of the primary suspect product.
Generic Name	Displays the generic name of the primary suspect product.
Coded Indication	Displays information about the product indication.
Gender	Displays the gender of the patient.
Age	Displays the age of the patient.
Report Type	Displays the report type.
Reporter Type	Displays the type of reporter reporting the event.
Company Diagnosis/Syndrome	Displays the company diagnosis.

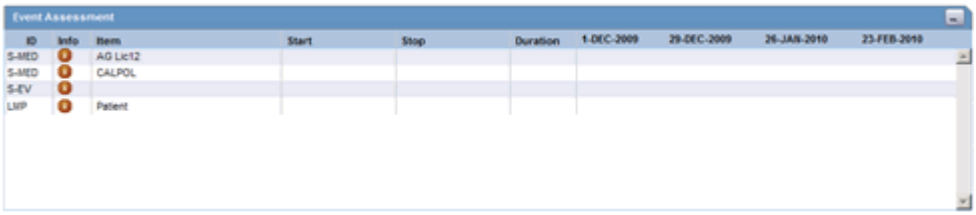
Field	Description
Case Serious	Displays whether the case is serious or not.
Company Agent Causal	Displays the case causality status.

About the Display Options Section The **Display Options** section enables you to select information to view in the **Event Assessment** section of the form. The following is an illustration of the **Display Options** section.

The following table lists each check box and describes the information that displays in the **Event Assessment** section.

Field	Description
Suspect Products	Select the check box to view Suspect Products in the Event Assessment Section.
Non-Suspect Products	Select the check box to view Non-Suspect Products in the Event Assessment Section.
Patient History	Select the check box to view Patient History in the Event Assessment Section.
Patient Lab Data	Select the check box to view Patient Lab Data in the Event Assessment Section.
Relevant Tests	Select the check box to view Relevant Tests in the Event Assessment Section.
Events - All Events, Serious Events Only	Select the check box as required to view All Events/Serious Events Only in the Event Assessment Section.

About the Event Assessment Section The **Event Assessment** section provides summary information about the adverse event.



The following table lists and describes the information in the **Event Assessment** section.

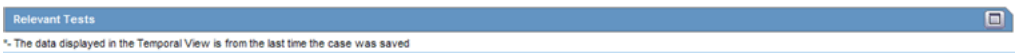
Field	Description
ID	Denotes the type of event. For example, HOSP means Hospitalized.
Info	Click the Info icon (i) to view details about the selected entity.
Item	Displays the item name.

Field	Description
Start	Displays the date from when the event assessment began.
Stop	Displays the last date of the event assessment.
Duration	Displays the duration of the event assessment.

The system opens a unique dialog box for the event you have chosen to view.

Name	Contents
View Death Information	Information about a death resulting from an adverse event.
View Event Information	Information about the adverse event.
Hospitalization Information	Information about the hospitalization that resulted from an adverse event.
View Patient History	Historical information about the patient associated with the adverse event.
Product Information	Information about the product that caused the adverse event.

About the Relevant Tests Section The **Relevant Tests** section provides information about any tests that were performed.



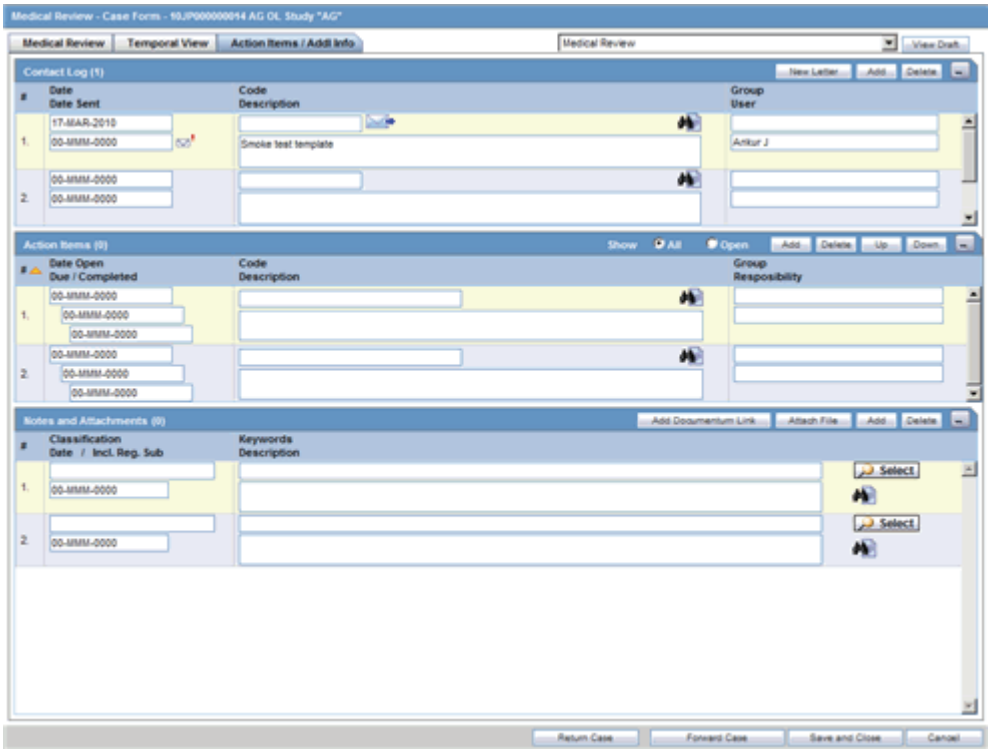
The following lists and describes

Field	Description
Relevant Tests	Displays information about any relevant tests, if any.
Zoom/Unzoom	Click the Zoom icon to view the report on a bigger scale. Click the Unzoom icon to revert to the earlier view.
Flag Icon	This icon displays the language text that is supported.
Notes Icon	Click this icon to view/enter notes.

Using the Action Items/Addl Info Tab

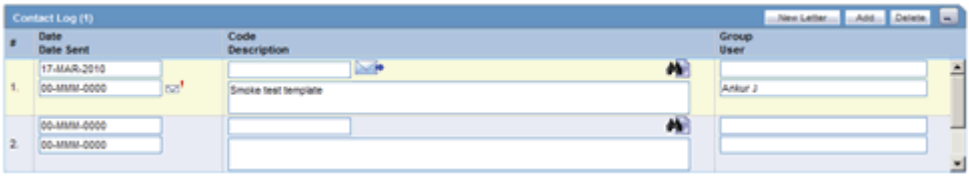
The **Action Items/Addl Info** tab enables you to enter contact log information, information about action items, and notes and attachments. The tab has three sections as shown in the following illustration. The sections are:

- Contact Log
- Action Items
- Notes and Attachments



About the Contact Log Section

The **Contact Log** section enables you to track correspondence about an adverse event. The following is an illustration of the **Contact Log** section.



Contact Log Fields and Field Descriptions

When using the **Contact Log** section, be aware of the following:

- The number displayed in parentheses in the header of each section - Contact Log, Action Item, Routing Comments, Case Lock/Archive - displays the total number of entities within the section.
- You can choose to view **All Action Items** or only **Open Action Items**, which shall display all the Open Action items within the case. By default, **All Action Items** are displayed.
- You can sort Action Items by clicking on the column headers.
- The system remembers the sort order on for the duration of the case.

The following table lists and describes the fields in the **Contact Log** section of the **Activities** tab.

Field	Description
Date	The date the letter was generated and sent. The following icons may be present: Click the letter icon to open the **Letter Preview** dialog. This allows you to view a letter or to modify it if it has not been sent already.
Date Sent	The date is automatically inserted when a letter is sent through the letter menu. You can also manually enter the date the letter was sent. If this field is completed, the letter will become read-only.
Code	The contact code for this entry. The Administrator can adjust the information in this list. Click this e-mail button to open a message editor.
Description	Enter a brief explanation for the letter, for example, "Initial Letter," or the details of a phone conversation.
New Letter	Click this button to generate a new letter
Group/User	Select a group responsible for the Contact item. From the list below, select a user from the selected group who will be responsible for the action. The Contact Item will appear in the Worklist for selected user. If "Any" is chosen as the group, the Action Item appears in all the users' Worklist. The Administrator can adjust the information in these lists.

Generating Letters You can generate letters from the **Contact Log** section. When generating letters, be aware of the following:

- The placeholders for the original letter template can be replaced by information that is specific to the current case.
- A letter is only added to a search if the **Correspondent** check box is checked.
- The Administrator can configure the system to generate letters automatically and to schedule them for a specific number of days after receiving details of an adverse event. For example, the system might schedule an Initial Response Letter to be sent the day after an adverse event is received. Auto letter scheduling is triggered when a case is initially saved.
- Letters cannot be auto-generated unless the "Date" [contact log date] is reached, to ensure that the latest information for the case has been updated to the letter.
- If the Primary Reporter is marked as a correspondence contact, the system sends Auto-scheduled letters are sent to the Primary Reporter. Otherwise, the letter is sent to the first correspondence contact.
- Auto-scheduled letters appear in the **Contact Log** section of the Case Form. You can view or print them by double clicking the letter icon. You can also edit letters that have not been sent. The system **does not** automatically send letters. You must send or remove letters manually.
- In addition to auto-scheduling letter, you can also configure auto action items, which prompt you to follow-up with a correspondent after a letter has been scheduled and sent. Auto action item scheduling is triggered once the sent date has been entered for a letter. Auto action items appear in the **Action Items** section on the Case Form and in the **Action Items** tab of the Worklist.

Use the following procedure to generate a letter.

To generate a letter

1. Go to **Contact Log** in the **Activities** tab and click **New Letter**.

2. The Custom Letter Templates dialog opens.
3. Select the required letter template from the list and click **OK** to open the letter in a separate window.
4. Make the necessary changes to the letter text.
5. Select **File-->Save** to save the changes.
6. If you modified the letter, select **Yes**.

   This attaches the letter to the Case Form by browsing to the location where you saved the changes.
7. After saving the letter, the system displays it in the **Contact Log** section of the **Activities** tab.
8. The system creates an action item for following-up on this letter in the **Action Items** section of the **Activities** tab.

Scheduling Action Items for Letters When specifying or changing the **Date Sent** field in a letter, you can schedule an action item if you wish to do so.

- If an action item is not specified, the field is blank.
- Any Action Item can be updated on the screen immediately after a case has been saved.
- Unless the Action Item has already been marked as completed, each time the **Date Sent** field is changed for a letter, the corresponding action item (if one exists) is also updated with a new Due Date of **Date Sent** of the Letter and the number of days specified for the **Action** in the Letter configuration

Opening a Message Editor To open a message editor

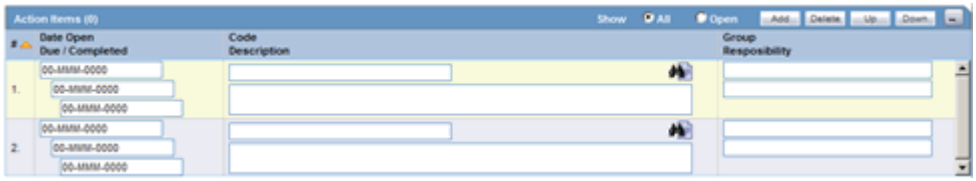
Click to open the message editor.

The following table lists and describes the fields in the dialog box

Field	Description
To	Displays the e-mail address specified for the **Primary Reporter** in the Case Form. You can edit this field.
From	Displays the e-mail address specified in the Return E-mail Address in Argus Console>Code Lists>Letter Configuration. You can edit this field also.
Subject	Displays the Case Number and the Description of the Contact log. You can edit this field.
Send	Enables you to send the e-mail to the intended recipient.

About the Action Items Section

The **Action Items** section enables you to enter action items and their related information. The following is an illustration of the **Action Items** section.

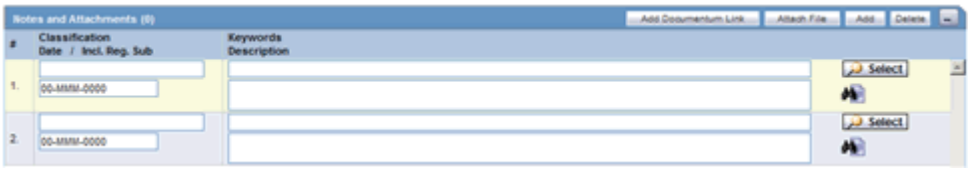


The following tables lists and describes the fields in the **Action Items** section.

Field	Description
Date Open	Enter the date the action item was created. Open action items appear in the Worklist of the user who is responsible for the action item. They also appear in the Open Action Items Report.
Due	Enter the date on which the action item is to be completed.
Completed	Enter the date on which the action item was actually completed.
Code	Select an Action Item code from the drop-down list. This will display the description of the selected Action Item Code. The Administrator can adjust this list.
Description	Selecting an Action Item code automatically enters information into this field. The text can be modified as required. The Administrator can adjust this list.
Group/User	Select a group responsible for the Action Item from the given drop-down list. From the drop-down list below this, select a user from the selected group who will be responsible for the action. The Action Item will appear in the Worklist for the selected user. If "Any" is chosen as the group, the Action Item appears in all the users' Worklist. The Administrator can adjust these lists.

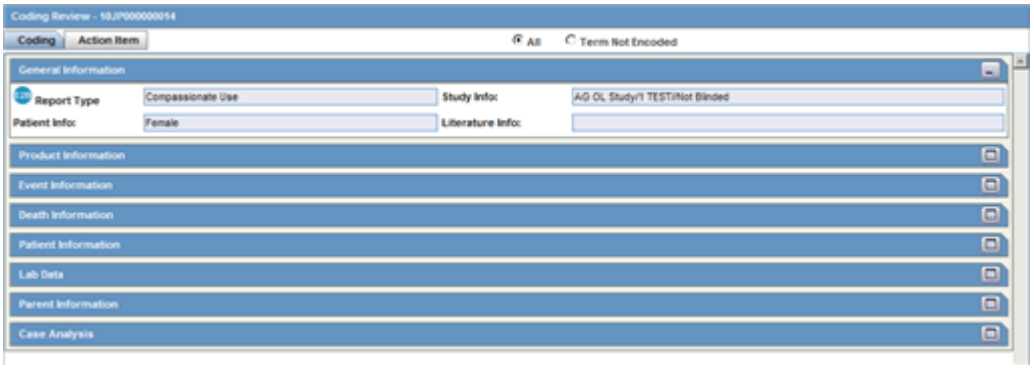
About the Notes and Attachments Section

The **Notes and Attachments** section enables you to view notes and attachments associated with a case. The following is an illustration of the **Notes and Attachments** section.



Using the Coding Review Function

The **Coding** tab provides a single entry point for viewing and coding several kinds of information. The following is an illustration of the coding tab.



General Information

The following is an illustration of the **General Information** section of the **Coding** tab.

The following table lists and describes the fields in the **General Information** section.

Field	Description
Report Type	Identifies the type of case.
Study Info	Displays study information about of the case.
Patient Info	Identifies the patient's age & gender.
Literature Info	Displays information about the Primary Literature of the case.

Product Information

The following is an illustration of the **Product Information** section of the **Coding** tab.

The following table lists and describes the fields in the **Product Information** section.

Field	Description
Product Name	Displays the product name.
Dosage Form	Displays the configured formulation for the drug.
Strength / Unit	Displays the configured Concentration and Units for the drug.
Indication Verbatim	Identifies the indication associated with the product.
IND Coded (LLT)	Displays the Coded PT with LLT in parenthesis.

Event Information

The following is an illustration of the **Event Information** section of the **Coding** tab.

The following table lists and describes the fields in the **Event Information** section.

Field	Description
Event verbatim	Event name as reported.
Coded PT (LLT)	Displays the Coded PT with LLT in parenthesis.
Seriousness	Displays the Event Seriousness for the Event.
Severity	Displays the Event Intensity for the Event.
Duration	Displays the Event Duration for the Event.

Death Information

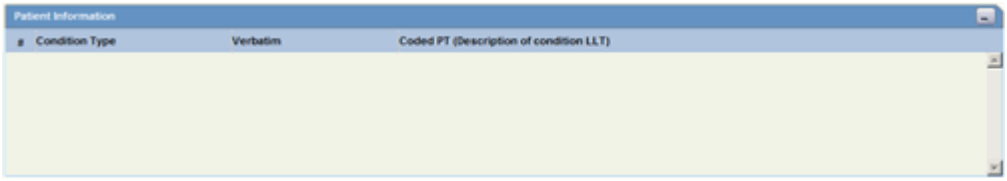
The following is an illustration of the **Death Information** section on the **Coding** tab.

The following table lists and describes the fields in the **Death Information** section.

Field	Description
Cause of Death	Displays the coded or un-coded event verbatim for cause of death.
Coded PT (LLT)	Displays the Coded PT with LLT in parenthesis.

Patient Information

The following is an illustration of the **Patient Information** section on the **Coding** tab.



The following table lists and describes the fields in the **Patient Information** section.

Field	Description
Patient -- Other Relevant history: Condition Type	Displays the condition type of the patient's previous history.
Patient -- Other Relevant history: Verbatim Coded (Description)	Displays the condition of the patient's previous history.
Coded PT (LLT)	Displays the Coded PT with LLT in parentheses.

Field	Description
Patient -- Other Relevant history: Condition Type if equal to Historical Drug	Displays the condition type of the patient's previous history.
Patient -- Other Relevant history: Verbatim Coded (Description)	Displays the condition of the patient's previous history.
Coded PT (LLT)	Displays the Coded PT with LLT in parentheses.
Indication Verbatim	Displays the Indication Verbatim for the Historical Drug.
Indication Coded PT (LLT)	Displays the Coded PT with LLT in parentheses.
Reaction Verbatim	Displays the Reaction Verbatim for the Historical Drug.
Reaction Coded PT (LLT)	Displays the Coded PT with LLT in parentheses.

Lab Data

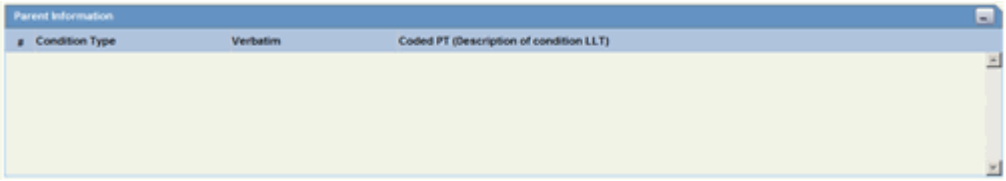
The following is an illustration of the **Lab Data** section on the **Coding** tab.

The following table lists and describes the fields in the **Lab Data** section.

Field	Description
Test Name	Displays the Lab Data Verbatim for the Lab Data.
Coded PT (LLT)	Displays the Coded PT with LLT in parenthesis.
Results / Units	Displays the entered Results and Units for the Lab Data.
Normal High / Low	Displays the configured Normal High and Low with Units for the Lab Data.

Parent Information

The following is an illustration of the **Parent Information** section on the **Coding** tab.



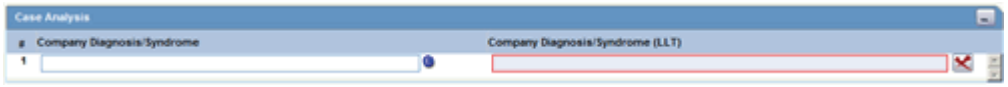
The following table lists and describes the fields in the **Parent Information** section.

Field	Description
Condition Type	Displays the condition type of the Parent previous history.
Verbatim Coded	Displays the condition of the Parent previous history.
Coded PT (LLT)	Displays the Coded PT with LLT in parenthesis.
Coded PT (LLT)	Displays the Coded PT with LLT in parenthesis.

Field	Description
Indication Verbatim	Displays the Indication Verbatim for the Historical Drug.
Indication Coded PT (LLT)	Displays the Coded PT with LLT in parenthesis.
Reaction Verbatim	Displays the Reaction Verbatim for the Historical Drug.
Reaction Coded PT (LLT)	Displays the Coded PT with LLT in parenthesis.

Case Analysis

The following is an illustration of the **Case Analysis** section of the **Coding** tab.

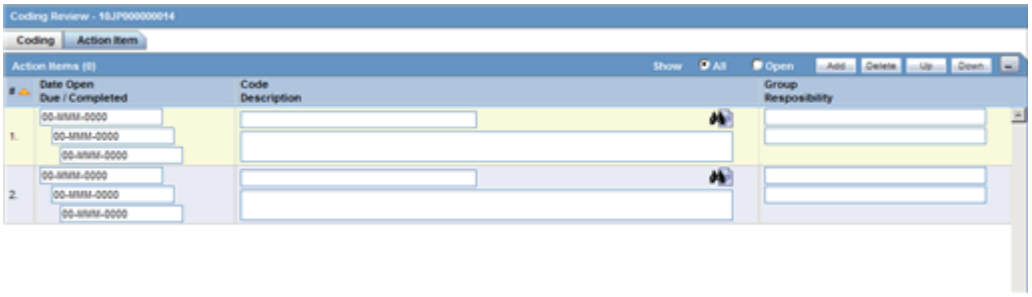


The following table lists and describes the fields in the **Case Analysis** section.

Field	Description
Company Diagnosis / Syndrome Verbatim	Displays coded or un-coded event term for diagnosis or syndrome that the company ascribes to the case.
Coded PT (LLT)	Displays the Coded PT with LLT in parenthesis.

Using the Action Item Tab

The **Action Item** tab enables you to view and track action items for a case. The following is an illustration of the **Action Item** tab.



Click the following link for information about the fields and controls on the **Action Items** tab.

Action Item Fields and Field Descriptions

The following lists and describes the fields and controls on the **Action Item** tab.

Field	Description
Show	Enables you to show all action items (open and closed) or show on the open action items.
Add	Enables you to add a new action item
Delete	Enables you to delete an action item.

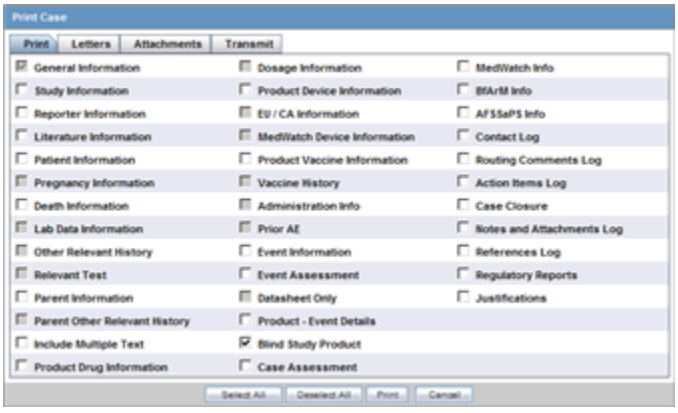
Field	Description
Up	Enables you to move to the previous action item in the list
Down	Enables you to move to the next action item in the list.
Date Open	Enter the date the action item was created. Open action items appear in the Worklist of the user who is responsible for the action item. They also appear in the Open Action Items Report.
Date Due	Enter the date the action item is due to be completed.
Completed	Enter the date the action item was actually completed.
Code	Select an Action Item code from the drop-down list. This will display the description of the selected Action Item Code. The Administrator can adjust this list.
Description	Selecting an Action Item code automatically enters information into this field. The text can be modified as required. The Administrator can adjust this list.
Group Responsibility	Select a group responsible for the Action Item from the given drop-down list. From the drop-down list below this, select a user from the selected group who will be responsible for the action. The Action Item will appear in the Worklist for the selected user. If "Any" is chosen as the group, the Action Item appears in all the users' Worklist. The Administrator can adjust these lists.
User	Select the user responsible for handling the action item.
Print	Enables you to print a list of action items
Draft Report	Provides access to the Draft Reports including Medical Summary Report. You cannot access to Medical Review Summary Report, if you do not have access to the Medical Review dialog.
Code	Opens the **Code** dialog box.

Using the Print Function

The **Print** function enables you to print the following:

- Case Form
- Medical Summary

You access each of these print functions from the **Case Actions** menu. The following is an illustration of the Print Case dialog box.



Accessing Print Case Form Functions

Use the following procedure to access the **Print Case Form** functions.

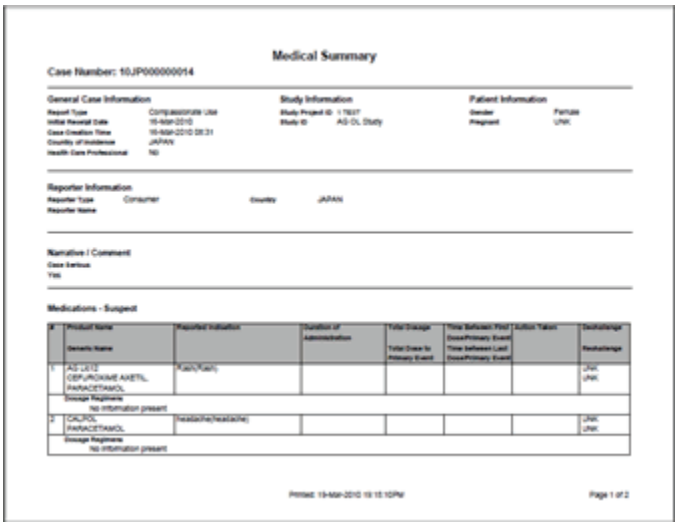
To access print Case Form functions

1. Open a case
2. Select Case Actions --> Print --> Case Form.
3. The system opens the **Print Cases** tabbed dialog box.

Accessing Print Medical Summary Functions

Use the following procedure to access the **Print Medical Summary** function.

1. Open a case.
2. Select Case Actions --> Print --> Medical Summary.
3. The system opens the **Medical Summary Report**.

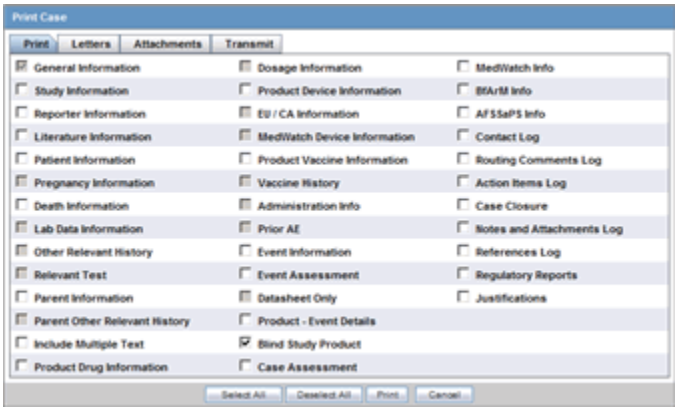


Printing a Case

The **Print Case** tabbed dialog box enables you to:

- Print a case form or any of its sections (**Print** tab)
- View and print letters associated with the case (**Letters** tab)
- View and print attachments associated with a case (**Attachments** tab)
- Transmit case information (**Transmit** tab)

The following is an illustration the tabbed **Print Case** dialog box.



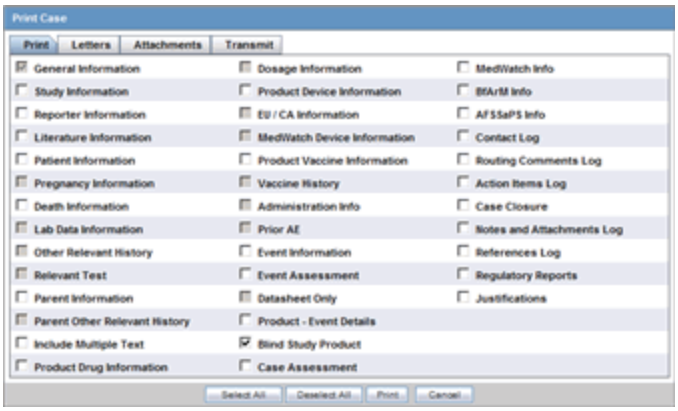
Click the following links for information about using the **Print Case** dialog box and printing cases, letters, and attachments and transmitting cases.

Printing a Case

The **Print** tab contains a check box for each section of the Case Form. You can print any or all of the sections on the Case form. However, the system only prints the sections you select. When printing a Case From be aware of the following:

- Select the **Include Multiple Language** Text check box, to print multiple language text
- Click the **Blind Study Product** check box to blind product information for study cases

The following is an illustration of the **Print** tab.



To print sections of the case form

1. Click the **check box** for each section of the Case Form you want to print

   OR

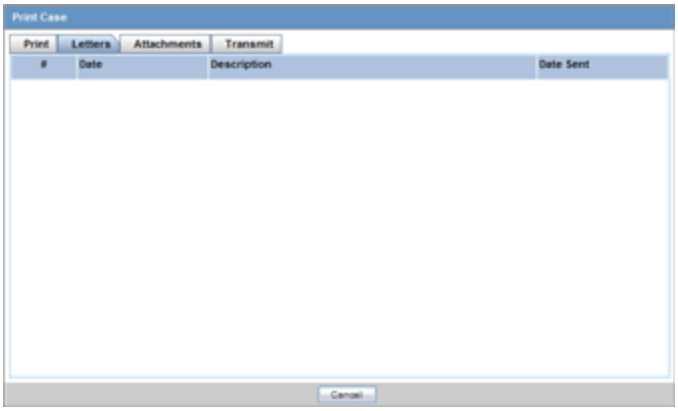
   Click **Select All** to select all the sections of the Case Form.

2. Click **Print** to print the case.

Note: If the printed cases do not appear to be formatted correctly, adjust your printer settings.

Viewing and Printing Letters

The **Letters** tab enables you to view and print completed letters.



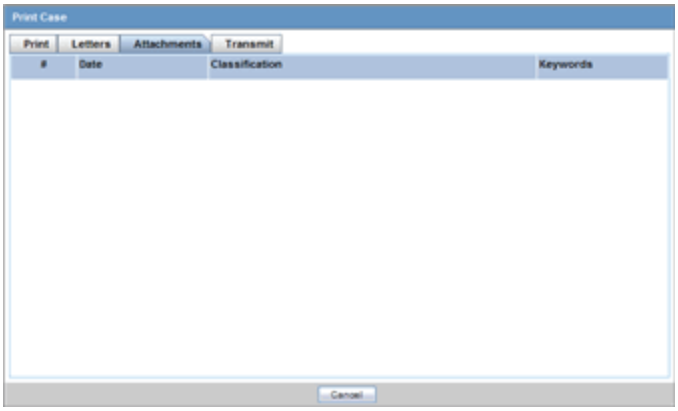
To view and print a letter

1. Click the **letter description link** to display the letter.
2. When the system opens the letter, click **Print** to print it.

Viewing and Printing Attachments

The **Attachments** tab enables you to view and/or print case attachments. The system prints date/time information:

- As footers on all printouts (except letters).
- In the following format: dd-mmm-yyyy hh24: mm: ss.

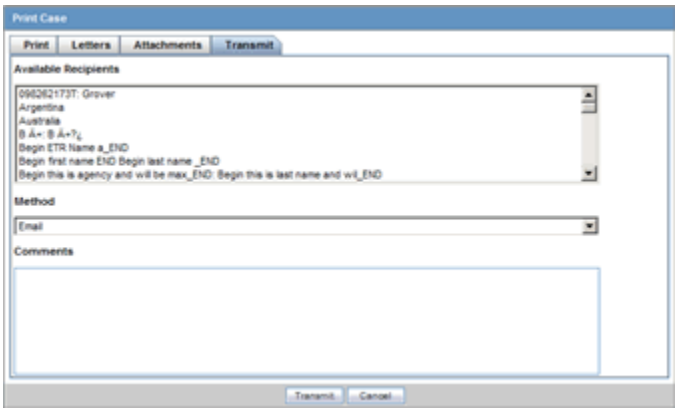


To print case attachments

1. Click the **attachment description link** to display the attachment.
2. When the system opens the letter, click **Print** to print it.

Transmitting a Case

The **Transmit** tab enables you to transmit a case electronically.

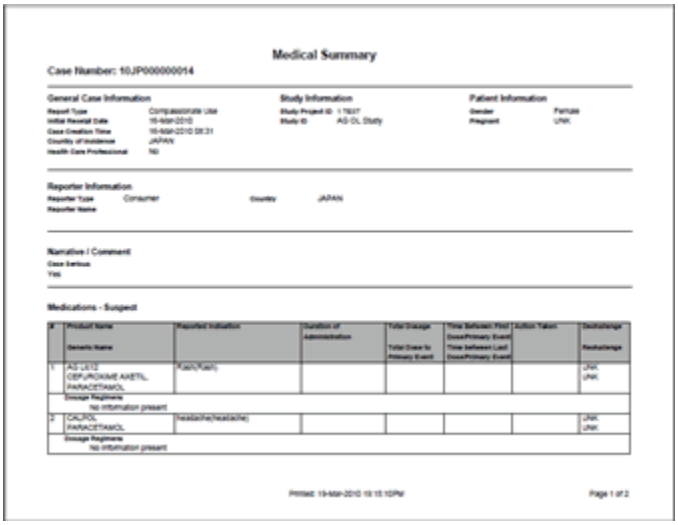


To transmit a case

1. Select the recipient from the **Available Recipients** list.
2. Select the transmission method from the **Method** list.
3. Enter any comments under **Comments**.
4. Click **Transmit**.

Printing a Medical Summary

The **Print Medical Summary** function enables you to print the medical summaries for a case. The following is an illustration of the Medical Summary Report.

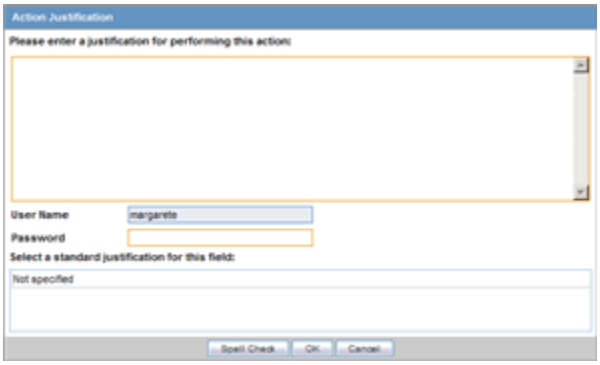


To print the Medical Summary

1. Open a case.
2. Select Case Actions --> Print --> Medical Summary.
3. The system opens the **Medical Summary Report**.
4. Select **File** - **Print** in the PDF to take a printout of the medical summary.

Deleting a Case

When you delete a case, you can no longer access it from the application. However, the system **does not** remove the case information from the database. Before the system permits you to delete a case, you must provide a justification. The following is an illustration of the delete justification dialog box.



To delete a case

1. Select Delete --> Case Actions.
2. When the system opens the **Action Justification** dialog box, do one of the following: Enter the justification manually in the Please enter a justification for performing this action field

   OR

   Select a pre-defined justification from the Select a standard justification field.
3. Type your Argus login password in the Password field.
4. Click **OK**.

Action Justification Dialog Box Fields and Field Descriptions

The following table lists and describes the fields in the **Action Justification** dialog box.

Field	Description
Please enter a justification for performing this action	Enter the text that justifies the need to delete a case.
Password	Enter your password
Select a standard justification for this field	Contains standard, pre-configured descriptions of justifications for deletion.
Spell Check	Checks the entered/selected text for any grammatical errors.
OK	Saves the justification entered/selected for case deletion.
Cancel	Exits out of this dialog without saving any justification.

Viewing Case Revisions

The **Case Revisions** feature enables you to view the Revisions made to cases. You can track the revision where follow-up information appended to the case. The follow-up designations are as follows:

- (S) F/U -- Indicates that significant follow- up information is attached to the case.

- (NS) F/U -- Indicates that the follow-up information attached to the case **is not** significant.

The following is an illustration of the Case Details dialog box.

To view case revisions

1. Open a case.
2. Select Case Actions --> Case Revisions.

   The system opens the **Argus Safety Case Details** dialog box. The dialog box provides the following information for the current case:

   - Scheduled Reports
   - Submitted Reports
   - Case Revisions

3. 4. Select the desired report from this list.
4. 5. The system displays the **Audit Log Details** screen containing a list of all revisions.

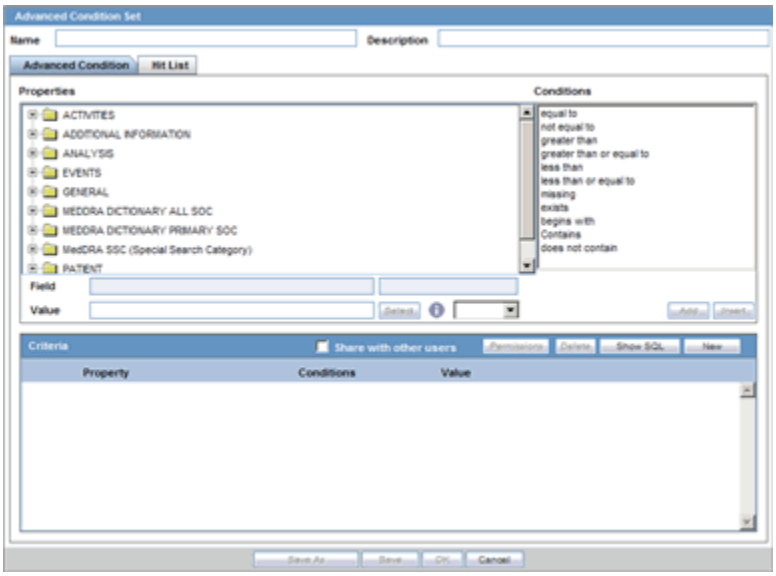
6

Advanced Conditions

Argus Safety provides a powerful search tool that enables you to build complex queries for retrieving system data. You can create complex or non-standard queries in the **Advanced Conditions** dialog box where you can define field-level search criteria. Detailed knowledge of the database schema is not required.

Advanced Conditions

Click the **Advanced Conditions** button to begin creating advanced conditions to open the Advanced Conditions dialog box.



From the **Advanced Condition** dialog box, you can save and retrieve sets of search criteria (advanced conditions) and add, edit, or delete them. Access rights and permissions can be assigned to individual advanced conditions. You can execute and modify rights to one or more groups on a per-advanced condition basis.

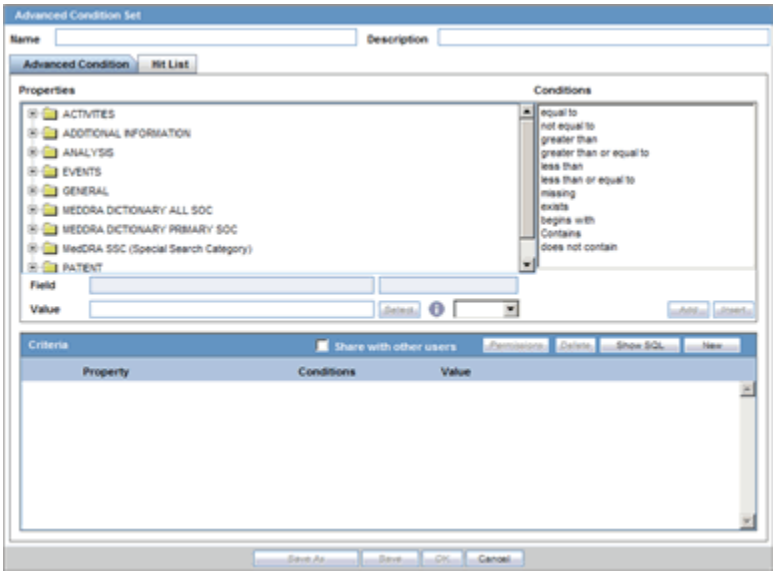
> **Note:** **Note:** Only users with execute rights for an advanced condition, can view the advanced condition in the drop-down list in the **Case Open** dialog.

When using Advanced Conditions, be aware of the following:

- By default, the **Advanced Conditions** drop-down list enables you to view only the **New**, **None**, and already selected Advanced Conditions.
- Select **New** or **None** from the drop-down list and click the AC button to create a new advanced condition.

About the Advanced Condition Screen

You can choose and rename a query set on the **Advanced Condition** screen. However, the rename function is restricted to users who have permission to modify the advanced condition. When you open an advanced condition or query set, the system places the current query name in the **Name** field. The following is an illustration of the **Advanced Condition** screen.



When using the **Advanced Condition** screen:

- You must click **Save** to record changes to the advanced condition name.
- The system disables the **Save** button until you enter an advanced condition name in the **Name** field.
- If you fail to enter a name before saving, the system displays the following message:

  Please enter the Advanced Condition name before saving. You have made changes to the existing item, if you press OK, changes made will be lost.

-
- When you click **Save**, the system saves the query set with the new name and description.
- When you click **Save**, the system refreshes the **Query Set** drop-down list.
- You can import a XLS, XLSX or TXT file with **one** column containing case numbers as shown in the following illustration.
- If you attempt to upload a file format other than XLS, XLSX, or TXT, the system displays the following message:

  Only XLS or Text Files are supported for Importing cases as a Hit List.

- When you upload a text file, each line in the file is considered a **complete** case number.
- When you click **Import**, the system enables you to browse to the file.
- If a case is missing (cannot be found), the system displays the following message:

  Case Number: XXXX is not found
- If a case has been deleted, the system displays the following message:

  Case Number: XXXX is deleted.
- If there are multiple missing or unfound cases, the system displays **all** of them in the message dialog box.
- If the same case has been entered multiple times; the system ignores it after it imports it.
- The system can import 1000 cases/60 seconds for the **Hit List**.
- After the system creates the **Hit List**, the user clicks **Store Hit List**. This system saves the advanced condition and stores the hit list so you can retrieve it for later use.
- When you click **Hit List**, the system displays the cases in the hit list, and all other data and options, on the **Case Open** screen for further processing
- When you click **Export** on the **Hit List**, the system exports the data in CSV format.

Filtering for Existing Advanced Conditions

Use the following procedure to filter for existing advanced conditions.

To filter for existing advanced conditions

1. Click in the **Case Search Criteria** section to open the **Advanced Conditions Lookup** dialog box.
2. Select one of the following options from the drop-down list under **Filter**
   - **Contains** - Enables you to filter for advanced conditions that contain the entered criteria.
   - **Starts With** - Enables you to filter for all advanced conditions that start with the entered criteria.
3. Enter the search criteria for the advanced conditions in the text box, as applicable.
4. Click **Filter** to display the advanced conditions matching the specified filtering criteria.
5. Select the appropriate advanced condition from the list.
6. Execute any of the actions below, as applicable:
   - Click **OK** to list the selected advanced condition in the **Advanced Conditions** drop-down list.
   - Click **AC** to display the details for the selected advanced condition in the **Advanced Conditions** dialog.
   - Click **Cancel** to close the **Advanced Condition Lookup** dialog without saving changes.
   - Select a previously selected advanced condition from the drop-down list to apply the search criteria for that condition.

Viewing Results from Existing Advanced Conditions

Use the following procedure to view the results of existing advanced conditions.

To view the results of an existing advanced condition.

1. Select an Advanced Condition from the **Advanced Conditions** drop-down list.
2. Click **Search**.
3. The system displays the cases matching the criteria specified in the selected Advanced Condition.
4. The system displays a list of matching cases is displayed in the **Total Number of Rows** section.

Working with Advanced Conditions

This section provides information about how to create and user Advanced Conditions.

Creating, Viewing or Modifying Advanced Conditions

Use the following procedure the create, view, or modify an advanced condition.

To create an advanced condition

1. Select **New** from the **Advanced Conditions** drop-down list

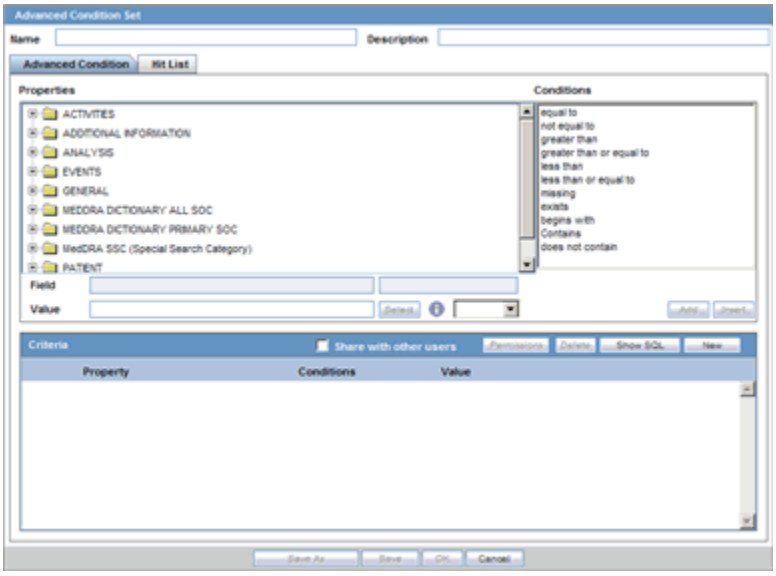
   OR

   Click the Advanced Conditions icon.
2. When the system opens the **Confirmation** dialog box:

   Click **Yes** to create a new advanced condition query set

   OR

   Click **No** to create a new advanced condition by associating logical operators (like AND, OR) with items from the Case Form.
3. If you select **No**, the system opens an **Advanced Condition Set** dialog box.



About the Advanced Condition Set Dialog Box

The Advanced Condition Set dialog enables you to search for those entities under the Properties tree-list, which are from either the case data or from the code list. The dialog box has two buttons that provide this functionality:

- From Code List -- If you select this option, the **Value** drop-down list displays a list of all values configured in the Code List
- From Case Data -- If you select this option, the **Value** drop-down list displays **only** the values actually in the cases.
- These radio buttons display **only** if the selected entity belongs to a code list. Select the relevant entity and one of the radio buttons, as applicable to search the entity based on the code list or case data, as specified.
- The Product name field can contain up to 70 characters for searching.
- In the Suspect Product Name, Product Name 2/Study Cases, Company Product, Study Drug, and Primary Suspect Drug sections, you select the product from the company product browser instead of the drop-down values by clicking the select button in the Read Only text field.
- When you click the select button, the system transfers the Product Name to the UI to enable you to search on the selected product.
- Select a property type from the **Properties** tree list.

Additional Information about Properties

The items available in the folders in the Properties list represent **Case Form** fields you can use to perform the search in the advanced conditions. Be aware of the following:

- You can auto-populate an Advanced Condition by right-clicking a field in the **Properties** section to enable a field-to-field comparison.
- When you select a Property for which terms can be encoded, the system enables the **Select** button. You can use the MedDRA Browser to select (possibly) multiple terms for the property. Refer to Using the MedDRA Browser for Advanced Conditions for further details.
- The system enables an SMQ icon when you select SMQ-related properties from the Properties tree-list. Click this icon to view the SMQ Info dialog. It contains details about the selected SMQ.
- In the **Conditions** list, select a condition that must apply to the item selected above.

  Available conditions are:

■ equal to	■ not equal to	■ missing
■ contains	■ greater than or equal to	■ does not contain
■ less than	■ less than or equal to	■ begins with
■ greater than	■ exists	

1. In the **Value** field, enter the value that applies to the property or select an appropriate value from the list.
2. If the created condition created is to be linked with another condition, select the appropriate logical operator from the list adjoining **Value**.
3. Click **Add** to add the newly created condition to the advanced condition.

Tip: You can use the AND and OR logical operators to link an existing condition to a new condition.

- If you are using the AND operator to link two conditions, both conditions must be TRUE for the advanced condition to be TRUE. In all other cases, the advanced condition evaluates to FALSE.
- If you are using the OR operator to link two conditions, the advanced condition is TRUE if either or both conditions are TRUE. The advanced condition evaluates to FALSE if both conditions are FALSE.

4. Repeat steps 3 through 8 to add more conditions to the advanced condition.
5. After entering each of the conditions required for the advanced condition, click **Save**.
6. Enter a name for the advanced condition and click **OK**.

Sharing Advanced Conditions

The system provides the option of share advanced conditions with other users. To enable other users to use the advanced condition, click the **Share with other users**.

When sharing advanced conditions with other users, be aware of the following:

- If an Advanced Condition is not shared with other users, the Advanced Condition does not appear in the Advanced Condition list for any user except the Administrator and the user who created it.
- If the Advanced Condition is shared, all users in the system can view the advanced condition, but **cannot** modify it.
- You **cannot** stop sharing an Advanced Condition, if the Advanced Condition is in use in the system.

Tip: To enter a customized Date Range:

1. Select **Custom Date Range** from the list.
2. Enter an appropriate date range in the custom date range dialog.
3. Click **OK**.

Using Advanced Conditions

You can use **Advanced Conditions** from the **Case Selection** dialog. Use the following procedure to do so.

To use advanced conditions

1. Select Case Actions --> Open.
2. Depending on how the criteria is to be used, you can do the following:
   - Use a set of previously saved criteria
   - Select the appropriate set of criteria from the **Advanced Condition** list.
   - Select the set of criteria from the **Advanced** list and click the adjoining Advanced Condition icon.
   - Add a new condition to a set of criteria
   - Create a new advanced condition by associating logical operators (like AND, OR) with items from the Case Form

Creating an Advanced Condition Query Set

Use the following procedure to create a Query Set of Advanced Conditions.

To create a Query Set of Advanced Conditions:

1. Select **New** from the **Advanced Conditions** drop-down list or click the Advanced Conditions icon.
2. A dialog that prompts for the creation of an advanced condition query set opens.
3. Click **Yes** to create a set of advanced conditions by linking together those advanced conditions that have been defined previously.
4. The **Advanced Condition Set** dialog appears. In this dialog, previously-created advanced conditions can be linked together using set operators like UNION, MINUS, and INTERSECT.
5. Click **Add** to add an advanced condition to the query set. A new row opens in the advanced condition selection area. In this row, select an appropriate advanced condition from the **Advanced Condition** list.

   Tip: To modify, open, or delete advanced conditions, click **Open** in the Advanced Conditions dialog. A list of all the advanced conditions will be displayed. In this list, select the appropriate advanced condition and click **Open** to open or modify it, or **Delete** to delete it.

   To view or modify the SQL statement associated with an advanced condition, click **Show SQL**. Make the required modifications to the SQL statement, if necessary.

6. Select an appropriate set operator from the **Set Operator** list. This set operator will link this advanced condition to the next advanced condition.
7. To add the next advanced condition to the query set, click **Add**.
8. Repeat steps 5 through 7 for each advanced condition that must be entered in the query set.

   Note: If the required advanced condition is not already present in the list, it can be created by selecting (New) from the list. If an existing advanced condition requires modification, select it and click Edit. The advanced condition can be edited by a user only if it was created by that user.

8. When each of the advanced conditions for the query set is entered, click **Save**.
9. Enter a name for the advanced condition and click **OK**.

   Note: To view or modify the SQL statement associated with an advanced condition, click Show SQL. Make the required modifications to the SQL statement, if necessary.

Renaming Query Sets You can rename a query set from the **Advanced Condition Set** screen. However, only users with the appropriate permissions can modify a query set. When the user opens an advanced condition or query set, the system places the current query name in the Name field. The following is an illustration of the

Advanced Condition Set screen.When renaming a query set, be aware of the following:

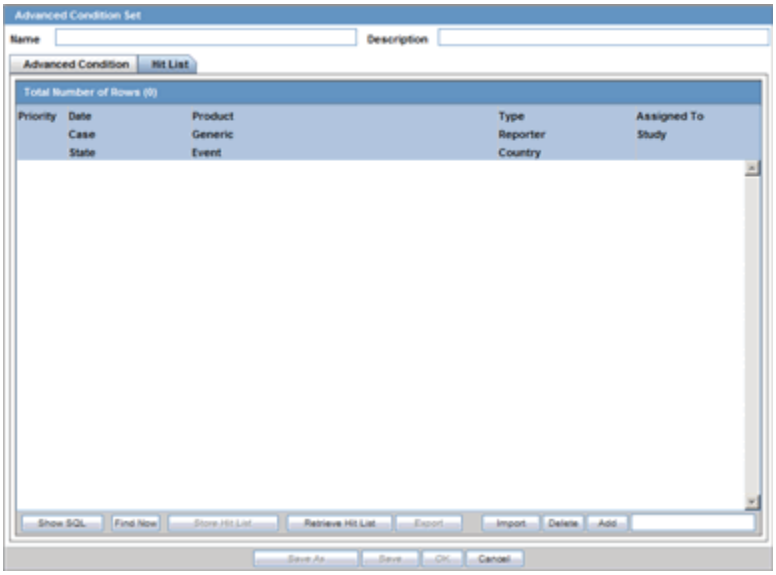
- Click **Save** to update the changes to the query set name.
- The system disables the **Save** button until you enter an advanced condition name in the **Name** field.
- When you click **Save**, the system saves the query set with the new name and description.
- When you click **Save**, the system refreshes the **Query Set** drop-down list.
- If you fail to enter a query set name before clicking **Save**, the system displays the following message:
- Please enter Advanced Condition Query Set Name before saving.
- If you rename the query set and attempt to close the **Advanced Condition Set** window without clicking **Save**, the system displays the following error message:
- You have made changes to the existing item. If you press OK, changes made will be lost.
- When you click **New**, the system clears all values from the **Name**, **Description**, and **Query Set** fields.

Using the Hit List Tab

The **Hit List** tab enables you to search for cases that match the query set criteria for the advanced condition.

To search for cases

1. Click **Find Now** in the **Hit List** tab of the Advanced Conditions dialog.
2. This system runs a search based on the selected query set criteria and displays a list of cases (if any) that satisfy the advanced condition query set.



The following table show the operations you can perform in the **Hit List** tab.

To...	Do the following
Manually add an existing case to the hit list	Click Add and enter the Case ID in the text box
Remove a case from the hit list	Click Delete
Save the hit list result for future use	Click Store Hit List
Retrieve results of the saved hit list	Click Retrieve Hit List
Save the hit list as a text file	Click Export
View SQL for Query	Click Show SQL
Run a Query	Click Find

7

Worklist

The worklist is an important part of the Argus Safety user interface. Therefore, the Administrator may have configured your user account so that the Worklist displays each time you log on to the system.

About Worklist

The worklist is an important part of the Argus Safety user interface. Therefore, the Administrator may have configured your user account so that the Worklist displays each time you log on to the system. Place the cursor over **Worklist** in the menu bar to view the available options.

General Usage Information

The worklist displays the following information:

- New cases created in the system
- Cases that are currently open
- **To Do** items like letters, reports, and other action items
- Transmission status of reports
- All bulk printed reports

When using the worklist, be aware of the following

- The **Worklist** dialogs have filtering options on **all elements** in each worklist as follows:
  - New/Open
  - Bulk Print
  - Reports
  - Action Items
  - Bulk Transmit
  - Bulk Transmit E2B Messages
  - Bulk Transmit E2B Reports
  - Coding Status
  - Coding Action Items
  - Contact/Letters

  - Letters
- You can filter on any element by clicking the **Filter** icon to display the filtering row.
- The system now provides a type ahead feature to enable you to filter on any text/date element.
- You can minimize the filtering options by clicking the **minimize** icon.
- The paper clip icon identifies the **maximize** icon.
- You can perform a *Like* search. In other words, if you search for "Cure," the system returns all elements starting with "Cure."
- You can perform a *wildcard* search. In other words, if you search for "Cure" the system returns all elements containing "Cure."
- The user can click the **Search** button to filter for reports in the reports list.
- These filtering options are available from worklist-specific views and when performing case or reports drill down searches from the **Dashboards**.
- The system saves **all** user preferences, including filtering options and filter views, for future use.
- The **Days Open** fields on the **WL | New and Open** have a drop-down list with values of <7, 7-15, >15, and the **Worklist Reports** has values of 7, 15
- The **Assigned To** filtering element has been removed from the **Worklist New** and **Open** dialogs in the **MAIN** filtering criteria
- All the worklist dialogs have a refresh icon beside the **View** option. This enables you to refresh worklist dialogs that use the preference saved in the worklist elements.
- All the worklist dialogs have a minimize button to minimize the filtering options. This increases the number of rows that display in the list.

Worklist Filtering

The Worklist Filtering options enable you to search for a specific case. The Filter contains editable fields that enable you to either select from a list of values or perform a Wild card search. This feature applies to all the Worklist Filters across all worklist items.

The Worklist filter in each Worklist entity contains the following filtering options:

- View Individual
- View Group and
- View All

The default filter is **Case Number**. This enables you to enter a Case Number to search for results matching a specified case number.

Worklist Options

The following worklist options are available to you.

- New and Open
- Action Items
- Coding Action Items

- Contacts
- Reports
- Bulk Transmit
- Bulk Print
- Coding Review
- Bulk Transmit E2B
- Local Labeling
- Coding Status
- Letters

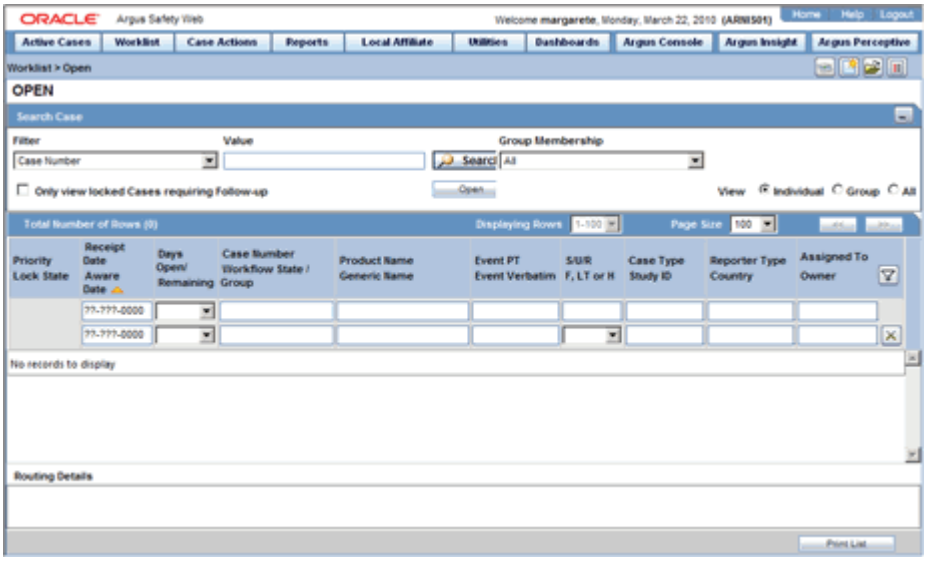
New and Open

This section discusses the features provided by the **Worklist - New** and **Open** menu items.

- When you select **New,** the system displays new worklist items that have been assigned but not yet accepted. You can also see unassigned cases.
- When you select **Open,** the system displays all cases that have been assigned and accepted.

To view the Worklist - New or Open page

1. Select Worklist --> New or Worklist --> Open
2. When the system opens the **Worklist - New** or **Worklist - Open** screen, enter



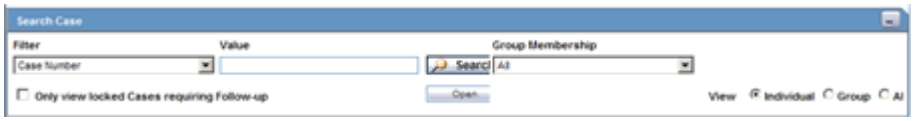
Tip: The same fields are displayed in the **Worklist - Open** screen also.

General Usage Information When using the **New/Open Worklist** screen, be aware of the following:

- The New/Open Worklist displays the Workflow Group and the Workflow State currently associated with the case.

- The Workflow Group is available in the Worklist New and Open printouts.
- You can sort on this field.
- The lock icon identifies cases that are locked.
- The Initial Date field has been renamed *Receipt Date* and enables you to view the date the case was first received. The new name displays on the UI and on the Printout.
- The system allows multiple assignments of cases for Workflow/Enterprise Managers **only** on the **Worklist New/Open** dialogs.
- The system displays the user name to enable you to select a User for reassignment.
- If the user has cases open, the system skips those cases.
- The system tracks updates in the audit log.
- When the user selects this option, the selected cases have the same user as modified by the user.

Search Case The following is an illustration of the **Search Case** section.



Field	Description
Filter	Performs searches for worklist items on the basis of the filtering criteria selected here.
Value	Enables the user to select the desired Value as the search criterion.
Search Button	Enables the user to open the selected or entered case ID.
Group Membership	Enables the user to select the type of Group Membership.
Case Owner	Enables the user to select the Case Owner.
Assigned To	Enables the user to select who the case has been assigned to.
Only view locked Cases requiring Follow-up	Select this checkbox to view only those locked cases that require follow-up.
View Individual	Enables the user to view individual items assigned to this group.
View Group	Allows the user to view all items assigned to this user group.
View All	Allows administrator and workflow manager to see all items in the system.

Filtering Functions The **Filter** function enables you to search for entities that are only in the worklist. The following is an illustration of the options available in the **Filter** drop-down list.

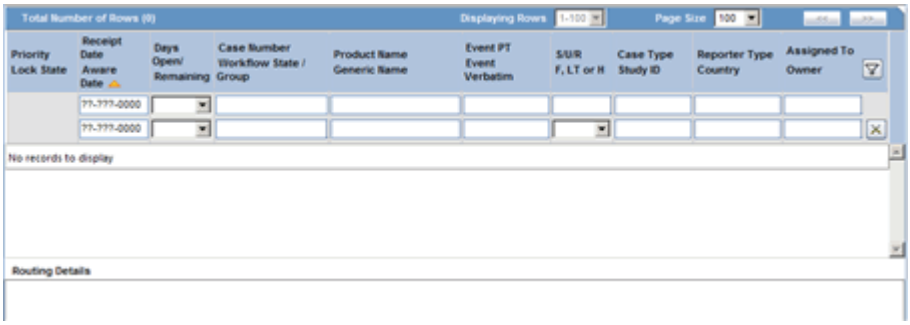
The following table describes the options available in the **Filter** drop-down list.

Option	Description
Case Number	Filters on Case Number.

Workflow State	Displays only those workflow states that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Product	Displays only those products that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Event Preferred Term	Displays only those Event PTs that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Event as Reported	Displays the name of the event as reported.
Case Report Type	Displays only those Report Types that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Product Group	Displays product groups where the Primary Suspect Drug occurs.

Note: The Assigned To option is not available if the user selects Individual radio button option from View.

Total Number of Rows The following is an illustration of the **Total Number of Rows** section



The following table describes the contents in the columns in the **Total Number of Rows** section.

Field	Description
Priority	Displays the Priority of the Case.

Field	Description
Lock Status	Enables the user to view the Locked state of the case by the icon. If the locked icon is present, it indicates that the case is locked and vice versa. **Note:** The lock icon is also displayed if the Case Status is **Initial** or **Follow up**. If the case is **Follow-up**, additionally, the Follow up number is also displayed. For example: Initial or F / U: 1. The icon (displayed in the lock state column) in the **Worklist - New**, **Open** and **Reports** screens denotes a SUSAR (Suspected Unexpected Serious Adverse Reaction) case. Lock State Header Options Click the **Lock State** header row. A pop-up appears listing the following sorting options: ■ Lock State ■ SUSAR ■ Exp/Per These options enable you to sort cases based on the case categorization.
Initial Date	Displays the Initial Receipt Date of the Case.
Aware Date	Displays the Aware Date of the case. **Note:** Aware date is the latest significant follow up which is received in the case or the Initial Receipt Date if there are no Significant follow ups present in the case.
Days Open	Displays the number of days that have elapsed since the Receipt Date.
Days Remaining	Displays the number of days that are remaining, as configured in the Administration module for Case Processing.
Case Number	Displays the Case Number. **Note:** Click the case number to open the case.
Workflow Status	Displays the current workflow status of the case.
Product Name	Displays the first suspect product in question.
Generic Name	Displays the generic name of the suspect product in question.
Event PT	Displays the Primary Event and Verbatim, as reported.
Event Verbatim	Displays the Event Verbatim, as reported, in the format Primary Event (Verbatim as Reported).
S/U/R	Displays the Case Level Assessments: ■ S denotes Serious (Y/N) ■ U denotes Unlisted (Y/N) ■ R denotes Causality (Y/N) Note: ■ Unknown is treated as a "?" ■ When the user clicks the SUR link, the Case Summary gets displayed.

Field	Description
F, LT or H	■ F denotes a Fatal (F) case ■ LT denotes Life Threatening (LT) ■ H denotes Hospitalized (H) Note: If any of the above are present together, then Fatal takes precedence followed by LT followed by H. If the case is neither of the above, **No** is displayed.
Case Type	Displays report type information.
Study ID	Displays the Study ID of the study cases. **Note:** If Study ID is not present, this field is blank.
Reporter Type	Displays the Reporter type for the Primary Reporter in the case. **Note:** If Reporter ID is not present, this field is blank.
Country	Displays the Country of the incident.
Assigned To	Displays the current owner or "Unassigned" user to the case.
Owner	Displays the Owner of the case. By default, the first user to accept a case after book-in becomes the "Case Owner". The Case Owner has the access right to assign the cases that he owns to another user. Though a Case Owner cannot be reassigned automatically after the initial assignment, he can be reassigned manually by a Workflow manager. **Note:** If Owner is not present, this field is blank.
Print List Button	Allows the user to print the current worklist for reference.

Note: You can open a case in read-only mode without creating a case lock. Use Open in Read-Only to open the case in read-only mode. You cannot save a case in a Read-Only mode.

The **Worklist>New** and **Worklist>Open** also display a status beside Priority, indicating that the time remaining has exceeded the allocated time.

Routing Details This section enables you to enter case routing details.

Workflow Options

The **Worklist** pages have some common options for your use. To see a list of these options, right-click the icon **Lock State** icon to display an option menu.

Worklist User Options

The following tables lists the different user options and where they are available

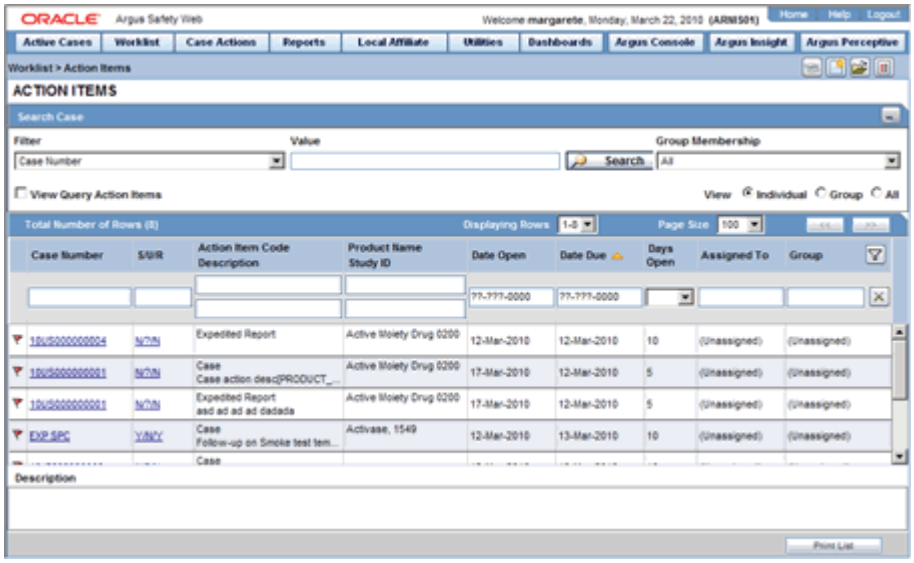
Option	Description	Option available under Worklist
Open Read Only	Opens the selected case in read-only mode.	New, Open

Option	Description	Option available under Worklist
Accept Case	Allows the user to accept the case and assign a user name as responsible for that case. A case marked with their name as responsible moves the case from the user's New tab to their Open tab.	New
Batch Accept	Allows the user to accept multiple cases at a time (up to 10 cases).	New
Un-Accept Case	Returns the case to the Open status.	Open
View Case	Opens the case.	Action Items
Batch Open	Allows the user to Batch open up to 5 Cases.	Action Items
Case Summary	Displays the Summary dialog to allow the user to view a summary of the case form data.	Action Items, Open, Reports
Adjust Priority	Allows the workflow manager to modify the priority level of the case.	New, Open
Adjust Assignment	Enables the Assigned User field for the selected row. Allows a workflow manager user to modify the assigned user.	New, Open, Reports
Adjust Case Owner	Enables the (re-)assignment of a Case Owner by a Workflow Manager.	New, Open
View Report	Allows user to open the report.	Reports
Accept Report	Allows the user to accept the unassigned report.	Reports
Approve Report	This option is enabled only if the report is in the **Generated** state. Select this option to automatically open the Routing tab of the Report Details pop-up window, with the Comment field active waiting for user input.	Reports
Local Labeling	Allows the user to open the local labeling for the case that the expedited report belongs to, showing all the non-assessed local labeling rows.	Reports
Mark for Non-Submission	Allows the user to mark the report required for Non-Submission. The report details dialog is displayed with focus to the Submission tab.	Reports
Mark Multiple for Non-Submission	Allows the user to also mark Multiple reports for Non-Submission. The notes and date entered are also reflected in all the reports.	Reports

Option	Description	Option available under Worklist
Close Action Item	Allows the user to close the highlighted action item. **Note**: Only the Owner of the action item can view this option, not all the users.	Action Items
Adjust Assignments	Allows the user to adjust assignments for multiple cases.	Open
Print Multiple Cases	Allows the user to print a case form from the New and Open worklist tabs.	New, Open
Archive Case	Allows a workflow manager to close a case from the worklist New and Open windows.	New, Open
Batch Archive	Allows a workflow manager to close multiple cases from the worklist New and Open windows.	New, Open
Medical Review	Allows the user to view the Medical Review dialog (if he has the access rights to view it).	New, Open, Reports
Medical Summary Report	Allows the user to view the Medical Summary Report (if he has the access rights to view it).	Reports
Coding Review	Allows the user to view the Coding Review dialog if the user belongs to a group with access rights to Coding Review (if he has the access rights to view it).	New, Open
Route Multiple Cases	Allows the user to route multiple cases to the selected workflow state.	New, Open

Worklist Action Items

This section discusses the features on the **Worklist - Action Items** page as shown in the following illustration:



To view the Worklist -- Action Items page

1. Select Action Items from Worklist.
2. When the system opens the Action Items screen, enter the information in the fields as necessary.

General Usage Information

The Worklist Action Items displays the entire description of the Action item selected in the Description field on the dialog. Be aware of the following:

- The system displays the Action Item Code with the Description of the Action Item.
- You can filter or sort the groups assigned to the **Action Items**.
- The **Product Name** and **Study ID** have been combined into a single column.
- The printout prints the new columns.
- **Worklist > Coding Action Items** displays the entire description of the action item selected in the **Description** field on the dialog.

Query Management

The system generates open **Query Action Items** based on the advanced conditions rules for the action item type.

- When the user saves the case or clicks the **Generate Query** icon on the **Quick Launch** toolbar, the system creates an open action item based on the profile switch.
- The assigned group is defined in the code list. If there is no defined group, the default group is **Unassigned**.
- The Due date for the action item is the System Date + the Due Date (in days) as defined in the code list.
- The Open Date is the system date on the day the Query is created for the case.

  When you click Generate Queries icon, the system generates the Action Item queries. These queries are based on the rules define for the Action Item types in Code List Maintenance where the Advance Condition satisfies the case criteria.

  This item displays on the Quick Launch Toolbar when the case it open.

Short cut key: CTRL+ALT+X

When you save or click **Generate Query**, the system evaluates **all open** query action types.

If, after the system schedules the action item query, unresolved queries are resolved or there are queries that do not meet the criteria of the Advance Conditions, the system closes the action item and uses the system date as the close date.

If there are open query action Items, the system **does not** create new action items with the same name when the system tries to resolve the open queries list in the case form.

Query Action Item Example

When querying action items, be aware of the following:

- The **Worklist | Action Items** enable you to query **only** query action items by clicking the **View Query Action Items** check box.
- By default, the system displays **all** types of action items to the user.
- The system allows all **open** query type action items to be populated in a **Letter** template by adding the following place holder **[OPEN_QUERY].** This populates the open queries letter template content as configured in the code list when the letter is being generated by the user in a separate line for each open query in the following format.

Attribute	Tool Tip	Example
Query Name	Name of Query to be included in the letter template.	QUERY_Preg_LMP (must begin with "QUERY_")
Query Condition	Advanced condition. If the condition is true, then insert text into the generated letter.	Patient is pregnant and date LMP missing (Advanced Condition)
Query Letter Text	Text to be inserted in generated letter if Query Condition is True. If Query Condition is no true, the no query item is created.	Please provide the Date of Last Menstrual Period (LMP) for the patient.
Query Item Text	Text to be display on the list of open queries	Patient missing Date of LMP.

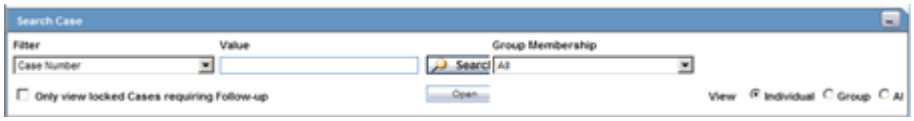
Example:

- Please provide Reporter Name (Adv. Cond is Reporter name is null)
- Please provide Physician's address (Adv. Cond is Reporter address is null)
- Please provide Physician's phone number (Adv. Cond is Reporter phone number is null)
- If the case is saved and the Reporter Name exists, the system creates two Action items.
- The following is an example of a generated letter:

Date: xx/xx/xx	Last F/U Date:
	Accession Number /Sequence Number
Jane Mary Doe 123 Patient Street Anytown, XX 99999	
Dear Jane Mary Doe, The staff of Anytown Medical Center has a continuing interest in its patients and would appreciate receiving the information requested below concerning your condition since you were treated here. We recommend that you have a physical examination annually for more often if warranted by you or your physician. [OPEN_QUERY] {This placeholder would fetch all the information of the letter placeholder content for the open queries which are present in the case. During letter generation, this tag will be removed and replaced with the data in green below} 1. Please provide Physician's address 2. Please provide Physician's phone number If you are unable to complete this questionnaire, it would be greatly appreciated if you could obtain the assistance of a friend or relative and supply as much information as possible. Any further comments you may wish to make may be written on the reverse side of this letter. A stamped, return-addressed envelope is enclosed for your convenience. Thank you for taking the time to respond to our patient information letter. We at Anytown Medical Center are genuinely interested in your health and look forward to hearing from you soon. Any questions may be directed to the Cancer Registry at (999) 555-9999.	
Sincerely yours, John Doe, M.D. Chair, Cancer Program	

Search Case

The following is an illustration of the **Search Case** section.



The following table lists and describes the fields and controls in the section.

Field	Description
Filter	Performs searches for worklist items on the basis of the filtering criteria selected here
Value	Enables the user to select the Value as the search criterion
Search Button	Enables the user to open the selected or entered case ID.
View Individual	Enables the user to view individual items assigned to this user.
View Group	Enables the user to view all items assigned to this user group.
View All	Enables administrator and workflow manager to see all items in the system.

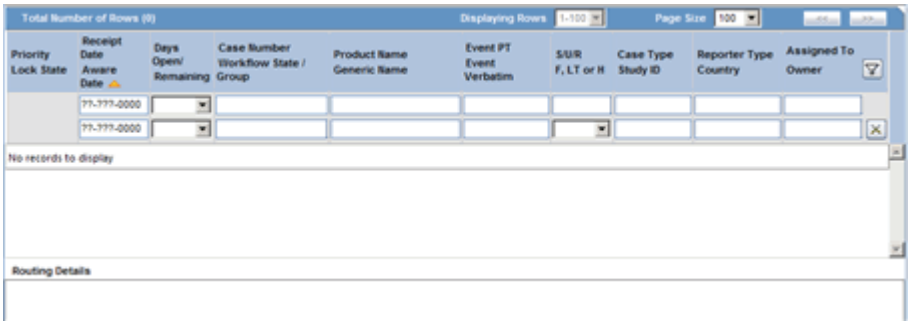
Filter Function

The **Filter** function enables you to search for entities in the worklist. The following tables describes the options available in the **Filter** drop-down list.

Option	Description
Case Number	Displays the Case Number
Workflow State	Displays only those workflow states that occur in the given work, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Product	Displays only those products that occur in the given work, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Event Preferred Term	Displays only those Event PTs that occur in the given work, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Event as Reported	Displays the Event as Reported
Case Report Type	Displays only those Report Types that occur in the given work, considering other filter elements such as **Case Owner**, **Assigned to**, etc.

Note: The Assigned To option is not available if you select the Individual radio button option from View.

Total Number of Rows The following is an illustration of the **Total Number of Rows** section.



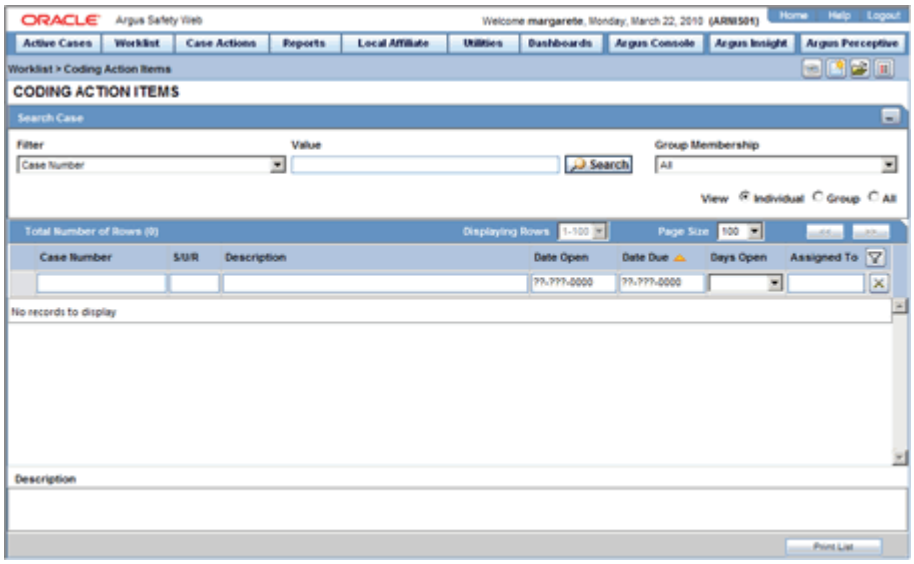
The following table describes the contents of each column in the **Total Number of Rows** section.

Column	Description
Case Number	Displays the Case Number. **Note:** Click the case number to open the case.
S/U/R	Displays the Case Level Assessments: ▪ S denotes Serious (Y/N) ▪ U denotes Unlisted (Y/N) ▪ R denotes Causality (Y/N) Note: Unknown is treated as a "?". When the user clicks the SUR link, the Case Summary is displayed.
Description	Displays the description of the Action Item in question.
Date Open	Displays the date the action item was opened.
Date Due	Displays the due date.

Column	Description
Days Open	Displays the number of days for which the action item has been open.
Assigned To	Displays the current owner or "Unassigned" user for the case
Print List Button	Allows the user to print the current worklist for reference.

Coding Action Items

This section discusses the features provided on the **Worklist - Coding Action Items** page.

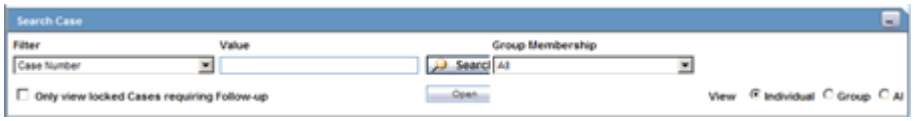


To view the Worklist - Coding Action Items page

1. Select Worklist --> Coding Action Items.
2. When the system opens the Coding Action Items page, enter the information in the fields as necessary.

Search Case

The following is an illustration of the **Search Case** section.



The following table lists and describes the fields in the **Search Case** section.

Field	Description
Filter	Performs searches for worklist items on the basis of the filtering criteria selected here
Value	Enables the user to select a value as a search criteria
Assigned To	Enables the user to search on the basis of who the case has been assigned to

Field	Description
View Individual	Enables the user to view only individual items assigned to this user group.
View Group	Enables the user to view all items assigned to this user group.
View All	Enables administrator and workflow manager to see all items in the system.

Filter Functions

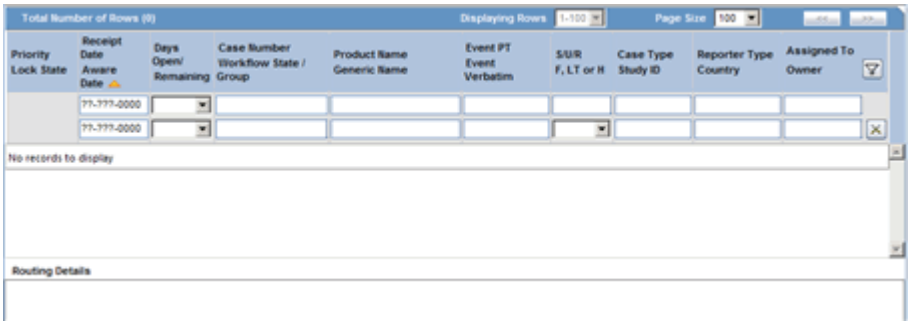
The **Filter** functionality performs searches on entities present in the worklist only. The following table lists and describes the options available in the **Filter** drop-down list.

Option	Description
All	Does not filter on any cases in the work list, excluding other filter elements that are specified, e.g. Case owner, etc.
Case Number	Displays the Case Number
Workflow State	Displays only those workflow states that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Product	Displays only those products that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Event Preferred Term	Displays only those Event PTs that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Event as Reported	Displays the name of the event as reported
Case Report Type	Displays only those Report Types that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.

Note: The Assigned To option is not available if the user selects Individual radio button option from View.

Total Number of Rows

The following is an illustration of the **Total Number of Rows** section.



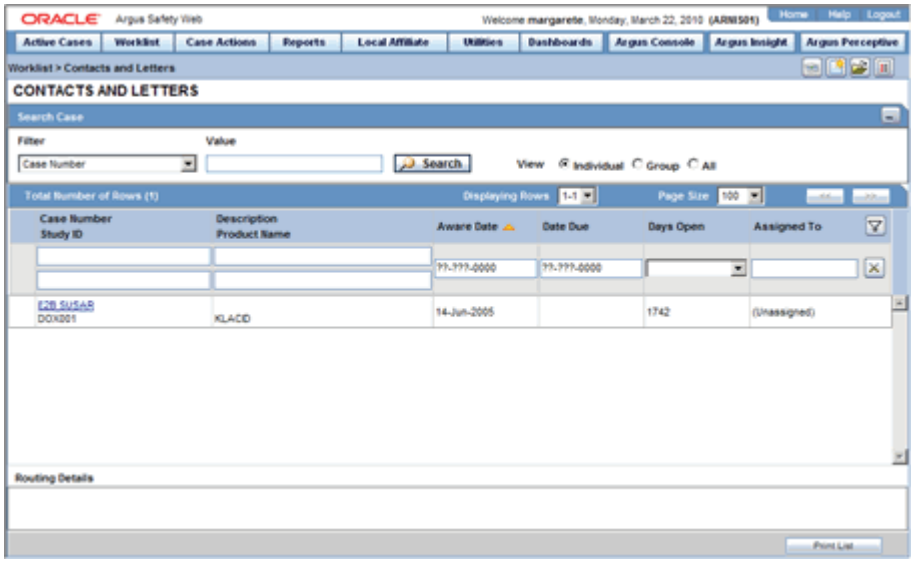
The following table describes the headers within **Total Number of Rows**:

Field	Description
Case Number	Displays the Case Number. **Note:** Click the case number to open the case.

Field	Description
S/U/R	Displays the Case Level Assessments: ▪ S denotes Serious (Y/N) ▪ U denotes Unlisted (Y/N) ▪ R denotes Causality (Y/N) Note: ▪ Unknown is treated as a "?" ▪ When the user clicks the SUR link, the Case Summary gets displayed.
Description	Displays the description of the Action Item in question.
Date Open	Displays the date the action item was opened.
Date Due	Displays the due date.
Days Open	Displays the number of days for which the action item has been open.
Assigned To	Displays the current owner or "Unassigned" user to the case
Print List Button	Allows the user to print the current worklist for reference.

Contacts

This section discusses the features provided on the **Worklist - Contacts** page.

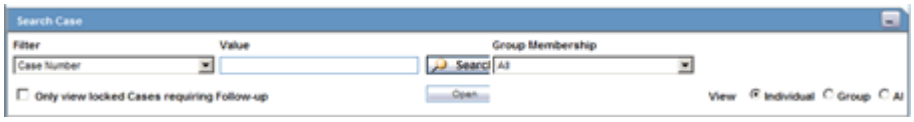


To view the Worklist -- Contacts page

1. Select Worklist --> Contacts.
2. When the system opens the **Worklist - Contacts** screen, enter the information in the fields as necessary.

Search Case

The following is an illustration of the **Search Case** section of the **Worklist -- Contacts** screen.



The following table lists and describes the fields in the **Search Case** section.

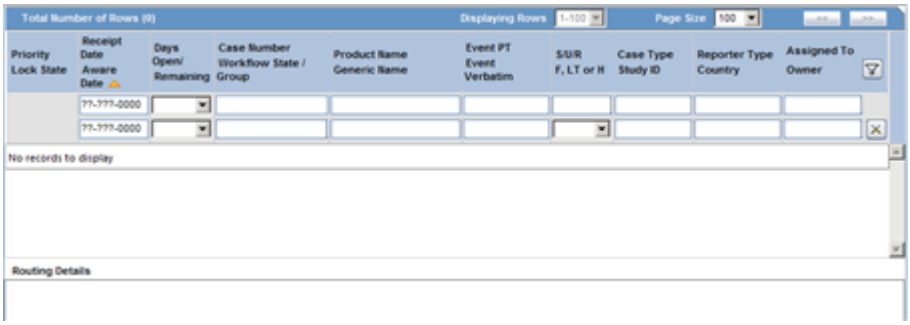
Field	Description
Filter	Performs searches for worklist items on the basis of the filtering criteria selected here
Value	Enables the user to select the Value as the search criterion
Select Button	Enables the user to open the selected or entered case ID.
Assigned To	Enables the user to select the user to whom the case has been assigned.
View Individual	Enables the user to view individual items assigned to this user group.
View Group	Enables the user to view all items assigned to this user group.
View All	Enables the administrator and workflow manager to see all items in the system.

Filter Functions The **Filter** function enables you to search for entities in the worklist. The following table below describes the options available in the **Filter** drop-down list.

Option	Description
Case Number	Displays the case number.

Note: The Assigned To option is not available if the user selects Individual radio button option from View.

Total Number of Rows The following is an illustration of the **Total Number of Rows** section



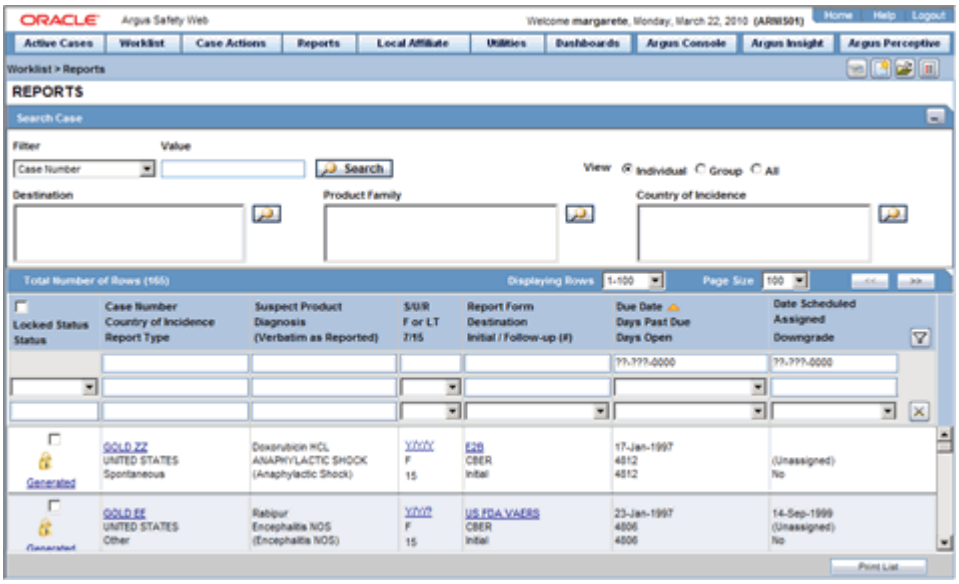
The following table describes the columns in **Total Number of Rows**:

Field	Description
Case Number	Displays the Case Number. **Note:** Click the case number to open the case.
Study ID	Allows the user to view the Study ID present in the case.

Field	Description
Description	Displays the description of the Action Item in question.
Product Name	Allows the user to view the Product Name of the Primary Suspect Drug.
Aware Date	Displays the Aware Date of the Case. Aware date is the latest significant follow up which is received in the case or the Initial Receipt Date if there are no Significant follow ups present in the case.
Date Due	Displays the due date.
Days Open	Displays the number of days for which the action item has been open.
Assigned To	Displays the current owner or "Unassigned" user to the case.
Print List Button	Allows the user to print the current worklist for reference.

Reports

This section discusses the features available from **Worklist - Reports** page.



To view the Worklist Reports page

1. Select Worklist --> Reports.
2. When the system opens the Worklist - Reports screen, enter the appropriate information as necessary.

Search Case

The following is an illustration of the **Search Case** section of the page.

The following table lists and describes the fields in the **Search Case** section.

Field	Description
Filter	Performs searches for worklist items on the basis of the filtering criteria selected here.
Value	Enables the user to select the Value as the search criteria.
Search Button	Enables the user to open the selected or entered case ID.
Assigned To	Enables the user to select the person to whom the case is assigned.
View Individual	Enables the administrator and workflow manager to see individual items in the system.
View Group	Enables the user to view all items assigned to this user group.
View All	Enables the administrator and workflow manager to see all items in the system.

Filter Function

The **Filter** function enables you to search for entities in the worklist. The following tables describes the options available from the **Filter** drop-down list.

Option	Description
Case Number	Displays the Case Number.
Reporting Destination	Displays the report destination (agency) for which the report is scheduled.
Product	Displays only those products that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Event Preferred Term	Displays only those Event PTs that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Report Status	Displays the status of the report as **Approved**, **Generated** or **Scheduled**.
Case Report Type	Displays only those Report Types that occur in the given worklist, considering other filter elements such as **Case Owner**, **Assigned to**, etc.
Report Form	Displays the description of the report.
Due Date	Enter a due date.

Note: The **Assigned To** option is not available if the user selects **Individual** radio button option from **View**.

General Usage Information When using filtering, be aware of the following:

- The filter options have a **Study ID** element that enables the user to filter cases within the list (not deleted).
- This option is a type ahead that enables users to enter values for studies defined in the configuration.
- The type ahead feature limits the users to 25 items in the drop-down list.
- When the user selects type ahead values, the system performs a *like* search.
- The filter options have a **Reporting Group** element that enables the user to filter cases in the list.

- This option is a type ahead that enables users to enter values for **Reporting Groups** defined for the reports in the worklist.
- The type ahead limits the users to 25 items in the drop-down list.
- When the user selects type ahead values, the system performs a *like* search.
- The filtering elements have the **Product and Reporting** destinations removed from the list.
- The user can mark multiple reports for approval by selecting the *Mark Multiple for Approval* option.
- The user can view the **Medical Summary** report for **all** users who have permission to print the Medical Summary report.
- The system displays the **Report Details** dialog and permits the user to enter the approval notes that are applied to all selected reports. The system skips any reports selected by the user that have the following statuses:
  - Scheduled
  - Disapproved
  - Approved
- The system hides the reports fields from the report details dialog and **does not** permit the user to access or modify any other tabs.
- The system hides the **Route** button to prevent users from modifying the **Report Status**.
- **Workflow Enterprise** users can access **View** and can modify the report details for **all** reports for **all** cases across multiple sites in their lists.

Filtering Reports by Report Destination When filtering by report destination, be aware of the following:

- You can click the magnifying glass icon to filter reports by report destination. The system displays the standard lookup dialog.
- The **Report Destination** filter multi-selection screen list contains the names of all agencies as configured in the **Argus Regulatory Authority CodeList**.
- The system displays only the report rows that match the authority/agency you selected.

Filtering Reports by Product Family When filtering reports by product family, be aware of the following:

- You can click the magnifying glass icon to filter reports by product family. The system displays the standard lookup dialog.
- The **Product Family** filter multi-selection screen contains a list of all product family names as configured in the **Argus Products Code List**.
- The system displays only the report rows that match the product you selected.

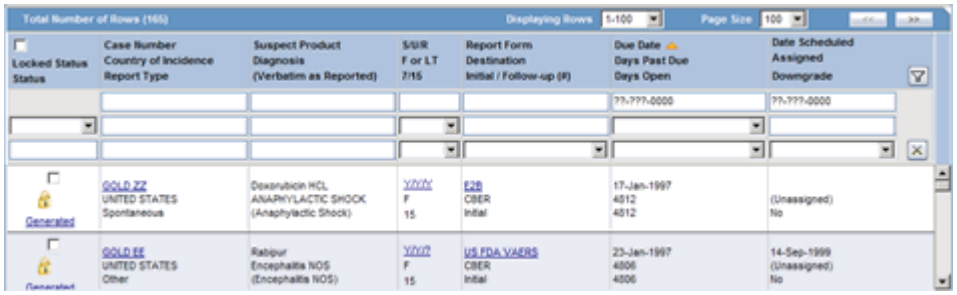
Filtering Reports by Country of Incidence When filtering reports by country of incidence, be aware of the following:

- You can click the magnifying glass icon to filter reports by country of Incidence. The system displays the standard lookup dialog.

- The **Country of Incidence** filter multi-selection screen contains a list of all available countries.
- The system displays only the report rows that match the country of incidence you selected.

Total Number of Rows

The following is an illustration of the **Total Number of Rows** section.



The following table lists and describes the columns in the **Total Number of Rows** section.

Field	Description
Selected	Allows the user to select the report.
Lock State	Allows the user to view the Locked state of the case by the icon. If the locked icon is present, it indicates that the case is locked and vice versa. **Note:** The lock icon is also displayed if the Case Status is **Initial** or **Follow up**. If the case is **Follow-up**, additionally, the Follow up number is also displayed. E.g. Initial or F / U: 1. The icon displayed in the lock state column, in the **Worklist - New**, **Open** and **Reports** screens denotes a SUSAR (Suspected Unexpected Serious Adverse Reaction) case. Lock State Header Options Click the **Lock State** header row. A pop-up appears listing the following sorting options: ■ Lock State ■ SUSAR ■ Exp/Per These options enable you to sort cases based on the case categorization.
Status	Displays the report status. Click the link displaying the report status to view the Report Details. Refer to the About the Report Details Dialog Box section for descriptions of each tab.
Case Number	Displays the Case Number. **Note:** Click the case number to open the case.
Country of Incidence	Displays the Country of incidence.
Report Type	Displays the Case Report Type.

Field	Description
Suspect Product	Displays the Trade name for which the report has been scheduled. A "+" displayed at the end of a Product Name indicates that more than one Suspect Company Products exist. A Device Name is also displayed for those Reports which were scheduled for the Device.
Diagnosis	Displays the Primary Event Diagnoses PT
Event Verbatim	Displays the event verbatim (verbatim as reported) of the Primary Event.
S/U/R	Displays the Case Level Assessments: ■ S indicates Serious (Y/N) ■ U indicates Unlisted (Y/N) ■ R indicates Causality (Y/N) Note: Unknown is treated as a "?". When the user clicks the SUR link, the Case Summary gets displayed.
F or LT	Indicates whether a case is fatal or life threatening as follows: ■ F identifies a Fatal (F) case ■ LT identifies a Life Threatening (LT) Note: If any of the above are present together, then Fatal takes precedence followed by LT. If the case is neither of the above, **No** is displayed.
7/15	Displays 7 if the report is due within 7 days Displays 15 if the report is due in more than 7 days
Report Form	Displays the description of the report. Click the link to view the DRAFT Report PDF.
Destination	Displays the report destination (agency) for which the report is scheduled.
Initial / Follow-up (#)	Displays if the report is Initial or Follow-up. If it is a Follow-up, the follow-up number is printed.
Due Date	Displays the date the report is due.
Days Past Due	Displays the number of days the report is past due date.
Days Open	Displays the number of days since the report has been open.
Date Scheduled	Displays the Scheduled Date of the report.
Assigned	Displays the name of the individual to whom the case has been assigned.
Downgrade	Displays Yes if the report is a downgrade report.
Print List Button	Allows the user to print the current worklist for reference.

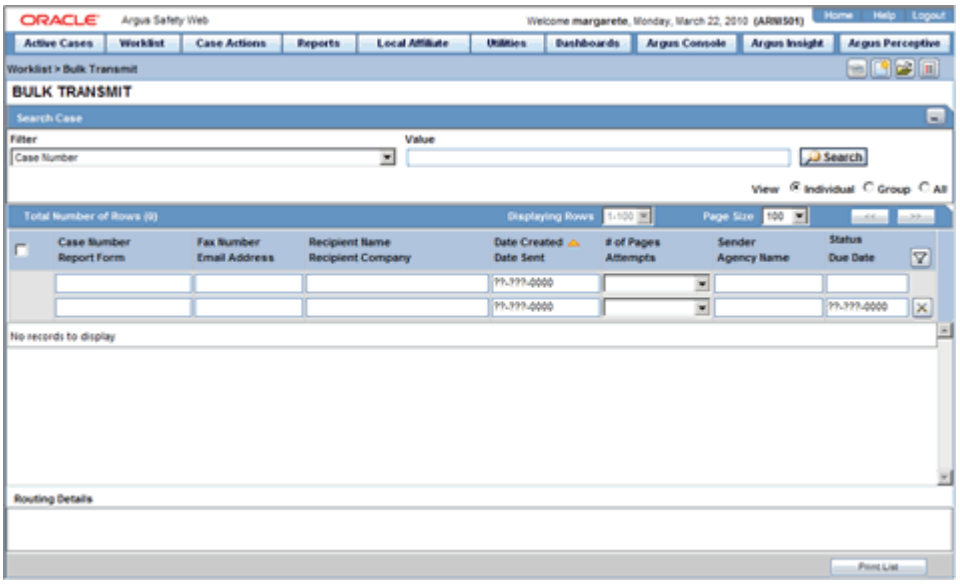
The following table lists and describes the options available under **Lock State**.

Option	Description
View Report	Enables the user to view the report as a PDF.
Report Details	Enables the user to view the report details.
Accept Report	Enables the user to accept the report.
Approve Report	Enables the user to approve the report.

Option	Description
Adjust Assignment	Enables the user to adjust assignment for the selected report.
Medical Review	Enables the user to view the Medical Review of the case.
Print Medical Summary	Enables the user to print the medical summary of the case.
Case Summary	Enables the user to view the case summary of the case.
Local Labeling	Enables the user to view the local labeling dialog. ▪ This option is available only if the user has access to Local Labeling within the groups to which the user belongs to. ▪ The Local Labeling can also be viewed by clicking the local labeling icon that is displayed next to S/U/R.
Mark for Non-Submission	Enables the user to mark the report for non-submission.
Mark for Submission	Enables the user to mark the report for submission.
View Multiple Reports	Enables the user to view multiple reports as a PDF.
Mark Multiple for Non-Submission	Enables the user to mark multiple reports for non-submission.
Mark Multiple for Submission	Enables the user to mark multiple reports for submission.

Bulk Transmit

The **Bulk Transmit** function lists the status for all transmission events against your assigned cases.



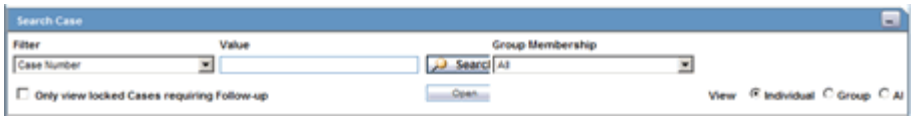
To view the Bulk Transmit page

1. Select Worklist --> Bulk Transmit.
2. When the system opens the Bulk Transmit screen, enter the appropriate information as necessary.

General Usage Information

Search Case Section

The following is an illustration of the **Search Case** section.



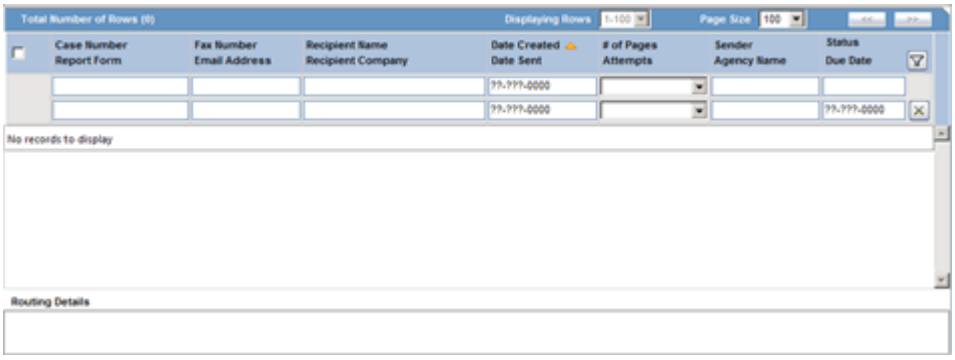
The following tables lists and describes the fields and controls in the **Search Case** section.

Field	Description
Filter	Performs searches for worklist items on the basis of the filtering criteria selected here
Value	Enables the user to select the Value as the search criterion
Search Button	Enables the user to open the selected or entered case ID.
View Individual	Enable users to view individual items assigned to this user group
View Group	Enable the user to view all items assigned to this user group.
View All	Enable administrator and workflow manager to see all items in the system.

Filter Function The **Filter** function enables you to search for entities in the worklist. The following table describes the options available from the **Filter** drop-down list.

Option	Description
Case Number	Displays the case number
Reporting Destination	Displays the report destination (agency) for which the report is scheduled.
Report Form	Displays the report form
Report Status	Displays the report status

Total Number of Rows The following is an illustration of the **Total Number of Rows** section.



The following table below describes the columns in **Total Number of Rows** section

Field	Description
Case Number	Displays the Case Number. Click the Case Number to view the case details.
Report Form	Displays the Description of the report Click the link to view the DRAFT Report PDF.
Fax Number	Displays the fax number of the report recipient
Recipient Name	Displays the name of the report recipient
Recipient Company	Displays the name of the company of the report recipient
Date Created	Displays the date on which the report was created.
Date Sent	Displays the date on which the report was transmitted to the recipient.
# of Pages	Displays the number of pages in the report
Attempts	Displays the number of attempts made to transmit the report. If you are using Right Fax, the value of this field is displayed as 0 even if the Right Fax had attempted it multiple times. This is an unsupported feature in Right Fax.
Sender	Displays the name of the sender of the report
Sender Agency Name	Displays the name of the agency that has generated the report
Status	Displays the Report Status e.g. Scheduled or Generated etc. Click the Report Status to view the Report Details. Refer to the About the Report Details Dialog Box section for descriptions of each tab.
Print List Button	Allows the user to print the current worklist for reference.

User Options The following table describes the user options.

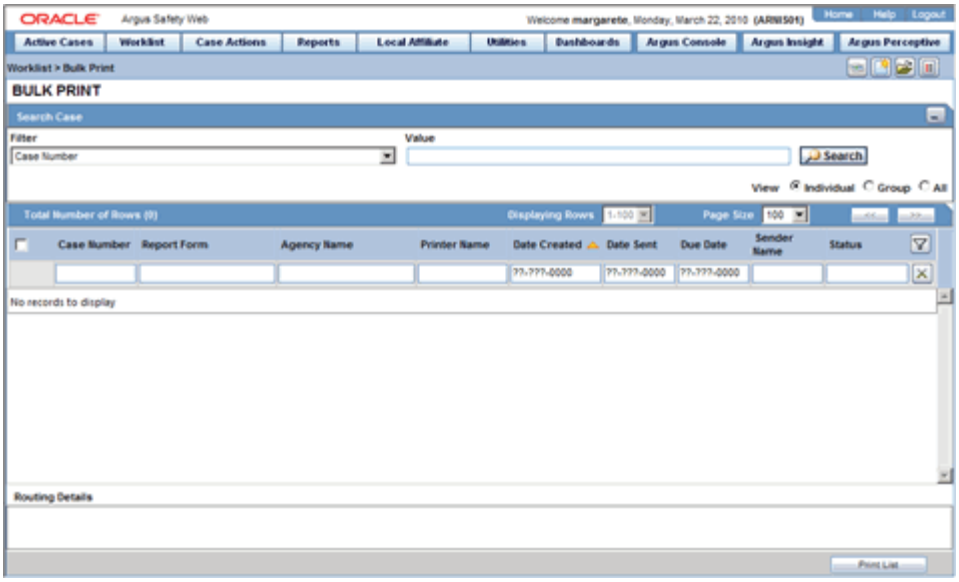
Option	Description
View Transmission	Displays the report in a PDF format.
Mark report as Submitted	Marks the report for the selected row as submitted. **Note:** This option is displayed to only those users who have the access rights to mark a report as submitted.
Remove transmission	Removes the transmission log entry from the list. **Note:** A report whose status is pending cannot be transmitted.
Re-transmit	This option is displayed if the selected row has a status of failure or success. Select this option to change the status back to pending and the re-fax the report.
Submit Multiple Reports	Multiple reports that are selected from the list can be marked as submitted simultaneously.
Re-transmit Multiple	The status of multiple reports that are selected from the list can be changed to "pending," and those reports can be re-transmitted.
Remove Multiple Transmissions	Transmission of multiple reports that are selected from the list can be removed.

Routing Details The following is an illustration of the **Routing Details** section. Enter routing details in this text box.

Note: Reports that appear in the Bulk Transmission section or the Bulk Print section do not display in the Reports section of the Worklist.

Bulk Print

The **Bulk Print** function displays a separate list for all Bulk Print events against reports.



To view the Bulk Print page

1. Select Worklist --> Bulk Print
2. When the system opens the **Bulk Print** page, enter the appropriate information.

General Usage Information

Search Case Section

The following is and illustration of the **Search Case** section.

The following table lists and describes the fields and controls in the **Search Case** section.

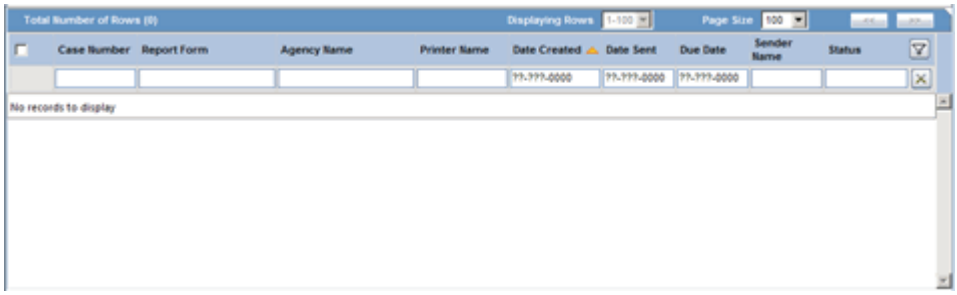
Field	Description
Filter	Performs searches for worklist items on the basis of the filtering criteria selected here.

Value	Enables the user to select the Value as the search criterion.
Search Button	Enables the user to search.
View Individual	Enables the user to view individual items assigned to this user group.
View Group	Allows the user to view all items assigned to this user group.
View All	Allows administrator and workflow manager to see all items in the system.

Filter Function The **Filter** function enables you to search for entities in the worklist. The following table below describes the options available from the **Filter** drop-down list.

Option	Description
Case Number	Displays the case number
Reporting Destination	Displays the report destination (agency) for which the report is scheduled.
Report Form	Displays the report form
Report Status	Displays the report status

Total Number of Rows Section The following is an illustration of the **Total Number of Rows** section.



The following table below describes the columns in **Total Number of Rows**:

Field	Description
Case Number	Displays the Case Number. Click the Case Number to view the case details.
Report Form	Displays the Description of the report Click the link to view the DRAFT Report PDF.
Agency Name	Displays the name of the agency that has generated the report
Printer Name	Displays the name of the printer.
Date Created	Displays the date on which the report was created.
Date Sent	Displays the date on which the report was transmitted to the recipient.
Sender	Displays the name of the sender of the report
Report Status	Displays the Report Status Click the Report Status to view the Report Details.

Field	Description
Print List Button	Allows the user to print the current worklist for reference.

Bulk Print User Options Click the icon associated with each report to view available user options. The following table describes the **Bulk Print** user options.

Option	Description
View Report	Displays the report in a PDF format.
Mark report as Submitted	Marks the report for the selected row as submitted. **Note:** This option is displayed to only those users who have the access rights to mark a report as submitted.
Remove Print Job	Removes the print job entry from the list. **Note:** A report whose status is pending cannot be printed.
Re-print	This option is displayed if the selected row has a status of failure or success. Select this option to change the status back to pending and the re-print the report.
Submit Multiple Reports	Multiple reports that are selected from the list can be marked as submitted simultaneously.
Re-print Multiple	The status of multiple reports that are selected from the list can be changed to "pending," and those reports can be re-transmitted.
Remove Multiple Print Jobs	Print jobs of multiple reports that are selected from the list can be removed.

Routing Details Section The following is an illustration of the **Routing Details** section. Enter routing details in this text box.

Note: The reports appearing in the Bulk Transmission section or the Bulk Print section are not displayed in the Reports section of the Worklist.

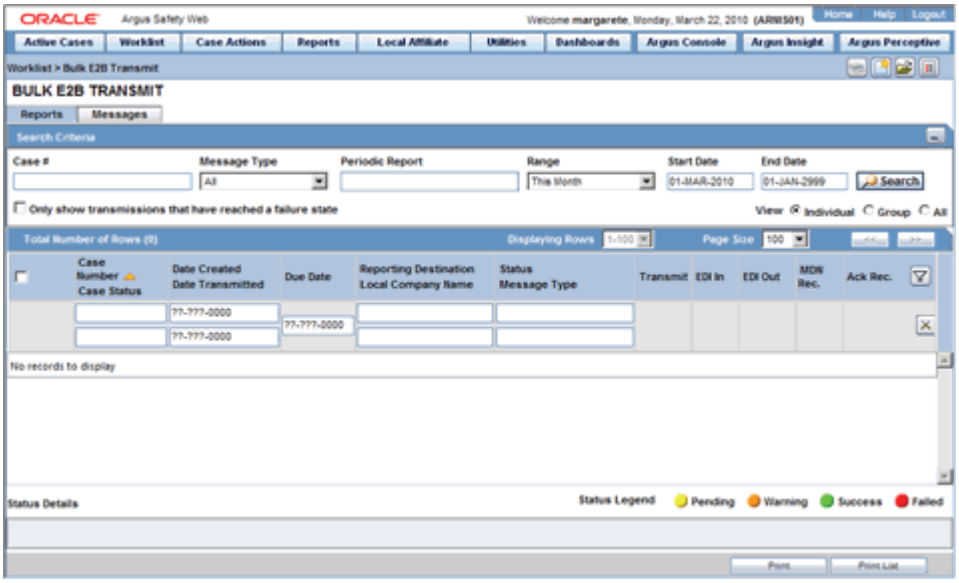
Bulk E2B Transmit

The **Bulk E2B Transmit** function displays only those E2B Reports that are awaiting submission (not in submitted state) when transmitted from "Bulk Report By Form" to the Trading partner.

This menu option is not displayed if Interchange is not licensed or if you do not have access to open worklist screens based on existing File Menu Access rights in the Group Configuration.

The **Bulk E2B Transmit** page has two (2) tabs as follows:

- Reports -- Displays the status of individual E2B Reports that are in the process of being transmitted.
- Messages -- Displays the status of ESM Messages which may contain multiple reports.

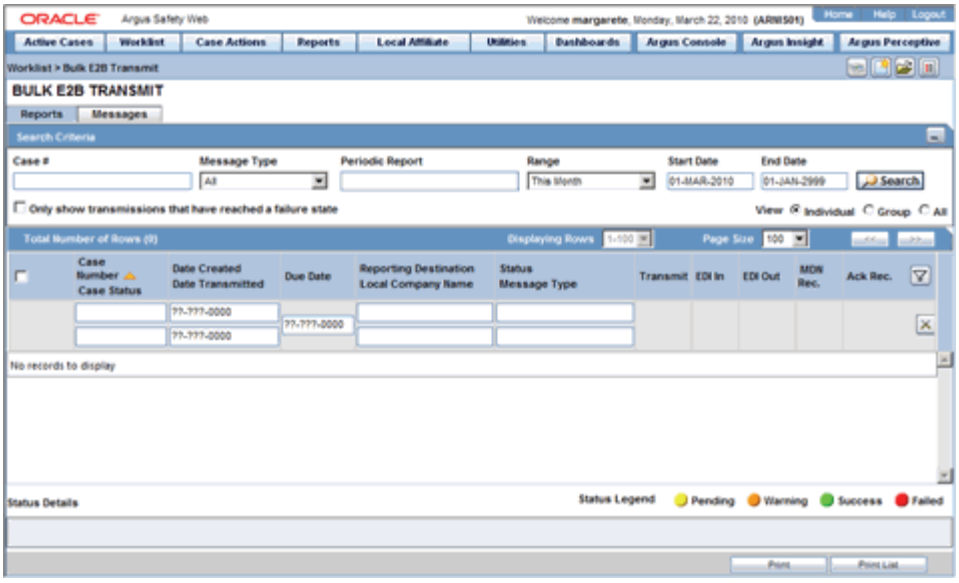


To view the Bulk E2B Transmit page

1. Select Worklist --> Bulk E2B Transmit.
2. When the system opens **Bulk E2B Transmit** page, entered the appropriate information as necessary.

General Usage Information

Reports Tab The following is an illustration of the **Reports** tab.



Click the following links for information about the sections and user option on the **Reports** tab.

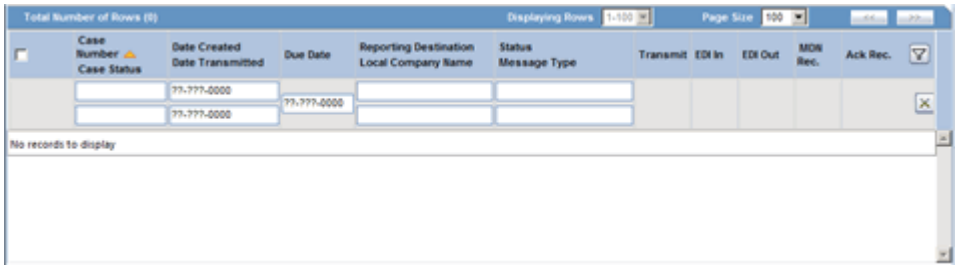
Search Criteria Section

The following is an illustration of the **Search Criteria** section.

The following table lists and describes the fields in the **Search Criteria** section.

Field	Description
Case #	Displays the Case Number. Click the Case Number to view the report.
Message Type	Select a pre-defined message type.
Periodic Report	This field is enabled message type "Periodic"
Start Date	Enter the start date.
End Date	Enter the end date.
Range	Select a date range.
Search button	Triggers search based on the search criteria.
Only show transmissions that have reached a failure state	Enable this checkbox to search for only those transmissions that have a failed status.
View Individual	Displays all items assigned only to the individual user.
View Group	Allows the user to view all items assigned to this user group.
View All	Allows administrator and workflow manager to see all items in the system.
Stage Legend	Shows the status (through colors) corresponding to each stage.

Total Number of Rows Section The following is an illustration of the **Total Number of Rows** section.



The following table describes the columns in the **Total Number of Rows** section.

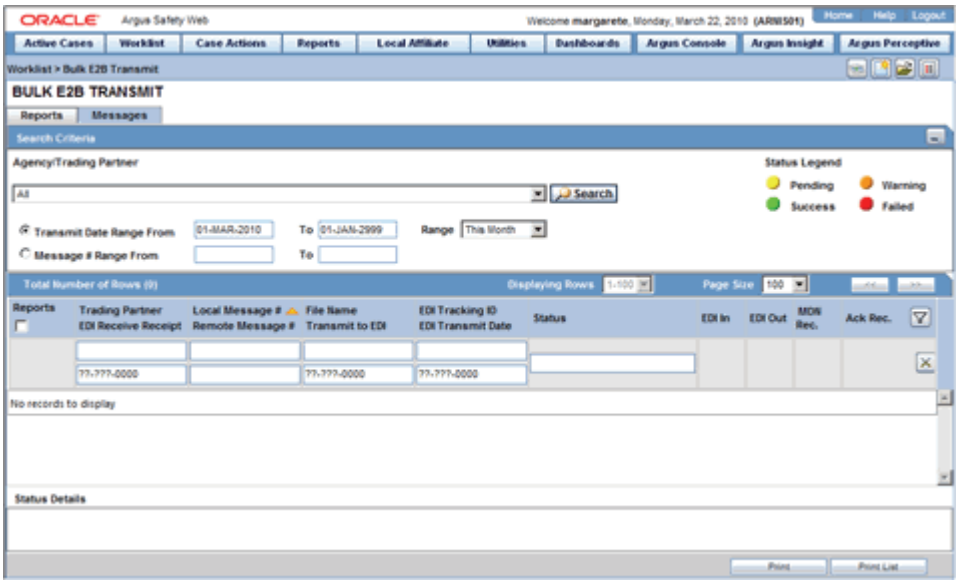
Field	Description
Action	Displays the icon containing the available user actions. Tip: Click on the case lock status (unlocked, locked or archived) for further options.
Case Number	Displays the Case Number. Click the Case Number to view the case details.
Case Status	Displays the current workflow of the state

Field	Description
Reporting Destination	Displays the name of the Reporting Destination
Date Created	Displays the date on which the report was created.
Date Transmitted	Displays the date when the report was transmitted.
Local Company Name	Displays the name of the local company that has sent the report.
Status	Displays the Report Status e.g. Scheduled or Generated etc. Click the Report Status to view the Report Details.
Message Type	Displays the ICSR message type for the transmission
Transmit	Denotes Processing Report
EDI In	Denotes EDI In
EDI Out	Denotes EDI Out
MDN Rec.	Denotes MDN Received
ACK Rec.	Denotes Acknowledgement Received
Status Details	Contains the details of the latest failure / success message for the selected row.
Print	Prints the row selected by the user
Print List Button	Allows the user to print the current worklist for reference.

Reports Tab User Options Click the **Action** icon with each report to view the available user options. The following table below describes the available options.

Option	Description
View Report Details (Read only)	Opens the existing Report Details dialog in read-only mode.
View E2B Report (E2b Viewer for the report)	Opens the existing E2B Viewer report.
E2B Transmission History (Transmission History for the selected report)	Opens the new Transmission History screen
Remove Transmission	Removes the transmission log entry from the list. **Note:** A report whose status is pending cannot be transmitted.
Re-Transmit	This option is displayed if the selected row has a status of failure or success. Select this option to change the status back to pending and the re-fax the report.
Remove Multiple Transmissions	Removes transmission of multiple reports that are selected from the list.
Re-Transmit Multiple Reports	The status of multiple reports that are selected from the list can be changed to "pending," and those reports can be re-transmitted.
Submit Multiple Reports	Multiple reports that are selected from the list can be marked as submitted simultaneously.

Messages Tab The following is an illustration of the **Messages** tab.

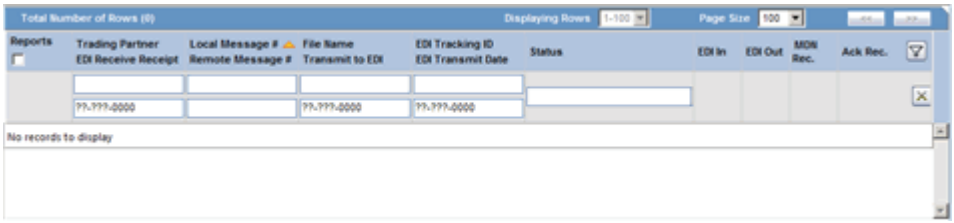


Search Criteria Section The following is an illustration of the **Search Criteria** section on the **Message** tab.

The following table lists and describes the fields and controls in the **Search Criteria** section.

Field	Description
Agency Trading Partners	Enter the agency or trading partner.
Transmit Date Range From	Select the transmit date range.
Range	Select a range to auto populate the Start Date and End Date. **Note:** The **Range** option is cleared if the Start Date or End Date is changed.
Message # Range	Select the message range.
Search button	Triggers search based on the search criteria.
Stage Legend	Shows the status (through colors) corresponding to each stage.

Total Number of Rows Section The following is an illustration of the **Total Number of Rows** section.



The following table below describes the column in the **Total Number of Rows** section.

Field	Description
Reports	Displays the number of reports.
Action	Displays the icon containing the available user actions.
Trading Partner	Displays the name of the agency or the trading partner.
EDI Receive Receipt	Displays the EDI Receipt status.
Local Msg #	Displays the Local Message Number.
Remote Msg #	Displays the Remote Message Number.
File Name	Displays the File Name.
Transmit to EDI	Displays the Transmit to EDI Status.
EDI Tracking ID	Displays the EDI Tracking ID.
EDI Transmit Date	Displays the EDI Transmit Date.
Status	Displays the Report Status e.g. Scheduled or Generated etc. Click the Report Status to view the Report Details.
EDI In	Denotes EDI In.
EDI Out	Denotes EDI Out.
MDN Rec.	Denotes MDN Received.
ACK Rec.	Denotes Acknowledgement Received.
Status Detail	Contains the details of the latest failure / success message for the selected row.
Print button	Prints the row selected by the user.
Print List button	Allows the user to print the current worklist for reference.

Message Tab User Options Click the Action icon associated with each report to view the available user options. The following tables lists and describes the available user options.

Option	Description
E2B Transmission History (Transmission History for the selected report)	Opens the new Transmission History screen
View Acknowledgement (Read only)	Displays the Acknowledgment report. **Note:** This menu option is not displayed if ACK has not been received for message.
View Reports	Opens the Bulk Transmit E2B in the report view for all the reports in the message.

Option	Description
View xml acknowledgement	Displays business level acknowledgement

Local Labeling

When using worklist local labeling, be aware of the following:

- Filtering by Product Family

Click the magnifying glass icon to filter the search results by product family.

You can filter products in the **Event Assessment** dialog based on the selected product families.

On filtering, the system displays only the assessment rows matching the selected product families.

- Events Assessment can show all listedness values. By default it shows listedness **only** for core datasheets and for those countries the user has permission to access.
- The filter options have a **Study ID** element and a **Case Number** (not a type ahead) added to filter cases in the list.
  - This option is a type ahead field that enables you to enter values for studies defined in the configuration.
  - The type ahead limits the number of values in the drop-down list to 25.
  - When you select type ahead values, the system performs a *like* search.
- Sorting

Search results can be sorted by case number and product name.

- Printing -- You can print the current view of the Worklist as defined by the filtering and sorting criteria.
- Saving

The system remembers the filtering and sorting selections for a particular session.

The system displays the default settings on the Worklist - Local Labeling for a new user session.

- The system displays the total number of rows in the **Search** header section (e.g., *20 cases of a possible 450 with 0 cases being processed.)*
- You can configure the number of cases to display on the **Page Size** drop-down list in the **Search** dialog (based on the profile settings for paging as a read only value).
- The system displays the number of cases currently in view and automatically updates the range based on the page size specified in the **Search** dialog (read only). For example, if you select 100, the system divides the displays rows into groups of 100 cases.
- You can go directly to a range of cases from the Displaying Rows drop down list.
- You can scroll through the Search results page-by-page, as defined by the Page Size drop-down list.
- You can filter search results by Product:
  - The product Filter drop down list contains all products listed in the event assessment.

  - The system enables you to filter on the Products in the Event Assessment dialog.
  - By default, the system displays all the products with the **<ALL>** option.
  - When filtering, the system displays only the assessment rows for the product you selected.
- Events assessment can show all listedness values. By default, it shows listedness **only** for the core datasheets and countries you have permission to access.
- Event
  - The **Event Filter** contains a drop down values of distinct Event PT.
  - The system enables you to filter on the events in the **Event Assessment** dialog.
  - By default, the system displays all events with the **<ALL>** option.
  - When filtering, the system displays **only** the assessment rows that match the product you selected.
- Diagnosis -- The **Diagnosis Filter** contains a drop-down list with the following values:
  - D (Diagnosis)
  - S (Symptoms)
  - In the **Events Assessment** dialog, you can filter on either the diagnosis or the symptom.
- By default, the system displays all events with the **<ALL>** option.
- When filtering, the system displays only the assessment rows that match the product you selected.
- Datasheets
  - The **Datasheets** drop-down contains a list of distinct datasheets.
  - You can filter on the datasheets in the **Event Assessment** dialog.
  - By default, the system displays all datasheets with the **<ALL>** option.
  - When filtering, the system displays only the assessment rows for the product you selected.
  - All the blank datasheets display as a single row of **Unspecified**.
  - When you click the **Datasheet** hyperlink, the system displays the datasheet notes.
- Licenses
  - The **Licenses** drop-down contains a list of distinct countries for the licenses.
  - In the **Event Assessment** dialog, you can filter on licenses.
  - By default, the system displays all licenses with the **<ALL>** option.
  - When filtering, the system displays only the assessment rows that match the product you selected.
  - All licenses not associated with a datasheet display under **Unspecified** and are aligned with the datasheet view.
  - When you click the **Licenses** hyperlink, the system displays the license references.

  - You can print the current **Search** view as defined by the filtering and sorting criteria.

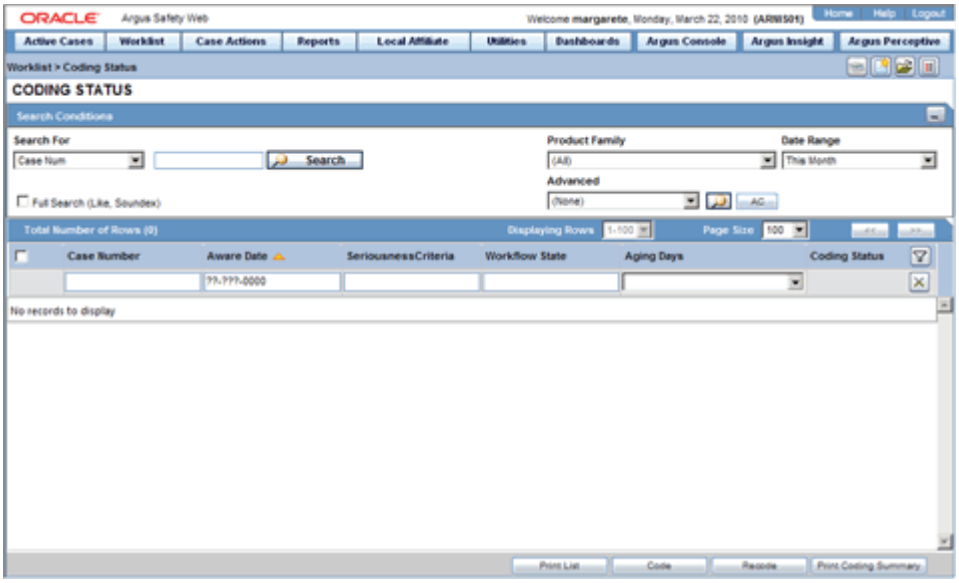
- For more information about **Local Labeling**, see the *LAM User Guide* for Worklist - Local Labeling requirements.

Coding Status

Coding Status enables you to perform the following functions:

- Coding Status View
- Single Case Coding / Recoding
- Bulk Coding / Recoding
- Coding Status Reports

Configured users can select **Coding Status** through the Worklist menu. The following is an illustration of the **Coding Status** screen.



Search Conditions Section

The following is an illustration of the **Search Conditions** section.

The following table lists and describes the fields and controls in the **Search Conditions** section.

Field	Description
Search For	Select the criteria by which the case must be searched for and enter an appropriate search item, if applicable. **Note:** You can search for cases based on multiple study identifiers. The option, "Prj/Othr/Stdy/Rptr/Pat" supports entry of Project ID, Study ID, Other ID, Center ID, Reporter ID, and Patient ID values separated by the "/" (forward slash) character. Any or all fields may be present.
Full Search	Select this checkbox, *if* **necessary**. Full search is best explained with an example. If the full search option is not used and the item that is entered under Search for is "AB", then a string such as "ABCESS" will match "AB", but a string such as "LABOR" will not. If the full search option is used, both these items will match "AB". Also, items whose first few letters sound similar (like "TIM" and "TIN") will also appear in the search results.
Product Family	Select the **Product Family** that the case belongs to, if applicable.
Date Range	Select a relevant **Date Range**, if applicable. **Tip:** To enter a customized date range, select **Custom Date Range** from the list. Enter an appropriate date range in the custom date range dialog and click **OK**.
Advanced	Select an **advanced condition** for the case, if applicable. Note: Click **AC** to create a new advanced condition.
Search	Displays the list of cases that match the entered search criteria

Total Number of Rows Section

The following is an illustration of the **Total Number of Rows** section.

The following table lists and describes the columns in the **Total Number of Rows** section.

Field	Description
Case Lock icon	Depicts the lock or unlock status of the case.
Case Number	Displays the case number. Click the link to view the case form.
Aware Date	Displays the Aware Date for the case.
Seriousness Criteria	Displays the Case level Seriousness Criteria. In case the case has any Fatal or Life Threatening event, it is displayed as such.
Workflow State	Displays the Workflow State of the case

Field	Description
Aging (Days)	If all code-able items of the case are coded completely, Aging is displayed as the Number of days from the Initial Receipt Date to the date when latest item of the case was coded. If any code-able item of the case is not coded, Aging is displayed as the Number of days from the Initial Receipt Date to the system date (Database Server).
Coding State	If all the events / products are encoded, the coding state is denoted with a green check mark. If the case has even a single code-able item as not coded, the coding state is shown as a red cross mark.

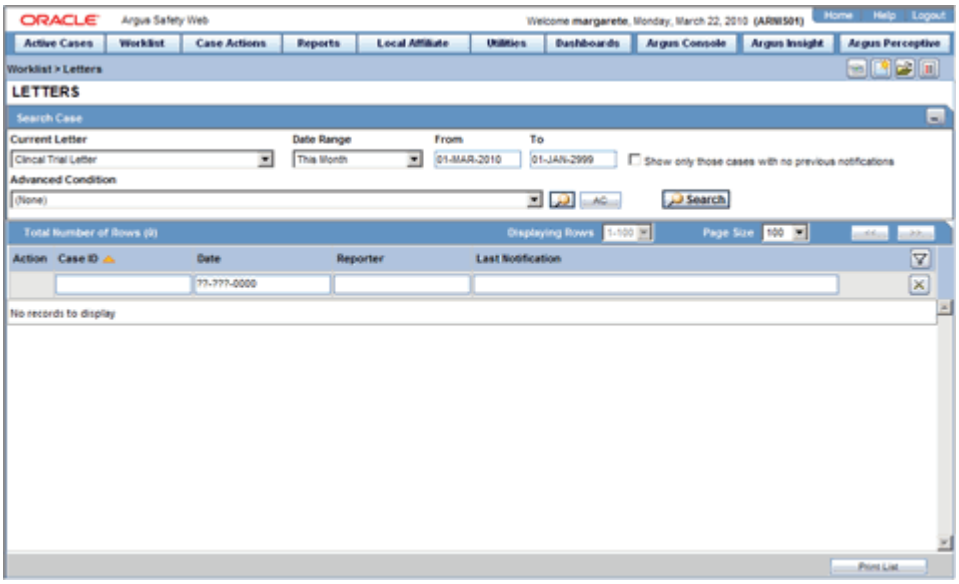
Coding Status Icons

The following table lists and describes the icons used to identify the coding status.

Icon	Description
	Displays that the verbatim text has not yet been coded.
	Displays that the verbatim text has been successfully coded.
	Is displayed if the verbatim text has been submitted to Central Coding, but no result has been returned to Argus yet.
	Is displayed if the term was submitted to Central Coding for coding and returned a status of error either from Central Coding or Argus.

Letters

The **Letters** function enables you to search for letters associated with a case.

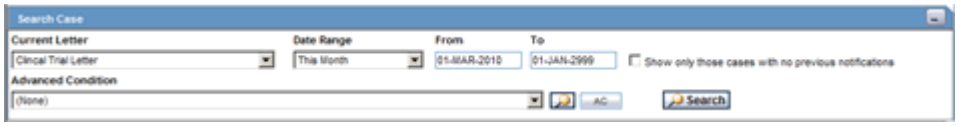


To access the Worklist - Letters page

1. Select Worklist --> Letters.
2. When the system opens the **Worklist - Letters** page, enter the appropriate information.

Search Case Section

The following is an illustration of the **Search Case** section.

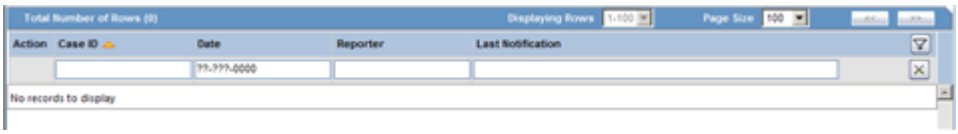


The following table lists and describes the fields and controls in this section.

Field	Description
Current Letter	Select the current letter from this list
Date Range	Allows the user to select a date range from which cases may be selected. The selection made from the Date Range drop-down list automatically populates the **From** and **To** fields.
Show only those cases with no previous notifications	Allows the user to filter the case list search to only those cases that have not had any correspondence letters sent.
Advanced Condition	Select an Advanced Condition from the list
AC	Creates a query for an Advanced Condition
Search button	Displays the results matching the search criteria

Total Number of Rows Section

The following is an illustration of the **Total Number of Rows** section.



The following table below describes the columns in the section.

Field	Description
Action	Displays the Action icon
Case ID	Displays the Case ID. Click the Case ID to view the case details.
Date	Displays the date
Reporter	Displays the reporter name
Last Notification	Displays the last notification date

J Literature Book-in

In Japan, the Drug Safety receives literature data from JAPICWMDIS (World Medical & Drug Information Service). This data includes a literature list of company-related drugs. When the safety division receives this information , it assesses the content and determines reportability for each type of literature on the list.

Import Tab

In Argus J, you can import these literature data files and assess reportability from the loaded data. The system enables you to book-in all necessary data. Select Literature Intake from the Worklist menu to open the New Literature Case Intake Worklist screen.

The following table lists and describes the fields on the New Literature Case Intake Worklist screen.

Field/Control Name	Description
Import Date Range	Enables you to import literature data for a specific time period.
Start Date	The beginning date for the import.
End Date	The end date for the import.
Range	The Range field of the data.
Search	Click Search to filter the import items.
Total # of Rows	The number of rows that display on a page.
Displaying Rows	The rows that the system currently displays.
Page Size	The number of rows that the system is configured to display on each results page.
Import Date	The date the literature data is loaded to the system from the shared folder. The date is in YYYY/MM/DD format.
Literature Type	The type of literature to display. Right=click to select the type to display.
Search Equation Number	The unique value associated with a specific search.
Document Number	The unique value that identifies a specific document.
Product Family	The produc family name associated with the Search Equation number or the name that has matching ingredients with the WMDIS data. The system displays all ingredients from WMDIS literature data inside a particular product family. ■ A forward slash (/) separates single product families with multiple ingredients. ■ A semi-colon (;) and /or a plus sign (+) is used to separate separate product ■ If you add the data manually, the system places an asterisk (*) after the product family name.
Ingredients	This column displays individual ingredent length.
Title	The title of the piece of literature.
Author	The name of the person who wrote the literature.
Journal	The name of the journal the literature was published in.
Vol.	The volume number of the issue the literature was printed in.

Field/Control Name	Description
Issue	The number that identifies the specific issue of the journal in which the literatue appeared.
Page	The page the data starts on.
Publish Year	The year the journal was published.
Screening	This column contains the screening results. It displays the one of the following: ■ Accept /Assigned User Name ■ Reject
Assigned to	Displays the name of the assigned user, if applicable.
Add Individual Information	When clicked, the system enables you to add individual literature information.
Print List	Enables you to print the list of data.

When using the Import tab, be aware of the following:

- You can filter all column items.
- Tabulation and sorting functions are available for your use.
- All Worklist basic functions are available to you.
- You can use a background process to import.
- The system permits you to import both JAPIC and WMDIS data.
  - If the data format does not match the JAPIC or WMDIS formats, the system does not import the file and places it in the Failures fold with the error description files.
  - The system assumes the contents are valid.
- The system imports the data and stores it in a shared table.
- The system does not validate the data content.
- The system can import .xls and .xslx files for WMDIS.
- When the system imports literature data, it sorts the data by date in descending order (newest at the top).
- If there are multiple items with the same date, the system sorts them by internal sequence number.
- The following right-click options are available in any row:
  - Accept -- Enables you to accept a highlighted. When clicked, the system displays "Accepted" in the Screening column.
    * If a product Family is not specified for the selected item, the system opens the Modify Product family dialog box to enable you to select a valid product family.
    * When an item is marked as accepted and assigned to a use, the system moves the data item to the Proccessing tab and saves the user name and date time stamp (GMT) in the source file.
    * If the system does not assign a user for an item, the data remains on the Import tab until a user is assigned.

- Reject -- enables you to reject the highlighted item. When clicked, the system displays "Rejected" in the Screening column.
  - * When you reject an item, the system opens a Justification dialog box, to enables you to enter or select a justification for rejecting the item.
  - * Rejected by the Standard Screening is the default value in the dialog box.
  - * Once an item is rejected, the system moves the data item to the Processed tab and saves the user name and date time stamp (GMT) in the source file.
- Assign User -- Enables you to assign another user to be the owner of the data item. The system opens the ”Reassign" dialog to enable you to assign an owner.
- Assign Literature Type -- Enables you to specify the Literature Type from the Console J Codelist. When clicked, the system opens the popup so you can assign an owner.
- Modify Product Family -- Enables you to define a product family for the literature when a Product Family is not available.
- Print Monitoring Check Report -- Enables you to print the Monitoring Check Report form in PDF format.
- Multiple Accept -- The Multiple Accept option enables you to accept all selected row items.
  - * When the system encounters any accepted items with a Product Family, it displays the following error message: "At least one product family is missing from the selected items. Only items with a product family are marked "Accepted."
  - * If the system encounters locked records, it displays the following message: "Data is being used by another user. The system cannot process this data.
- Multiple Reject -- The Multiple Reject option enables you to reject all selected items.
  - * When you reject an item, the system opens the Justification dialog box to enable you to enter a reason for rejecting the item.
  - * The default value is "Rejected by the Standard Screening."
  - * The justification you enter in this dialog box applies to all selected items.
  - * If you are a trying to process locked records, the system displays the following message "Data is being used by another user. The system cannot process this data."
- Assign Multiple Users -- The Assign multiple users option enables you to assign users for the assessment in the Processing tab for all selected rows.
- Assign Literature Type to Multiple Items -- The Assign Literature Type to multiple items option enables you to specify the literature type for all selected rows.
- Literature Duplicate Search -- Enables you to perform a duplicate search.

The following table lists and describes the fields on the Duplicate

Field/Control Name	Description
Title	Displays the title of the current search item.

Field/Control Name	Description
Vol.	Displays the volume number associated with the current search item.
Issue	Displays the issue associated with the current search item.
Page	Displays the number of the page where the current search item appears.
Publish Year	The year the current search item was published.
Search from Literature Intake	When selected, the system executes the search from the Literature Intake Import tab, Processing tab, and Processed tab. This is the default. The system executes the search on all Import, Processing, and Processed tabs. Howeve , the search result does not include the original search item.
Search from the Case Data	When selected, the systm executes the search from the case data.
Search	Click Search to start the search operation.
Reject Literature Information	When clicked, the system removes the selected line from the imported list.
Close Duplicate Search	Cancels the search operation and closes the Duplicate Search screen.
Total # of Rows	The total number of rows in the search results.
Displayed rows	The total number of rows currently displayed.
Page Size	The maximum number of data rows that appear on a page.
Search Equation Number	The unique value that identifies the search operation.
Document Number	The unique numeric identifier assigned to a selected piece.
Ingredients	A list of ingredients discussed in the literature.
Title	The title of the piece of literature.
Author	The author of the article.
Journal	The name of the Journal in which the article appeard.
Vol	The volume number associated with the journal in which the article appeared.
Issue	The issue of the journal in which the article appeared.
Publish Year	The year the article was published.
Status/Case Number	The status of the data. This can be one of the following: ■ Accepted -- the data is marked as "accepted." ■ Rejected -- the data is marked as "rejected." ■ Not necessary -- the data is asses and processed and is deemed "not necessary." ■ Case Number -- Displays the number of the case if the the data is accepted as case in the Processed tab.
Screening Owner	The user name of the person who first accepted the imported literature.
Assessment Owner	The user name of the person who performed the second assessment.

When performing a duplicate search, be aware of the following:

- A duplicate search searches for title, vol, issue, page and publish year and is executed in the Processed imported literature date and the Case Data.
- By default, the system searches processed data.The system enables you to search for case data by selecting a radio button. When you do so, the system displays the data in the table at the bottom of the screen.
- You can modify field content and click the sesarch button as in E2B Duplicate Search.
- You can use the % character to perform a partial search.
- When the system displays the search result, it enables the Reject Literature Information button if it finds at least one duplicate. When you click the button, the system marks the original item "rejected."
- If the result set contains more than 1000 items, the system only displays the first 1000 items.
- When you execute a duplicate search from the Case Data tab, the columns that do not appear in the Case data (Search Equation Number, Document Number, Issue, Screening Owner, and Assessment Owner, are left blank.
- The system displays the generic name for the ingredients in the Case Data.
- The system displays Author J, Title, J, and Journal J in Japanese. If Japanese values are not availble, the system displays the English values.
- When you click "Add Individual Information" button, the system enables you to enter data about an individual piece of literature. The system opens the Add Individual Information dialog box.
- When you click Select, the system opens the Literature Lookup dialog to enable you to select literature from the Code list.
- When you click Add, the system adds the entered nformation to the Import table.
- When you click Cancel, the system closes the section.

Processing Tab

The Processing tab enables you to provide information for processing literature data.

The following table lists and describes the fields and controls on the Processing tab.

Field/Control Name	Description
Date Range	Enables you to enter a range of import or screening dates.
Start Date	The date to start the search.
End Date	The date to end the search
Range	The range field for the data. This is the value from the Date Range code list item.
Search	Click Search to initiate the search.
View Individual All	Enables you to view a single piece of data or all retrieved items.
Total # of rows	The total number of rows in the search results.
Displaying rows	The total number of rows that are displaying.

Field/Control Name	Description
Page Size	The total number of rows to displays on a single page.
Import Date	The date the literature is loaded into the system from the shared folder.
Literature Type	The selected literature type.
Search equation number	The unique value that identifies this search query.
Document Number	The unique value that identifies a specific document.
Ingredients	The list of ingredients referenced n the piece of literature.
Title	The title of the article.
Author	The author of the article.
Magazine Name	The name of the publication where the article appeared.
Vol	The vol of the magazine in which the article is published.
Issue	The specific issue in which the article is published.
Page	The page on which the article appears.
Publish year	The year the article was published.
Assessment	Enables you to view the result of the second assessment (when available). When you click Assessment, the system opens the Justification dialog box.
Owner	The assigned owner of the literature.
Print List	Enables you to print the list.

The following right-click options are available in any row:

- Assessment
- Assessment Result
- Multiple Assessment
- Create Case/Process Unnecessary Assessment

Assessment

When you select Assessment from the drop-down list, the system opens the Justification dialog box.

The following table lists and describes the fields on the Justification dialog box.

Field/Control Name	Description
Assessment Result	This drop-down list enables you to select the assessment result you want to view.
Possibility of occurrence of serious disease such as cancer, disorder, or death	Enables you to choose whether to include assessments where there is a possibility of serious disease.

Field/Control Name	Description
Significant change on event or infection occurrence number, frequency and condition.	Enables you to choose whether to include assessments where there has been a significant change in and event or condition.
Doesnt' have acknowledged effectiveness	Enables you to choose whether to include assessments where there hasn't been any acknowledged effectiveness.
Problems	Enables you to enter information about any problems.

Assessment Result Drop-Down List

The Assessment Result drop-down list includes the following items. The selection you make determines what is mapped to the case form.

Item	Description
Not Necessary	Select this item to move the data item to the Processed tab after the "Create Case/Process Unnecessary Assessment" action.
AE Case	Select this item to move the data item to the Processed tab after the "Create Case/Process Unnecessary Assessment" action.
Research/Infection Report (Marketed Drug)	Select this option to move the data item to Analysis/PMDA General/Reporting Category.
Research/ADR Report (Marketed Drug	Select this option to move the data item to Analysis/PMDA General/Reporting Category.
Research/Infection Report (Investigational Drug)	Select this option to move the data item to Analysis/PMDA General/Reporting Category.
Research/ADR Report (Investigational Drug	Select this option to move the data item to Analysis/PMDA General/Reporting Category.
Research Report (Quasi Drug)	Select this option to move the data item to Analysis/PMDA General/Reporting Category.
Research Report (Cosmetics)	Select this option to move the data item to Analysis/PMDA General/Reporting Category.
Measures in foreign countries including discontinuation of manufacture, recall and withdrawn (Marketed Drug)	Select this option to move the data item to Analysis/PMDA General/Reporting Category.
Measures in foreign countries including discontinuation of manufacture, recall and withdrawn (Investigational Drug)	Select this option to move the data item to Analysis/PMDA General/Reporting Category.

Multiple Assessment

Selecting this option enables you to assess all selected row items.

Create Case/Process Unnecessary Assessment

When you select this option the system does the following:

- If "Assessment" for the Literature data is marked "not necessary," the system moves the data to the Processed tab.

- If Assessment for liter data is marked with any of the other options, the system opens the Book-in screen with all the literature data populated. The system copies the assessment result to Case Data.
- When you select "Create case/Process unnecessary assessment," the system verifies there is a valid Japanese license available to the product family. If the product family doesn't have a Japanese license, the book-in fails and the system displays the following message: "This product family does not have a valid Japanese license."
- If a matching product family does not exist at the time of the book-in, the system does not populate the product on the book-in screen.
- If an assessment is not completed for the literature data you select "Create Case/Process Unnecessary Assement," the system displays teh following message: "Assessment result does not exist."
- When booking is complete, the system presents the following message: "New Case <case name> successfully created. Do you want to open the case?"
- Once the booking is complete the system moves the processed item to the Processed tab.

Processed Tab

The Processed tab enables you to provide information about processed literature data.

The following table lists and describes the fields and controls on the Processing tab.

Field/Control Name	Description
Date Range	Enables you to enter a range of import or screening dates.
Start Date	The date to start the search.
End Date	The date to end the search
Range	The range field for the data. This is the value from the Date Range code list item.
Search	Click Search to initiate the search.
Total # of rows	The total number of rows in the search results.
Displaying rows	The total number of rows that are displaying.
Page Size	The total number of rows to displays on a single page.
Import Date	The date the literature is loaded into the system from the shared folder.
Literature Type	The selected literature type.
Search equation number	The unique value that identifies this search query.
Document Number	The unique value that identifies a specific document.
Product Family	The product family referenced n the piece of literature.
Title	The title of the article.
Author	The author of the article.
Magazine Name	The name of the publication where the article appeared.

Field/Control Name	Description
Vol	The vol of the magazine in which the article is published.
Issue	The specific issue in which the article is published.
Page	The page on which the article appears.
Publish year	The year the article was published.
Screening	Enables you to view the screening results.
Date	The screening date.
Owner	The assigned owner of the literature.
Assessment	Enables you to view the assessment results.
Date	The assessment date
Assigned	The user name of the person who performed the assessment.

When using the Processed tab, be aware of the following:

- The grid only displays accepted literature data.
- The Status Detail field opens when you highlight a single item.

8

MedDRA Browser

The *Medical Dictionary for Regulatory Activities (MedDRA)* can be used to encode diseases, symptoms, signs, and so forth.

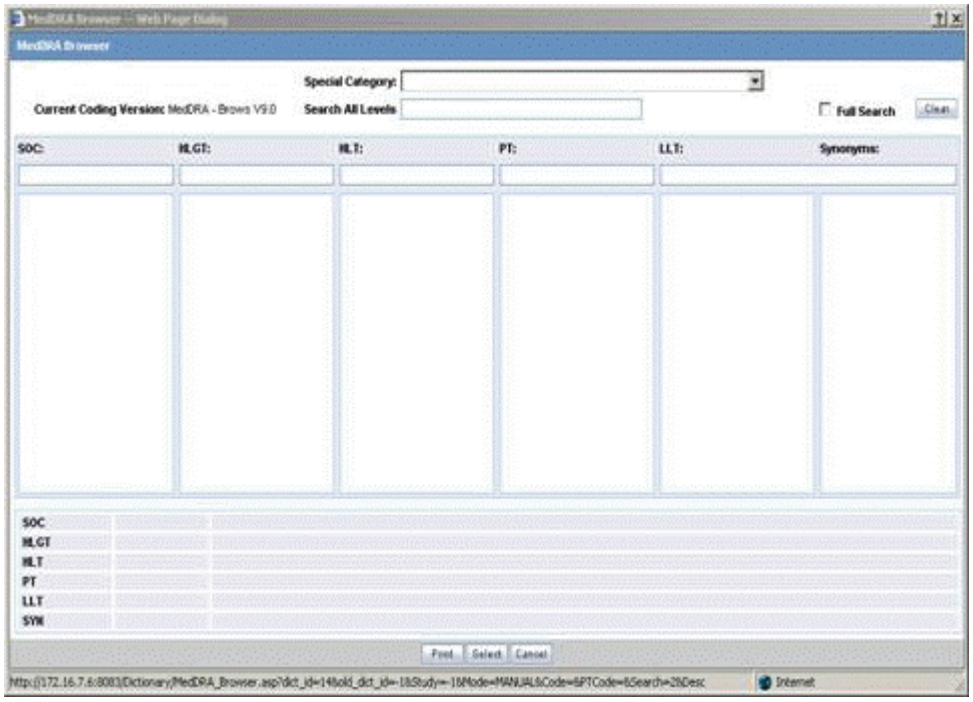
This chapter describes the MedDRA Browser. When using MedDRA J Browser, the following are different:

- English MedDRA terms are searched in the English MedDRA Browser, and Japanese MedDRA J terms are searched in the MedDRA J Browser.
- When a specific term is selected by the user, the bottong table of the MedDRA J Browser displays all terms in the hierarchy in both English and Japanese, side by side. The English MedDRA Browser displays all terms, in English only.

MedDRA Browser Functionality

The *Medical Dictionary for Regulatory Activities (MedDRA)* can be used to encode diseases, symptoms, signs, and so forth. In Argus Safety, using such a dictionary provides consistency when assigning terms for adverse events. When loading the new MedDRA dictionary, the system places a check mark in the default MedDRA browser check box.

The following is an illustration of the **MedDRA Browser** screen.



To view the MedDRA Browser

1. Select Utilities --> MedDRA Browser.

   The system opens the **MedDRA Browser** screen.

Using the MedDRA Browser

Your Argus Safety Administrator might have configured the system to use the MedDRA Browser for encoding events or indications.

If this is the case, the **MedDRA Browser** dialog opens when you click the **Encode** button. The dialog can also be invoked while creating Advanced Conditions or by selecting **MedDRA Browser** in the **Utilities** menu.

Note: Unlike MedDRA - Browser V9.0, MedDRA - Browser V10.0 does not display the Special Category field. However, it displays the MedDRA SMQ drop-down list. This list enables the user to select from all available Standard MedDRA Queries (SMQs).

MedDRA Browser Dialog Fields and Field Descriptions

The following table lists and describes the fields in the **MedDRA Browser** dialog box.

Field	Description
Coded Version	Shows the version of the dictionary under which this event was originally encoded.
Terminology	Allows you to select the version of the dictionary in which you wish to encode this event.
Full Search	If you select this check box, the search text you enter will be matched within each word of the terms. If this check box is cleared, the system will only return the terms that begin with the text you entered.

Field	Description
Special Category	You can select a special category in the MedDRA dictionary from this list in order to display the terms related to that category.
Clear	Clears all entries in the dialog.
Search All Levels	You can enter text in this field and press ENTER in order to search for the text across all of the five levels of the dictionary.
SOC column	System Organ Class. You can enter text in this field to search for the term in this particular level.
HLGT column	High Level Group Term. You can enter text in this field to search for the term in this particular level.
HLT column	High Level Term. You can enter text in this field to search for the term in this particular level.
PT column	Preferred Term. You can enter text in this field to search for the term in this particular level.
LLT column	Low Level Term. You can enter text in this field to search for the term in this particular level.
Synonyms	This level can list company-specific synonyms for LLT terms.
Print	Creates a report of the information that is currently on the dialog. This report will be in PDF format.
Select	Click this button to enter the terms that have been selected into the encoding.
Cancel	Click this button to close the dialog without making any changes.

MedDRA Searches and Search Results

Use the following procedure to search for terms.

Execute these steps to search for terms:

1. Enter the required term in one of the five levels of encoding.
2. You can enter as little information as necessary in order to get a broader set of results. Alternatively, you can enter the term under **Search All Levels** to search for the term across all levels.
3. Select the **Full Search** check box, if necessary.

   Full search is best explained with an example: If the full search option is not used and the item that is entered under **Search for** is "AB", then a string such as "ABCESS" will match "AB", but a string such as "LABOR" will not. If the full search option is used, both these items will match "AB."
4. Press **ENTER**. A list of search results opens.

About Search Results When using search results, be aware of the following:

- You can click the **Select** button to transfer the selected terms to the Case Form or the Advanced Conditions dialog, depending on where the browser was invoked from. The button only becomes available after terms at all levels have been selected.
- If you double-click an LLT term, a **Term Details** dialog appear. The dialog displays the following details about the term:
  - Indicate if the term is current or non-current

  - MedDRA code for the highlighted term
  - Primary SOC code and term
  - Secondary SOC code(s) and term(s), if applicable
  - Dictionary identifier
- When you select a term in a particular column, the other columns will be filled-in with the appropriate terms that correspond to the selected term.
- The Primary SOC Path is highlighted by using bold text for the path.
- To perform a synonym search, select an LLT among the search results. A synonym for the LLT will appear in the **Synonyms** column. When you select a synonym, the LLTs for that synonym will appear in the Synonyms column.

Using the MedDRA Browser for Advanced Conditions When you select a field for which the terms can be encoded in the **Advanced Conditions** dialog, the **Select** button appears.

Click this button to view the **MedDRA Browser** dialog. You can search and select the required terms from the MedDRA browser. These terms are automatically transferred to the Advanced Conditions dialog.

MedDRA Recoding

The MedDRA recoding tool displays the following options for each case with the existing data elements after the case number in the XLS export or tab delimited file:

- Current Workflow State.
- Current Workflow Group.
- If Excel is the output format and the number of record returned is more than 60K, the system splits the record set into multiple worksheets of 64K each.
- These options are available for the end user logs.
- The SOC/HLGT/HLT/PT/LLT and Synonym columns in the MedDRA schema and the MedDRA table have been expanded to 250 characters to conform to the ICH guidelines.

The following table lists the tables that support MedDRA Recoding and their locations in the Argus application.

Argus Database Table	Location in Argus
CASE_PAT_HIST	Argus Safety > Case Form > Patients Tab > Parent Section > Other Relevant History
CASE_EVENT	Argus Safety > Case Form > Events Tab > Event Information
CASE_PROD_INDICATIONS	Argus Safety > Case Form > Products > Products Indication
CASE_ASSESS	Argus Safety > Case Form > Events Tab > Event Assessment > Event PT (Description)/LLT
CASE_DEATH_DETAILS	Argus Safety > Case Form > Events Tab > Seriousness Criteria > Death Details > Cause of Death & Autopsy Details
CASE_LAB_DATA	Argus Safety > Case Form > Patient Tab > Lab Data
LM_PRODUCT	Argus Console > Business Configuration > Products and Licenses > Primary Indication
LM_LAB_TEST_TYPES	Argus Console > Code Lists > Lab Test Type

MedDRA Recoding Logic

The following logic is used during the MedDRA recoding:

1. Get the Lower Level Term (LLT).
2. Check LLT_Code column in the MEDDRA_PREF_TERM_LLT table to see if LLT is not current (LLT_CURRENCY = N).

   Decisions:

   - If LLT cannot be found in MEDDRA_PREF_TERM_LLT then record as exception to be noted in LOG file.
   - If LLT is not current then get PT_CODE from MEDDRA_PREF_TERM_LLT and use as LLT (Each PT exists as LLT also - always).
   - If LLT is current then keep LLT as it is.
3. If a current LLT can be found in previous step then continue with next step else go to 1 and select next set of Terms.
4. Based on the LLT, get the Preferred Term (PT_CODE) from MEDDRA_PREF_ TERM_LLT. Get the rest of the hierarchy from MEDDRA_MD_HIERARCHY, based on PT_CODE and PRIMARY_SOC_FG = 'Y'.
5. Match all the 5 levels of Code and Description and update the data, if required.
6. Populate the following columns:

- DICT_ID = Current MedDRA Dictionary ID, present under Case Form Configuration.
- CODE_STATUS = 1 (displaying that this set of terms has been encoded).

9

Argus Affiliate Module

Argus Affiliate Module Information

Please see the *Oracle® Argus Affiliate User's Guide* for detailed information about each option available to Central and Affiliate Users under the Local Affiliate menu.

10

Argus Reports

This chapter contains detailed information about Argus reports.

Reports

Several different kinds of reports are available in Argus. You can access them from the **Reports** menu. When using reports, be aware of the following:

- The system prints a DRAFT watermark across the entire page starting from the bottom left to top right for the following on all pages:
  - ALL Expedited reports including E2B CIOMS and MedWatch on the E2B Viewer
  - ALL Periodic Reports including Expedited reports part of the Periodic and Aggregate reports part of Periodic
- If you select **Internal** or a value for **Other text** for PSUR/CTPR reports, the system prints "Internal" or the other text value as the watermark on the PDF reports that include the expedited reports that are part of the periodic for all pages.
- The screen has a **Study ID** filter option that enables you to filter cases in the list.
- When using the **Study ID** filter, be aware of the following:
  - The **Study ID** is a type ahead field the system enables you to enter the study ID values defined for cases.
  - There can be a maximum of 25 items on the drop-down list.
  - When you select values from the drop-down list, the system performs a *like* search.
- The system prints the user-defined summaries in the order they are listed in the Periodic report.

This chapter discusses these reports in detail and also about the reports in the following categories. The following is a list of all available Argus reports.

- Compliance Reports
- Expedited Reports
- Periodic Reports
- Submitted Reports
- Aggregate Reports
- Case Data Analysis Reports
- CIOMS II Line Listing Reports
- Case Listing Reports
- Memorized Reports
- Periodic Reports
- Clinical Trial Periodic Reports
- ICH PSUR Reports
- US IND Periodic Reports
- US NDA Periodic Reports
- Bulk Reporting
- Incoming E2B Reports
- Processed E2B Reports
- Report Mapping

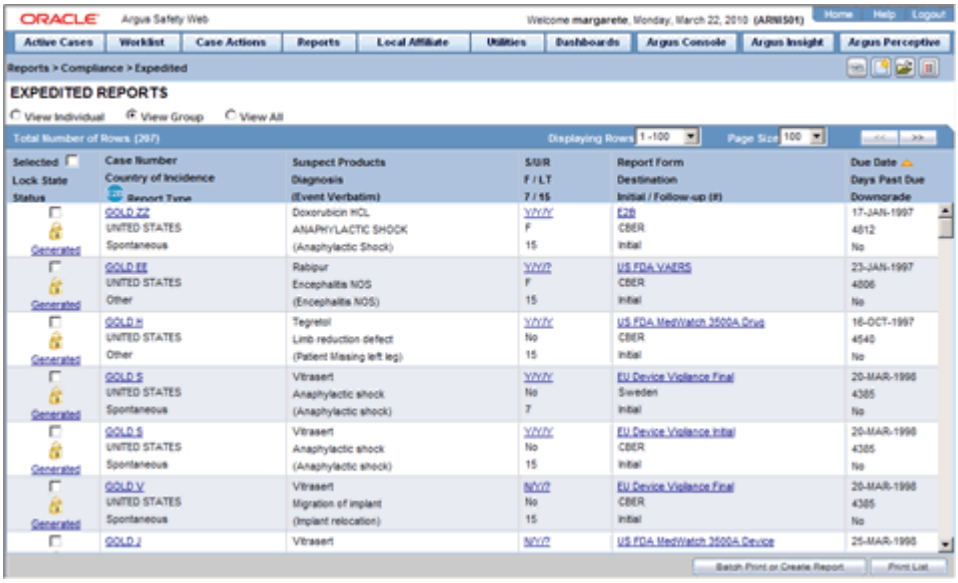
Compliance Reports

This section lists the different Compliance Reports in Argus and discusses about each of them in detail.

Place the cursor over the **Compliance** option in the **Reports** tab to go to any of the Compliance Reports.

About Expedited Reports

Expedited Reports provide access to the list of previously scheduled or generated but not submitted expedited reports.



Apart from viewing these reports, you can also schedule a new expedited report from this dialog.

Depending on the regulations set forth by the Regulatory Authorities, expedited reports might need to be submitted for the adverse events pertaining to your company's products.

You can generate several different kinds of expedited reports as follows:

- CIOMS-I Form (English)
- CIOMS-I Local Form (English)
- CERFA 65-0040 (French)
- CERFA 65-0044 (French)

- MHLW Clinical (Japanese)
- MHLW Spontaneous (Japanese)
- US FDA MedWatch Form 3500A (English)
- US FDA MedWatch Form 3500A (English) Drug Only
- MCA Clinical (English)
- MCA Spontaneous (English)
- US FDA VAERS Form (English)
- EU EMEA Clinical Form (English)
- EU EMEA Spontaneous Form (English)
- EU Device Vigilance Initial Form (English)
- EU Device Vigilance Final Form (English)
- German BfArM form 643 / PEI Form (German) French CERFA (French)
- E2B
- Spain Clinical
- Spain Spontaneous
- Canadian Device Form
- Canadian Expedited Form

General Usage Information When using Expedited Reports, be aware of the following:

- The following expedited report forms **do not** print a follow up number when the user selects **DRAFT** on the **Regulatory Reports** tab or when he/she selects the **Quick Launch Draft** option:
  - US FDA MedWatch Drug/Device
  - US FDA VAERS
  - CIOMS I/CIOMS I (Local)
  - French CERFA
  - Spanish Spontaneous/Clinical
- The system enables you to print draft expedited reports from the **Batch Print** or **Create Reports** without printing DRAFT on the reports from the **Case Open or the Reports | Compliance | Expedited Reports** dialog.
- When you select the **Draft** option, the system enables you to print a DRAFT watermark on the expedited reports.
- If you **do not** enter a value, the system **does not** print a watermark on the expedited reports.
- You can enter a maximum of 10 characters in the text field.

Storing Expedited Reports in Documentum Argus Safety lets you store your Expedited Reports in Documentum.

- Mark an Expedited Report as submitted from within Argus. to insert the report into the Documentum system as a PDF.

- If the report is to be transmitted via fax or email, Argus Safety Service marks the report as a successful submission in Documentum only **after** the fax or email transmission has succeeded.

Understanding Follow-up Reports Follow-up reports are created when significant follow-up information is entered for the case. This is indicated by entering follow-up information in the **General Information** section of the **General** tab and when one of the following two things happens:

- Data for a case changes
- Update information for a case has been entered
- Depending on the configuration set up by the Administrator, the system analyzes the scheduled reports prior to the data changes to see if they are still required.
- If the system determines that they are not required, the report status is marked as "Downgrade". New reports are automatically scheduled, if required.
- If the system determines the report is still needed and needs to be updated, one of two functions can take place depending on the configuration done by the Administrator:
  - The system overwrites the report
  - The system schedules a new report in addition to the old report
- If the system has been configured to overwrite the existing report, the report status becomes "New Data Available."
- In the Worklist, the status for this report shows "New Data Available" for this report. When you re-generate the report, you can select whether or not you would like to re-generate the report with the new data.
- If the system is configured to create a follow-up report, the previous report remains in its current state and a new report is scheduled with the status of "Scheduled."
- If a report has been previously submitted, this report is never deleted under any configuration.

Viewing a Summary of Expedited Regulatory Reports The following table below describes how to view a summary of Expedited Regulatory Reports:

To..	Do..
View the regulatory reports for a particular case (scheduled, generated and submitted)	Open the **Regulatory Reports** tab of the Case Form.
View all scheduled, generated, and approved reports, as well as other outstanding action items	Select **Reports** from the **Worklist** menu.
View a list of all scheduled, generated, and approved reports	Select Compliance | Expedited from the Reports menu.
View all the submitted reports in the system	Select Compliance |Submitted from the Reports menu.

User Options Several common features are available in the **Expedited Reports** section. These include:

- Lock State Header Options

- Lock Icons
- Lock Icon Options

Lock State Header Options

Click the **Lock State** header row to sort on the following category of cases. A pop-up appears listing the following sorting options:

- Lock State
- SUSAR
- Exp/Per

Click on the required option to sort cases based on the selected case categorization.

> **Note:** The icon displayed in the lock state column in the Reports-> Compliance - Expedited and Submitted screens denotes a SUSAR (Suspected Unexpected Serious Adverse Reaction) case.

Lock Icons

The following table describes the meaning of each icon when attached to a case.

Icon...	Identifies...
	A case marked for a Periodic ICSR submission.
	A locked case.
	An unlocked case
	A SUSAR (Suspected Unexpected Serious Adverse Reaction) case.

Lock Icon Options

Click the lock icon to view the list of options described in the following table:

Field	Description
View Report	Displays the details of the selected report.
Report Details	Displays specific information about the report as entered in the **Regulatory Reports** section. **Note:** The information displayed in the fields of the Report Details dialog is fetched from the data entered in the Regulatory Reports section of Case Form. Refer to the About the Report Details Dialog Box section for descriptions of each tab.
Case Summary	Displays the Case Summary dialog
Remove Report	Deletes the report from the case on being asked for a justification.

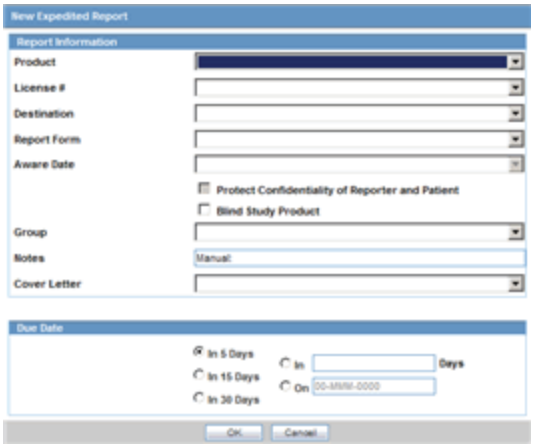
Field	Description
Mark for Non-Submission	Displays the **Submission** tab in the Report Details dialog. Select **No** for **Mark for Non-Submission** and enter the reason for the non-submission.
Remove Multiple Reports	Deletes multiple reports from the case on being asked a justification.
Mark Multiple for Non-Submission	Displays the **Submission** tab in the Report Details dialog. Select **No** for **Mark Multiple for Non-Submission** and enter the reason for the non-submission. This is applied to all selected reports.

Scheduling Reports Use the following procedure to schedule reports.

1. Open the case for which the report has to be scheduled.
2. When the system displays the Case Form for the selected case, select **Regulatory Reports --> Schedule New Reports.**
3. When the system opens the **Schedule New Expedited Report** dialog box, enter the appropriate information in the fields in the dialog box.
4. Click **OK** to schedule the report.
5. Save the case to save the report.

Schedule New Expedited Reports Dialog Box Fields and Field Descriptions

The following table lists and describes the fields in the **Schedule New Expedited Report** dialog box.



Field	Description
Product	Select the relevant company product from the list. All company products associated with the particular case appear in the list. **Note:** The items appearing in the drop-down list are listed in the following format: Trade Name, Product Name, Formulation, Concentration and Indication.
License #	Select the appropriate license. **Note:** The items appearing in this drop-down list are listed in the following format: Country of License, License Type and License Number

Field	Description
Destination	Select the regulatory authority for which the report is to be scheduled.
Form	Select the type of the report that is to be created.
Message Type	Select the Message Type from the drop-down list.
Aware Date	This drop-down list is only populated and enabled after a license has been selected. The Aware Dates are displayed in descending order of the Current Aware Date. The list of the aware dates is determined based on the license type selected in the following two groups: i. Drug/Vaccine - follow-up dates that are marked significant ii. Device - follow-up dates that are marked as "device" significant If the system is configured to not have separate significant indication for Drug and Device, only the standard (Drug/Vaccine) significant follow-up dates are considered. The resulting expedited report **Due Date** is based on the selected **Aware Date** and the duration of the **Due Date** section. **Note:** The selected Aware Date has no impact on the Actual Due Date if the user specifies an absolute **Due Date**. For instance, selecting a date in the **Due Date** field causes the report to be due on the specified date, regardless of the selected **Aware Date**.
Protect Confidentiality of Patient and Reporter	Select this check box if identifying information about the patient and the reporter must not appear on the report.
Notes	Enter any relevant notes in this field.
Group	Select the group that will be responsible for the report.
Cover Letter	Select a cover letter for the report, if relevant.
Due Date	Specify the due date of the report by selecting the number of days after which it will be due, or by specifying the exact date.

Generating Reports You can generate a report using either of the following procedures.

Method 1: Generating a Report

1. Verify that the relevant case has been locked and the required report has been scheduled.
2. Open the selected case to display its associated **Case Form**.
3. Open the report from the **Regulatory Reports** tab of the Case Form.
4. When the system opens the Regulatory Reports details for the selected case, locate the relevant report and click the **Final** link to generate the report.
5. The system generates the selected report.

Method 2: Generating a Report

1. Verify that the relevant case has been locked and the required report has been scheduled.
2. Select Case Actions --> Open to view the Case Open form.
3. Click **Search** to view cases matching the search criteria.

4. When the system displays the search results, click the **Lock State** icon and select **Case Details**.
5. When the system opens the **Argus Safety Case Details** dialog, open the **Scheduled Regulatory Reports** folder and select the relevant regulatory report.
6. The system automatically generates the report.

Note: ■To preview a report in draft mode, click the **DRAFT** link for the report in the Case Form.

- You do not need to lock the case to preview a report in draft mode.
- If you have access rights to view or print blinded information, you are prompted to select whether you would like to view a blinded or unblinded version of the report. If your access rights disallow you from viewing or printing unblinded information, you can view only a blinded version of the expedited report. The following items are not displayed when viewing a blinded version of the expedited report:
- Clinical Treatment Given (Study Drug field)
- Study Drug Formulation and Concentration
- Study Drug Dose, Daily Dose and Route
- Study Drug Batch/Lot # and Expiration Date
- If the case is locked you can generate the report from the Worklist | Reports, Reports | Bulk Reporting and Reports | Compliance | Expedited screens.

Approving Reports Use the following procedure to approve reports.

1. Open the case associated with the report that needs to be approved.
2. When the system opens the **Case Form**, click the **Regulatory Reports** tab to displays the case details.
3. Click the icon associated with the report you wish to approve and select **View Report Details**.
4. When the system opens the **Report Details** dialog, click the **Routing** tab.
5. When the system opens the **Routing** tab, select **Approved** from the **State** drop-down list and click **Route**.
6. When the system opens a dialog box, enter the required information and click **OK** to approve the report.

Note: Refer to Report Routing to understand how you can route a report to another state.

Creating Unscheduled Expedited Reports Use the following procedure to create unscheduled expedited reports.

1. Select Reports --> Expedited --> Compliance.

   Expedited Reports Dialog Box Fields and Fields Descriptions

Field	Description
Selected	Click the checkbox to select the report.
Lock State	Displays if the case is locked or un-locked.
Status	Displays the Report Status e.g. Scheduled or Generated etc. **Note:** Click the link displaying the status to view the report details.
Case Number	Displays the Case Number. **Note:** Click the link displaying the Case Number to open the selected case.
Country of Incidence	Displays the Country of Incidence for the selected case.
Report Type	Displays the Report Type of the selected case.
Suspect Product	Displays the Trade Name for which the report has been scheduled. A (+) displayed at the end of the Product Name denotes that more than one Suspect Company Product exists. For Reports which were scheduled for the Device, the Device name gets displayed.
Diagnosis	Displays the Primary Event Diagnoses PT
Event Verbatim	Displays the (verbatim as reported) of the Primary Event.
S/U/R	Displays the Case Level Assessments ■ S - Serious (Y/N) ■ U - Unlisted (Y/N) ■ R - Causality (Y/N) ■ Unknown is displayed by a "?" Click the SUR link to view the Case Summary.
F / LT	Denotes Fatal / Life Threatening If the case is both **F** and **LT**, only **F** is displayed. If the case is neither **F** nor **LT**, **No** is displayed.
7/15	Displays 7 if the report is due within 7 days Displays 15 if the report is due in more than 7 days
Report Form	Displays the Description of the report. Click the link to view the DRAFT Report PDF.
Destination	Displays the Report Destination (Agency) for which the report is scheduled.
Initial / Follow-up (#)	Displays the status whether it is Initial or Follow-up. If it is Follow-up, the follow-up number is also displayed.
Due Date	Displays the due date. This date is based on the previously submitted report for the MedWatch Reports under the G7 Section for 5, 7, 10, 15 and 30 Days.
Days Past Due	Displays the number of days the report is past due date.
Downgrade	Displays Yes if the report is a Downgrade Report.
View All	Allows the administrator and workflow manager to see all items in the system.
View Group	Allows the user to view all items assigned to this user group.
Individual	Allows the user to view all items assigned to him.

Field	Description
Print List Button	Allows the user to print the current Expedited Reports List for referencing the current view of the Expedited Reports List.
Batch Print	Allows the user to batch schedule Expedited Reports for Locked or Unlocked Cases.

2. Click **Batch Print or Create Report** and search for the case for which the expedited report has to be scheduled.
3. When the system displays the search results, select the locked cases for which the expedited report is to be scheduled.
4. Click **Batch**.
5. When the system opens the **Batch Print or Create Reports** dialog box, enter the appropriate information and click **OK**.
6. The system generates the unscheduled expedited report.

Batch Print or Create Reports Fields and Field Descriptions

The following table lists and describes the **Batch Print** fields.

Field	Description
Reporting Destination	Displays the different reporting destinations.
Report Form	Displays the report form types.
License Type	Select the license type as investigational or marketed or any type of license.
Message Type	Select the message type from the drop-down list
Format	Enables you to print reports **As Draft** or **As Final**. ■ The **Print As Final** option is available **only** if all the selected cases are locked. ■ If **Print As Final** is selected, then the option **Save with case, mark as submitted** is also available as a checkbox option. ■ Click the options **Print As Final** and **Save with case, mark as submitted** to generate final Regulatory Reports and create a submission record with each case identical to the current functionality. ■ Click the options combination of **Print As Final** only (and not Save with case, mark as submitted) to generate final Regulatory Reports without creating a submission record with each case. ■ If the report is associated with a blinded study, select the **Blind study product** check box.
Destination	Click the **Printer** check box to print the report
Protect Confidentiality of Reporter and Patient	Click this check box to hide the Reporter and Patient information on the expedited reports.

Field	Description
Scheduling	■ If **Run Now** is selected, all the selected reports run against all selected cases and a PDF is generated. ■ The **Run Now** option is visible only when a MedWatch, MedWatch Drug, CIOMS, or VAERS form is selected on the Batch Expedited Report screen. ■ 2Select **Run at** and enter the appropriate date and time when the generation of reports should occur. ■ Note that if you select an unlocked case, the report gets printed in draft form only and is not saved.

Creating Batch Reports You can use the **Batch Reports** function to schedule and generate reports for multiple cases. Before using this function, verify that no cases or reports are open.

Use the following procedure to create batch reports.

1. Select Expedited Reports from the Reports - Compliance menu.
2. When the system opens the **Expedited Reports** dialog box, click **Batch Print or Create Report**.

Expedited Reports Dialog Box Fields and Field Description

The following table lists and describes the fields in the Expedited Reports dialog box.

Field	Description
Selected	Click the check box to select the report.
Lock State	Displays if the case is locked or un-locked.
Status	Displays the Report Status e.g. Scheduled or Generated etc. **Note:** Click the link displaying the status to view the report details.
Case Number	Displays the Case Number. **Note:** Click the link displaying the Case Number to open the selected case.
Country of Incidence	Displays the Country of Incidence for the selected case.
Report Type	Displays the Report Type of the selected case.
Suspect Product	Displays the Trade Name for which the report has been scheduled. A (+) displayed at the end of the Product Name denotes that more than one Suspect Company Product exists. For Reports which were scheduled for the Device, the Device name gets displayed.
Diagnosis	Displays the Primary Event Diagnoses PT
Event Verbatim	Displays the (verbatim as reported) of the Primary Event.
S/U/R	Displays the Case Level Assessments ■ S - Serious (Y/N) ■ U - Unlisted (Y/N) ■ R - Causality (Y/N) ■ Unknown is displayed by a "?" Click the SUR link to view the Case Summary.

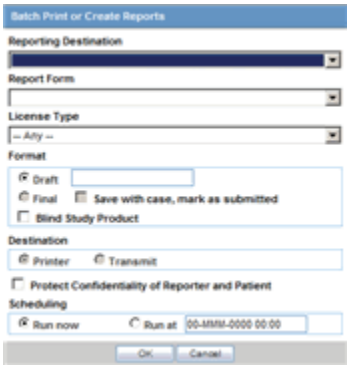
Field	Description
F / LT	Denotes Fatal / Life Threatening If the case is both **F** and **LT**, only **F** is displayed. If the case is neither **F** nor **LT**, **No** is displayed.
7/15	Displays 7 if the report is due within 7 days Displays 15 if the report is due in more than 7 days
Report Form	Displays the Description of the report Click the link to view the DRAFT Report PDF.
Destination	Displays the Report Destination (Agency) for which the report is scheduled.
Initial / Follow-up (#)	Displays the status whether it is Initial or Follow-up If it is Follow-up, the follow-up number is also displayed.
Due Date	Displays the due date.
Days Past Due	Displays the number of days the report is past due date.
Downgrade	Displays Yes if the report is a Downgrade Report.
View All	Allows the administrator and workflow manager to see all items in the system.
View Group	Allows the user to view all items assigned to this user group.
Individual	Allows the user to view all items assigned to him.
Print List Button	Allows the user to print the current Expedited Reports List for referencing the current view of the Expedited Reports List.
Batch Print	Allows the user to batch schedule Expedited Reports for Locked or Unlocked Cases.

1. When the system opens the **Expedited Reports** dialog box, search for the cases for which the expedited report needs to be scheduled.
2. When the system displays the search results, select the appropriate cases and click **Batch**.
3. When the system opens the **Batch Print or Create Reports** dialog box, enter the appropriate information in the fields and click **OK**

The **Expedited Batch Printing** dialog supports printing Batch CIOMS, Medwatch, and VAERS on Argus Web locally.

Batch Print or Create Reports Dialog Box Fields and Field Descriptions

The following tables lists and describes the fields in the **Batch Print or Create Reports** dialog box.



Field	Description
Reporting Destination	Displays the different reporting destinations.
Report Form	Displays the report form types.
License Type	Select the license type as investigational or marketed or any type of license.
Message Type	Select the message type from the drop-down list
Format	Enables you to print reports **As Draft** or **As Final**. ■ The **Print As Final** option is available **only** if all the selected cases are locked. ■ If **Print As Final** is selected, then the option **Save with case, mark as submitted** is also available as a checkbox option. ■ Click the options **Print As Final** and **Save with case, mark as submitted** to generate final Regulatory Reports and create a submission record with each case identical to the current functionality. ■ Click the options combination of **Print As Final** only (and not Save with case, mark as submitted) to generate final Regulatory Reports without creating a submission record with each case. ■ If the report is associated with a blinded study, select the **Blind study product** check box.
Destination	Click the **Printer** check box to print the report
Protect Confidentiality of Reporter and Patient	Click this check box to hide the Reporter and Patient information on the expedited reports.
Scheduling	1. If **Run Now** is selected, all the selected reports run against all selected cases and a PDF is generated. The **Run Now** option is visible only when a MedWatch, MedWatch Drug, CIOMS, or VAERS form is selected on the Batch Expedited Report screen. **Note:** If you select an unlocked case, the report gets printed in draft form only and is not saved. 2. Select **Run at** and enter the appropriate date and time when the generation of reports should occur.

Expedited Reporting Rules Algorithm The expedited reporting rules algorithm affects the following:

- Suppression of Duplicate Reports

- Blinded/Forced Distribution
- Letter Placeholder for the IND Cover Letter

Suppression of Duplicate Reports

You can suppress duplicate expedited reports to be scheduled at the reporting destination level, according to the following criteria:

- The **Suppress Duplicate Reports** option **only** applies to drug reports. It **does not** apply to device reports.
- This option **does not** reduce the number of reporting rules the system evaluates. However, it **does** prevent the system from scheduling and generating expedited reports that match the duplication criteria.
- When you select **Suppress Duplicate Reports**, the system uses the following attributes to determine whether the reports are duplicates of other reports:
  - Report Form
  - Reporting Destination
  - Aware Date
- If two or more duplicate reports have different due dates (regardless of license type), the system schedules the report with the earliest due date.

Blinded/Forced Distribution

The system enables you to configure the **Blinding Study** option for products in the case.

- When the user selects this checkbox, the system blinds the study products for the report being sent to the reporting destination in a manner similar to the Bulk Reporting dialog option.
- If the user selects either of the **Blind Study** product options (**Reporting Rules** or **Bulk Reporting**), the system blinds the study product information on the report form.
- The system blinds **only** active blinded studies. It **does not** blind the following case reports even if the **Blind Study** product is selected
  - Open Label Studies
  - Study is eligible for unblinding
- In cases where expedited reports are due, the system permits the user to force-distribute the reports based on user-defined reporting rules, even if case processing is incomplete.
- When the user selects the **Force Distribution** rule, the following occurs:
- If a case encounters a rule where a report is due is locked, the system schedules the report based on the rule and does the following:
  - Generates the report on the due date.
  - Dynamically replaces the current case comment with the force distribution case comment.
  - Transmits the report based on the preferences defined by the reporting destinations.
  - Displays the status in the **Worklist Bulk Transmit/Transmit** E2B dialogs.

- The **AG Service Force Reporting** process for expedited reports completes the process by:
  - Checking the reports required for force distribution
  - Locks the case (if it's not already locked)
  - Generates the reports and makes sure it is ready for transmission
- The system adds case comments to the following reports:
  - CIOMS I
  - CIOMS I (Local)
  - Spanish Spontaneous
  - Clinical Forms
- If a user has a case open, the system skips the case until the user releases the case.
- After transmitting the reports (sent to the WL Status dialogs), the system does the following:
  - Unlocks the case
  - Uses the justification of the unlock as the case comment (as defined in the Profile switch)
  - Determines whether there are any unsubmitted reports and, if there are unsubmitted reports, sends the current forced distribute reports to the **Bulk Reporting** queue for transmission.
- The system puts the following in the Notes field of the report:
  - Auto-scheduled; Forced Distributed: (EU) 15 day EMEA Mkt; Cure All
  - During the time the case is locked and reports are being generated, the system **does not** allow the user to edit the case. The system displays the following message:
  - The case is in use by XXXX user

    where:
  - *XXXX* is the name of the AG Service user executing the report scheduling.
- The notes for the **Case Locking/Unlocking** are the same as those defined as the common profile value for the **Forces Distribution** option; **System** is the user.

Letter Placeholder for the IND Cover Letter

Be aware of the following:

- You can define a placeholder for the **IND_SIMILAR_EVENTS** table. The system uses data from this table to populate the **Case Number**, **Protocol Number**, **Subject ID**, and **Adverse Event** terms for previously submitted cases reporting the same events.
- If the placeholder is used in a letter template, the system prints the information shown in the following table.

Adverse Event Report No. (AER#)	Protocol Number	Subject ID Number	Adverse Event Term(s)
CASE001	CUREALL	P101	Verbatim[PT]

where:

AER# is the case number when an Investigational IND MedWatch was previously submitted and included the same Related Event Term as the current case.

Protocol Number is the Project ID for the case in (a).

Subject ID is the Patient ID for the case in (a).

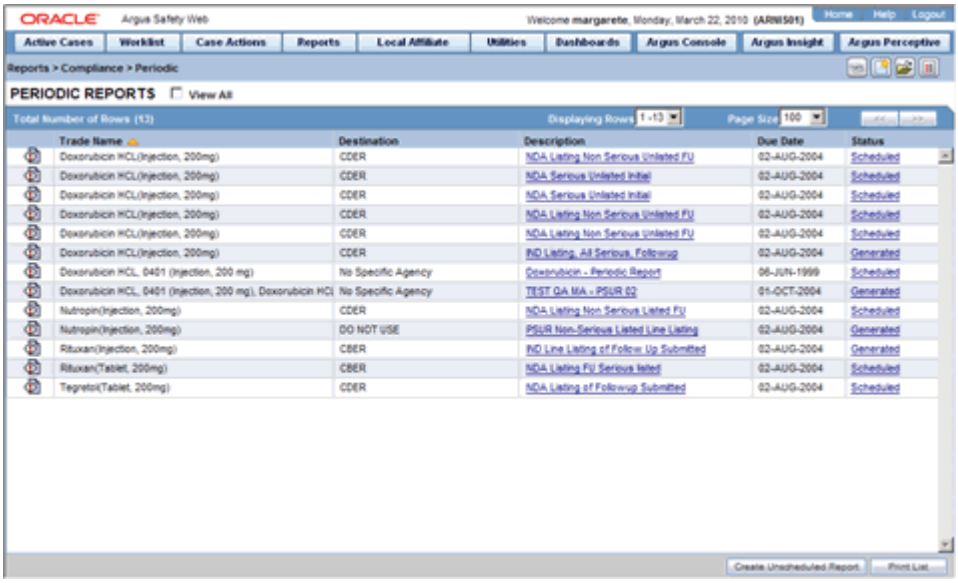
Adverse Event Terms(s) are the Related Events for the licensed product in case(a).

If no reports were submitted, the system prints **None Submitted** instead of the table.

The placeholder only prints this information when it is used in the cover letter for the **Regulatory Report**. The system uses the license associated with the scheduled report to track other cases where the same product license was previously submitted for the same events in the current case.

About Periodic Reports

This section discusses the different fields and features available in Periodic Reports.



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General Usage Information When using periodic reports be aware of the following:

- You can filter cases in the following period reports based on the **Case Locked/Archived** date:
  - NDA
  - IND
  - PSUR
  - CTPR
- When you select the **Case Locked/Archived** date, the system limits the cases based on whether the case has been locked or archived within the specified time frame.
- The locked date is the lock date for the current case.

- If there is significant FU in the reporting time frame, the system considers the case a follow-up case in the group options of the PSUR/CTPR reports.
- If you specify the time frame for the case locked/archived date, the system disables the following:
  - Include Follow-up
  - Exclude Follow-up
  - Include Summary of Unlocked Cases
  - Include Unlocked Cases
- For the 15 day report section of the NDA Reports, the system uses the timestamp to determine whether there are further follow-up or downgraded cases in that date range.

Periodic Report Features The following table lists and describes the data that appear in the columns on the **Periodic Reports** screen:

Field	Description
View All	Enables the user to view all available periodic reports.
Trade Name	Displays the Trade Name.
Destination	Displays the name of the Destination.
Description	Displays the report name. Click this to open the selected report in PDF format.
Due Date	Displays the Due Date.
Status	Opens the Report Details dialog for the selected report.
Print List	Allows the user to print the current Periodic Reporting for referencing the current view of the Periodic Reporting.

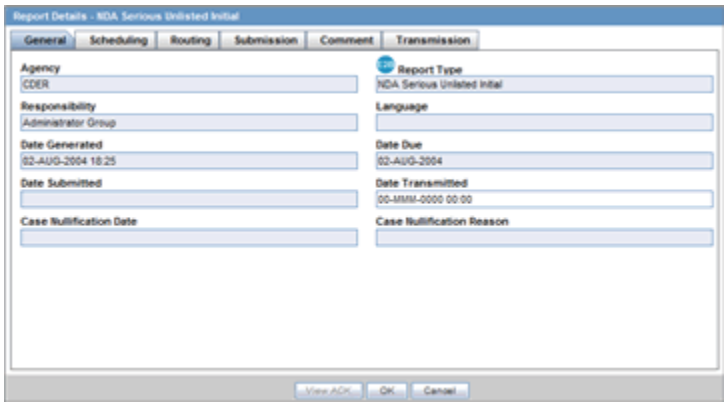
User Options Common features on the Period Reports page. Click the icon associated with each report to view the following options:

Option	Description
View Report	Opens the Individual Periodic Report selected by the user.
Report Details	Displays specific information about the report as entered in the Regulatory Reports section. Note: The information displayed in the fields of the Report Details dialog is fetched from the data entered in the Regulatory Reports section of Case Form.

About the Report Details Dialog Box The **Report Details** dialog box includes several tabs.

General Tab

The General tab displays the general information about the report. The information on this tab cannot be modified.



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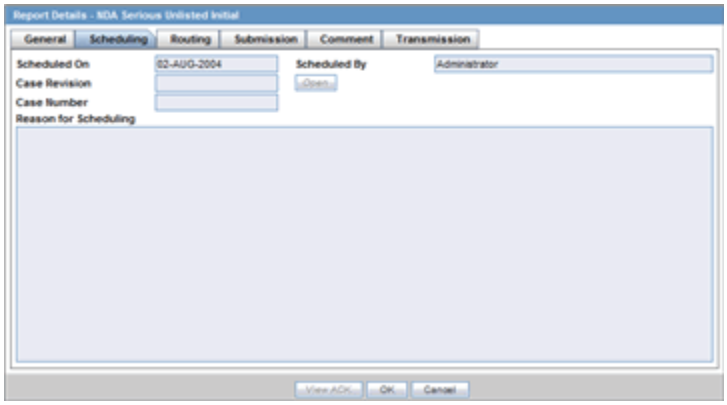
The following table lists and describes the fields on the **General** tab.

Field	Description
Agency	Displays the Reporting Destination for which the report is scheduled.
Responsibility	Displays the User Group to which the report is assigned.
Date Generated	Displays the date when the report was generated.
Date Submitted	Displays the date when the report was submitted.
Report Type	Displays the Expedited Report Form of the report.
Language	Displays the language in which the report has been made.
Date Due	Displays the date when the report is due.
Date Transmitted	Displays the date when the report was transmitted.
Case Nullification Date	Displays the date when the case was nullified.
Case Nullification Reason	Displays the reason entered when a case is logically deleted in Argus.

Scheduling Tab The **Scheduling** tab displays a reason for scheduling this report. It also shows the date on which the report was scheduled.



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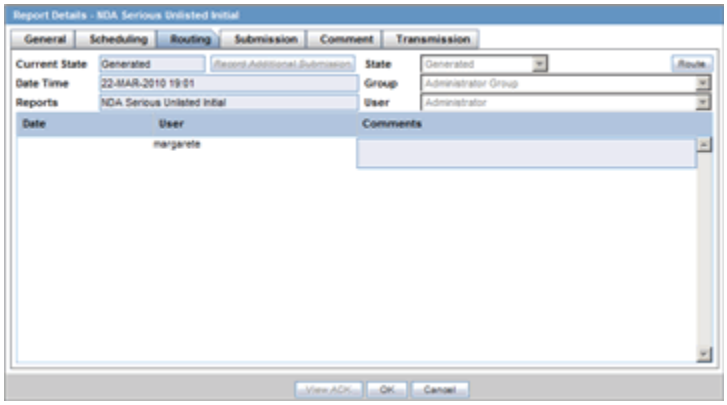
The following table lists and describes the fields on the **Scheduling** tab.

Field	Description
Scheduled On	Displays the date when the report was scheduled.
Scheduled By	Displays the name of the person who schedule the report.
Case Revision	Displays the case revision number.
Case Number	Displays the case number.
Reason for Scheduling	Displays the reason for scheduling the report.

Note: All fields in this tab are auto-populated as per records entered in Argus.

Routing Tab The Routing tab displays the routing history of the report. To route the report, click Route.



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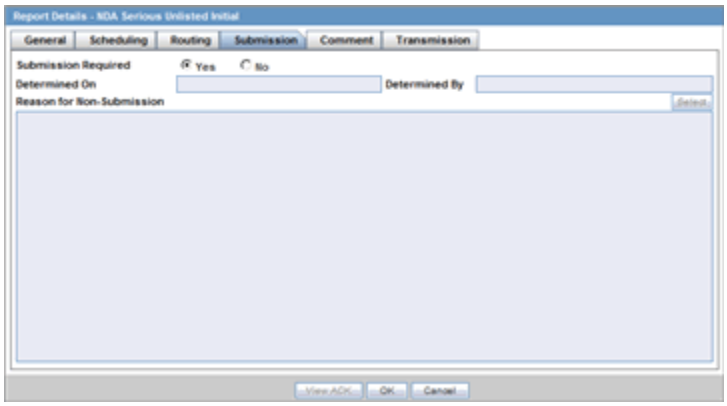
The following table lists and describes the fields on the **Routing** tab.

Field	Description
Current State	Displays the current state of the report.
State	Displays the state of the report. This button is enabled when you click the **Route** button.
Date Time	Displays the date and time of the report routing.
Group	Displays the group of the report. This button is enabled when you click the **Route** button.
Reports	Displays the type of report it is.
User	Displays the state of the report. This button is enabled when you click the **Route** button.
Comments	Displays routing comments entered before routing the report.

Submission Tab The Submission tab enables you to specify whether submission is required and enter a reason for not submitting the report.



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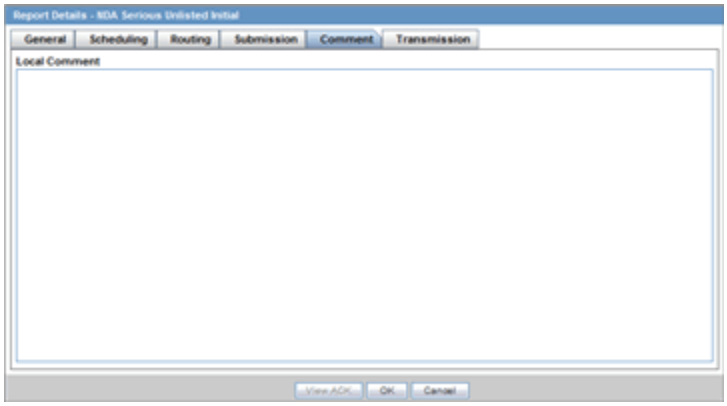
The following table lists and describes the fields on the **Submission** tab.

Field	Description
Submission Required	Enables you to select if this report is not required to be submitted to the regulatory authority.
Determined On	Displays the date when the report was considered not required to be submitted.
Determined By	Displays the name of the user who decided the report was not required to be submitted.
Reason for Non-Submission	Click **Select** to select the reason for non-submission.

Comment Tab The **Comment** tab enables you to enter a local comment that prints out on that specific report when generated. Each report has its own **Local Comment** section.



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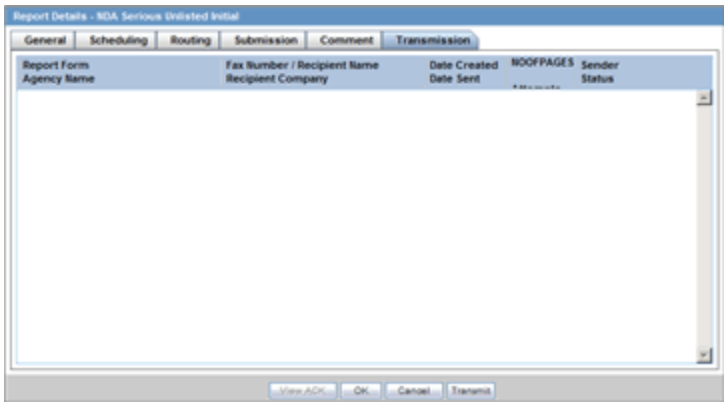
The following describes the **Local Comment** field on the **Report Details** tab.

Field	Description
Local Comment	Enables you to enter any remarks about the report.

Transmission Tab

To transmit a report

1. Click the icon associated with a report and select the **Transmission** tab from **Report Details**.
2. When the system opens the **Report Details** The **Report Details** dialog opens.



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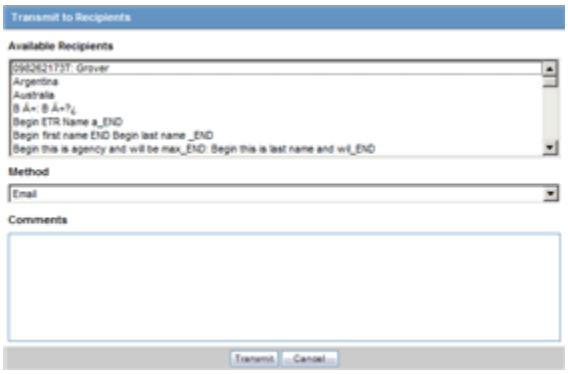
3. This dialog displays the status of reports that have been transmitted to different recipients.

   The following table lists the fields that comprise the **Report Details** dialog.

Field	Description
Report Form	Displays the name and type of report being transmitted.
Agency Name	Displays the agency name for the report.
Fax Number / Recipient Name	Displays the Fax Number or name of the recipient of the report.
Recipient Company	Displays the name of the company that is receiving the report.
Date Created	Displays the date when the report was created.
Date Sent	Displays the date when the report was sent.
# of Pages	Displays the number of pages present in the report.
Attempts	Displays the number of attempts in transmitting the report.
Sender	Displays the sender of the report.
Status	Displays the transmission status of the report.

4. Click **OK** or **Cancel** to approve the transmission or discard any changes, respectively.
5. Click the **Transmit** button to transmit a report. The **Transmit to Recipients** dialog is displayed.



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6. Select the recipients of the report, as applicable from the **Available Recipients** list.
7. Select the method of transmission from **Method**, as applicable.
8. Enter remarks in **Comments**.
9. Click **Transmit**.
10. The selected report is transmitted to the specified recipients.

Creating Unscheduled Periodic Reports To create Unscheduled Periodic Reports

1. Click the Create Unscheduled Report button
2. The system opens **Periodic Reports** dialog box that provides a list of configured reports of the following types:
   - PSUR - Containing ICH PSUR Line Listing Reports
   - IND - Containing US IND Periodic Reports
   - NDA - Containing US NDA Periodic Reports
   - CTPR - Containing CT Periodic Reports
3. Click the **(+) icon** against the desired category to view all the reports within that category.
4. Select the report you wish to create from this list and click **Select**.
5. When the system opens the **Report Batch Printing** dialog, select **Run Now** or **Run at**, as appropriate.

   Note: If you select **Run Now**, specify PDF, RTF, or CSV from the drop-down menu for the report output option to generate the PSUR or CTPR report in the selected format.

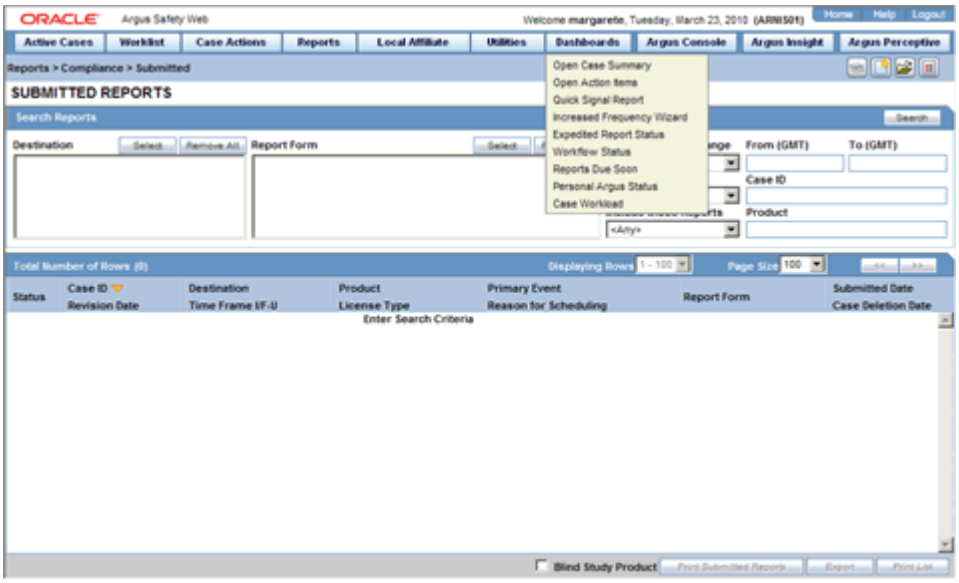
   If you select **Run at**, specify the date/time to schedule the PSUR report to be generated by Argus Safety Service. This enables only **Final** and disables all other **Print As** options.

6. Select what you want printed on the report: **Final**, **Draft**, **Internal**, or enter **Other** information.
7. Click **OK**.

8. The system generates the periodic report.

Submitted Reports

This section provides information about how to submit and view reports. The following is an illustration of the **Submitted Reports** page.



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The following table lists and describes the icons that appear on the **Submitted Reports** page.

Field	Description
View Report	Enables you to view the report.
Report Details	Enables you to view the report details.
Unsubmit Reports	Enables you to unsubmit reports through a confirmation dialog. If you select the option to send a nullification report before clicking OK, a justification dialog also appears, as shown in the section on Deleting a Case.

Submitting Reports

Before you can mark a report as submitted, the report must first be approved.

Use the following procedure the submit an approved report.

1. Open the case for which the report has to be approved.
2. Open the Regulatory Reports tab in the Case Form.
3. When the system opens the Regulatory Reports details for the selected case, click the icon associated with the report you wish to approve.
4. Select View Report Details.

Note: The **Case Nullification Date** is the date when the case is deleted, the **Case Nullification Reason** is the comment entered when the case is logically deleted in Argus.

5. Select **Submitted** from the **State** list in the **Routing** tab and click **Route**.
6. When the system opens a dialog box, enter the required details and click **OK**.
7. The report is approved.

Note: A user who has "Workflow Manager" rights can undo the submission of a report, if necessary.

Viewing Submitted Reports

Use the following procedure to view submitted reports.

1. Select the Reports --> Compliance --> Submitted Reports.
2. When the system opens the **Submitted Reports page**, enter the appropriate search criteria and click **Search**.
3. The system displays the **Search Results**.

Submitted Reports Fields and Field Descriptions

The following table lists and describes the search fields on the **Submitted Reports** page.

Field	Description
Destination	Select one or more Reporting Destination(s).
Report Form	Select one or more Report Form(s).
Submission Date Range	Specify a specific date range from the drop-down list. **Tip:** To specify your own dates use the **To** and **From** dates.
License Type	Select the License type. **Note:** Only reports that have been scheduled based on the selected license type will be displayed.
Case ID	Enter the specific case number. **Tip:** Use wild cards such as 2007% to search for cases starting with 2007.
Include these Reports	Select the required report type or case status to be displayed.
Product	Select the product as required. The reports scheduled for these products will be displayed.

Submitted Reports Search Results

The following table lists and describes the contents of the columns in the **Submitted Reports Search Results.**

Field	Description
Status	Displays the status of the report.
Case ID	Displays the Case Number for the report.

Field	Description
Revision Date	Displays the date when the last revision was made.
Destination	Displays the destination of the report (agency name).
Time Frame (I/F-u)	Displays the whether the report was initial or follow-up.
Product	Displays the first suspect product for the case on which the report is based (expedited reports).
License Type	Displays the license type of the report.
Primary Event	Displays the first event term for the case on which the report is based (expedited reports).
Reason for Scheduling	Displays the reason provided for scheduling the report.
Report Form	Displays the type of report scheduled (form) and initial/follow-up status (e.g. "Initial Report" or "Follow-up #3").
Submitted Date	Displays the report's submission date.
Case Del. Date	Displays the date when the case was deleted.
Blind Study Product	Enables you to mark the study product as blinded.
Print All Submitted Reports	Enables you to print all the submitted reports.
Export	Enables you to export the report.
Print List	Enables you to print the report as a PDF.

Unsubmitting Reports

Cases that are archived while unsubmitting reports can be reopened from the **Archived Case** dialog.

Use the following procedure to unsubmit such cases.

1. Enter the password and notes required in the **Archived Case** dialog box.
2. When the system opens the **Report Unsubmit** dialog box, enter the reason for unsubmitting the report and click **OK.**
3. The system unsubmits the report.

> **Tip:** The icon (displayed in the lock state column) in the **Reports-> Compliance - Expedited** and **Submitted** screens denotes a SUSAR case.

Lock State Header Options

Click the **Lock State** header row. A pop-up appears listing the following sorting options:

- Lock State
- SUSAR
- Exp/Per

These options enable you to sort cases based on the case categorization.

Aggregate Reports

Argus Safety has powerful system reporting capabilities that enable you to monitor the following:

- Product safety profiles
- Case progress
- Company productivity during the case handling process

This section provides information about the Argus Aggregate Reports.

To view an aggregate report

Select Reports --> Aggregate Reports --> <*Report Type*>. P

General Usage Information

When using **Aggregate** reports, be aware of the following:

- The date and time printed on the following reports are the date and time the query is executed for case qualification. They **are not** the date/time the query was completed and the report obtained Web Server.
- Case Listing Report
- Case Data Analysis Report
- The system converts the following elements that display in the case form as actual text on the Case Listing and CIOMS II Line Listing reports:
- Duration of Administration
- Time Between First Dose/Primary Event
- Time between Last Dose/Primary Event
- Another field has been added to the **Regulatory Reports** section for the report follow up number. The system prints the report follow-up number on the expedited reports in the following format:

F/U# X

where:

X is the report follow-up number.

- For an initial report, the system prints **initial** in the column.
- If there are no reports for the case in the Case Listing/CIOMS II Line Listing, the column is left blank.
- This option is available on the CIOMS II Line Listing/Case Listing reports.
- The system uses the IE offset of the client workstation to print the date and time component for **all** system-calculated fields on the **Case Listing/CIOMS II Line Listing** reports for the following fields

Table Name	Column Name	Local IE Adjustment
case_master	close_date	Yes
case_master	date_locked	Yes
case_routing	route_date	Yes
cmn_reg_reports	date_approved	Yes

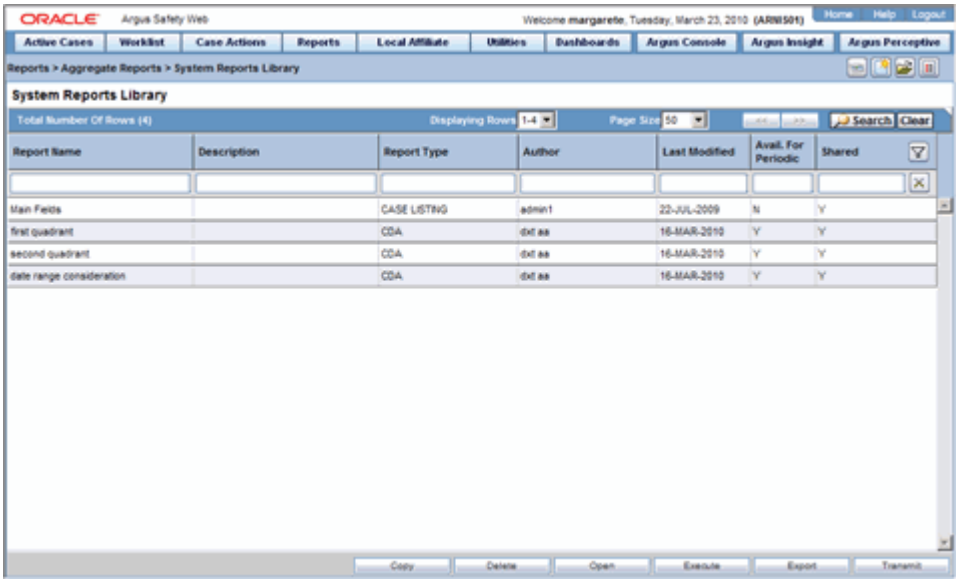
cmn_reg_reports	DATE_GENERATED	Yes
cmn_reg_reports	date_scheduled	No
cmn_reg_reports	date_submission_determined	Yes
cmn_reg_reports	date_submitted	Yes
cmn_reg_reports	date_xmt	Yes
rpt_routing	route_date	Yes

- You can filter cases in the following aggregate reports based on the lock/archived date:
- Case Listing
- Case Data Analysis
- CIOMS II Line Listing
- When you select **Case Locked/Archived** date, the system limits the cases based on whether the case is locked/archived within the specified time frame.
- The lock date is considered the locked date.
- If you select the **Case Patient** or **Reporter** Information in the Case Listing or CIOMS II Line Listing reports and the **Protect Confidentiality** field is checked for the patient or reporter Information, the system **does not** print the relevant patient or reporter Information selected in the Case Listing or CIOMS II Line Listing report.
- If you **do not** have permission to view the reporter or patient information, the corresponding reporter or patient elements selected on the Case Listing or CIOMS II Line Listing report are blank.

If the report doesn't have cases that meet the criteria, the system prints the PDF with a "No data found" message.

Using the System Reports Library

You can access the **System Reports Library** from **Reports --> Aggregate Reports --> System Reports Library**.



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When using the **System Reports Library**, be aware of the following:

- The user can use the following fields to query all memorized reports:
  - Report Name (type ahead)
  - Description (type ahead)
  - Report Type (type ahead)
    - Case Data Analysis
    - CIOM II Line Listing
    - Case Listing
- Author (type ahead)
- Last Modified
  - Date (date text box)
  - Upgrade populates this with System Date
- Avail. for Periodic (text box)
  - Blank
  - Yes
  - No
- Shared (text box)
  - Blank
  - Yes
  - No
- The user can enter wildcards in **Name** and **Description** fields.
- The following are in **Search and Navigation** bar:

  - Displaying Records Drop-down list (standard functionality)
  - Page Size Drop-down list (standard functionality)
  - Back Button (page back standard functionality)
  - Forward Button (page forward standard functionality)
  - Search Button (executes the search with any entered criteria)
  - Clear Button (clears the search drop-downs or text boxes)
- The system displays the following columns on the screen:
  - Report Name - The report name given by the user.
  - Description - A description of the report as defined by the user.
  - Report Type - The report type.
  - Author - The name of the author of the report.
  - Last Modified - The date the report was last modified. This is the system date.
  - Avail. for Periodic - Indicates whether the report is available for Periodic reports
  - Shared (See System Rule below)
- The system displays the following buttons on the page:
  - Copy
  - Delete
  - Open
  - Execute (standard functionality)
  - Export
  - Transmit
- When the user clicks the **Filter** icon, he/she can filter on any element.
  - The system provides the type ahead feature to enable the users to filter on any text element.
  - When the user clicks X, the system closes the filtering options.
  - When the user specifies filtering criteria, the filter icon changes to the paper clip icon to indicate that filtering criteria has been specified.
  - The system permits the user to conduct a like search, For example, if user searches for "Cure" the system returns all elements beginning with Cure.
  - The system permits the user to conduct wildcard searches. For example, if the user searches for "%Cure," the system returns all elements containing Cure.
  - When the user clicks Search, the system filters reports in the report list.
- The system saves **all** user preferences for future use.
- The following fields word wrap, but do not scroll:
  - Report Name
  - Description (200 Characters)
- If a record in a row is available for periodic reporting, the system places a Yes in the **Avail. for Periodic** column; otherwise the system displays No in the column.

  - The user must select the available for periodic reporting option when he/she creates the report.

- If the system report is shared, the system places a Yes in the **Shared** column; otherwise it displays No in the column.
  - The user must set the report creation or modification options when he/she creates the report.
- The user can click the column heading to sort the column in ascending or descending order.
  - **Report Name** is the default sort column and is sorted in ascending order.
  - Ascending (A to Z, 1&emdash;10, etc.) is the default sort order.
  - A sorted column has an up or down arrow to indicate whether the column is sorted in ascending or descending order.
- When the user clicks **Copy**, the system displays a copy of the report in the appropriate popup. The system displays the Case Data Analysis Report, the CIOM II Line Listing Report, or the Case Listing Report.
  - The system names the copy of the report *Copy of xxxxxx*

    where:

    The system displays the following columns on the screen:

    xxxxxx is the name of the report the system is copying.

    If there are too many characters in the report name, the system truncates the name.
- When the user clicks **Delete**, the system displays the following message:

  Are you sure you want to delete?
  - If the user clicks Yes, the system deletes the selected row.
  - If the user clicks No, the pop-up window closes and nothing changes.
  - If the report is in use, the system displays the following message:

    The report which is selected is being used and cannot be deleted.
- When the user clicks **Open**, the systems displays the appropriate Report pop-up box:
  - If the has not selected a row, the system disables the **Open** button.
  - The system determines the appropriate dialog box based on the report type.
    * If the user selects a Case Data Analysis report, the system displays the **Case Data Analysis** popup.
    * If the user selects a CIOMS II Line Listing report, the system displays the **CIOM II Line Listing** popup.
    * If the user selects a Case Listing report, the system displays the **Case Listing** popup.
  - If the selected report is in use, the system displays the following:

    The report which is selected is being used by XXXX and cannot be modified.

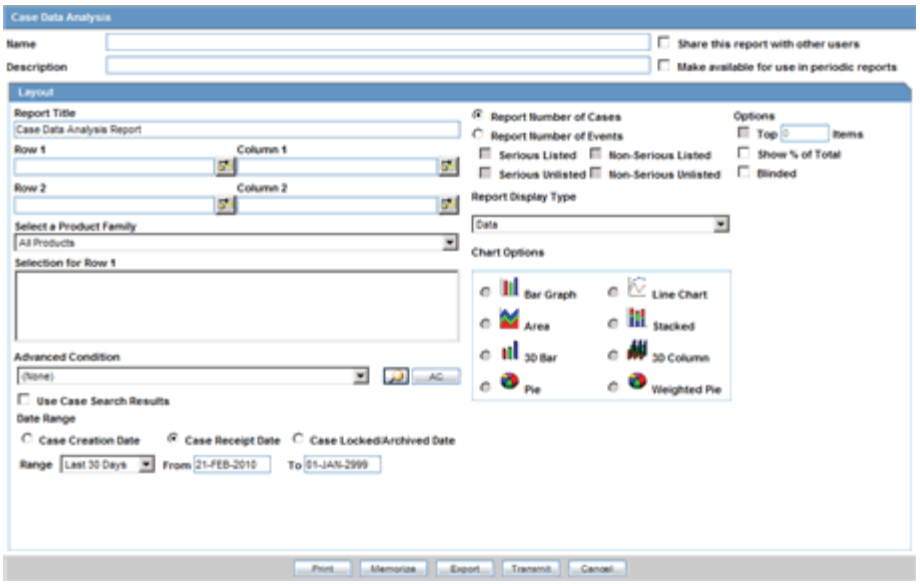
    where:

    XXX is the full user name of the person using the report.

- When the user clicks **Execute**, the system generates the selected reports.
  - If the user has not selected a row, the system disables the **Execute** button.
  - The system creates and displays the report in PDF format just as it does when the user clicks **OK** on the individual report pages.
- When the user clicks **Export**, the system generates the selected report and starts the export process (i.e., CSV file download).
  - If the user has not selected a row, the system disables the **Export** button.
- If the user clicks **Transmits**, the system generates the selected report and starts the transmit process.
  - The system displays the **Recipient** popup.
  - If the user has not selected a row, the system disables the **Transmit** button.
- The **Memorize** button in the **System Report** dialog enables the user to enter the memorize details in the report configuration options.
  - If the user fails to enter the **Name** in the memorize section, the system disables the **Memorize** button.
    * Case Listing
    * CIOMS II Line Listing
    * Case Data Analysis

About Case Data Analysis Reports

The **Case Data Analysis Report** enables you to view quantities of cases over time in a Cross-Tabular Fashion. Use the following procedure to create a **Case Data Analysis** report. The following is an illustration of a **Case Data Analysis Report**.



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Creating a Case Data Analysis Report

Use the following procedure to create a **Case Data Analysis** report.

To create a Case Data Analysis Report

1. Select Reports --> Aggregate Reports --> Case Data Analysis.
2. In the **Case Data Analysis Report** view, select the information that must appear in the report.
3. In **Row1**, select the field the system uses to group cases by row.
4. In **Column1**, select the data the system uses to group cases by column.
5. In **Row2**, select the field by which each **Row1** item will be categorized.
6. In **Column2**, select the field by which each **Column1** item will be categorized.
7. Select a product family to which the report applies, if appropriate.
8. In **Selection for Row1**, select the value for row 1 by which the report must be restricted.
9. Specify an advanced condition, as appropriate.
10. Select **Report Number of Cases** or **Report Number of Events**, depending on the number of cases or the number of events to be entered in the report.
11. If you select Report Number of Events, you can specify the kind of events (serious listed, non-serious listed, serious non-listed, or non- serious non-listed) that will appear in the report.
12. Select whether only the top few items should be displayed and enter the number of items that should be displayed.
13. Select the **Show % of Total** check box to specify the percentage in each cell in the report.
14. Select the **Blinded** check box to hide blinded information in the report.
15. Select the **Use Case Search Results** checkbox to limit the Case Data Analysis only to the cases present in the Case Search dialog.
16. Specify a date range for the cases that will appear in the report.
17. 1In **Report Type**, select whether the report is to be printed in text (data) format or in graphical (chart) format.

    If you select **Chart**, you can specify the kind of chart (bar graph, line chart, etc.) that will be used to display the information.
18. Enter a title for the report.

Memorizing the Criteria Specified for a Particular Report.

To memorize the criteria for a specific report

1. Click **Memorize** to open the **Memorized Report** dialog box.
2. Click **Save.**

Saving, Deleting, or Cancelling a Report

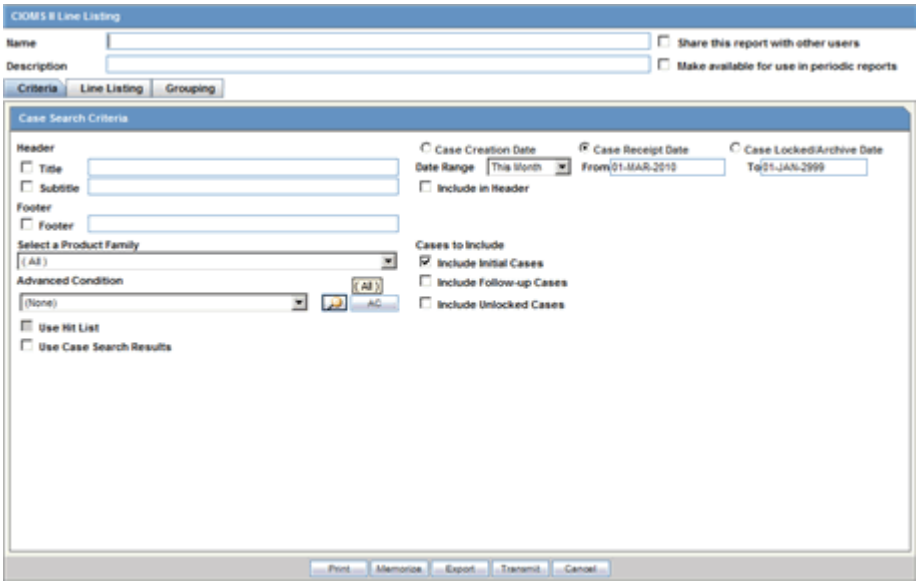
Use the following procedure to save, delete, or cancel a report, as applicable.

To save, delete or cancel the report, as applicable

1. Click **OK** in the **Case Data Analysis** screen to generate the report in PDF format.
2. To export a report in CSV format, click **Export**.
3. To transmit a report using Argus Safety Service, click **Transmit**

About CIOMS II Line Listing Reports

The CIOMS II line listing report is a common format desired by Drug Safety professionals for reviewing cases. Create this report from the **CIOM II Line Listing** dialog box shown in the following illustration.



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Creating a CIOMS II Line Listing Report

Use the following procedure to create a **CIOMS II Line Listing** report.

To create the CIOMS II Line Listing report

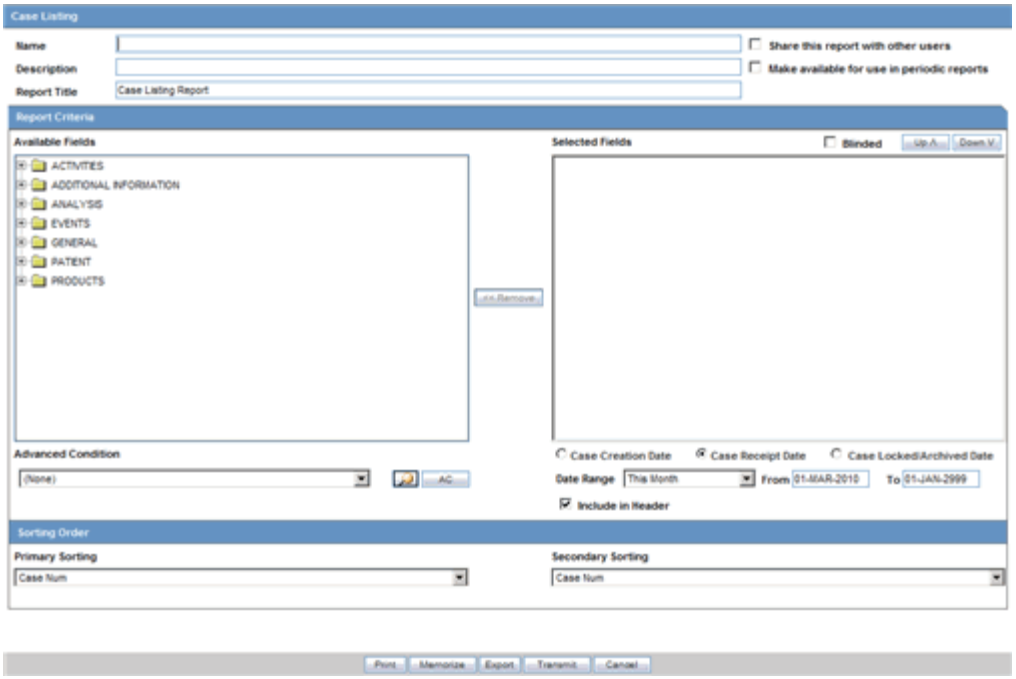
1. Select CIOMS II Line Listing from Reports -->Aggregate Reports --> CIOMS II Line Listing.
2. On the CIOMS II Line Listing **Criteria** tab, select information for the header, footer, product family, advanced condition (if any), cases to include, and date.
3. Select either the **Case Creation Date** or **Case Receipt Date** radio button and specify a date range to run the report.

> **Note:** If you perform a search and return a list of cases to the Case Search screen, the **Use Case Search Results** is visible. Checking this box will disable all selection criteria with the exception of "Include Unlocked Cases". For example, the Advanced Condition and Date Range will be disabled.

4. In the Line Listing tab, add or remove the appropriate fields.
5. In the **Grouping** tab, add or remove elements, insert a page break and change the sort order (if desired).
6. Click **Memorize** to open the **Memorized Report** dialog box.
7. **Save**, **Delete** or **Cancel** the report, as applicable.
8. Click **OK** in the **CIOMS II Line Listing** screen to generate the report in PDF format.
9. Click **Export** to export a report in CSV format.
10. Click **Transmit**, to use Argus Safety Service to transmit a report.

About Case Listing Reports

The **Case Listing Report** enables you to filter cases based on **Case Initial Receipt Date** and **Case Creation Date**. You can select multiple entities from the List of available fields using the CTRL+CLICK functionality. The following is an illustration of the **Case Listing** dialog box.



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Creating a Case Listing Report

Execute the steps below to create a Case Listing report:

1. Select Reports --> Aggregate Reports --> Case Listing.
2. When the system opens the in the **Case Listing Reports** view select the information to appear on the report.
3. Select the fields that are to appear in the report from the **Available Fields** list.
4. Click **Add**. Repeat this process for each field that must appear in the report.

5. Use **Move Up** and **Move Down** to arrange the fields in the **Selected Fields** list.
6. Select the **Blinded** checkbox to hide blinded information in the report.
7. Specify an **Advanced Condition**, if appropriate.
8. Specify a date range for the cases to be displayed in the report.
9. If you select the Include in Header check box, the selected date range is displayed on the report.
10. Under Sorting Order, select the fields by which the cases will be sorted. The first field allows you to create a list that is sorted with respect to that particular field. Groups of cases that are identical with respect to the first field can be sorted by specifying the second field.

> **Note:** You cannot sort the cases by fields that do not appear on the report.

11. Enter the title of the report.
12. Click **Memorize** to memorize the criteria specified for a particular report. The **Memorized Report** dialog appears.
13. **Save**, **Delete** or **Cancel** the report, as applicable.
14. Click **OK** in the **Case Listing Reports** screen to generate the report. The report will be generated in PDF format.
15. To export a report in CSV format, click **Export**.
16. To transmit a report using Argus Safety Service, click **Transmit**.

About System (Memorized) Reports

The **Memorized Reports** enables you to recall a memorized Case Listing, CIOMS II Line Listing or Case Data Analysis Report criteria. You can save (memorize) search criteria and reuse these criteria when generating future reports.

The **Memorized Reports** dialog displays current user reports as well as reports that are shared by all users. Use the following procedure to create **Memorized Report**.

To create a Memorized report

1. Select Reports --> Aggregate Reports --> Memorized Reports to open the Memorized Report dialog box.
2. Select a memorized report and click **Open**.
3. Click the **Share this report with other users** check box to make the report criteria available to all users. Previously memorized reports appear in the **Your Memorized Reports** list.
4. Click **Delete** to delete a selected memorized report.
5. Select the **Make available for use Periodic Reports** check box to use this report in periodic reports like PSUR, CTPR, IND, and NDA.

> **Note:** A shared report can only be deleted by the Administrator or the user who created it.

General Usage Information

When using the **System (Memorized) Reports**, be aware of the following.

- The following **Line Listing Available** fields functionality boxes have been updated:
  - Reports > Aggregate Reports > CIOMS II Line Listing, (Line Listing tab) to allow select fields.
  - Reports > Aggregate Reports > Case Listing to allow the user to select fields.
  - Reports > Aggregate Reports > Case Data Analysis.
- A tree view, similar to the advanced condition tree view, has been created for the available fields. The fields are the same as those currently displayed and the field text box is read-only.
- If you select a field from the tree view and adds it to the Selected Fields list, the system removes the field from the **Available Fields** list.
- If the you try to add the field again, the system displays a message and displays the name of the selected field inside brackets ([ ]). If you wish to remove the selected field, click **Yes**.

Periodic Report Types

This section lists the different Periodic Reports in Argus and discusses about each of them in detail. Place the cursor over the **Periodic Reports** option in the **Reports** tab to go to any of the Periodic Reports.

You can create four kinds of periodic report.

- Clinical Trial Periodic Reports
- ICH PSUR Reports
- US IND Periodic Reports
- US NDA Periodic Reports

Storing Periodic Reports in Documentum

Argus Safety enables you store your Periodic Reports in Documentum.

When you approve an expedited report from within Argus, the system exports the report as a PDF file and saves it in the **Documentum** database by Argus Safety Service. From this point, you can perform document reviews within the Documentum system.

When the report is ready to be submitted, mark the report as submitted from within Argus. Argus Safety Service updates the status of the report within Documentum to **Submitted**.

If the report is to be transmitted via fax or email, Argus Safety Service marks the report as a successful submission in Documentum only **after** the fax or email transmission has succeeded.

Viewing a Summary of Periodic Regulatory Reports

You can select any of the following options in viewing the summary of a periodic regulatory report:

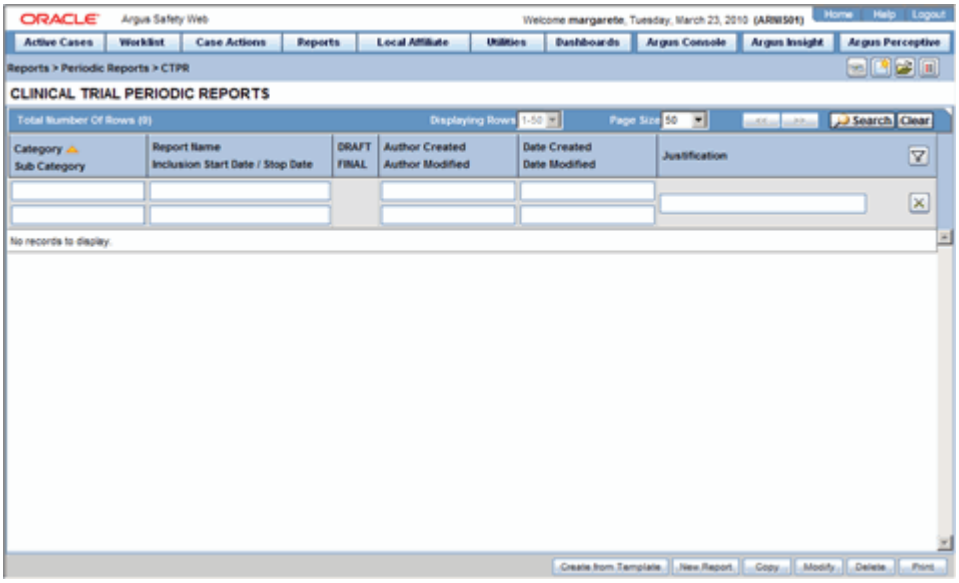
- To view the regulatory reports for a particular case (scheduled, generated, and submitted), open the **Regulatory Reports** tab of the Case Form.

- To view all scheduled, generated, and approved reports, as well as other outstanding action items assigned to you or your user group, select **Reports** in the **Worklist** menu.
- To view a list of all scheduled, generated, and approved periodic reports, select **Periodic Reports** from the **Reports | Compliance** menu.

Using the Library Page

The periodic reports have a library page for the following reports:

- PSUR
- CTPR
- IND
- NDA



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The following table lists and describes the fields on the **Library Page**

Field/Control Name	Purpose
Category	Enables the user to view the report Category.
Sub Category	Enables the user to view the report Sub Category.
Report Name	Enables the user to view the name of the Periodic Report
Inclusion Star Date/Stop Date	Enables the user to view the report start and stop dates as defined in the configuration.
DRAFT/FINAL	Enables the user to view the draft and/or final report
Author Created	Enables the user to view the name of the author who created the report.
Date Created	Enables the user to view the date the report was created.
Date Modified	Enables the user to view the date the report was last modified.

Field/Control Name	Purpose
Justification	Enables the user to view the justification for updating the report. The system displays the standard Justifications dialog that contains the lasts justification entered by the user.
Search	When the user clicks Search, the system initiates the search operation. When the system displays the search results, the user can enter search parameters in various fields and click Search to narrow the search results.
Clear	Enables the user to clear user-entered data from the fields

When using the **Library Page** be aware of the following:

- The system places the total number of records displayed on the library page in the **Total Number of Row (x)** read-only field in the **Report** header.
- The user can select the number of cases to display from the **Page Size** drop-down list.
- The page size drop-down list contains the following values:
  - 50
  - 100 (default)
  - 250
  - 500
  - 1000
  - 2000
- The system displays the number of reports currently in view and the system automatically updates the range based on the selected page size. For example, if the user selects a page size of 100, the system displays reports in groups of 100.
- The user can go directly to a range of cases from the **Displaying Rows** drop-down option.
- The user can scroll through the reports page-by-page in increments as defined in the **Page Size** drop-down list.
- The user can sort on **all** columns in the **Reports** view by clicking the column header. The system displays an up arrow or a down arrow depending on whether the column is sorted in ascending (A-Z, 1-10, etc.) or descending order (Z-A, 10-1, etc.).
- Initially, the reports are sorted by **Category**.
- The default sort order is ascending.
- When you click the **Filter** icon, the system displays the filtering row to enable you to filter on any element.
- The type ahead feature enables you to filter on any element except Draft/Final.
- Click the appropriate icon to minimize the filtering options.
- Click the **X** to close the filtering options.
- If filtering criteria is defined, the system displays the filtering elements icon to indicate that filtering elements exist.

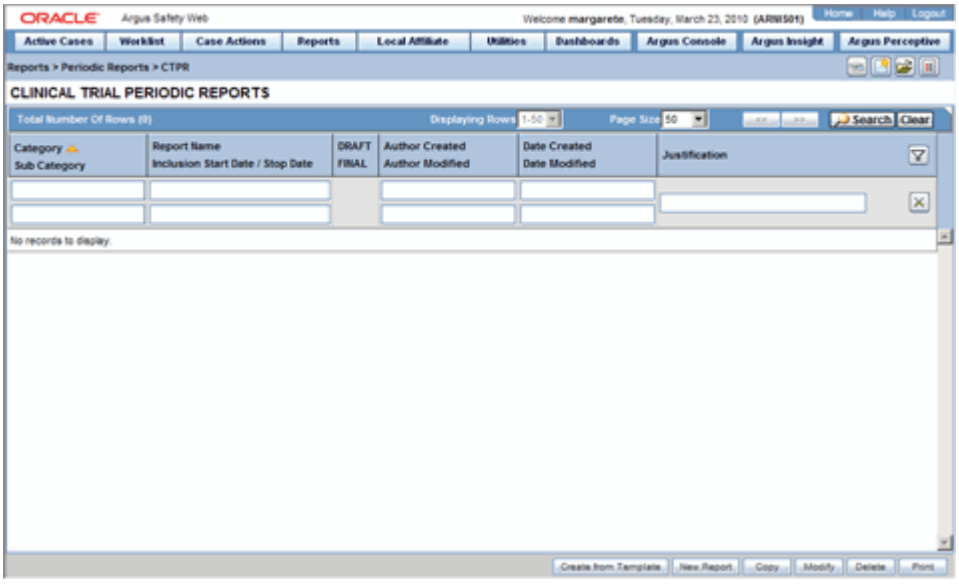
- If filtering criteria **is not** defined, the system displays the no filtering elements icon to indicate that no filtering elements are defined.
- The system enables you to perform a *like* search. For example, if the user searches for Cure, the system returns all elements that **start** with Cure.
- The system enables you to perform *wildcard* searches. For example, if the user searches for %Cure, the system returns all elements that **contain** Cure.
- When you click **Clear**, the system clears the filtering criteria from the fields.
- Clicking the filter icon enables you to filter for reports in the list of reports.
- The system saves all user preferences for future use. If the user has already entered filter elements, the system displays the filter details for the last search when it displays the dialog.
- If another user is modifying a report, the system displays the following:
- The report which is being selected is being used by XXXX and cannot be modified.

  where:

  XXXX is the full user name of the person using the report.

About Clinical Trial Periodic Reports

The **Clinical Trial Periodic Reports (CTPR)** are created to report the IND Annual reports and EU Clinical Trial Directive line listing reports to FDA.



To create Clinical Trial Periodic Reports

1. Select Reports --> Periodic --> CTPR (Clinical Trial Periodic Reports) to open a list of CTPR Reports.
2. To create a new report from an existing report in the list, click **Copy** or **Modify**.
3. Click **New Report** to create an entirely new report. The **Clinical Trial Periodic Reports** dialog opens.
4. Enter an appropriate name for the report under **Report Name**.
5. Use the tabs in this dialog to configure the **CTPR**.

General Usage Information

When using the CTPR, be aware of the following:

- The system enables you to group cases by **Product Name** and **Drug Regimen Frequency**:
- Product Name
  - This option enables you to group the Product Name - Formulation - Concentration with Units when the elements are separate with a hyphen (-).
  - If an element is missing, the system **does not** print the hyphen (-).
  - The system groups the cases based on the primary drug in the report.
- Dosage Regimen Frequency
  - This option enables you to group the frequency of the primary dosage regimen for the primary drug in the report.
  - The system prints Frequency: followed by the frequency as defined above.
- You can select datasheets for specific report types similar to the PSUR Report for the Inclusion criteria. If you select any rows in the inclusion criteria, the system disables the **Datasheet** selection dialog.
- **Report Type.**This portion lists the report types (configured in Code List | Report Type) the report will be run against (LM_REPORT_TYPE). The user must select a report type so the system knows to save the criteria row.
- **Serious Criteria.**This enables you to specify the seriousness of the cases for the selected report type as follows:
  - **Serious.**Case Level or Primary Event is Serious.
  - **Non-Serious.**Case Level or Primary Event is Non-Serious.
  - If you select both **Serious** and **Non-Serious**, the system ignores the criteria.
  - **Fatal.** At least one event has a Fatal event outcome.
  - **Non-Fatal.**No events have a Fatal event outcome.
  - If you select both **Fatal** and **Non-Fatal**, the system ignores the criteria.
- Listedness.
  - When using the case level assessment, the system **does not** consider the datasheet. Cases appear in the PSUR if the case level assessment matches the selected criteria.
  - When using the primary event assessment in conjunction with a datasheet, the system uses **only** the **As Determined** listedness for the primary event when determining whether a case should be included in the PSUR report.
  - If both **Listed** and **Unlisted** are selected, the system ignores the criteria and includes all listedness values (including **Unknown**).
- **Datasheet.**This enables you to specify which Datasheet to use when looking for Listedness (LM_DATASHEET). The system uses the datasheet criterion only when you select the primary event assessment as the CMN_PROFILE assessment.
- When you select the **<ALL>** datasheet option, the listedness for the primary event on at least one datasheet **must** match the selected criteria.
- Related/Non-Related.

  - When using case level assessment, cases appear in the PSUR when the case level causality matches the selected criteria.
  - When using the Primary Event assessment, cases appear only if the causality for the primary event **as reported** or **as determined** matches the selected criteria.
  - When using the **All Events** assessment, cases appear if any case events with **as reported** or **as determined** causality match the selected criteria.
  - If you select both **Related** and **Non-Related**, the system ignores the related/non-related criteria.
- **HCP/Non-HCP.** To have a case included in the PSUR, you must identify at least one case reporter as a HCP or Non-HCP. If this is being used in conjunction with the **Primary Reporter Only** checkbox, the system evaluates **only** the primary reporter for this criterion.
- **Primary Reporter Only.** This enables the system to perform the HCP/Non-HCP check against **only** the primary reporter. This updates the entire configuration whether checked or unchecked.
- You can copy an existing template by clicking the **Create from Template** button on the CTPR reports list.
- When you click **Create from Template**, the system displays **the Create from Template** dialog.
- You can choose the CTPR Group Name (as configured in the Product Name configuration) from a type ahead field.
- When you enter the CTPR Group Name in the **Select CTPR Group Name** field and the **From** and **To** dates in the **Create from Template** dialog and click **OK** the system does the following:
  - Saves the CTPR Configuration with the new dates.
  - Replaces the products in the list of selected products with **all** products as defined for the selected CTPR name.
  - Replaces the periodic report name in the newly configured periodic reports with a new name in the following format:

    XXXX: YYYY to ZZZZ

    where:

    XXXX is the selected CTPR Name.

    YYYY is the From Date entered by the user.

    ZZZZ is the To Date entered by the user.
  - Replaces the date ranges for the **From** and **To** date fields **only** for the Periodic Report.
  - Bases the remaining configuration, including the security permissions, on the selected CTPR template.
- When you enter the CTPR Group Name in the **Select CTPR Group Name** field and the **From** and **To** dates in the **Create from Template** dialog and click **Print and Save,** the system does the following:
  - Saves the CTPR Configuration with the new dates.

- Replaces the products in the list of selected products with **all** products as defined for the selected CTPR name.
- Replaces the periodic report name in the newly configured periodic reports with a new name in the following format:

  XXXX: YYYY to ZZZZ

  where:

  XXXX is the selected CTPR Name.

  YYYY is the From Date entered by the user.

  ZZZZ is the To Date entered by the user.
- Replaces the date ranges for the from and to date fields **only** for the Periodic Report.
- Calls the Report Batch Printing dialog.
- Bases the remaining configuration, including the security permissions, on the selected CTPR template.

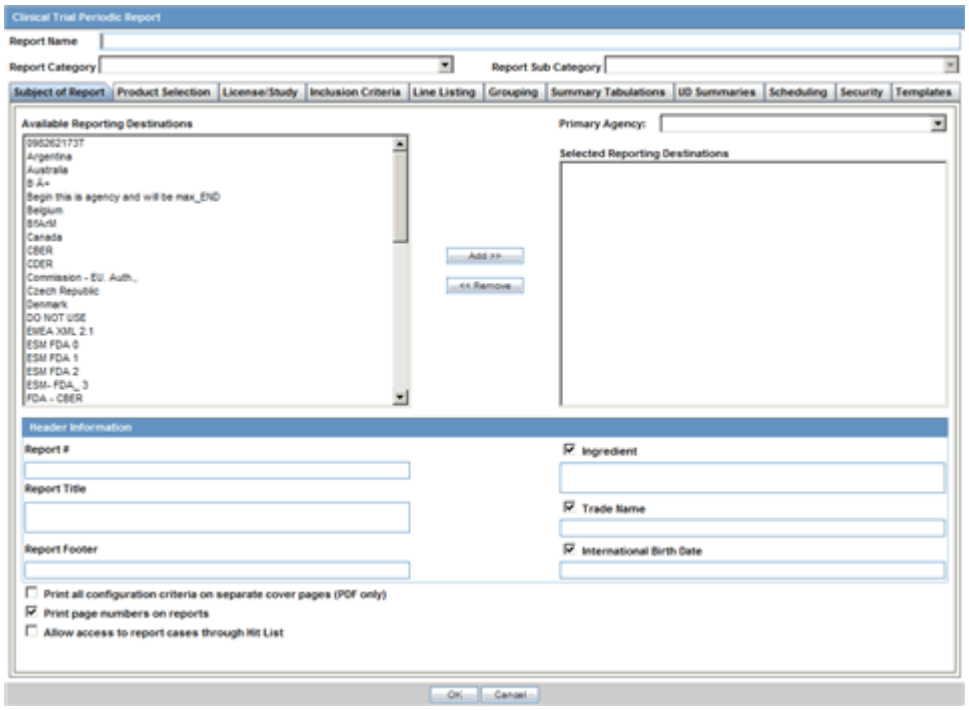
Common Tab Fields

The **Report Name**, **Report Category** and **Report Sub-Category** fields are common to all tabs of the Reports.

The following table below describes these fields:

Field	Description
Report Name	Enter a name for the Report. The name entered here is displayed in the Reports menu.
Report Category	Select a category for the Report. This is displayed in the Reports menu. **Tip:** Select **New** to define a subcategory within the report category. The **Periodic Report Category** dialog is displayed. Enter a category name in **Category** and click **OK**. The category is entered in the **Report Category** drop-down list.
Report Sub Category	Select a subcategory for the report. **Tip:** Select **New** to define a subcategory within the report sub-category. The **Periodic Report Category** dialog is displayed. Enter a category name in **Category** and click **OK**. The category is entered in the **Report Sub-Category** drop-down list.

Subject of Report Tab The **Subject of Report** tab is used to configure the report header and to specify the agency, products, etc. for which the CTPR is applicable.



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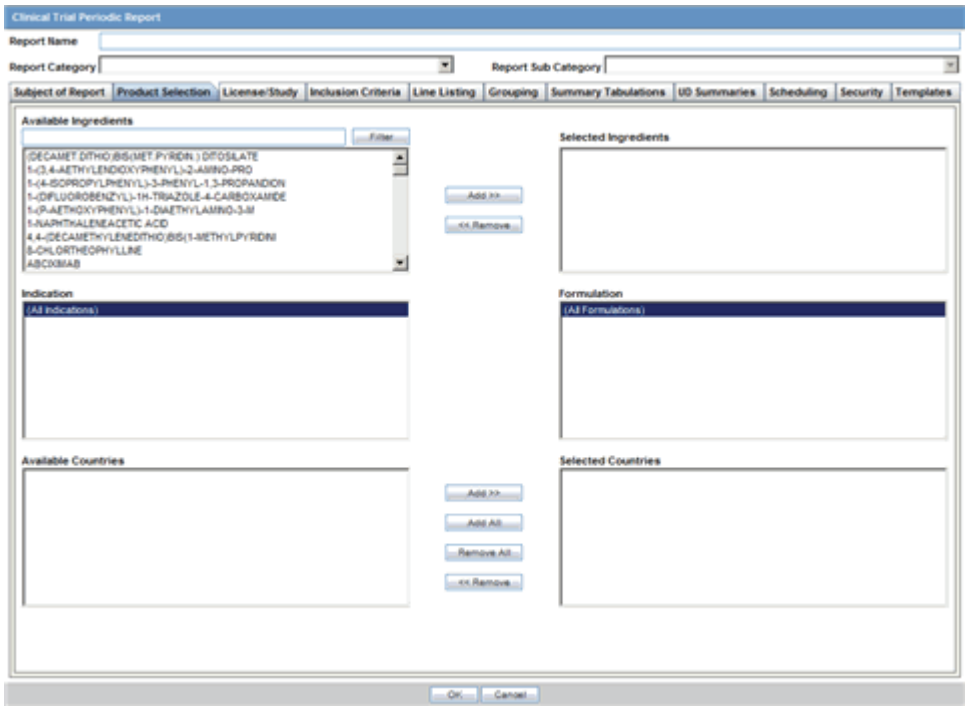
The following table lists and describes the fields on this tab.

Field	Description
Available Reporting Destination	Displays the list of configured Regulatory Agencies. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. Select multiple agencies by holding the **CTRL** key when you click them. Likewise, select an agency from the **Selected Destination** list and click **Remove** to remove it from the selected destination.
Primary Agency	Select the primary agency for the report. **Note:** When you submit a Periodic report, it goes to the selected Primary Agency.
Selected Reporting Destination	Displays the list of agencies where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. Select multiple agencies by holding the **CTRL** key when you click them. Likewise, select an agency from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.
Report #	Enter a report number for this report
Report Title	Enter a report title for this report
Ingredient	Automatically displays the "Ingredient" as provided in the Subject of Report dialog. **Note:** You can choose whether to view this field or not. Click the checkbox displayed with this field to hide or view it.

Field	Description
Trade Name	Automatically displays the "Trade Name(s)". Multiple trade names are also displayed together, separated by commas. **Note:** You can choose whether to view this field or not. Click the checkbox displayed with this field to hide or view it.
International Birth Date	Automatically displays the earliest license awarded date, when a user selects an Ingredient and a Product. **Note:** You can choose whether to view this field or not. Click the checkbox displayed with this field to hide or view it.
Report Footer	Enter the footer for the report
Print all configuration criteria on separate cover page	Mark this box to print out the configuration of this report when the report is printed. This is only available when PDF option is selected during printing.
Print page numbers on reports	When checked, this option enables the user to print page numbers on a periodic report. This is the default for all report configurations. If this checkbox **is not checked**, the following occur. ■ The "Include Periodic Page Numbering" option in the CTPR Summary Tabulations CIOMS Report section is inactive and grayed out. ■ The "User Periodic Numbering on the report" option on CTPR Summary Tabulations FDA PSUR support section is grayed out and inactive. ■ The "Additional Separate Page Numbering for UD Summaries" option on the CTPR UD Summaries tab is grayed out and inactive. ■ The system removes all existing report page numbering and the option to check page number check boxes on the report configuration tabs are grayed out and inactive.
Allow access to report cases through Hit List	When the report is run as final, it creates a Hit List, which can be retrieved from other areas of the application where advanced conditions can be selected. Click this checkbox to report cases through the Hit List.

Product Selection Tab The **Product Selection** tab enables you to select the products included in the **CTPR** report.



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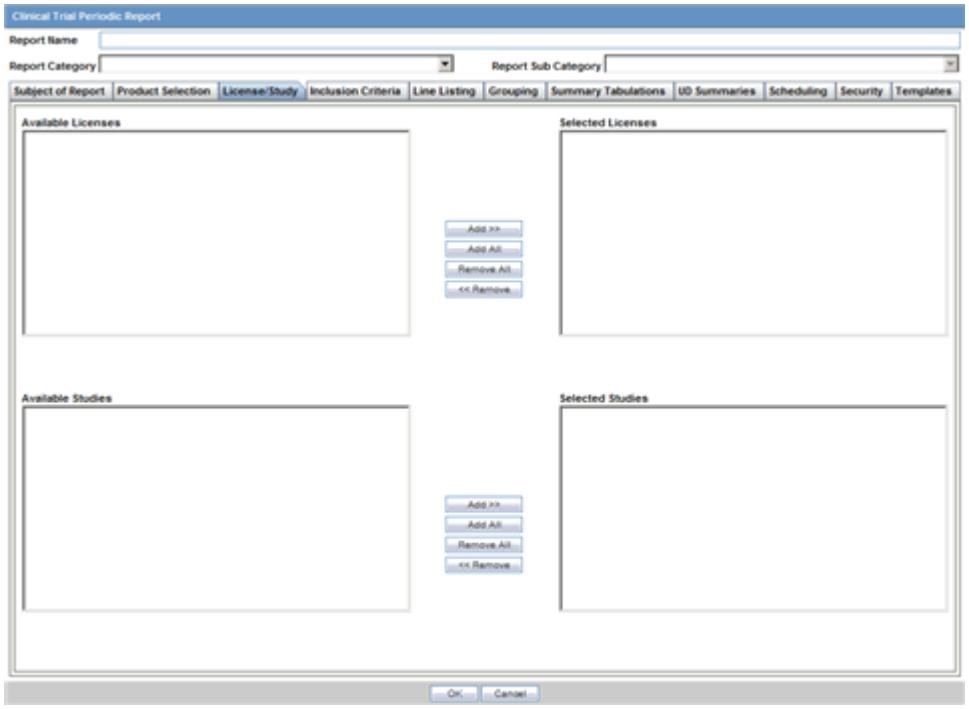
The following table lists and describes the fields on the **Product Selection** tab.

Field	Description
Available Ingredients	Displays the list containing the Ingredients used for the product configuration. Select an ingredient from the list displayed in **Available Ingredients** and click **Add/Remove** to add/remove the ingredient. You can select multiple ingredients at a time.
Filter	Enter an Ingredient name and click **Filter** to search for the entered ingredient within the Available list of Ingredients.
Selected Ingredients	Displays the list of ingredients selected from the **Available Ingredients** list.
Available Countries	This list is auto-populated and displays only the countries with a license containing the ingredient selected from the **Available Ingredients** list.
Selected Countries	Displays the countries selected from the **Available Countries** list.
Indication	This list contains the Indication configured for the product containing the ingredients in the **Available Ingredients** section. The selections made from this list get displayed in the **Available Products** section. **Note:** You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Formulation	This list contains the Formulation configured for the product containing the ingredients in the **Available Ingredients** section. The selections made from this list get displayed in the **Selected Products** section. **Note:** You can select multiple Formulations from the list at a time by pressing the CTRL key and clicking the different Indication entities.

License/Study Tab The **License/Study** tab is used to configure the report header and to specify the agency, products, etc. for which the CTPR will be applicable.



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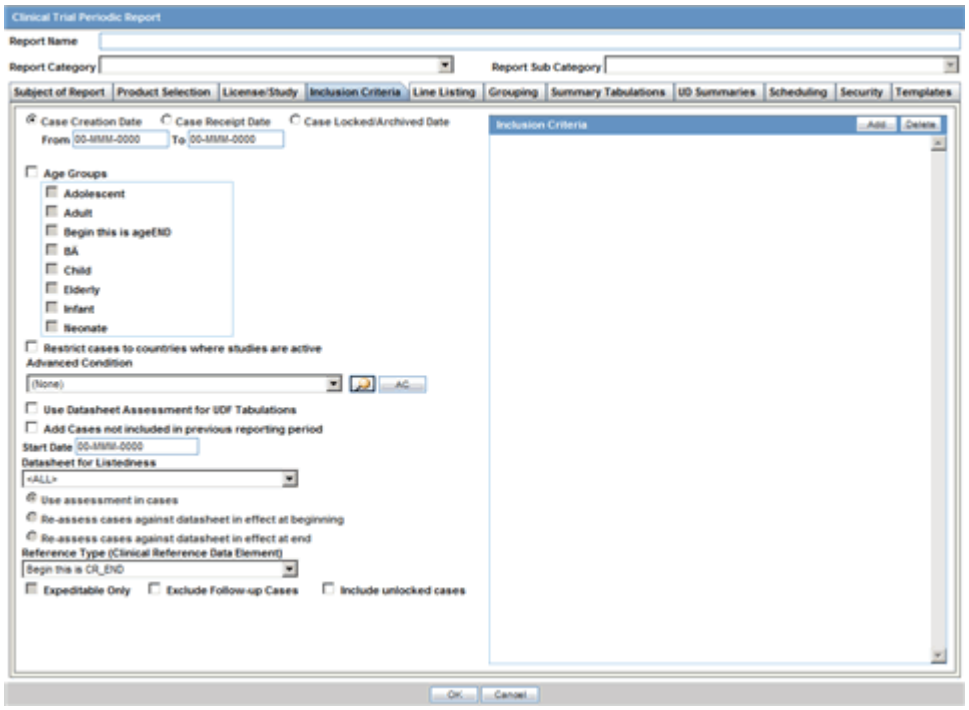
The following tables lists and describes the fields on the **License/Study** tab.

Field	Description
Available Licenses	Contains licenses that use the ingredient selected in the **Ingredient** field. This field is automatically populated when an ingredient has been selected.
Selected Licenses	Displays the licenses selected from the **Available Licenses** list by clicking **Add/Add All**. You can select Licenses that are related to different ingredients for a report.
Available Studies	Contains studies that use the ingredient selected in the **Ingredient** field. This field is automatically populated when an ingredient has been selected.
Selected Studies	Displays the studies selected in the **Available Studies** list by clicking **Add/Add All**. You can select studies that are related to different ingredients for a report.

Inclusion Criteria Tab The **Inclusion Criteria** tab allows you to select search parameters for inclusion of cases in a periodic report.



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The top section of the dialog allows you to specify the type of cases that will be included in the periodic report.

The following table lists and describes the fields on the **Inclusion Criteria** tab.

Field	Description
Case Creation Date	Allows you to specify a range of cases by the date when the case was created.
Case Receipt Date	Allows you to specify a range of cases by the initial receipt date. **Note:** The **Date Range** is only available when an unscheduled CTPR is being created. You must specify only one date range out of **Case Creation Date** and **Case Receipt Date**.
Use Current Version	Allows you to use the latest revision to populate the data within the selected reports.
Use DLP Version	Allows you to use the case data of the version as of the specified DLP Version.
Age Groups	Allows you to include or exclude cases based on the patient's age group. Select all the age group categories that apply.
Restrict Cases to countries where studies are active	References study configuration to determine if the case was submitted during the dates the study was active. **Note:** This option is available only if a study is selected from the **Available Studies** section in the **License/Study** tab. It should not be used for Centrally approved products (CAP), which only have an EU license.

Field	Description
Advanced Condition	Allows you to specify an advanced condition that must be satisfied by each case that is included in the report. Ensure that the advanced condition or the advanced condition query set that is specified here does not contradict any other criteria specified in the dialog.
Datasheet for Listedness	Select the Datasheet to look against for Listedness when running the report. **Note:** Select the **ALL** datasheet to use the most conservative listedness for the primary event, or the Case Listedness for the tabulation.
Use Assessment in Cases	When selected, the CTPR Report will use the Case Event Assessment when performing datasheet listedness calculations.
Re-assess cases against datasheet in effect at the beginning	When selected, the CTPR will re-assess the cases in the line listing based on the Active Datasheet on or before the Start Date of the Reporting period.
Re-assess cases against datasheet in effect at end	When selected, the CTPR will re-assess the case in the line listing based on the Active Datasheets on or closest to the end date of the CTPR Reporting end date range without exceeding that date.
Reference Type (Clinical Reference Data Element)	Select the reference type to be displayed on the Main Listing if **Clinical Study Reference** is selected as a **Data Element** in the **Available Data Elements** section of the **Line Listing** tab.
Expeditable Only	This option is enabled only when an agency has been specified on the **Subject of Report** tab. Check this option to include only those cases that have submitted expedited reports to the specified Primary Agency.
Exclude Follow-up cases	Follow-up cases are cases with a significant follow-up in the Clinical Trial reporting period where the initial receipt date is in a prior period. Check this option to exclude follow-up cases from appearing on the Clinical Trial report.
Include Unlocked Cases	Check this option to allow cases that have not been locked for reporting to appear on the report.
Use Datasheet Assessment for UDF Tabulations	Allows you to select datasheet for a report to make UDF tabulations.If no datasheet is selected, the most conservative listedness is chosen, i.e. Unlisted followed by Listed.
Add Cases not included in previous reporting period	Allows you to add cases which were not included in the previous reporting period. You can enter the start date of the period in the Start Date field.

Using the DLP Version DLP primarily uses two processes:

- Next Case Revision
- Last Case Revision

DLP Options

Be aware of the following DLP Options.

- **Last Completed Version --** This option always uses the case version with the last lock that existed prior to the DLP or "As of reporting" date. This option does not enable data cleaning

  Note: DLP saves only the last revision when multiple saves are performed in the same job session.

- **Next Completed Version** -- This option uses the current case lock or the next following case lock if the case version was initiated prior to the DLP or the "As of reporting" date with two exceptions:
  - If there is no case lock for the current version that was received prior to the DLP, the last (current) case revision is used.
  - If there is a case version after the case lock that was created for the purpose of data cleaning, it is to be used instead of the first locked case revision.
  - If there are multiple contiguous case versions following the first case lock for the purpose of data cleaning, the last case data cleaning version is used.

  Note: The Data Cleaning option is only available with the DLP option **Use Next Completed Version (Includes Data Cleaning)**.

Dates for Using DLP/"As of reporting" Function You can perform DLP queries for the following:

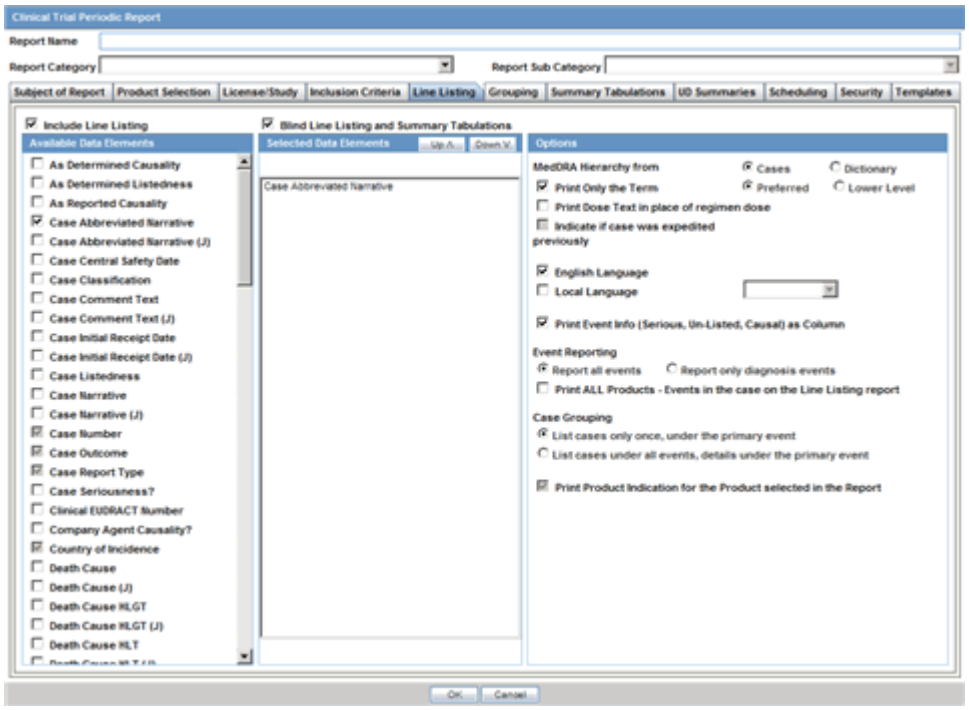
- Receipt Date -- date entered by the user during case creation
- Initial / Follow up Receipt Date
- Safety / Safety Follow up Receipt Date
- System Date (Case Creation Date) - date the case was physically entered

As of Reporting Function The **as of reporting** function returns the same case version results as the DLP Options, with the only difference that the date depends on the "as of date" instead of a DLP date.

Availability of DLP/As of query functionality The DLP / as of query functionality is available in the following application modules:

- Periodic Reports
  - PSUR including all User defined Tabulations and expedited reports within the Periodic Report
  - CTPR including all User defined Tabulations and expedited reports within the Periodic Report
  - IND including all User defined Tabulations
  - NDA including all User defined Tabulations and expedited reports within the Periodic Report
- System Reports
  - CIOMS II Line Listing
  - CDA Reports
  - Case Listing Reports

Line Listing Tab The **Line Listing** tab contains the following fields and sections:



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Field	Description
Include Line Listing	Allows you to select whether you want the Line Listing Data Elements printed with the CTPR Report.
Blind Line Listing and Summary Tabulations	Hides the selected listings from being displayed

Available Data Elements A number of optional fields are available in the **Available Data Elements** frame. Select the check box associated with a data element to add the data element to the report. Be aware of the following:

- By default, the system print s unavailable fields on the report, and they cannot be changed.
- Required data elements are printed as columns in the report. The optional data elements are printed as separate rows below the column data for each case.

Refer to the following table for a list of data elements on this tab.

Data Element	Notes
As Determined Causality	Optional.
As Determined Listedness	Optional.
As Reported Causality	Optional.
Case Abbreviated Narrative	Required and multi-language available.
Case Classifications	Multiple classifications are displayed in separate lines.

Data Element	Notes
Case Central Safety Date	Optional.
Case Comment Text	Optional.
Case Initial Receipt Date	Optional.
Case Listedness	Optional.
Case Narrative	Optional.
Case Number	Required.
Case Outcome	Required.
Case Report Type	Required.
Case Seriousness?	Optional.
Clinical EUDRACT # Number	Optional.
Clinical Study Reference	Optional.
Company Agent Causality	Optional. Displays event causality from product name. Multiple causalities are displayed in separate lines.
Country of Incidence	Required.
Death Cause	Optional. Multi-language available.
Death cause as reported	Optional
Death Cause HLGT	Optional.
Death Cause HLT	Optional.
Death Cause LLT	Optional.
Death Cause SOC	Optional.
Dosage Regimen Batch/Lot #	Optional.
Dosage Regimen Daily Dose	Required.
Dosage Regimen Duration	Required.
Dosage Regimen Frequency	Required.
Dosage Regimen Route of Administration	Required.
Dosage Regimen Start Date/Time	Required. For the selected product the report is based on. List for all dose regimens.
Drug Dechallenge?	Required.
Product Indication	Optional. For the selected product the report is based on.
Product Indication HLGT	Optional. For the selected product the report is based on.
Product Indication HLT	Optional. For the selected product the report is based on.
Product Indication LLT	Optional. For the selected product the report is based on.
Product Indication SOC	Optional. For the selected product the report is based on.
Drug Rechallenge?	Optional.

Data Element	Notes
Event Description as Reported	Required.
Event Onset Date/Time	Required.
Event Preferred Term	Required.
Lab Data - Tabular	Optional.
Literature Author	Optional.
Literature Journal	Optional.
Literature Pages	Optional.
Literature Title	Optional.
Literature Volume	Optional.
Literature Year	Optional.
Literature reference	Optional.
Outcome of Event	Optional.
Patient Age	Required.
Patient Gender	Required.
Patient Initials	Optional.
Patient Relevant History	Optional. Multi-language.
Patient Subject #	Optional.
Product Name	Optional. Displays "product name (generic name) product type, formulation, concentration unit" "daily dose," "dose dose_freq, route"
Product Name Report Inclusion	Optional. Prints the Products that were part of the CTPR Report for the case. Displays "product name (generic name) product type, formulation, concentration unit" "daily dose," "dose dose_freq, route"
Report Comment	Optional.
Study ID	Optional.
Study Other ID	Optional.
Study ID Protocol #	Optional.

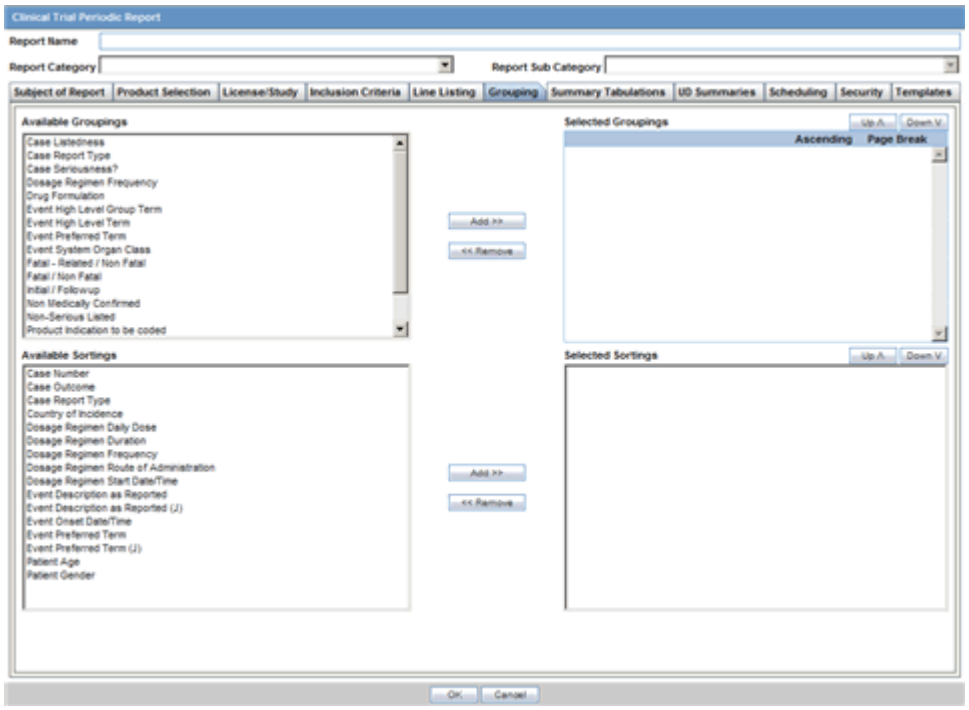
Selected Data Elements This section lists the selected elements and enables you to arrange the order in which these are to be printed. Click the Up or Down buttons to arrange the listed elements above or below in order of priority.

Options

Field	Description
MedDRA Hierarchy from Cases/Dictionary	Select **Cases** to populate the data from the case data. Select **Dictionary** to populate the data from the MedDRA dictionary.
Print Only the Term (Preferred Term or Lower Level Term)	Prints only the event Preferred Term (PT) or event Lower Level Term (LLT) as per the selected radio button. Select the PT option to print only the preferred term and not the verbatim description.

Field	Description
Print Dose Text in place of regimen dose	Prints the dosage and frequency information from **Dose Description** field instead of **Regimen Dose**.
Indicate if case was expedited previously	This checkbox is selected if a primary agency has been selected in the **Subject of Report** tab. Cases for which an expedited report was previously submitted to the selected authority are marked with an asterisk.
English Language	Provides the option to print the descriptions in English
Local Language	Allows a user to specify which Local language for a multi-language field is to be printed i.e. the Abbreviated Narrative field.
Print event info (Serious, Un-listed, Related) as Column	Select this check box to print the Seriousness, Listedness and Causality under the Event Verbatim column. **Note:** Events having listedness of "Unknown" are considered "Unlisted." If only diagnoses are assessed for event assessment, the events which are associated with a Diagnosis but have been marked with Diagnosis as "Np" display " - " for both listedness and causality.
List cases only once, under the primary event	Select this option to view the details of cases in the Main Line Listing only once under the Primary Event
List cases under all events, details under the primary event	Select this option to view the details of cases in the Main Line Listing only once under the Primary Event, while non-primary events are listed under their respective event hierarchy with a reference to the primary event body system. Therefore, use this option when grouping on Main Line Listing is by the Event Body System.
Print Product Indication for the product selected in the report	Select this option to print Product Indication for the product selected in the report.

Grouping Tab Refer to the following table for a description of items in the **Grouping** tab.



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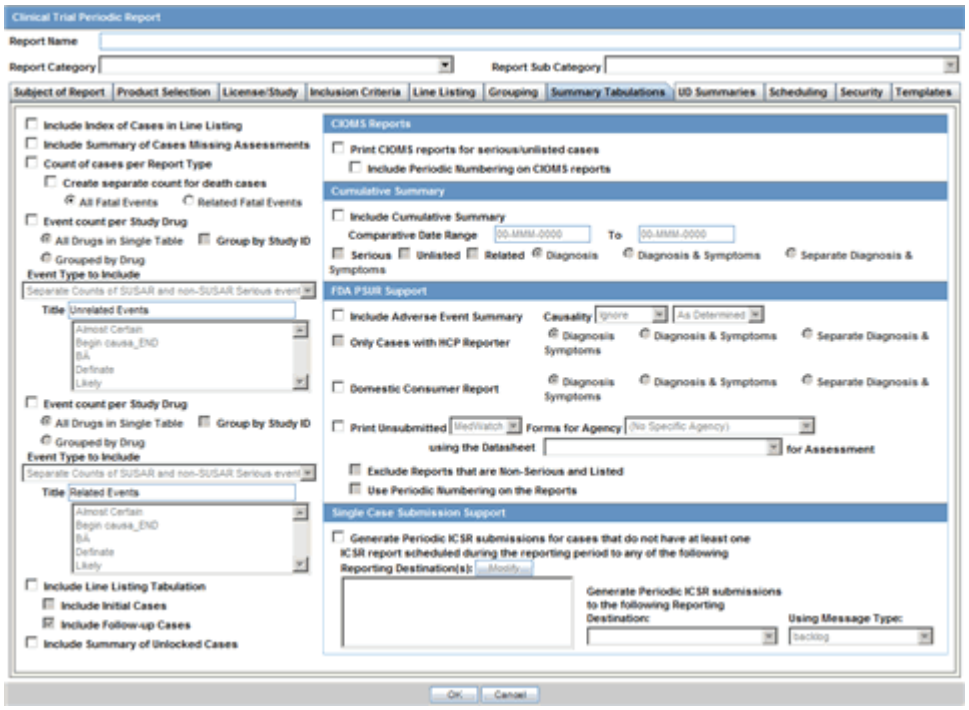
Field	Description
Available Groupings	Allows a user to group cases together from the given list. Select the desired groupings from the list and click **Add** to move the grouping to the Selected Groupings list. Up to 10 grouping options can be selected.
Selected Groupings	Lists the added groupings made available from the Available Groupings list, and reports the groups in the order they were selected.
Ascending	Select this check box to sort the selected entities in ascending order.
Page Break	Select this check box to start the cases from a new page, while also keeping the sorting together for every selected page break.
Available Sortings	Allows a user to sort cases together from the given list. Select the desired sortings from the list and click **Add** to move the sorting to the Selected Sortings list.
Selected Sortings	Allows a user to further sort cases without a total count for each sorted item. Up to 3 levels of sorting can be selected from the Available Sortings list.

Summary Tabulations Tab The **Summary Tabulations** tab enables you to specify which summary tabulations/Listings will appear along with the line listing.



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The following table lists and describes the fields on the tab.

Field	Description
Include Index of Cases in CTPR	Create an index page of case numbers, for all cases included in the CTPR.

Field	Description
Include Summary of Cases Missing Assessments	This option creates a sub-report of cases missing one of the following items: ■ Seriousness ■ Case Causality ■ Case Listedness ■ Case Outcome ■ Event Causality ■ Event Listedness Click this checkbox to create one or both of the following sub reports: **Cases Missing Assessments** - This sub-report displays cases that have been included in the CTPR line listing, but one or more of the following have not been assessed: ■ Case Seriousness ■ Case Causality ■ Case Listedness ■ Case Outcome ■ Event Causality ■ Event Listedness **Cases Not Included in Report** - This sub-report displays cases that have not been included in the CTPR line listing as a result of missing one or more of the following items: ■ Lock Status ■ Safety Date ■ Uncoded Event ■ Causality
Count of Cases per Report Type	This option prints a Sub Report that counts the number of cases versus the Report Type, based on the cases within the CTPR. The Cases per Report Type can be either of the following: **Count Cases with Initial Expedited Reports:** Counts cases with initial Expedited report. Count of cases with "Follow-up" Expedited report: Counts cases with Follow-up Expedited report. **Total Count of "Initial" Cases in the Report:** Counts any (serious - non-serious) cases received during the reporting period. **Total Count of "Follow-up" Cases in the Report:** Counts any (serious - non-serious) follow-up cases entered during the reporting period. **Cumulative Count**: Count of cases received from the start of the trial.
Event Count per Study Drug	Creates a sub-report with Event count per Study Drug based on the selected causality. 2 configurations are possible as to allow for a count of related events vs. non-related events.
All Study Drugs in Single table	Suppresses '0' current columns (with their cumulative) and print everything in a single cross tab.
Grouped by Study Drug	Prints a cross tab report for every product. Prints the cumulative totals even if the current period has no events.

Field	Description
Event Type to Include	Prints SUSAR events on the CTPR Report based on the option selected from the drop-down list: ■ Separate counts of SUSAR and non-SUSAR events Prints SUSAR and non-SUSAR events listed separately. SUSAR events are marked with an asterisk ■ Combined count of SUSAR and non-SUSAR event Prints SUSARs. Normal events are grouped into one (current functionality) ■ Only count SUSAR events Prints Only SUSARs i.e. non-SUSARs would not be printed
Title	Enables you to select a title.
Include Line Listing Tabulation	Select this check box to view a pre-defined summary tabulation of Report type, Seriousness and Listedness of all cases in the CTPR.
Include Initial Cases	Select this check box to include initial cases in the CTPR tabulation.
Include Follow-up Cases	Select this check box to include follow-up cases in the CTPR tabulation.
Include Summary of Unlocked Cases	Enables you to print the list of Case Numbers that are included in the Periodic Reports but are not locked.

CIOMS Reports

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Field	Description
Print CIOMS reports for serious/unlisted cases	Allows a user to print CIOMS I forms for all Serious/Unlisted (Case Level) cases appearing in the CTPR. **Note:** CIOMS contain Internal or Other text printed on them when the CTPR is printed using the Internal or Other option.
Include Periodic Numbering on the CIOMS reports	Numbers the requested CIOMS I with a periodic format. (i.e. A-1-1 of 2, A-1-2 of 2, A-2-1 of 1, A-3-1 of 1 etc.). The index is modified to also contain the Periodic paging of each CIOMS report.

Cumulative Summary

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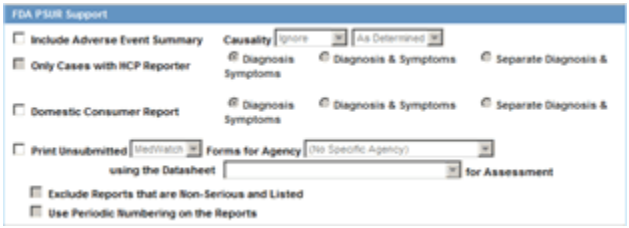
Field	Description
Include Cumulative Summary	Select the checkbox to create a sub-report count of events, grouped by Product and Body System (SOC) and sorted by Preferred Term. The sub-report contains a previous date range count of events (comparative date range), a current date range count (current CTPR date range) and a cumulative count (all dates) of events assessed against the product(s) of the CTPR and matching the inclusion criteria.
Comparative Date Range	Allows a user to specify the previous date range as a comparison date for the events counted, and therefore should not overlap with the current date range specified on the CTPR inclusion criteria tab.
Serious	Select this check box to include only serious events.
Unlisted	Select this check box to include only unlisted events selected in the Datasheet on the "Inclusion Criteria Tab." If no datasheet is selected, then any Unlisted license is included.
Related	Select this check box to include only those events that are assessed as Related or Causal.
Diagnosis	Select this radio button to include only those events that are marked as diagnosis "Yes" and are without any symptoms associated with diagnosis.
Diagnosis & Symptoms	Select this option to include all events in the sub-report.
Separate Diagnosis & Symptoms	Select this option to include all SUSAR events in the CTR Report.

FDA CTPR Support



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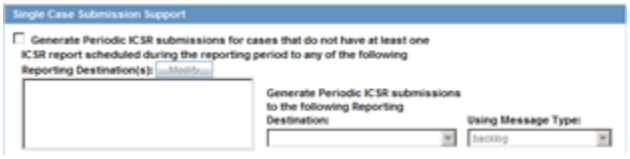
Field	Description
FDA CTPR Support Section	
Include Adverse Event Summary	Select this option to generate a sub-report of events from the line listing. This sub report is grouped by Body System and Preferred Term. **Note:** This section can be used if the company has obtained an FDA waiver to submit a CTPR instead of an NDA report.

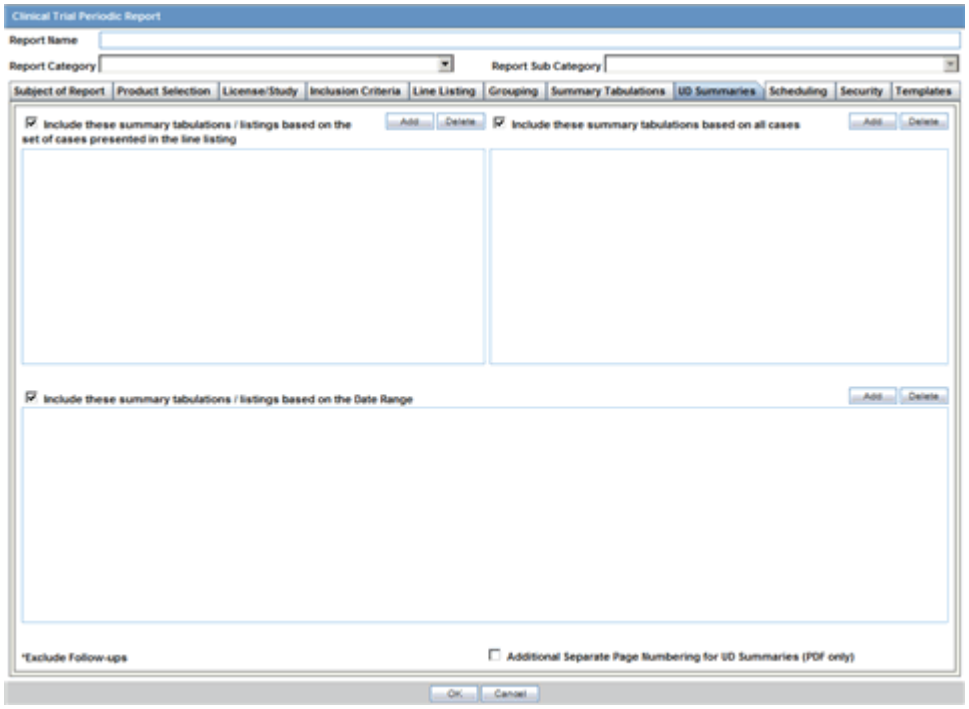
Field	Description
Causality	Select the desired causality from the list. **Ignore** - Counts events regardless of causality assessment. **Causal** - Counts events where the causality is considered reportable in the Causality Category configuration in List Maintenance. **Not Causal** - Counts events where the causality is considered non-reportable in the Causality Category configuration in List Maintenance. **As Determined** - Counts events where 'As Determined' causality meets the above selected causality criteria. **As Reported** - Counts events where 'As Reported' causality meets the above selected causality criteria. **Both** - Counts events where both 'As Reported' and 'As Determined' causality meet the above causality criteria. **Either** - Counts events where either the "As Reported" or "As Determined" causality meets the causality criteria.
Only Cases with HCP Reporter	Select this check box to include events for only those cases that feature an HCP reporter
Diagnosis	Select this radio button to ensure that only events marked as diagnosis are counted.
Diagnosis & Symptoms	Select this option to ensure that all events are counted in the sub-report.
Separate Diagnosis & Symptoms	Select this option to include all SUSAR events in the CTR Report.
Domestic Consumer Report	Enables you to select domestic consumer report.
Print Unsubmitted	This option allows a user to print MedWatch or VAERS forms for U.S. cases. The following types of cases will be excluded: ■ Foreign Cases (Country of Incidence not equal to U.S.) ■ Clinical Trial Cases (Case Report type in list maintenance has "this type includes cases from clinical trials" checked.) ■ Literature Cases (Case Report type in list maintenance has "this type include case from literature" checked.) ■ Cases with submitted expedited reports to the Agency selected in the PSUR.
Exclude Reports that are Non-Serious and Listed	Allows a user to suppress MedWatch or VAERS forms from printing for Non-Serious listed cases where all events are non-serious and listed for the datasheet specified.
Use Periodic numbering on the Reports	Numbers the requested forms with a periodic format. (i.e. Periodic Page 1 - 1, Periodic Page 1 - 2, Periodic Page 2 - 1, Periodic Page 2 - 2, etc.) An index with the Case Number is also included.

Single Case Submission Support



Field	Description
Single Case Submission Support Section	
Generate Periodic ICSR Submissions for any cases in this Periodic Report that does not have at least one scheduled single-case report during the reporting period to the following Reporting Destination(s): Modify	Select this check box to generate the E2B Reports only for the cases, where a Periodic E2B Report for the message type chosen, does not exist. Select one or more trading partners from the list box. **Important**: Any case that does not have an expedited or single case periodic submission to a trading partner, must have an E2b report scheduled as a part of the Periodic submission. Click Modify to select a different Reporting Destination.
Schedule these single-case Periodic Reports to the following Reporting Destination	Select a single-destination trading partner for Periodic Reports from the drop-down list box.
Using the Message Type	Select the required message type from the drop-down list box

UD Summaries Tab The **UD Summaries** tab allows you to specify which summary listings will appear along with the line listing.



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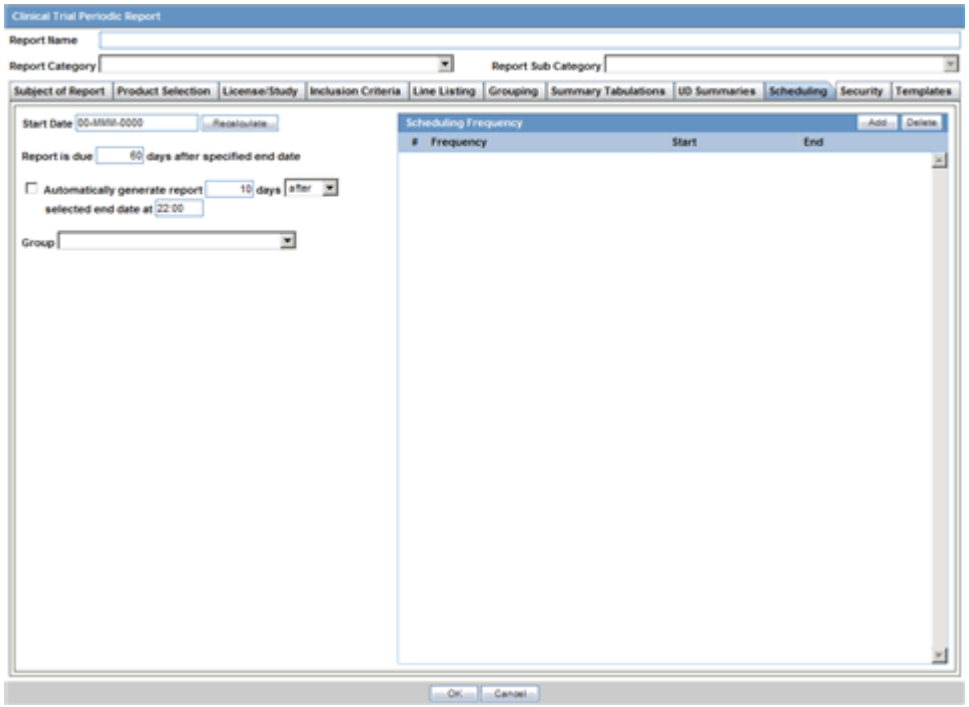
Field	Description
Include these summary tabulations/listings based on the set of cases presented in the line listing	Allows you to select from pre-configured summary tabulations/listings based on Case Data Analysis, Case listing or CIOMS II line listing reports. These tabulations are based only on the data included in the line listing. Select the **Exclude Follow-up Cases** check box to filter out follow-up cases from the attached report. **Note:** If the Exclude Follow-up Cases option is selected on the Inclusion criteria tab, this option is ignored and follow-up cases are always filtered out.
Include these summary tabulations based on all cases	Allows for additional sub-reports based on the 'Case Data Analysis' template, to be included as an output for the all cases in the database that meet the CTPR inclusion criterion for all dates.
Include these summary tabulations/listings based on the Date Range	This option allows for additional sub-reports based on Case Data Analysis, Case listing or CIOMS II line listing reports to be included as an output for the cases meeting the CTPR inclusion criterion for the Date Range specified when adding the sub-report. The dates are based on either the "Case Creation Date" or the "Initial Receipt Date" as entered on the CTPR Inclusion Criteria tab. Click the checkbox to the right of the sub-report to ignore considering follow-up cases for the sub-report.
Additional Separate Page Numbering for Summaries	Enables you to include additional separate page numbering for summaries.

Scheduling Tab The **Scheduling** tab allows you to specify details of how often the periodic report will be scheduled.



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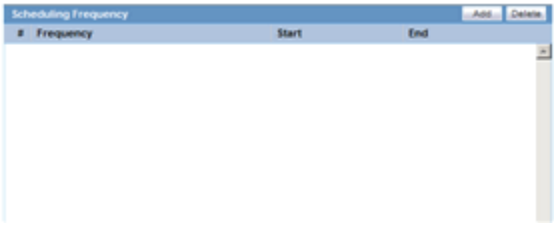
The following table lists and describes the fields on the **Scheduling** tab.

Field	Description
Start Date	This is the International Birth Date for the CTPR product. This date is computed as the earliest Awarded date for any license of any type.
Recalculate	Allows a user to recompute the International Birth Date of the CTPR Product. This date can be overwritten/manually entered, if needed.
Report is due xx days after selected end date (creation or receipt date)	Enter the number of days when the report will be due after the end date specified for the scheduling period.
Automatically generate report xx days before/after selected end date at xx:xx	Allows a user to specify the timing of the automatic report generation, by specifying the number of days before/after the selected end date of the report.
Group	Allows the user to select the group to which the automatically generated report is to be assigned

Scheduling Frequency



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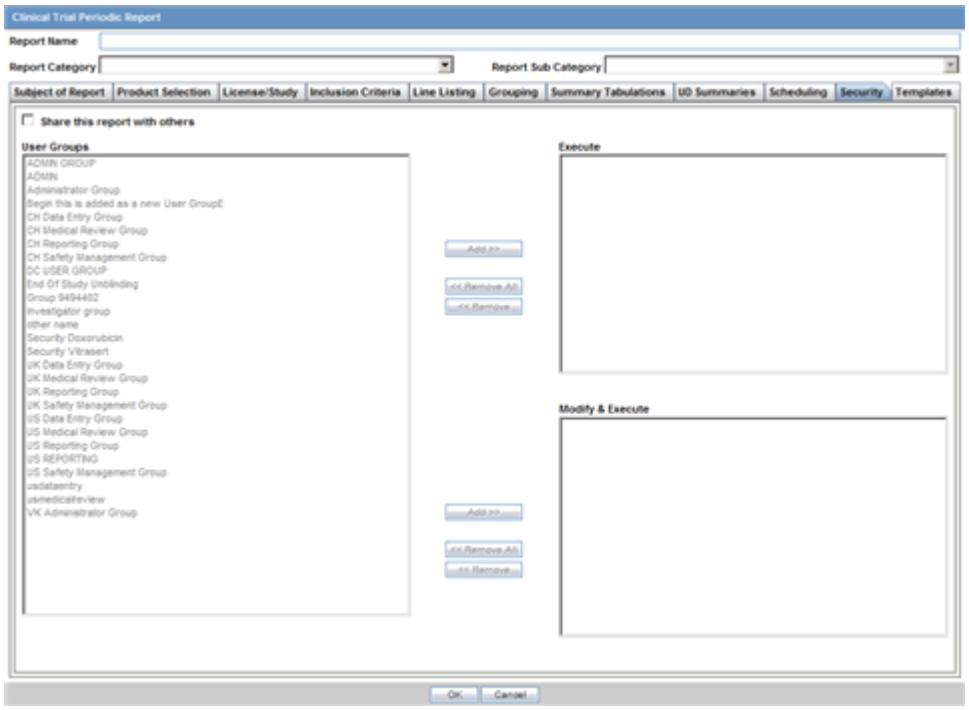
The following table lists and describes the fields in the **Scheduling Frequency** section.

Field	Description
Frequency	Allows a user to specify the interval required for this scheduling period.
Start	Allows the user to specify when the scheduling period starts.
End	Allows the user to specify when the scheduling period starts.
Add	Allows a user to add another scheduling interval.
Delete	Allows a user to delete a scheduling interval.

Security Tab The **Security** tab is used to configure the security level for the CTPR.



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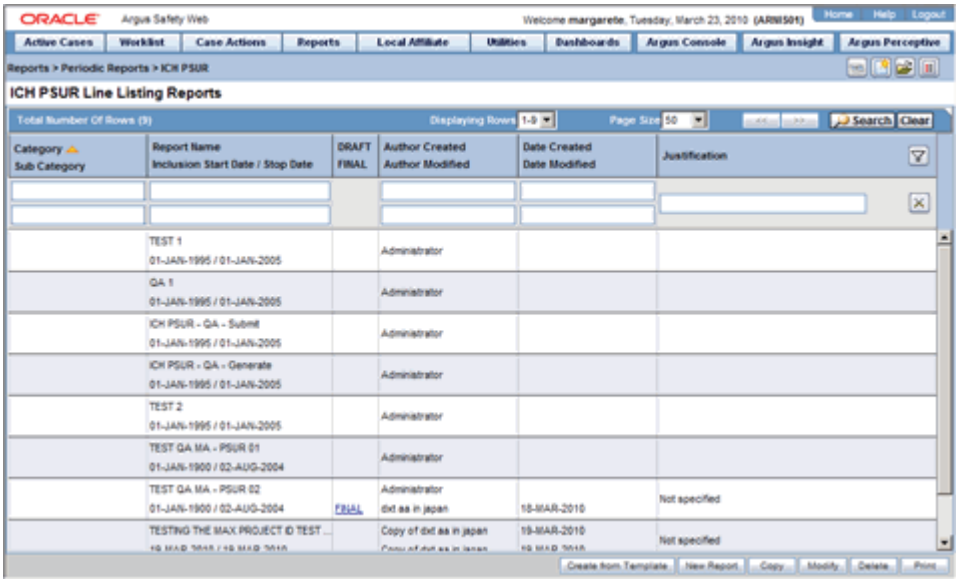
The following table lists and describes the fields on the **Security** tab.

Field	Description
Share this Report with Other Users	Click this check box to share this report with other users. Specify the privileges to be granted to groups by adding the group name from the Users Groups list to either the "Execute" or "Modify and Execute" list. A user group can exist in only one of these access lists.
User Groups	The groups listed here have no access to the CTPR report template. Click **Add** or **Remove** to move them to another access list.
Execute	The groups listed here have read and execute access to the shared CTPR report template.
Modify & Execute	The groups listed here have read, execute and modify access to the shared CTPR report template.

ICH PSUR Reports

The Periodic Safety Update Reports (PSURs) are created on a periodic basis to enable regulatory authorities to monitor the safety of a marketed product. This information is used to view new data about the product acquired from appropriate sources. It helps relate this data to the patient exposure and also indicates whether changes should be made to the product information in order to optimize the use of the product. Requirements on the due date of periodic reports may differ for different regulatory authorities.



To create Periodic Safety Update Reports (PSURs)

1. Select **Reports --> Periodic --> ICH PSUR Reports**. A list of PSUR Reports opens in the right frame.
2. Click **Copy** or **Modify** to create a new reports from an existing report.

   OR

   Click **New Report** to create an entirely new report.
3. When the system opens the **ICH PSUR Line Listing Reports** dialog box, enter an appropriate report name in the **Report Name** field.
4. Use the tabs to configure the PSUR.

General Usage Information

You can group cases for the PSUR Report by **Product Name** and **Dosage Regimen Frequency** as follows:

- Product Name
- This option enables you to group the Product Name - Formulation - Concentration concatenated with Units separated by a hyphen (-).
- If any elements are missing, the system **does not** print the hyphen (-).
- The groups the cases based on the Primary Drug in the report.
- Dosage Regimen Frequency
  - This option enables you to group the frequency of the primary dosage regimen for the primary drug in the report.
  - The system prints **Frequency**: followed by the frequency as defined.
- You can copy an existing template by clicking the **Create from Template** button.
- When you click **Create from Template**, the system displays the **Create from Template** dialog.
- You can choose the PSUR Group Name (as configured in the Product Name configuration) from a type ahead field.

- When you enter the PSUR Group Name in the **Select PSUR Group Name** field and the **From** and **To** dates in the **Create from Template** dialog, and click **OK** the system does the following:
  - Saves the PSUR Configuration with the new dates.
  - Replaces the products in the list of selected products with **all** products as defined for the selected PSUR name.
  - Replaces the periodic report name in the newly configured periodic reports with a new name in the following format:

    XXXX: YYYY to ZZZZ

    where:

    XXXX is the selected PSUR Name.

    YYYY is the From Date entered by the user.

    ZZZZ is the To Date entered by the user.
  - Replaces the **From** and **To** date ranges **only** for the periodic report.
  - Bases the remaining configuration, including the security permissions, on the selected PSUR template.
- When you enter the PSUR Group Name in the **Select PSUR Group Name** field and the **From** and **To** dates in the **Create from Template** dialog and click **Print and Save**, the system does the following:
  - Saves the PSUR Configuration with the new dates.
  - Replaces the products in the list of selected products with **all** products as defined for the selected PSUR name.
  - Replaces the periodic report name in the newly configured periodic reports with a new name in the following format:

    XXXX: YYYY to ZZZZ

    where:

    XXXX is the selected PSUR Name.

    YYYY is the From Date entered by the user.

    ZZZZ is the To Date entered by the user.
  - Replaces the **From** and **To** date ranges **only** for the Periodic Report.
  - Calls the Report Batch Printing dialog.
  - Bases the remaining configuration, including the security permissions, on the selected PSUR template.

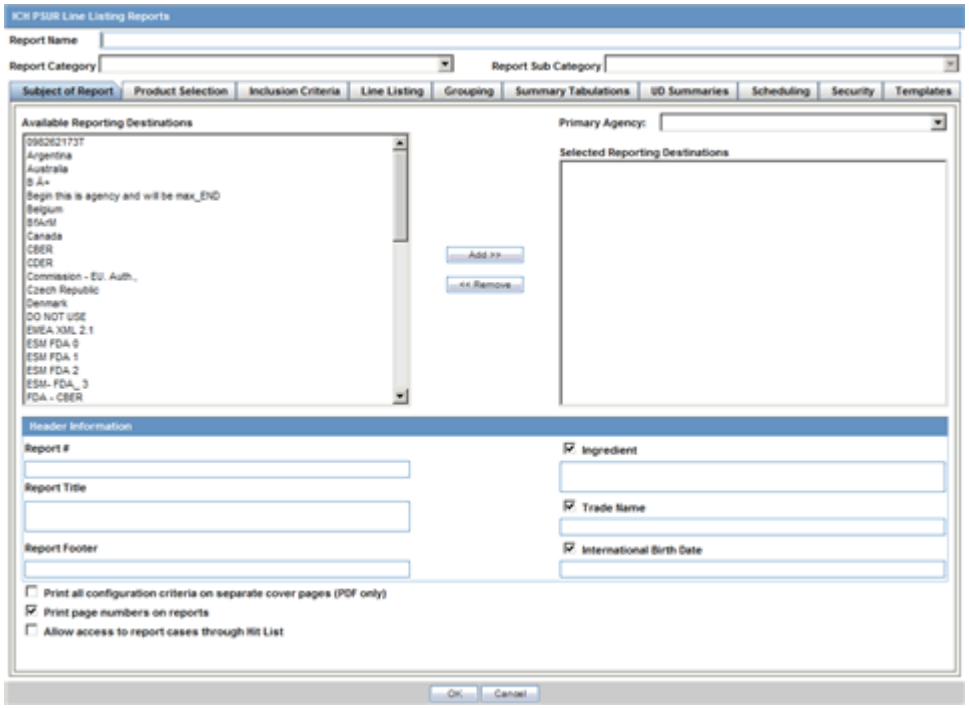
Common Fields The **Report Name**, **Report Category** and **Report Sub-Category** fields are common to all tabs of the Reports.

The following table below describes these fields:

Field	Description
Report Name	Enter a name for the Report. The name entered here is displayed in the Reports menu.

Field	Description
Report Category	Select a category for the Report. This is displayed in the Reports menu. **Tip:** Select **New** to define a subcategory within the report category. The **Periodic Report Category** dialog is displayed. Enter a category name in **Category** and click **OK**. The category is entered in the **Report Category** drop-down list.
Report Sub Category	Select a subcategory for the report. **Tip:** Select **New** to define a subcategory within the report sub-category. The **Periodic Report Category** dialog is displayed. Enter a category name in **Category** and click **OK**. The category is entered in the **Report Sub-Category** drop-down list.

Subject of Report Tab The **Subject of Report** tab is used to configure the report header and to specify the agency, products, etc. for which the PSUR will be applicable.



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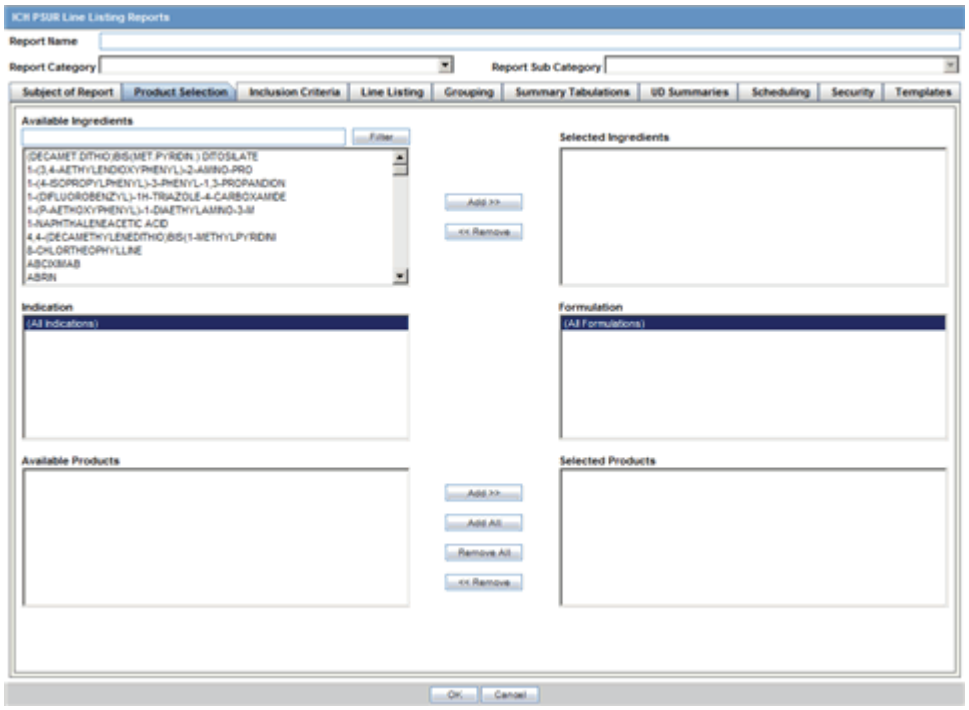
Field	Description
Primary Agency	Select the Primary Agency.
Reporting Destination	Displays the list of agencies from where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. You can select multiple agencies from the list of agencies such that the report can be submitted to multiple agencies at the same time. Likewise, select a report from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.

Field	Description
Selected Destination	Displays the list of agencies where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. You can select multiple agencies from the list of agencies such that the report can be submitted to multiple agencies at the same time. Likewise, select a report from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.
Report #	Enter a report number for this report.
Report Title	Enter a report title for this report.
Ingredient	Automatically displays the "Ingredient" as provided in the Subject of Report dialog. **Note:** You can choose whether to view these field or not. Click the checkbox displayed with this field to hide or view it.
Trade Name	Automatically displays the "Trade Name(s)" as provided in the Subject of Report dialog. Multiple trade names are also displayed together, separated by commas. **Note:** You can choose whether to view this field or not. Click the checkbox displayed with this field to hide or view it.
International Birth Date	Automatically displays the earliest license awarded date, when a user selects an Ingredient and a Product. **Note:** You can choose whether to view this field or not. Click the checkbox displayed with this field to hide or view it.
Report Footer	Enter the footer for the report.
Print all configuration criteria on separate cover page	Mark this box to print out the configuration of this report when the report is printed. This is only available when PDF option is selected during printing.
Print page numbers on reports	When checked, this option enables the user to print page numbers on a periodic report. This is the default for all report configurations. If this checkbox **is not checked**, the following occur. ■ The "Include Periodic Page Numbering on CIOMS reports" option on the PSUR Summary Tabulations CIOMS Reports section is grayed out and inactive. ■ The "Use Periodic Numbering on the reports" option in PSUR Summary Tabulations FDA PSUR section is grayed out and inactive. ■ The "Additional Separate Page Numbering for UD Summaries" in the PSUR UD Summaries tab is grayed out and inactive. ■ The system removes all existing report page numbering and the option to check page number check boxes on the report configuration tabs are grayed out and inactive.
Allow access to report cases through Hit List	When the report is run as final, it creates a Hit List, which can be retrieved from other areas of the application where advanced conditions can be selected. Click this checkbox to report cases through the Hit List.

Product Selection Tab Refer to the table below for a description of fields in the **Product Selection** tab.



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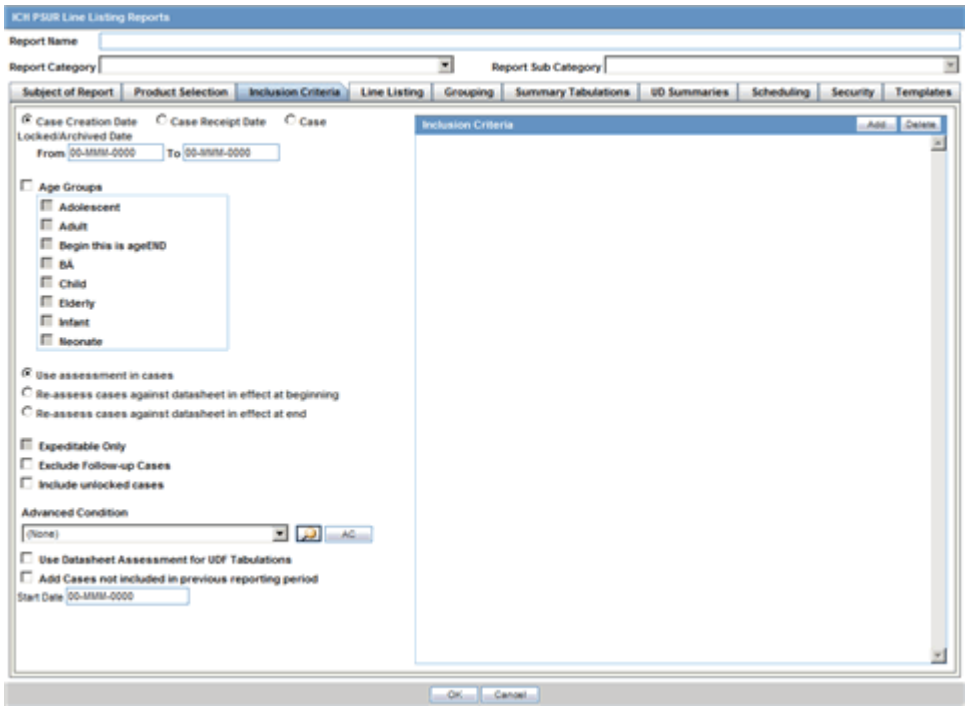
Field	Description
Available Ingredients	Displays the list containing the Ingredients used for the product configuration. Select an ingredient from the list displayed in **Available Ingredients** and click **Add/Remove** to add/remove the ingredient. You can select multiple ingredients at a time.
Filter	Enter an Ingredient name and click **Filter** to search for the entered ingredient within the Available list of Ingredients.
Selected Ingredients	Displays the list of ingredients selected from the **Available Ingredients** list.
Indication	This list contains the Indication configured for the product containing the ingredients in the **Available Ingredients** section. The selections made from this list get displayed in the **Available Products** section. **Note:** You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Formulation	This list contains the Formulation configured for the product containing the ingredients in the **Available Ingredients** section. The selections made from this list get displayed in the **Selected Products** section. **Note:** You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Available Products	This list is automatically populated with the selections made in the **Indication** section.
Selected Products	This list contains products selected by the user from the **Available Products** list. When a product is selected, the **Trade Name** field and International Birth Date fields are auto-populated with the license trade name ("formulation", "concentration") and earliest License Award Date for the product.

Inclusion Criteria Tab The **Inclusion Criteria** tab allows you to select search parameters for inclusion of cases in a periodic report. The top section of the dialog allows you to specify the type of cases that are to be included in the periodic report.



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Click **Add** to add a criterion. Select appropriate items from the list of items that appear.

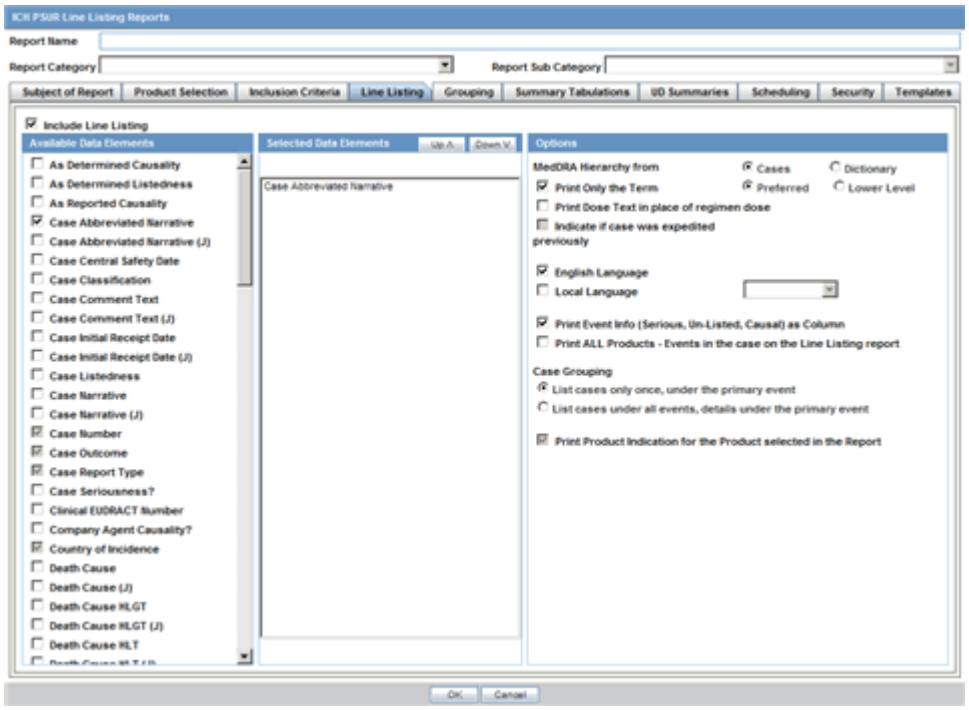
Field	Description
Case Creation Date	Allows you to specify a range of cases by the date when the case was created.
Case Receipt Date	Allows you to specify a range of cases by the initial receipt date.
Use Current Version	Allows you to use the latest revision to populate the data within the selected reports.
Use DLP Version	Allows you to use the case data of the version as of the specified DLP Version.
Age Groups	Allows you to include or exclude cases based on the patient's age group. Select **Age Groups** and then select all the age group categories that apply.
Use Assessments in Cases	When selected, the PSUR Report will use the Case Event Assessment when performing datasheet listedness calculations.
Re-assess cases against datasheet in effect at the beginning	When selected, the PSUR will re-assess the cases in the line listing based on the Active Datasheet on or before the Start Date of the Reporting period.
Re-assess cases against datasheet in effect at end	When selected, the PSUR will re-assess the case in the line listing based on the Active Datasheets on or closest to the end date of the PSUR Reporting end date range without exceeding that date.

Field	Description
Expeditable Only	This checkbox is available only when an agency is selected in the **Subject of Report** tab. If you select this check box, only the cases classified as submitted expedited reports to the specified agency are used.
Exclude Follow-up Cases	Filters out follow-up Reports from the PSUR Line Listing Report.
Include Unlocked Cases	Allows you to include unlocked cases in the periodic report.
Advanced Condition	Allows you to specify an advanced condition that must be satisfied by each case that is included in the report. Ensure that the advanced condition or the advanced condition query set that is specified here does not contradict any other criteria specified in the dialog.
Use Datasheet Assessment for UDF Tabulations	Allows you to select datasheet for a report to make UDF tabulations. If no datasheet is selected, the most conservative listedness is chosen, i.e. Unlisted followed by Listed.
Add Cases not included in previous reporting period	Allows you to add cases which were not included in the previous reporting period. You can enter the start date of the period in the Start Date field.

Inclusion Criteria When using the Inclusion Criteria tab, the system enables you to exclude blinded cases from the Inclusion criteria section of the report. It also enables you to select All from the Inclusion criteria for the report type. This would include all configure report types in the report.

Field	Description
Dropdown list	Select the appropriate report type from the drop-down list.
Datasheet	This list allows you to specify which datasheet is to be checked to determine the listedness (listed or unlisted) of the case.
Serious / Non-Serious	If you select **Serious** and clear **Non-serious**, only cases having a "serious" event are included and vice-versa. If you select both **Serious** and **Non-Serious** the seriousness criteria is ignored.
Fatal / Non-Fatal	Select **Fatal** when at least one event has an event outcome of 'Fatal". If not, select **Non-Fatal**. If you select both **Fatal** and **Non-Fatal**, both types of cases are included.
Listed / Unlisted	Select Listed to view only Listedness values. If you select both **Listed** and **Unlisted**, all Listedness values (including Unknown) are included.
Related / Non-Related	Relatedness refers to the more conservative of reported or company causality. Select **Related** for any reportable causality type, and **Non-Related** for any non-reportable causality type.
HCP / Non-HCP	**HCP** refers to cases that identify a Health Care Professional in the **Reporter** section within the **General** tab of the Case Form.
Primary Reporter Only	This check box displays whether the Primary Reporter has been selected to determine the HCP status.

Line Listing Tab The **Line Listing** tab contains the following fields and sections:



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Field	Description
Include Line Listing	Allows you to select whether you want the Line Listing Data Elements printed with the PSUR Report.

Available Data Elements The following illustration shows the optional fields under **Available Data Elements**.

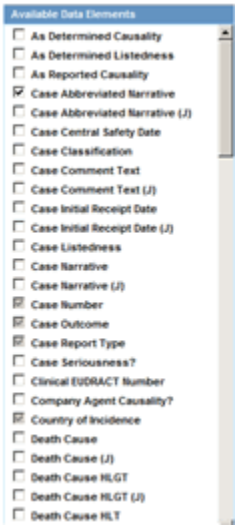
- Select the check box displayed against each data element to add it to the report.
- The unavailable fields are printed on the report by default and cannot be changed.
- Refer to the table below for a list of the data elements that are included in this tab.
- The mandatory data elements are printed as columns in the report.

Data Element	Notes
As Determined Causality	Optional.
As Determined Listedness	Optional.
As Reported Causality	Optional.
Case Abbreviated Narrative	Required and multi-language available.
Case Classifications	Required. Multiple classifications are displayed in separate lines.
Case Central Safety Date	Optional.
Case Comment Text	Optional.

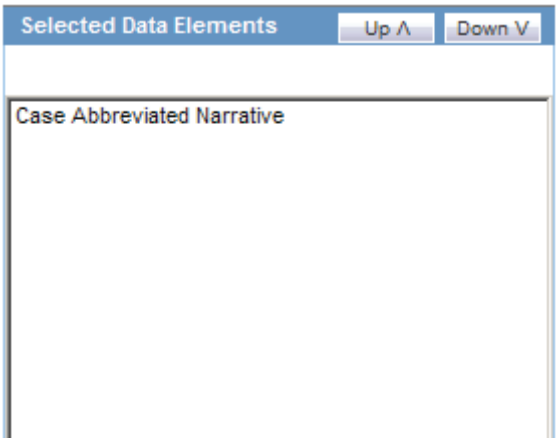
Data Element	Notes
Case Initial Receipt Date	Optional.
Case Listedness	Optional.
Case Narrative	Optional.
Case Number	Required.
Case Outcome	Required.
Case Report Type	Required.
Case Seriousness?	Optional.
Company Agent Causality	Displays event causality from product name. Multiple causalities are displayed in separate lines.
Country of Incidence	Required.
Death Cause	Multi-language available.
Death Cause HLGT	Optional.
Death Cause HLT	Optional.
Death Cause LLT	Optional.
Death Cause SOC	Optional.
Dosage Regimen Batch/Lot #	Optional.
Dosage Regimen Daily Dose	Optional.
Dosage Regimen Duration	Optional.
Dosage Regimen Frequency	Optional.
Dosage Regimen Route of Administration	Optional.
Dosage Regimen Start Date/Time	Required. For the selected product the report is based on. List for all dose regimens.
Drug Dechallenge?	Optional.
Drug Primary Indication	Optional. For the selected product the report is based on.
Drug Primary Indication HLGT	Optional. For the selected product the report is based on.
Drug Primary Indication HLT	Optional. For the selected product the report is based on.
Drug Primary Indication LLT	Optional. For the selected product the report is based on.
Drug Primary Indication SOC	Optional. For the selected product the report is based on.
Drug Rechallenge?	Optional.
Event Description as Reported	Required.
Event Lack of Efficacy	Optional.
Event Onset Date/Time	Required.
Event Preferred Term	Required.
Lab Data - Tabular	Optional.
Literature Author	Optional.

Data Element	Notes
Literature Journal	Optional.
Literature Pages	Optional.
Literature Title	Optional.
Literature Volume	Optional.
Literature Year	Optional.
Indication	Displays indication for product name.
Listedness	Displays datasheet, product and listedness event preferred term
Literature reference	Optional.
Outcome of Event	Optional.
Patient Age	Required.
Patient Gender	Required.
Patient Initials	Optional.
Patient Relevant History	Multi-language.
Patient Subject #	Optional.
Product Name	Displays "product name (generic name) product type, formulation, concentration unit" "daily dose," "dose dose_freq, route"
Product Name Report Inclusion	Prints the Products that were part of the CTPR Report for the case. Displays "product name (generic name) product type, formulation, concentration unit" "daily dose," "dose dose_freq, route"
Report Comment	Optional.
Reporter Reference Number	Optional. If you select this value the report includes the reporter reference number as specified in the cases included in the Periodic report of All reporters within the case. If the case does not have values, then label is not printed in the Line Listing for the report.
Reporter Type	Optional.
Study Blinded Status	Optional. The system enables you to exclude blinded cases from the inclusion criteria.
Study Center ID	Optional.
Study Drug	Optional.
Study ID	Optional.
Study ID Protocol #	Optional.

Selected Data Elements This section lists the selected elements and enables you to arrange the order in which these are to be printed.



Click the Up or Down buttons to arrange the listed elements above or below in order of priority.



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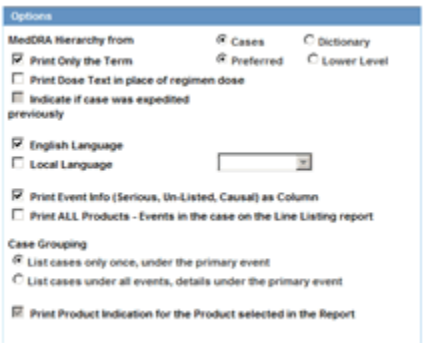
Options



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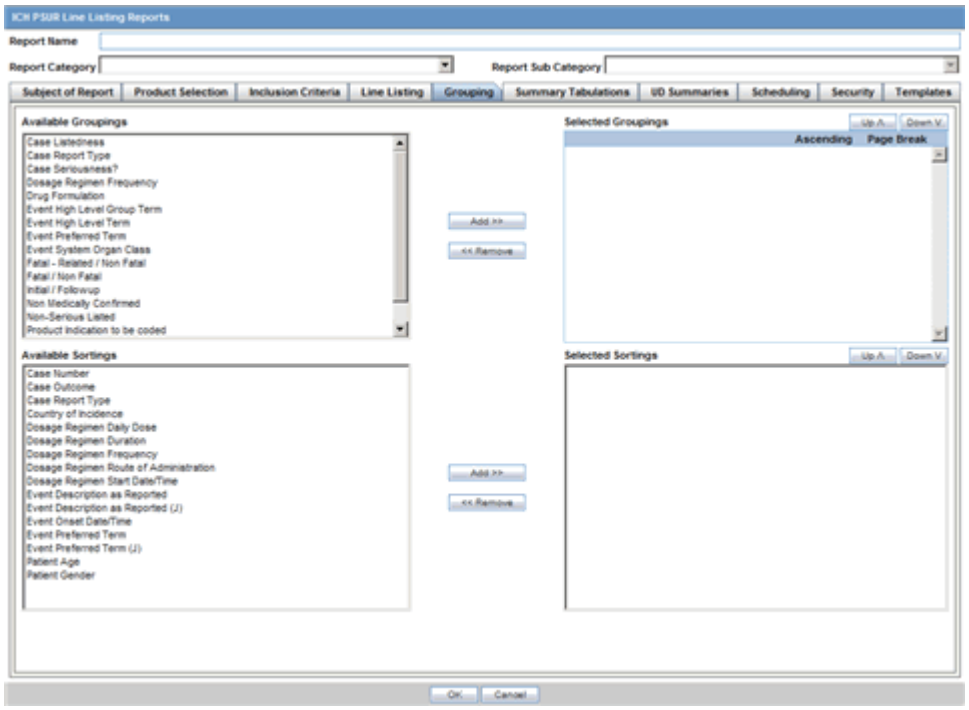
Field	Description
MedDRA Hierarchy from Cases/Dictionary	Select **Cases** to populate the data from the case data. Select **Dictionary** to populate the data from the MedDRA dictionary.
Print Only the Term (Preferred Term or Lower Level Term)	Prints only the event Preferred Term (PT) or event Lower Level Term (LLT) as per the selected radio button. Select the PT option to print only the preferred term and not the verbatim description.
Print Dose Text in place of regimen dose	Prints the dosage and frequency information from **Dose Description** field instead of **Regimen Dose**.
Indicate if case was expedited previously	This checkbox is selected if an agency has been selected in the **Subject of Report** tab. Cases for which an expedited report was previously submitted to the selected authority are marked with an asterisk and the date of submission appears in the line listing. Any case that has been previously expedited to a selected agency, is listed in the list of Agencies in the Subject of Reports tab.
English Language	Provides the option to print the descriptions in English
Local Language	Allows a user to specify which Local language for a multi-language field is to be printed i.e. the Abbreviated Narrative field.
Print event info (Serious, Un-listed, Related) as Column	Select this checkbox to print the Seriousness, Listedness and Causality under the Event Verbatim column. **Note:** Events having listedness of 'Unknown' are considered 'Unlisted'. If only diagnoses are assessed for event assessment, the events which are associated with a Diagnosis but have been marked with Diagnosis as 'No' display '-' for both listedness and causality.
List cases only once, under the primary event	Select this option to view the details of cases in the Main Line Listing only once under the Primary Event
List cases under all events, details under the primary event	Select this option to view the details of cases in the Main Line Listing only once under the Primary Event, while non-primary events are listed under their respective event hierarchy with a reference to the primary event body system. Therefore, use this option when grouping on Main Line Listing is by the Event Body System.
Print Product Indication for the Product selected in the Report	Enables you to print the product indication for the product selected in the report.

Grouping Tab Refer to the following table for a description of items in the **Grouping** tab.



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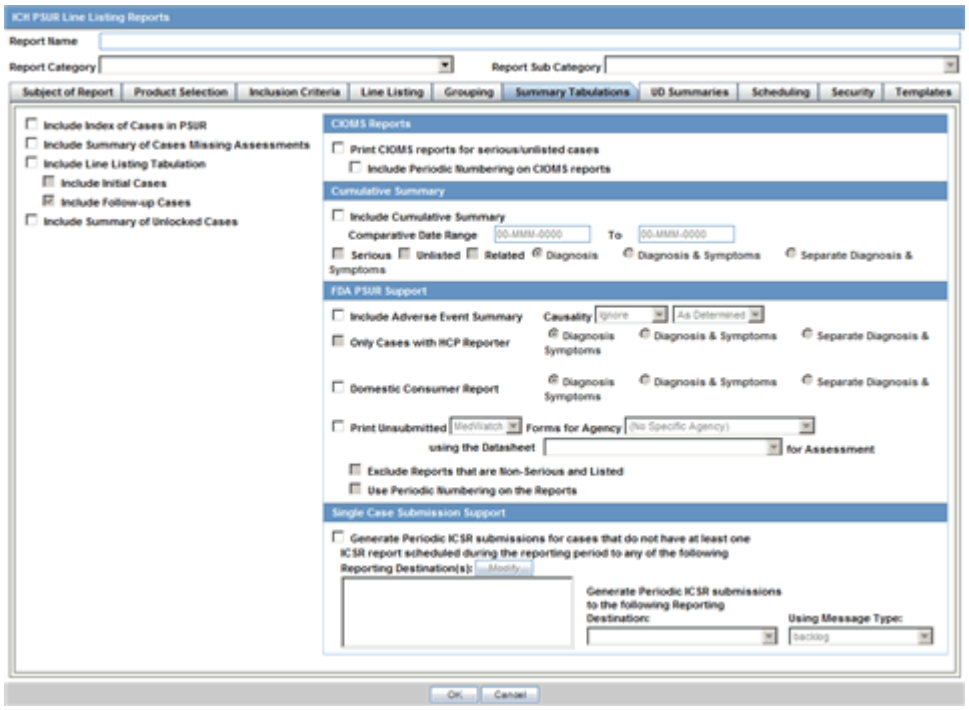
Field	Description
Available Groupings	Allows a user to group cases together from the given list. Select the desired groupings from the list and click **Add** to move the grouping to the Selected Groupings list.
Selected Groupings	Lists the added groupings, and reports the groups in the order they were selected. Up to 5 grouping options can be selected from the Available Groupings list.
Ascending	Select this checkbox to sort the selected entities in ascending order
Page Break	Select this checkbox to start the cases from a new page, while also keeping the sorting together for every selected page break.
Available Sortings	Allows a user to sort cases together from the given list. Select the desired sortings from the list and click **Add** to move the sorting to the Selected Sortings list.
Selected Sortings	Allows a user to further sort cases without a total count for each sorted item. Up to 3 sorting options can be selected from the Available Sortings list. This list is populated with the Mandatory Line Listing entities plus any optional data elements chosen for this configuration.

Summary Tabulations Tab The **Summary Tabulations** tab enables you to specify which summary tabulations/listings will appear along with the line listing.The system enables you to separate the cumulative summary by seriousness, relatedness, and listedness. If you choose this option, the system separates the product event detail into the following categories: Serious/Non-Serious, Related/Non-Related, and Unlisted/Listed events.



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It contains the following fields and sections:

Field	Description
Include Index of Cases in PSUR	Create an index page of case numbers, for all cases included in the PSUR.

Field	Description
Include Summary of Cases Missing Assessments	This option creates a sub-report of cases missing one of the following items: ■ Seriousness ■ Case Causality ■ Case Listedness ■ Case Outcome ■ Event Causality ■ Event Listedness Click this checkbox to create one or both of the following sub reports: **Cases Missing Assessments** - This sub-report displays cases that have been included in the PSUR line listing, but one or more of the following have not been assessed: ■ Case Seriousness ■ Case Causality ■ Case Listedness ■ Case Outcome ■ Event Causality ■ Event Listedness **Cases Not Included in Report** - This sub-report displays cases that have not been included in the PSUR line listing as a result of missing one or more of the following items: ■ Lock Status ■ Safety Date ■ Uncoded Event ■ Causality
Include Line Listing Tabulation	Select this check box to view a pre-defined summary tabulation of Report type, Seriousness and Listedness of all cases in the PSUR.
Include Initial Cases	Select this checkbox to include initial cases in the PSUR tabulation.
Include Follow-up Cases	Select this checkbox to include follow-up cases in the PSUR tabulation.
Include Summary of Unlocked Cases	Enables you to print the list of Case Numbers that are included in the Periodic Reports but are not locked.

CIOMS Reports

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Field	Description
Print CIOMS reports for serious/unlisted cases	Allows a user to print CIOMS I forms for all Serious/Unlisted (Case Level) cases appearing in the PSUR. **Note:** CIOMS contain Internal or Other text printed on them when the PSUR is printed using the Internal or Other option.

Field	Description
Include Periodic Numbering on the CIOMS reports	Numbers the requested CIOMS I with a periodic format. (i.e. A-1-1 of 2, A-1-2 of 2, A-2-1 of 1, A-3-1 of 1 etc.). The index is modified to also contain the Periodic paging of each CIOMS report.

Cumulative Summary

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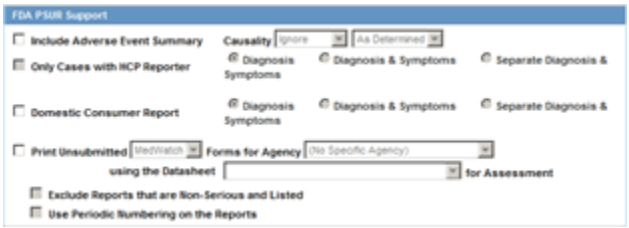
Field	Description
Include Cumulative Summary	Select the check box to create a sub-report count of events, grouped by Product and Body System (SOC) and sorted by Preferred Term. The sub-report contains a previous date range count of events (comparative date range), a current date range count (current PSUR date range) and a cumulative count (all dates) of events assessed against the product(s) of the PSUR and matching the inclusion criteria.
Comparative Date Range	Allows a user to specify the previous date range as a comparison date for the events counted, and therefore should not overlap with the current date range specified on the PSUR inclusion criteria tab.
Serious	Select this check box to include only serious events.
Unlisted	Select this check box to include only unlisted events selected in the Datasheet on the "Inclusion Criteria Tab." If no datasheet is selected, then any Unlisted license is included.
Related	Select this check box to include only those events that are assessed as Related or Causal.
Diagnosis	Select this radio button to include only those events that are marked as diagnosis "Yes" and are without any symptoms associated with diagnosis.
Diagnosis & Symptoms	Select this radio button to include diagnosis and symptoms together in the sub-report.
Separate Diagnosis & Symptoms	Select this radio button to include diagnosis and symptoms separately in the sub-report. Selecting this option means that the case numbers are separated by Diagnosis and Symptoms respectively.

FDA PSUR Support



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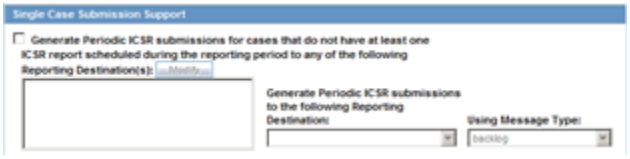
Field	Description
FDA PSUR Support Section	
Note: This section can be used if the company has obtained an FDA waiver to submit a PSUR instead of an NDA report.	
Include Adverse Event Summary	Select this option to generate a sub-report of events from the line listing. This sub report is grouped by Body System and Preferred Term.
Causality	Select the desired causality from the list. **Ignore** - Counts events regardless of causality assessment. **Causal** - Counts events where the causality is considered reportable in the Causality Category configuration in List Maintenance. **Not Causal** - Counts events where the causality is considered non-reportable in the Causality Category configuration in List Maintenance. **As Determined** - Counts events where 'As Determined' causality meets the above selected causality criteria. **As Reported** - Counts events where 'As Reported' causality meets the above selected causality criteria. **Both** - Counts events where both 'As Reported' and 'As Determined' causality meet the above causality criteria. **Either** - Counts events where either the 'As Reported' or 'As Determined' causality meets the causality criteria.
Only Cases with HCP Reporter	Select this checkbox to include events for only those cases that feature an HCP reporter
Diagnosis	Select this radio button to ensure that only events marked as diagnosis are counted.
Diagnosis & Symptoms	Select this radio button to ensure that all events are counted in the sub-report.
Separate Diagnosis & Symptoms	Select this radio button to include diagnosis and symptoms separately in the sub-report. Selecting this option means that the case numbers are separated by Diagnosis and Symptoms respectively.
Domestic Consumer Support	Select this radio button to enable domestic consumer support.
Print Unsubmitted	This option allows a user to print MedWatch or VAERS forms for U.S. cases
Exclude Reports that are Non-Serious and Listed	Allows a user to suppress MedWatch or VAERS forms from printing for Non-Serious listed cases where all events are non-serious and listed for the datasheet specified.
Use Periodic numbering on the Reports	Numbers the requested forms with a periodic format. (i.e. Periodic Page 1 - 1, Periodic Page 1 - 2, Periodic Page 2 - 1, Periodic Page 2 - 2, etc.) An index with the Case Number is also included.

Single Case Submission Support



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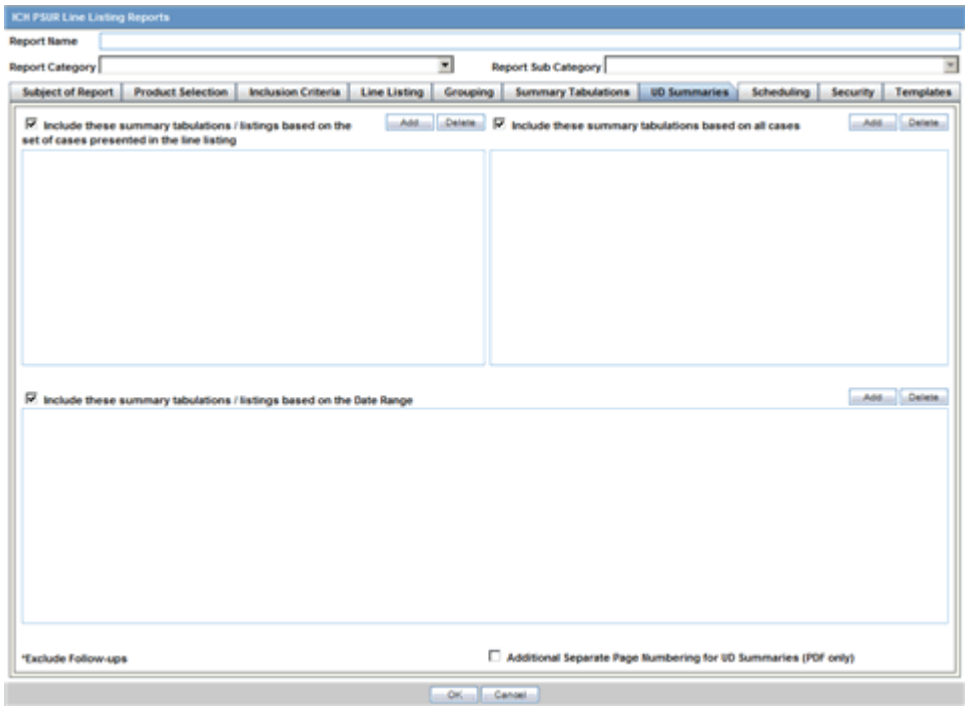
Field	Description
Single Case Submission Support Section	
Generate Periodic ICSR Submissions for any cases in this Periodic Report that does not have at least one scheduled single-case report during the reporting period to the following Reporting Destination(s): Modify	Select this checkbox to generate the E2B Reports only for the cases, where a Periodic E2B Report for the message type chosen, does not exist. Select one or more trading partners from the list box. **Important**: Any case that does not have an expedited or single case periodic submission to a trading partner, must have an E2b report scheduled as a part of the Periodic submission. Click Modify to select a different Reporting Destination.
Schedule these single-case Periodic Reports to the following Reporting Destination	Select a single-destination trading partner for Periodic Reports from the drop-down list box.
Using the Message Type	Select the required message type from the drop-down list box

UD Summaries Tab

The **UD Summaries** tab allows you to specify which summary listings will appear along with the line listing.



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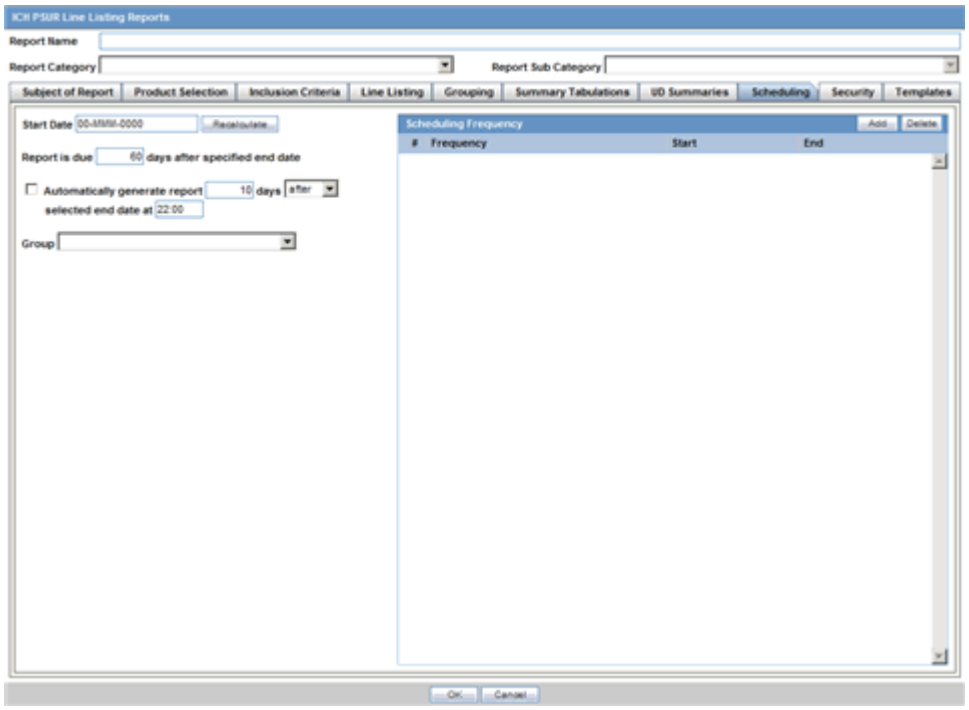
The following lists and describes the fields on the **UD Summaries** tab.

Field	Description
Include these summary tabulations/listings based on the set of cases presented in the line listing	Allows you to select from pre-configured summary tabulations/listings. These tabulations are based only on the data included in the line listing. Selecting the **Exclude Follow-up Cases** check box filters out follow-up cases from the attached report. **Note:** If the Exclude Follow-up Cases option is selected on the Inclusion criteria tab, this option is ignored and follow-up cases are always filtered out.
Include these summary tabulations based on all cases	Allows for additional sub-reports based on the 'Case Data Analysis' template, to be included as an output for the all cases in the database that meet the PSUR inclusion criterion for all dates.
Include these summary tabulations/listings based on the Date Range	This option allows for additional sub-reports based on Case Data Analysis, Case listing or CIOMS II line listing reports to be included as an output for the cases meeting the PSUR inclusion criterion for the Date Range specified when adding the sub-report. The dates are based on either the "Case Creation Date" or the "Initial Receipt Date" as entered on the PSUR Inclusion Criteria tab. Click the checkbox to the right of the sub-report to ignore considering follow-up cases for the sub-report.
Additional Separate Page Numbering for Summaries	Enables you to include additional separate page numbering for summaries.

Scheduling Tab

The **Scheduling** tab enables you to specify details of how often the periodic report will be scheduled.



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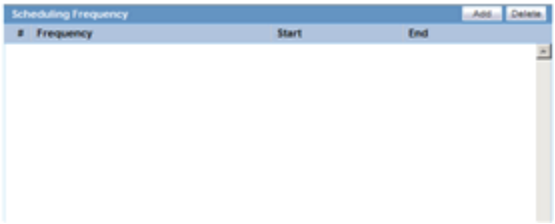
Field	Description
Start Date	This is the International Birth Date for the PSUR product. This date is computed as the earliest Awarded date for any license of any type.
Recalculate	Allows a user to recompute the International Birth Date of the PSUR Product. This date can be overwritten/manually entered, if needed.
Report is due xx days after selected end date (creation or receipt date)	Enter the number of days when the report will be due after the end date specified for the scheduling period.
Automatically generate report xx days before/after selected end date at xx:xx	Allows a user to specify the timing of the automatic report generation, by specifying the number of days before/after the selected end date of the report.
Group	Allows the user to select the group to which the automatically generated report is to be assigned

Scheduling Frequency



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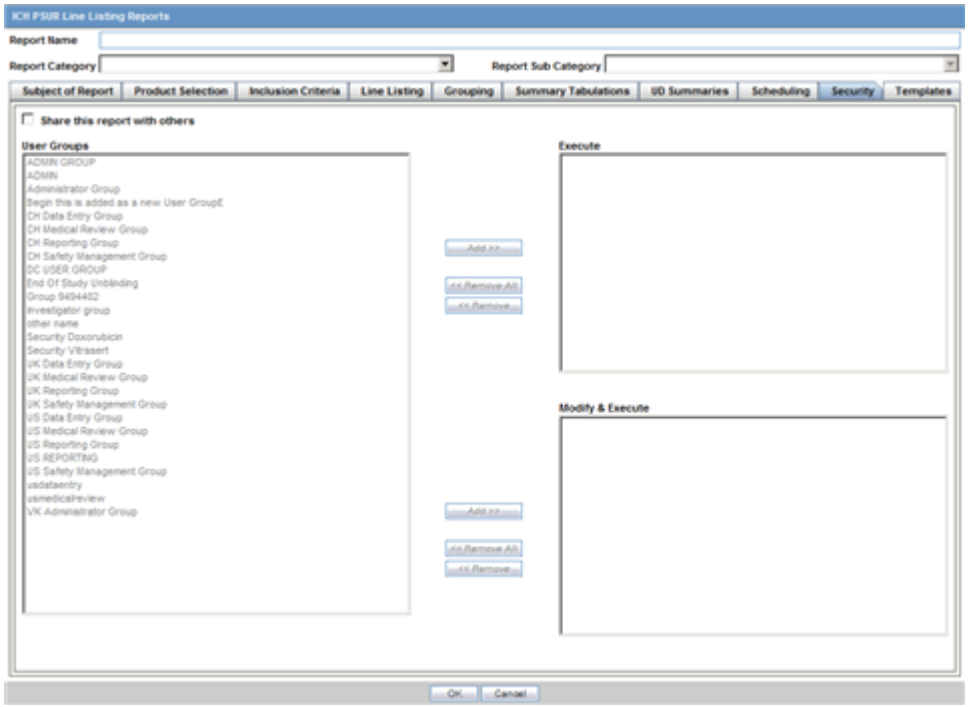
The following table lists and describes the fields in the **Scheduling Frequency** section.

Field	Description
Frequency	Allows a user to specify the interval required for this scheduling period.
Start	Allows the user to specify when the scheduling period starts.
End	Allows the user to specify when the scheduling period starts.
Add	Allows a user to add another scheduling interval.
Delete	Allows a user to delete a scheduling interval.

Security Tab

The **Security** tab is used to configure the security level for the PSUR.



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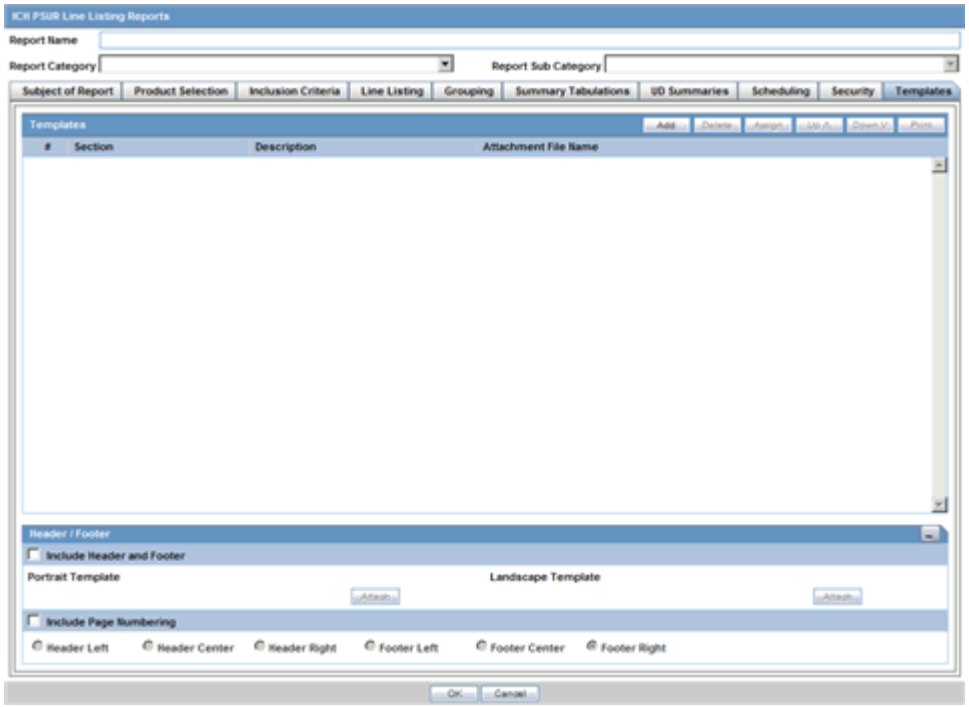
Field	Description
Share this Report with Other Users	Click this check box to share this report with other users. Specify the privileges to be granted to groups by adding the group name from the Users Groups list to either the "Execute" or "Modify and Execute" list. A user group can exist in only one of these access lists.
User Groups	The groups listed here have no access to the PSUR report template. Click **Add** or **Remove** to move them to another access list.
Execute	The groups listed here have read and execute access to the shared PSUR report template.

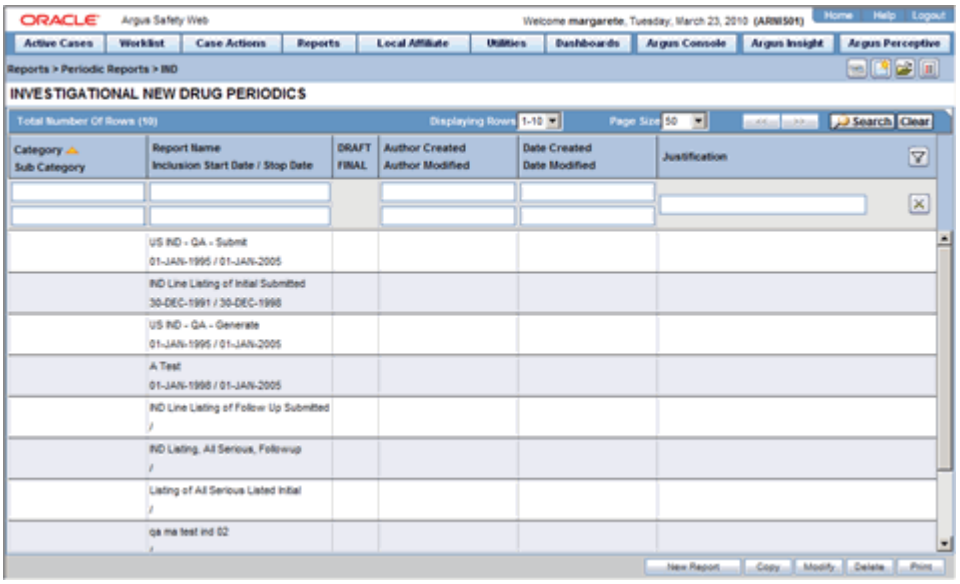
Field	Description
Modify & Execute	The groups listed here have read, execute and modify access to the shared PSUR report template.

Templates Tab Refer to the **ePSUR User Guide** for a description of fields in the **Templates** tab.



US IND Periodic Reports

The system enables you to define an IND summary report. You can add a new report as well as copy, modify and delete existing reports.



Use the following procedure to create and IND Summary Report

1. Select Reports --> IND Reports to open IND Subject of Report view.
2. Click **New Report**.

   OR

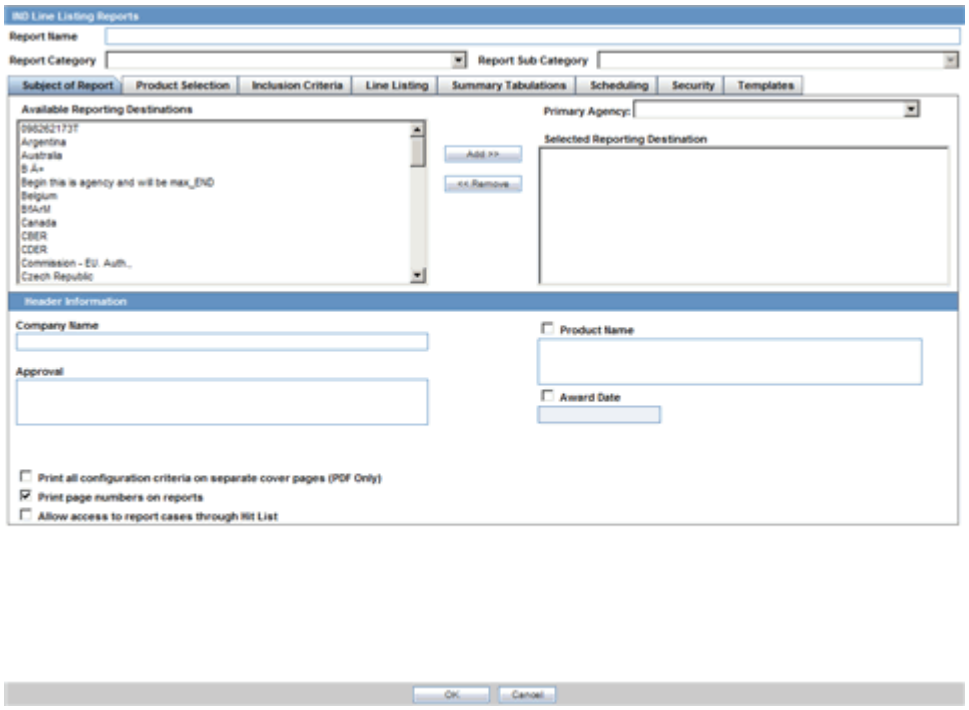
   Select an existing report from the list and click **Copy** or **Modify**.
3. When you click **New Report**, the **IND Line Listing Reports** dialog opens.
4. Enter an appropriate name for the report under **Report Name**.
5. Use the tabs in this dialog to configure the IND Report.
6. From each tab in the IND Summary Report, you can choose to Print all configuration criteria on separate cover pages (PDF Only).

Common Fields

The **Report Name**, **Report Category** and **Report Sub-Category** fields are common to all tabs of the Reports. The following table describes these fields.

Field	Description
Report Name	Enter a name for the Report. The name entered here is displayed in the Reports menu.
Report Category	Select a category for the Report. This is displayed in the Reports menu. **Tip:** Select **New** to define a subcategory within the report category. The **Periodic Report Category** dialog is displayed. Enter a category name in **Category** and click **OK**. The category is entered in the **Report Category** drop-down list.
Report Sub Category	Select a subcategory for the report. **Tip:** Select **New** to define a subcategory within the report sub-category. The **Periodic Report Category** dialog is displayed. Enter a category name in **Category** and click **OK**. The category is entered in the **Report Sub-Category** drop-down list.

Subject of Report Tab The **Subject of Report** tab is used to configure the report header and to specify the agency, products, and other elements. Select multiple ingredients for a configured IND Report to view the multiple licenses to be selected for the report.



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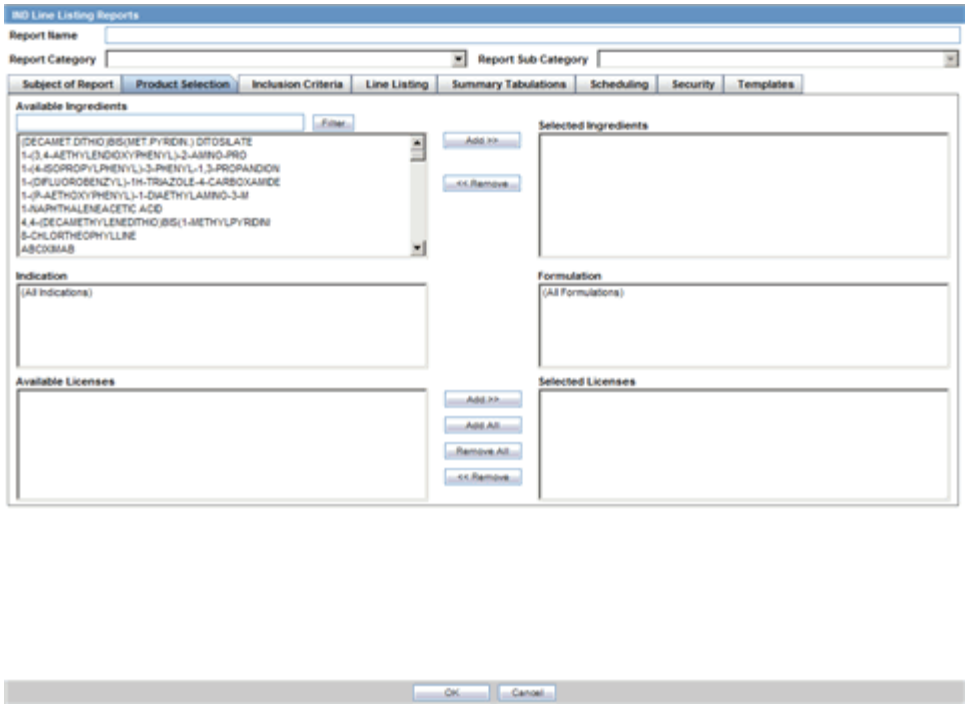
Field	Description
Primary Agency	Select the Primary Agency.
Reporting Destination	Displays the list of configured Regulatory Agencies. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. Select multiple agencies by holding the **CTRL** key when you click them.
Selected Destination	Displays the list of agencies where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. Select multiple agencies by holding the **CTRL** key when you click them. Likewise, select an agency from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.
Company Name	If a regulatory agency is selected in the **Subject of Report** tab, then the company name associated with the regulatory agency (this association is created by the Administrator) is automatically entered in this field.
Product Name	This field is automatically filled as per the **Ingredient** field. **Note:** Click the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Approval	This field is automatically filled with License numbers, separated by commas. This is an editable field.

Field	Description
Award Date	This field is populated with the earliest awarded Investigational License for US amongst the licenses selected. This field cannot be edited. **Note:** Click the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Print all configuration criteria on separate cover page	Click this checkbox to print out the configuration of this report when the report is printed. This is only available when the PDF option is selected during printing.
Print page numbers on reports	When checked, this option enables the user to print page numbers on a periodic report. This is the default for all report configurations. If this checkbox **is not checked**, the following occur. ■ The "Additional Separate Page Numbering for UD Summaries" option on the IND Summaries Tabulation tab is grayed out and inactive. ■ The system removes all existing report page numbering
Allow access to report cases through Hit List	When the report is run as final, it creates a Hit List, which can be retrieved from other areas of the application where advanced conditions can be selected. Click this checkbox to report cases through the Hit List.

Product Selection Tab Use the **Product Selection** tab to select product information to include in the report.



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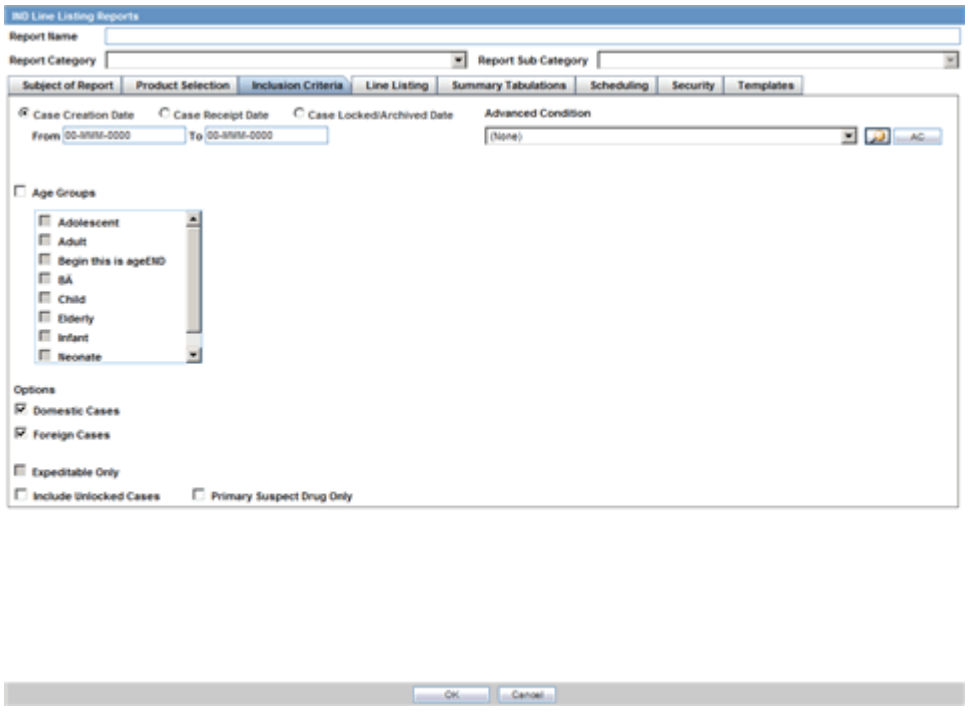
Field	Description
Available Ingredients	Displays the list containing the Ingredients used for the product configuration. Select an ingredient from the list displayed in **Available Ingredients** and click **Add/Remove** to add/remove the ingredient. You can select multiple ingredients at a time.
Filter	Enter an Ingredient name and click **Filter** to search for the entered ingredient within the Available list of Ingredients.
Selected Ingredients	Displays the list of ingredients selected from the **Available Ingredients** list.
Indication	This list contains a list of all the indications for the products containing the selected ingredient. The selections made from this list are displayed in the **Available Products** section. **Note:** You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Formulation	This list contains the Formulations configured for the product containing the selected ingredient and indication. The selections made from this list get displayed in the **Selected Products** section. **Note:** You can select multiple Formulations from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Available Licenses	This list is automatically populated with the licenses from the **Indication** section.
Selected Licenses	This list contains licenses selected by the user from the **Available Licenses** list. When a product is selected, the **Trade Name** and **International Birth Date** fields are auto-populated with the license trade name ("formulation", "concentration") and earliest License Award Date for the product.

Inclusion Criteria Tab The **Inclusion Criteria** tab allows you to select search parameters for inclusion of cases in a periodic report.



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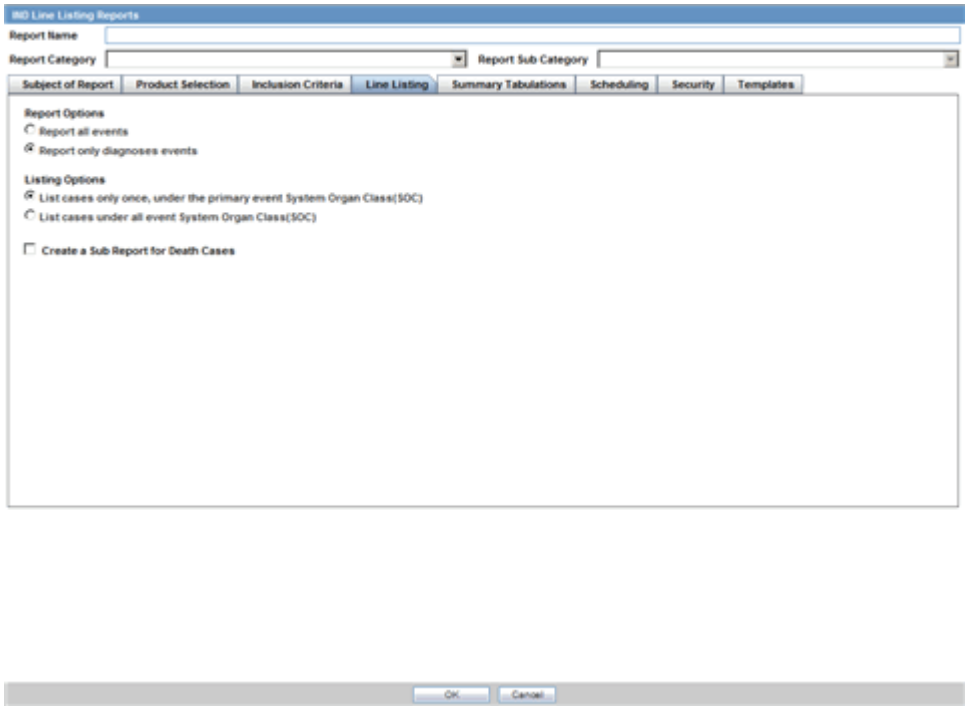
Field	Description
Case Creation Date	Allows you to specify a range of cases by the date when the case was created.
Case Receipt Date	Allows you to specify a range of cases by the initial receipt date.
Use Current Version	Allows you to use the latest revision to populate the data within the selected reports.
Use DLP Version	Allows you to use the case data of the version as of the specified DLP Version.
Age Groups	Allows you to include or exclude cases based on the patient's age group. Select the **Age Groups** checkbox to activate the age groups and select all the age group categories that apply.
Options - Domestic/Foreign Cases	This option allows the user to include domestic and foreign cases within the periodic report. Select Domestic if Country of Incidence is USA and Foreign if Country of Incidence is not USA.
Expeditable Only	This checkbox is available only when an agency is selected in the **Subject of Report** tab. If you select this check box, only the cases classified as submitted expedited reports to the primary agency are used.
Include Unlocked Cases	Allows you to include unlocked cases in the periodic report.
Advanced Condition	Allows you to specify an advanced condition that must be satisfied by each case that is included in the report. Ensure that the advanced condition or the advanced condition query set that is specified here does not contradict any other criteria specified in the dialog.

Line Listing Tab The following table describes the fields in the **Line Listing** tab.



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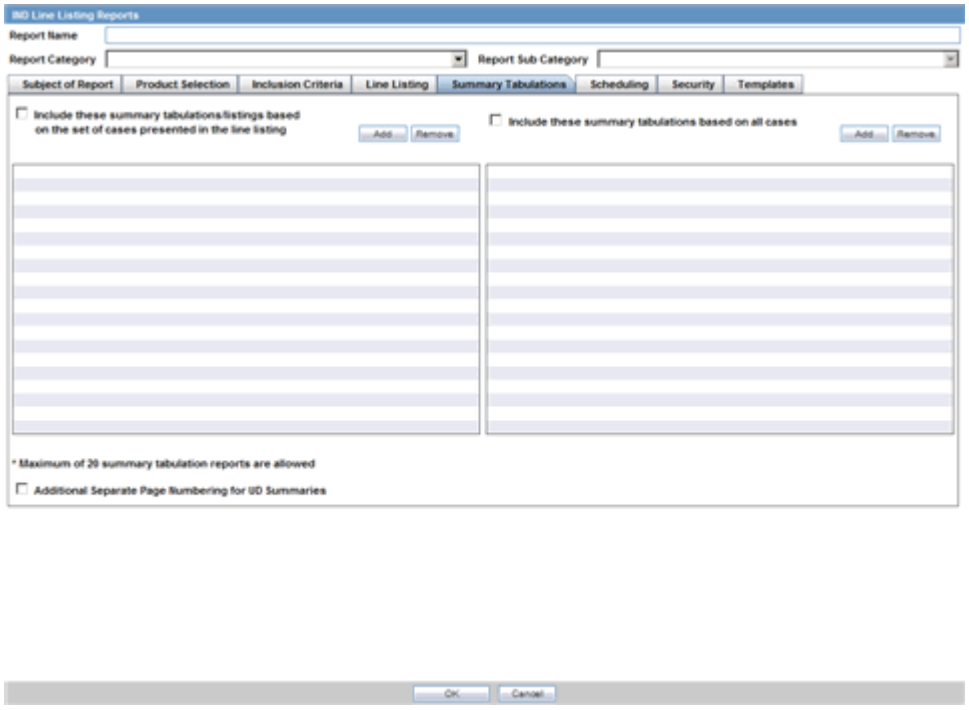
Field	Description
Report All Events	Select this option to report all events.
Report only Diagnosis Events	Select this option to report only diagnosis events (only the diagnosis events that are either explicitly marked as diagnosis or are non-related symptoms).
List cases only once, under the primary event	Select this option to view the details of cases in the Main Line Listing only once under the Primary Event
List cases under all events, details under the primary event	Select this option to view the details of cases in the Main Line Listing only once under the Primary Event, while non-primary events are listed under their respective event hierarchy with a reference to the primary event body system. Therefore, use this option when grouping on Main Line Listing is by the Event Body System.
Create a Sub Report for Death Cases	Select this check box to separate death cases from the main IND listing. If the check box is checked, all death cases (Identified by any event marked as death in Seriousness Criteria or any event having a Event Outcome as Death) are filtered out from the IND Line Listing. All death case show up in a sub report, called "IND Line Listing (Death Cases)."

Summary Tabulations Tab The **Summary Tabulations** tab enables you to specify which summary tabulations will appear along with the line listing.



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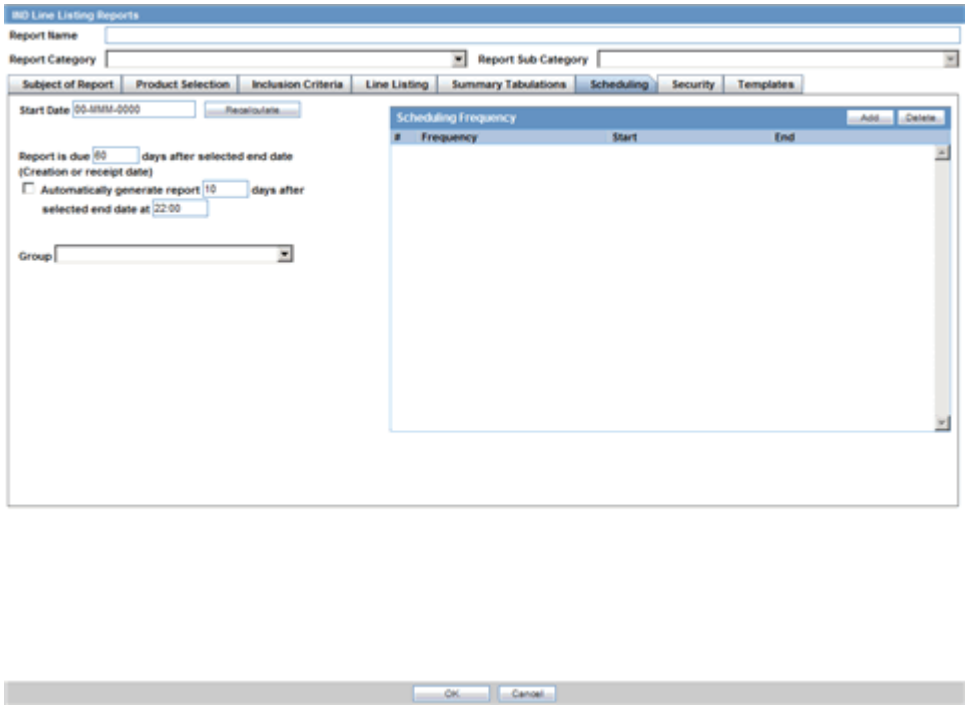
Field	Description
Include these summary tabulations/listings based on the set of cases presented in the line listing	Allows you to select from pre-configured summary tabulations/listings. These tabulations are based only on the data included in the line listing. Select the **Exclude Follow-up Cases** check box to filter out follow-up cases from the attached report. **Note:** If the Exclude Follow-up Cases option is selected on the Inclusion criteria tab, this option is ignored and follow-up cases are always filtered out.
Include these summary tabulations based on all cases	Allows for additional sub-reports based on the 'Case Data Analysis' template, to be included as an output for the all cases in the database that meet the IND Report inclusion criterion for all dates.
Add	Displays a list of memorized Case Data Analysis Reports that have been marked for availability in a periodic report.
Remove	Click this button to remove a selected report.
Additional Separate Page Numbering for Summaries	Enables you to include additional separate page numbering for summaries.
Include Summary of Unlocked Cases	Enables you to print the list of Case Numbers that are included in the Periodic Reports but are not locked.

Scheduling Tab The **Scheduling** tab allows you to specify details of how often the periodic report will be scheduled.



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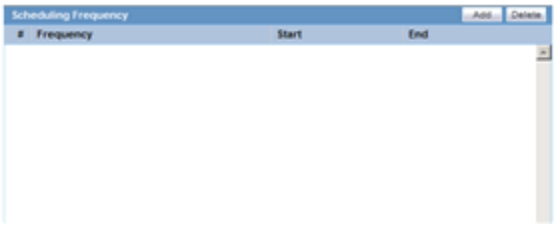
The following table lists and describes the fields on the **Scheduling** tab.

Field	Description
Start Date	This is the International Birth Date for the IND Report product. This date is computed as the earliest Awarded date for any license of any type.
Recalculate	Allows a user to recompute the International Birth Date of the IND Report Product. This date can be overwritten/manually entered, if needed.
Report is due xx days after selected end date (creation or receipt date)	Enter the number of days when the report will be due after the end date specified for the scheduling period.
Automatically generate report xx days before/after selected end date at xx:xx	Allows a user to specify the timing of the automatic report generation, by specifying the number of days before/after the selected end date of the report.
Group	Allows the user to select the group to which the automatically generated report is to be assigned.

Scheduling Frequency Description of fields in **Scheduling Frequency**:



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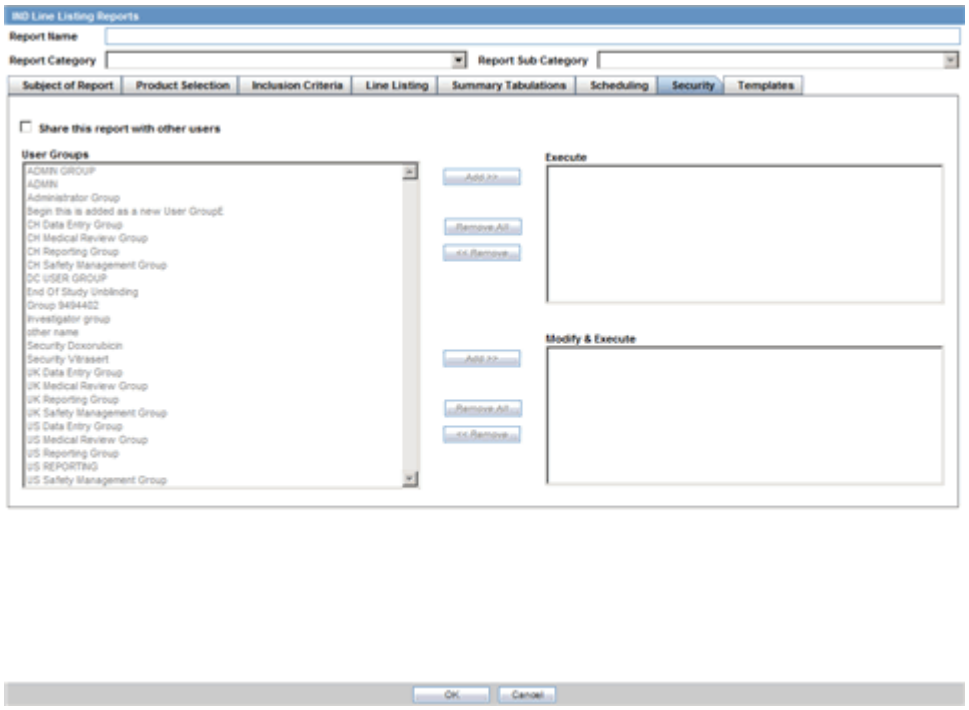
Field	Description
Frequency	Allows a user to specify the interval required for this scheduling period.
Start	Allows the user to specify when the scheduling period starts.
End	Allows the user to specify when the scheduling period starts.
Add	Allows a user to add another scheduling interval.
Delete	Allows a user to delete a scheduling interval.

Security Tab The **Security** tab is used to configure the security level for the IND Reports.



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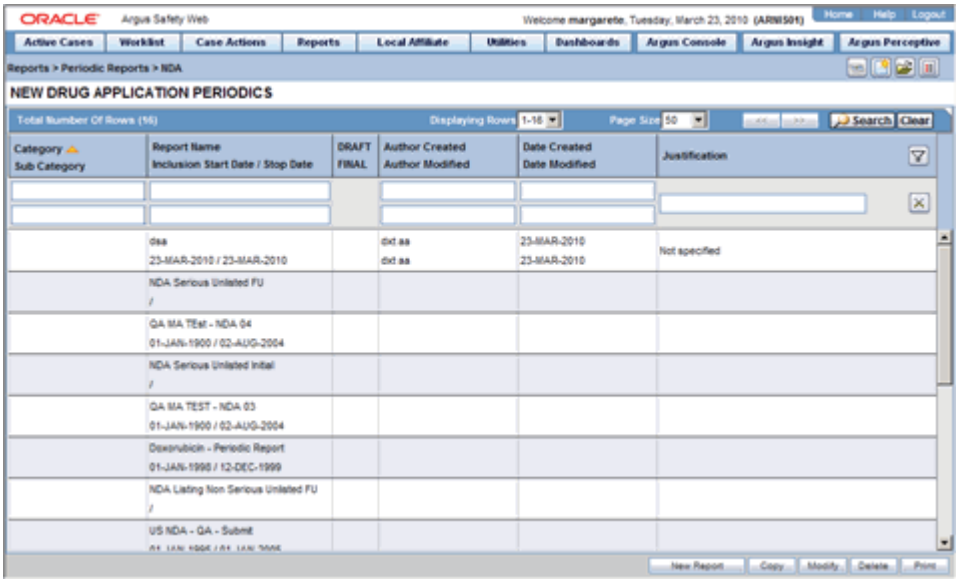
The following table lists and describes the fields on the **Security** tab.

Field	Description
Share this Report with Other Users	Click this check box to share this report with other users. Specify the privileges to be granted to groups by adding the group name from the Users Groups list to either the "Execute" or "Modify and Execute" list. A user group can exist in only one of these access lists.
User Groups	The groups listed here have no access to the IND Report template. Click **Add** or **Remove** to move them to another access list.
Execute	The groups listed here have read and execute access to the shared IND Report template.
Modify & Execute	The groups listed here have read, execute and modify access to the shared IND Report template.

US NDA Periodic Reports

The **US NDA Periodic Reports** enable you to define an NDA Periodic report. You can add a new report as well as copy, modify and delete existing reports.



Use the following procedure to create an NDA Periodic report

To create NDA Summary Reports:

1. Select Reports --> NDA Reports to open the NDA Subject of Report view.
2. Click **New Report** to create an entirely new report,

   OR

   Select an existing report from the list and click **Copy** or **Modify**.
3. When you click **New Report**, the **NDA Line Listing Reports** dialog opens.
4. Enter an appropriate report name in the **Report Name** field
5. Use the tabs in this dialog to configure the NDA Report.
6. From each tab in the NDA Report, you can choose to Print all configuration criteria on separate cover pages (PDF Only).

General Usage Information

When using NDA Reports be aware of the following:

- You can print an Index of Cases included in the NDA report.
- If you select this option, the system lists the cases from the following sections **once** at the end of the configuration pages:
  - Sequential List of cases
  - Serious Listed Initial/Follow up
  - Non Serious Listed Initial/Follow up
  - Non Serious Unlisted Initial/Follow up
  - 15 Day Submission
- The page numbering for this sub-report continues from the configuration pages.
- You can separate initial case events from follow-up case events in the **Summary Tabulation** tab of the NDA Report.

  - If you select this option, the system counts events in the **Initial** section if the case is in the **Serious Listed**, **Non-Serious Listed**, or **Non-Serious Listed/U**nlisted sections.
  - If you select this option, the system counts events in the **Follow-up** section if the case is in the **Serious Listed** or **Non-Serious Listed/Unlisted** follow-up sections of the NDA report.
  - For the **15 Day** events, if the case has not been previously reported in a NDA, the system counts it in the **Initial** section then the **Follow-up** section.
  - If you select List cases once under the **Primary Event System Organ Class (SOC)**, the system displays a footnote with an asterisk (*) printed across all the System Organ Classes on the report and the following statement: *Primary Event System Organ Class*.

- If you select the **Print FDA-3500A/VAERS form at the end** option, the system prints the report sections in the following order:
- Configuration (Including Case Indices (e.g. Sequential Case Listing, Listing by Seriousness/Listedness, Listing of Cases Missing Analysis)
  - Line Listing
  - Summary Tabulations
  - MedWatch/VAERS reports at the end of the report
- Page numbering for the MedWatches reports continue from the last page of the NDA report.
- The configuration pages have been updated to reflect the updates made to the NDA Reports
- The configuration pages are printed at the beginning of the NDA report.
- By default, these are unchecked on all the existing configured reports.

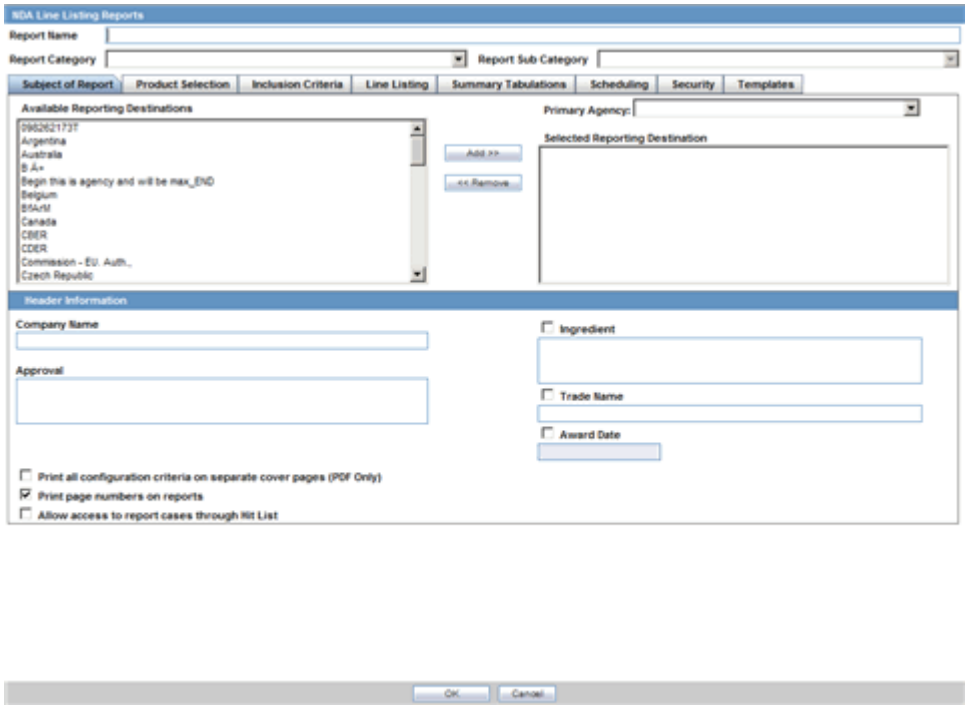
Common Fields

The **Report Name**, **Report Category** and **Report Sub-Category** fields are common to all tabs of the Reports. The following table describes these fields:

Field	Description
Report Name	Enter a name for the Report. The name entered here is displayed in the Reports menu.
Report Category	Select a category for the Report. This is displayed in the Reports menu. **Tip:** Select **New** to define a subcategory within the report category. The **Periodic Report Category** dialog is displayed. Enter a category name in **Category** and click **OK**. The category is entered in the **Report Category** drop-down list.
Report Sub Category	Select a subcategory for the report. **Tip:** Select **New** to define a subcategory within the report sub-category. The **Periodic Report Category** dialog is displayed. Enter a category name in **Category** and click **OK**. The category is entered in the **Report Sub-Category** drop-down list.

Subject of Report Tab

On the **Subject of Report** tab you can select multiple Ingredients for a configured NDA Report per allowable variations of product and license configuration and periodic reporting requirements for the FDA. Select multiple ingredients to view the multiple licenses to be selected for the report.



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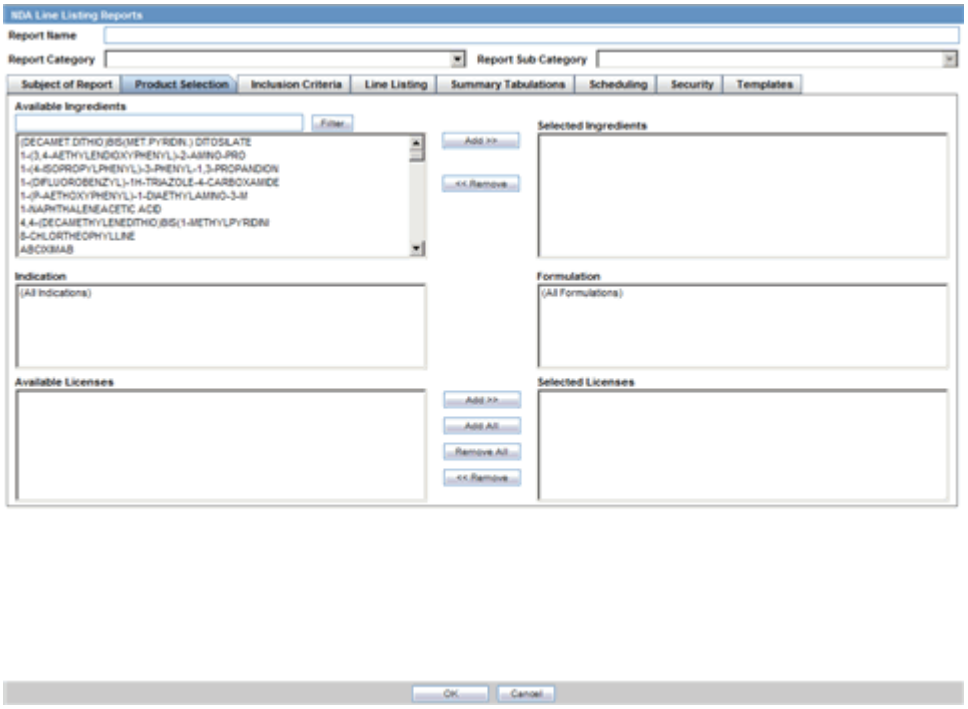
The following table describes the items in the **Subject of Report** tab.

Field	Description
Primary Agency	Select the Primary Agency.
Reporting Destination	Displays the list of configured Regulatory Agencies. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. Select multiple agencies by holding the **CTRL** key when you click them.
Selected Destination	Displays the list of agencies where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. Select multiple agencies by holding the **CTRL** key when you click them. Likewise, select an agency from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.
Company Name	If a regulatory agency is selected, the company name associated with the regulatory agency (this association is created by the Administrator) is automatically entered in this field.

Field	Description
Ingredient	This field is populated with ingredient selected in the **Subject of Report** tab. **Note:** Click the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Approval	This field is automatically filled with License numbers, separated by commas. This is an editable field.
Trade Name	Automatically displays the Trade Name. Multiple trade names are also populated from license trade name (formulation, concentration) of selected licenses, separated by commas. **Note:** Click the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Award Date	Automatically displays the earliest license awarded date, when a user selects an Ingredient and a Product. **Note:** Click the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Print all configuration criteria on separate cover page	Click this checkbox to print out the configuration of this report when the report is printed. This is only available when the PDF option is selected during printing.
Print page numbers on reports	When checked, this option enables the user to print page numbers on a periodic report. This is the default for all report configurations. If this checkbox **is not checked**, the following occur. ■ The "Use Periodic Numbering on the reports" option in the NDA Line Listing tab is grayed out and inactive ■ The "Additional Separate Page Numbering for UD Summaries" in the NDA Summary Tabulations tab is grayed out and inactive. ■ The system removes all existing report page numbering and the option to check page number check boxes on the report configuration tabs are grayed out and inactive.
Allow access to report cases through Hit List	When the report is run as final, it creates a Hit List, which can be retrieved from other areas of the application where advanced conditions can be selected. Click this checkbox to report cases through the Hit List.

Product Selection Tab

The **Product Selection** tab enables you to select product information to include on the report.



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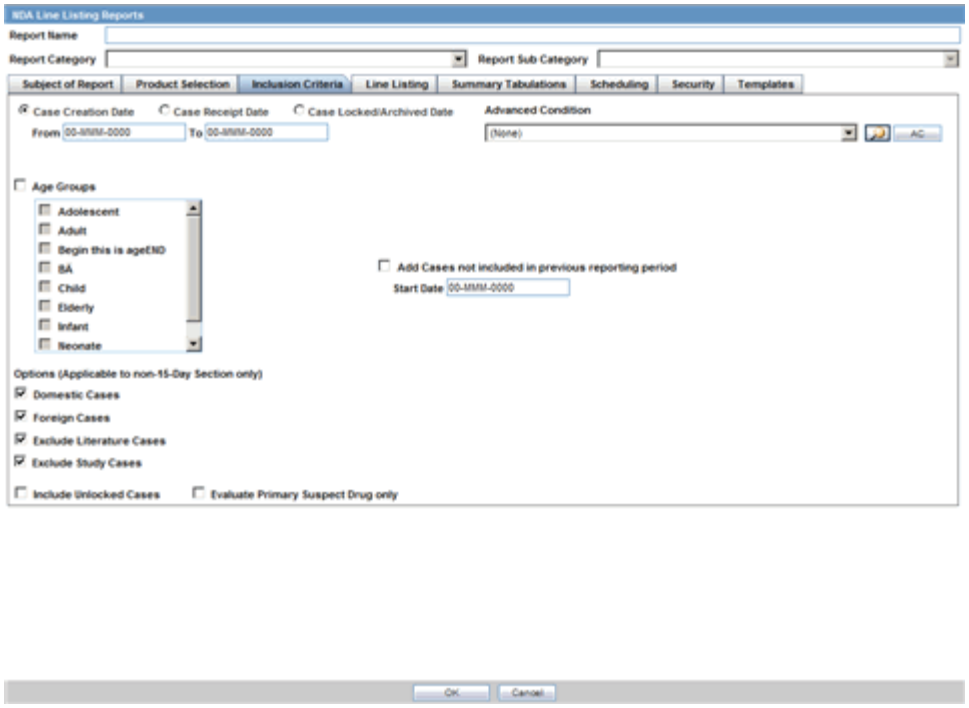
The following table lists and describes the fields on the tab.

Field	Description
Available Ingredients	Displays the list containing the Ingredients used for the product configuration. Select an ingredient from the list displayed in **Available Ingredients** and click **Add/Remove** to add/remove the ingredient. You can select multiple ingredients at a time.
Filter	Enter an Ingredient name and click **Filter** to search for the entered ingredient within the Available list of Ingredients.
Selected Ingredients	Displays the list of ingredients selected from the **Available Ingredients** list.
Indication	This list contains a list of all the indications for the products containing the selected ingredient. The selections made from this list are displayed in the **Available Products** section. **Note:** You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Formulation	This list contains the Formulations configured for the product containing the selected ingredient and indication. The selections made from this list get displayed in the **Selected Products** section. **Note:** You can select multiple Formulations from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Available Licenses	This list is automatically populated with the licenses from the **Indication** section.

Field	Description
Selected Licenses	This list contains licenses selected by the user from the **Available Licenses** list. When a product is selected, the **Trade Name** and **Award Date** fields are auto-populated with the license trade name ("formulation", "concentration") and earliest License Award Date for the product.

Inclusion Criteria Tab

The following table describes the items in the **Inclusion Criteria** tab.



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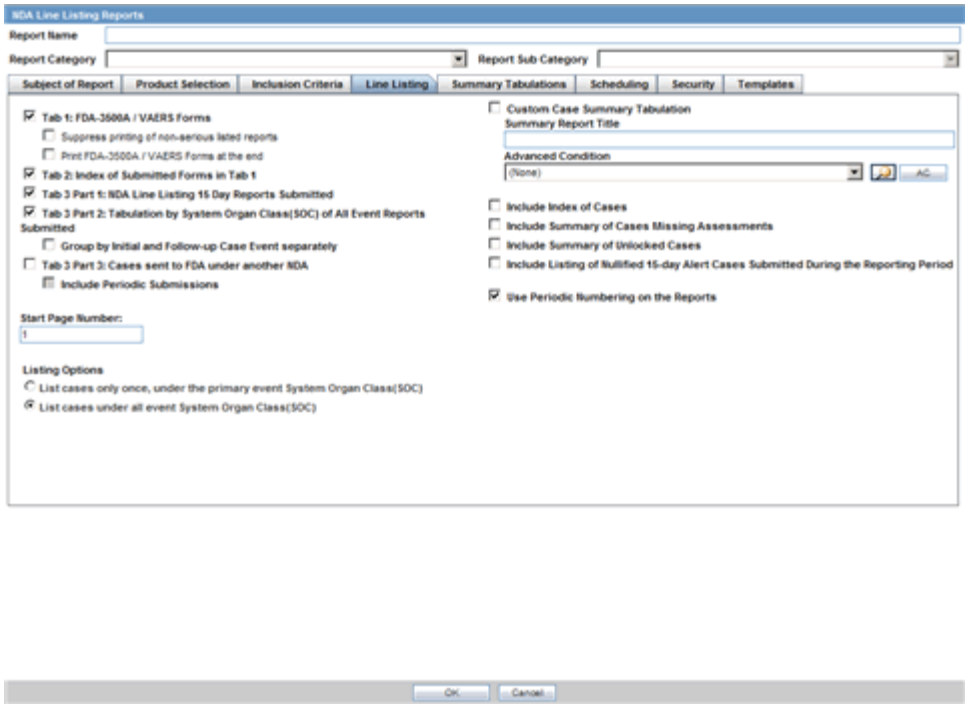
Field	Description
Case Creation Date	Allows you to specify a range of cases by the date when the case was created.
Case Receipt Date	Allows you to specify a range of cases by the initial receipt date.
Use Current Version	Allows you to use the latest revision to populate the data within the selected reports.
Use DLP Version	Allows you to use the case data of the version as of the specified DLP Version.
Age Groups	Allows you to include or exclude cases based on the patient's age group. Select the **Age Groups** checkbox to activate the age groups and select all the age group categories that apply.
Option (Applicable to Non-15-Day Selection Only)- Domestic/Foreign Cases	This option allows the user to include domestic and foreign cases within the periodic report. Select Domestic if Country of Incidence is USA and Foreign if Country of Incidence is not USA.

Field	Description
Option (Applicable to Non-15-Day Selection Only)- Exclude Literature Cases/Study Cases	This option allows the user to exclude Literature and Study Cases from being considered for the NDA Report. Select **Exclude Literature Cases** to exclude literature cases and select **Exclude Study Cases** to exclude study cases.
Advanced Condition	Allows you to specify an advanced condition that must be satisfied by each case that is included in the report. Ensure that the advanced condition or the advanced condition query set that is specified here does not contradict any other criteria specified in the dialog.
Add Cases not Included in a previous reporting period Start Date	Enter the start date. This adds cases not included in a previous reporting period with the specified start date.
Include Unlocked Cases	Allows you to include unlocked cases in the periodic report.
Evaluate Primary Suspect Drug Only	Allows you to select only the Primary Suspect Drug.

Line Listing Tab

The NDA report comprises of three tabs. The options for these tabs can be configured in the **Line Listing** tab.



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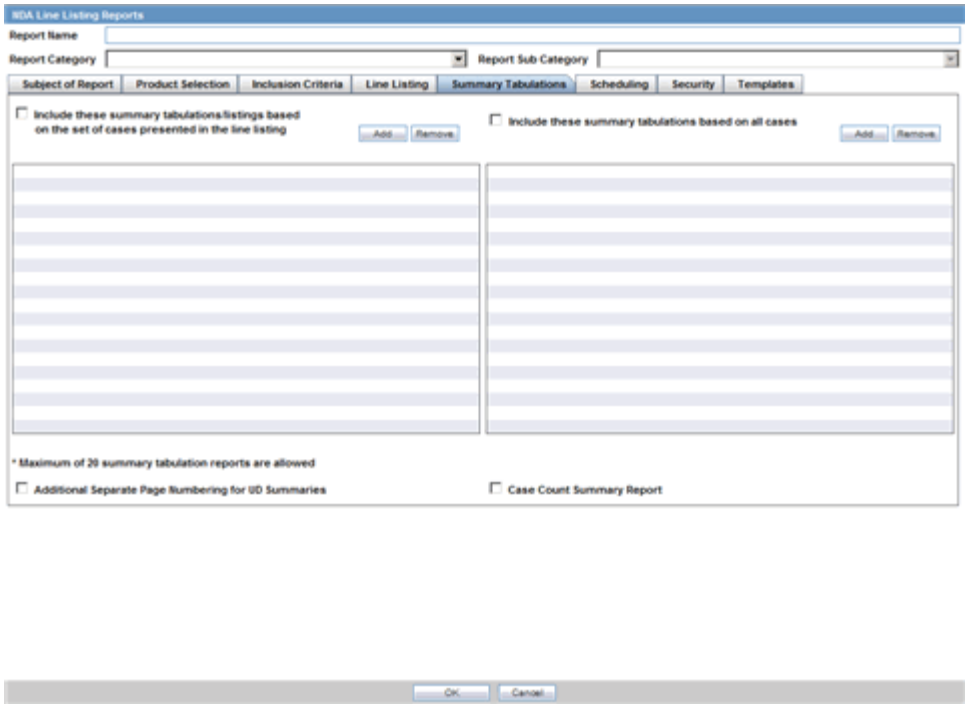
The following tables lists and describes the fields on the tab.

Field	Description
Tab 1: FDA - 3500/VAERS Forms	Select this checkbox to generate the MedWatch 3500A (Drug) or VAERS reports which are serious listed or non-serious
Suppress printing of non-serious listed reports	Select this checkbox to prevent printing the non-serious listed reports but print their case numbers in the main NDA report indices **Note:** Tab 1 of the NDA Line Listing report cannot be generated without Tab 2. However, Tab 2 can be generated without Tab 1
Tab 2: Index of Submitted Forms in Tab 1	Select this checkbox to generate an index of the forms from Tab 1 It prints all MedWatch/VAERS forms for the following cases: ■ Serious Listed ■ Non-Serious Unlisted ■ Non-Serious Listed **Note:** Previously expedited 15-day reports that are Serious and Unlisted that have already been submitted to the FDA do not need to be re-submitted with this periodic report
Tab 3 Part 1: NDA Line Listing of 15 Day Reports Submitted	Select this checkbox to generate a list of all serious unlisted expedited reports within the specified time period. **Note:** The dates in these reports are in GMT.
TAB 3 Part 2: Tabulation by System Organ Class (SOC) of All Event Reports Submitted	Select this checkbox to generate a tabulation by System Organ Class (SOC) of all events reported during the specified time period. This includes the cases for which expedited reports were previously generated, as well as the cases that are submitted as part of the current report
TAB 3 Part 3: Cases sent to FDA under another NDA	Select this checkbox to print a list of all the serious unlisted events for which reports were submitted to the FDA previously **Note:** If you select to print out the Tab 3 Part 3 section, the NDA report looks for other submissions (E2B, MW, MW Drug, or VAERS) to the same agency for the same case against other (not included in selection criteria for this report) marketed licenses. Any submission matching this criterion is listed on the Tab 3 Part 3 section of the NDA report. If there are multiple submissions against different licenses, then each one is listed. Each license is listed only once
Include Periodic Submissions	Select this checkbox to include all cases that have been sent under another NDA
Start Page Number	Select the page number for the first page of the report
Listing Options	These options for "List cases only once, under the primary event body system" and "List cases under all events body systems" only apply to the NDA Line Listing of Expedited Reports Submitted report
List cases only once, under the primary event System Organ Class	Select this option to list cases only once
List cases under all events System Organ Classes	Select this option to list cases under each SOC for each event
Include Summary of Cases Missing Assessments	Select this checkbox to include a Summary of Cases missing Assessments at the end of the report
Include Summary of Unlocked Cases	Select this option to include a summary of unlocked cases

Field	Description
Include Listing of Nullified 15-day Alert Cases Submitted During the Reporting Period	Select this option to include cancelled 15-day alert cases during the reporting period **Note:** The dates in these reports are in GMT.
Use Periodic numbering on the Reports	Select this option to use periodic numbering on reports
Custom Case Summary Tabulation	Enter the Summary Report Title
Advanced Condition	Select the Advanced Condition from the drop-down list

Summary Tabulations Tab

The **Summary Tabulations** tab allows you to specify which summary tabulations will appear along with the line listing.



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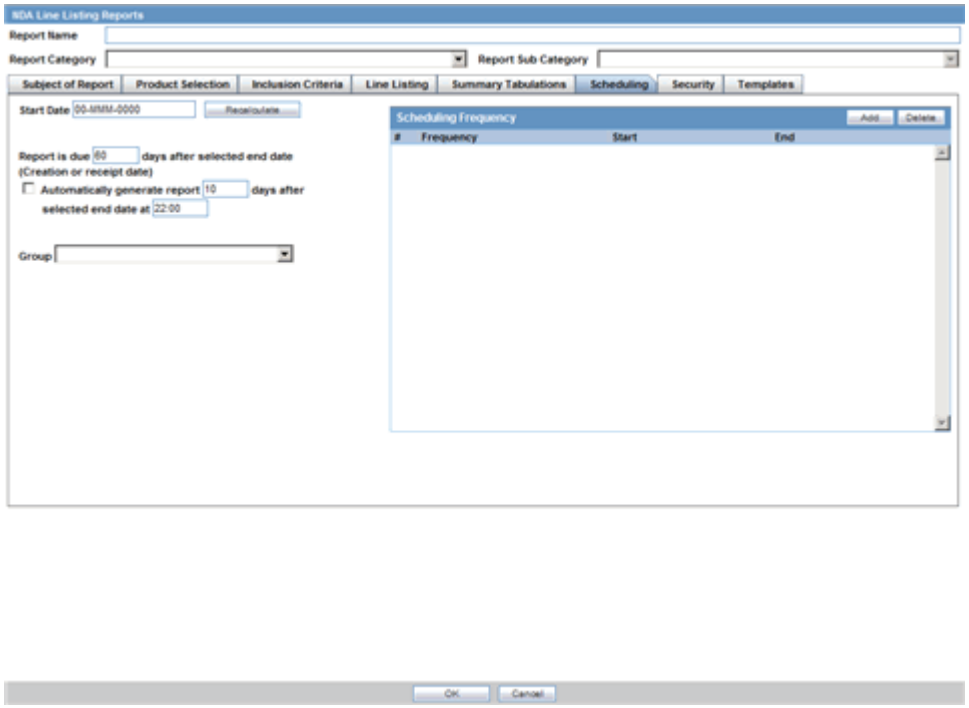
The following table lists and describes the fields on the tab.

Field	Description
Include these summary tabulations/listings based on the set of cases presented in the line listing	Allows you to select from pre-configured summary tabulations/listings. These tabulations are based only on the data included in the line listing. Select the **Exclude Follow-up Cases** check box to filter out follow-up cases from the attached report. **Note:** If the Exclude Follow-up Cases option is selected on the Inclusion criteria tab, this option is ignored and follow-up cases are always filtered out.

Field	Description
Include these summary tabulations based on all cases	Allows for additional sub-reports based on the 'Case Data Analysis' template, to be included as an output for the all cases in the database that meet the NDA Report inclusion criterion for all dates.
Add	Displays a list of memorized Case Data Analysis Reports that have been marked for availability in a periodic report.
Remove	Click this button to remove a selected report.
Additional Separate Page Numbering for Summaries	Enables you to include additional separate page numbering for summaries.
Case Count Summary Report	Enables you to print the list of Case Numbers that are included in the Periodic Reports but are not locked.

Scheduling Tab

The **Scheduling** tab allows you to specify details of how often the periodic report will be scheduled.



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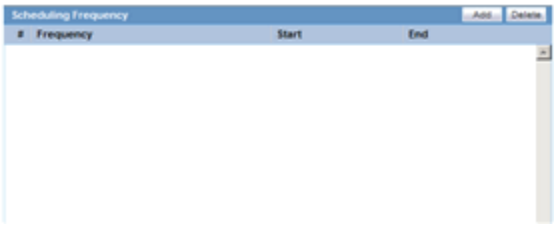
The following table lists and describes the fields on the tab.

Field	Description
Start Date	This is the International Birth Date for the NDA Report product. This date is computed as the earliest Awarded date for any license of any type.
Recalculate	Allows a user to recompute the International Birth Date of the NDA Report Product. This date can be overwritten/manually entered, if needed.

Field	Description
Report is due xx days after selected end date (creation or receipt date)	Enter the number of days when the report will be due after the end date specified for the scheduling period.
Automatically generate report xx days before/after selected end date at xx:xx	Allows a user to specify the timing of the automatic report generation, by specifying the number of days before/after the selected end date of the report.
Group	Allows the user to select the group to which the automatically generated report is to be assigned.

Scheduling Frequency The following is an illustration of the **Scheduling Frequency** section.



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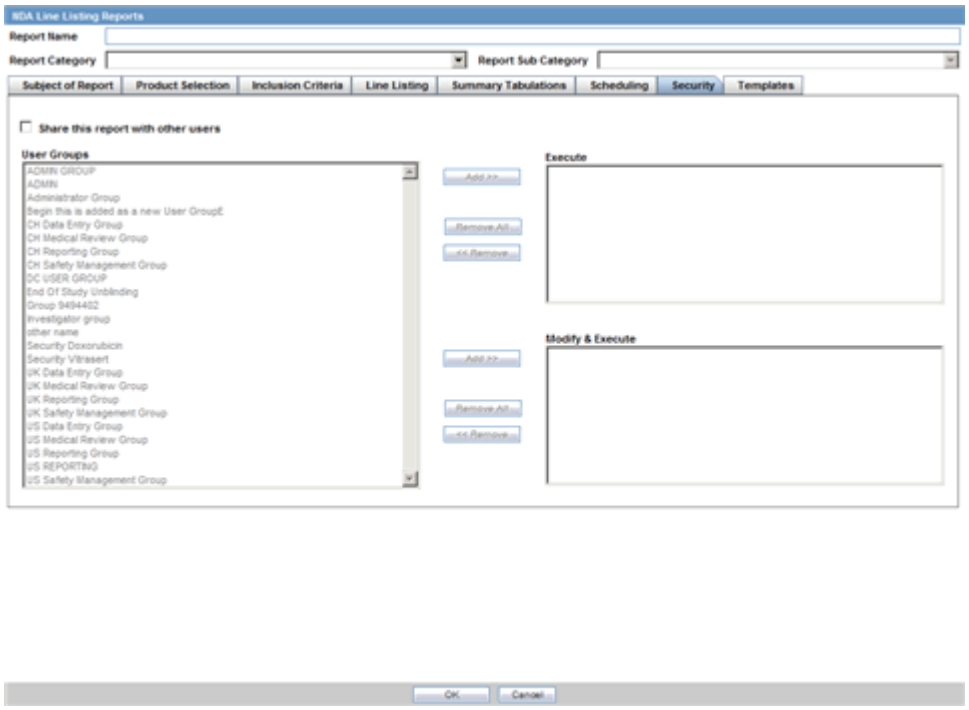
The following table lists and describes the **Scheduling Frequency** fields.

Field	Description
Frequency	Allows a user to specify the interval required for this scheduling period.
Start	Allows the user to specify when the scheduling period starts.
End	Allows the user to specify when the scheduling period starts.
Add	Allows a user to add another scheduling interval.
Delete	Allows a user to delete a scheduling interval.

Security Tab

The **Security** tab is used to configure the security level for the NDA Reports.



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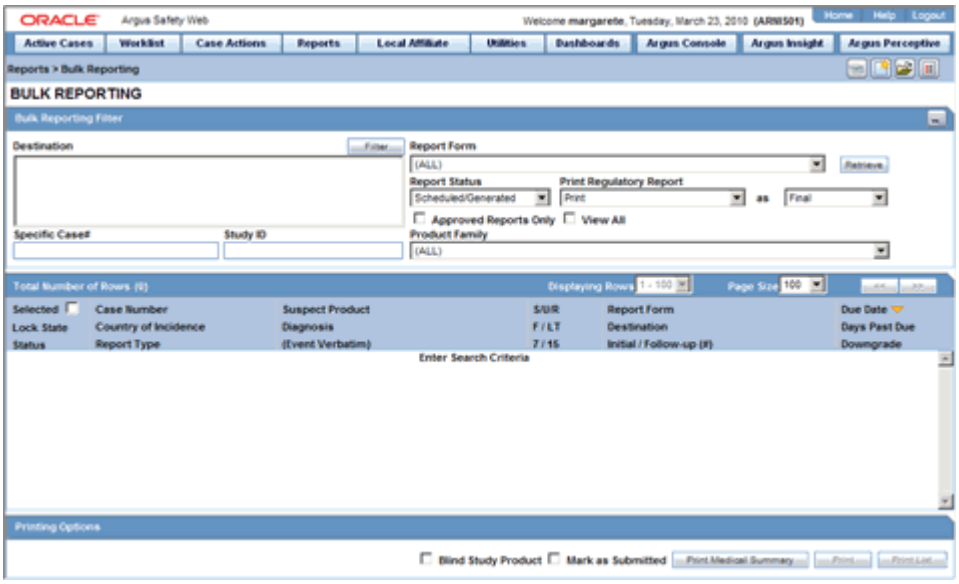
Field	Description
Share this Report with Other Users	Click this checkbox to share this report with other users. Specify the privileges to be granted to groups by adding the group name from the Users Groups list to either the 'Execute' or 'Modify and Execute' list. A user group can exist in only one of these access lists.
User Groups	The groups listed here have no access to the NDA Report template. Click **Add** or **Remove** to move them to another access list.
Execute	The groups listed here have read and execute access to the shared NDA Report template.
Modify & Execute	The groups listed here have read, execute and modify access to the shared NDA Report template.

Bulk Reporting

Bulk Reporting enables you to print, transmit and/or submit reports in bulk.

Select **Reports --> Bulk Reporting** to view the **Bulk Report** screen shown in the following illustration.



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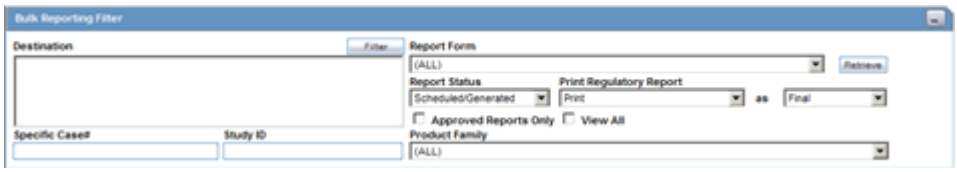
Bulk Reporting Filter Section

The **Bulk Reporting Filter** sections enables you to filter reports.



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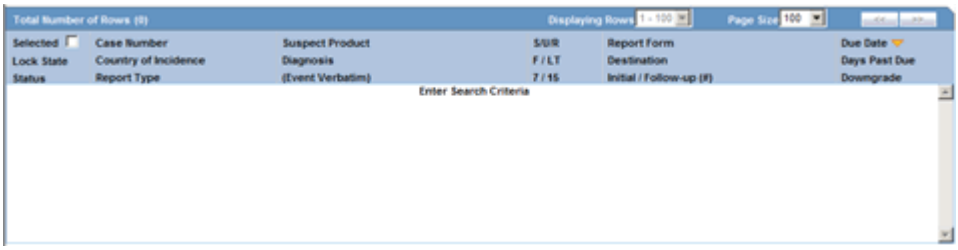
The following table lists and describes the fields in this section

Field	Description
Destination	Select an Agency to filter reports by that particular agency. Only the agencies that have reports in the Scheduled, Approved and Generated states are displayed. Click **Filter** to select multiple agencies from the **Reporting Destinations** dialog. The previous filtering criteria is saved and retained when the user invokes this dialog. By default, all agencies are assumed.
Report Form	Select any of the listed report forms to view reports belonging to the selected report form only.
Report Status	Choose either Scheduled/Generated, Pending, Failed, or Printed/Transmitted from the drop-down list.
Print Regulatory Report	Prints the report as Draft or Final. The Draft option is disabled when the printing option is set to **Transmit**. Select **Medical Summary** to view the list of only medical summaries of distinct cases in a PDF.
Approved Reports Only	Filters reports for only approved reports.

Field	Description
View All	Displays the bulk reports applicable to your filter selections.
Product Family	Enter a Product family to view all cases where the scheduled reports belong to the searched Product family.
Specific Case #	Searches a specific case. To do so, enter the Case Number of the case you wish to search and click the **Retrieve** button. This stores the agency selections last made.

Total Number of Rows Section

The system displays the search results in the **Total Number of Rows** section.



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The following table lists and describes the fields and columns in this section.

Field	Description
Selected	Allows the user to select the report.
Lock State	Displays the Case status of the case to depict if the case is locked or un-locked.
Status	Displays the Report Status e.g. Scheduled or Generated etc. Click the status to view the report details.
Case Number	Displays the Case number. Click the Case Number link to open the case.
Country of Incidence	Displays the view Country of Incidence.
Report Type	Displays the Case Report Type
Suspect Product	Displays the Trade Name for which the report has been scheduled. If more than one Suspect Company Product exists for the case, an "(+)" is placed at the end of the product name. For Reports which were scheduled for the Device, the Device name is displayed.
Diagnosis	Displays the Primary Event Diagnoses PT
(Event Verbatim)	Displays the (Verbatim as reported) of the Primary Event.

Field	Description
S/U/R	■ Displays the Case Level Assessments: ■ Serious (Y/N) ■ Unlisted (Y/N) ■ Causality (Y/N) ■ Unknown is treated as a "?" ■ The SUR link displays the Case Summary associated with the selected case.
F or LT	Fatal / Life Threatening If any of the events in the case are Fatal or Life Threatening F or LT is displayed. If the case is both **F** and **LT**, only **F** is displayed. If the case is neither **F** nor **LT**, only **No** is displayed.
7/15	Displays 7 if the report is due within 7 days Displays 15 if the report is due in more than 7 days
Report Form	Displays the Description of the report Click the Report form link to view the DRAFT Report as a PDF.
Destination	Displays the report destination (agency) for which the report is scheduled.
Initial / Follow-up (#)	Initial or Follow-up If Follow-up, the follow-up number is printed
Due Date	Displays the due date.
Days Past Due	Displays the number of days the report is past due date.
Downgrade	Allows the user to view if the report is downgrade. Displays Yes if the report is a downgrade report else.
View All	Allows administrator and workflow manager to see all items in the system.

Tip: The icon (displayed in the lock state) in the Reports-> Bulk Reporting screen denotes a SUSAR (Suspected Unexpected Serious Adverse Reaction) case.

Printing Options

Several printing options are available to you.

The following table lists and describes the available printing options

Field	Description
Blind Study Product	Select this check box to print study cases with blinded information.
Mark as Submitted	Select this check box to mark reports as **Submitted** when the transmission/e-mail has been sent. A dialog is displayed is this check box is not selected. This dialog prompts you to confirm if the report is to marked as submitted or not. Select **Yes** or **No**, as required. This selection is remembered for the next time when you print a report.

Field	Description
Print Medical Summary	Allows the user to print the Medical Summaries.
Print	Allows you to choose the printer for the selected report from the **Select Site Printer** dialog. Select the **Site** and **Printer Name** where you wish to print the report and click **OK**.
Print List	Allows the user to print the current view of the Bulk Reporting.

User Options

The following options are available to you.

- Lock State Header Options
- Lock State Icon Options

Lock State Header Options To sort the cases based on the following case status, click the **Lock State** header row. A pop-up appears listing the following sorting options:

- Lock State
- SUSAR
- Exp/Per

These options enable you to sort cases based on the case categorization.

> **Tip:** The icon (displayed in the lock state) in the Reports-> Bulk Reporting screen denotes a SUSAR (Suspected Unexpected Serious Adverse Reaction) case.

Lock State Icon Options Click the **Lock State** icon to view the list of options.

The following table describes these options:

Field	Description
View Report	Displays the Draft report.
Report Details	Displays specific information about the report as entered in the **Regulatory Reports** section.
Case Summary	Displays the Case Summary dialog
Remove Report	Deletes the report from the case on being asked for a justification
Mark for Non-Submission	Displays the **Submission** tab in the Report Details dialog. Select **No** for **Mark for Non-Submission** and enter the reason for the non-submission.
Remove Multiple Reports	Deletes multiple reports from the case on being asked a justification.
Mark Multiple for Non-Submission	Deletes multiple reports from the case on being asked a justification. The notes and date entered for the selected report are applicable for all the reports selected for Non Submission.

Incoming E2B Reports

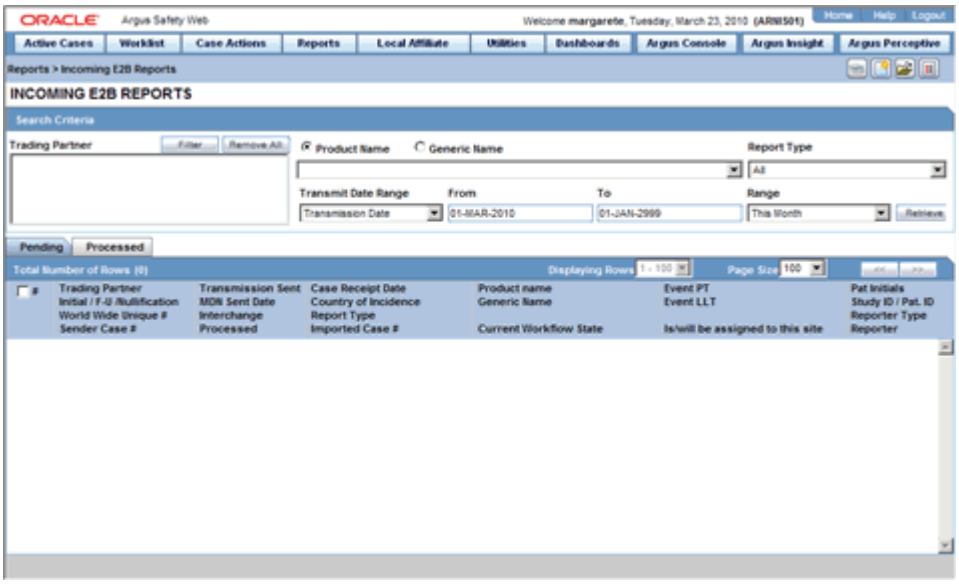
The **Incoming E2B Reports** page enables you to:

- View the E2B reports sent by the agency or the trading partner
- Process an incoming E2B report.

You can do the following:

- Check all the E2B values of the reports sent and determine whether to accept or reject the reports
- Provide a user password and acceptance notes/rejection reason and accept or reject an incoming E2B report

Select **Reports --> E2B Pending Reports** to view **Incoming E2B Reports** page show in the following illustration.



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Incoming E2B Reports Fields

The following table describes the fields on the **IncomingE2B Reports** page.

Field	Description
Trading Partner	Enter the trading partner. Click **Filter** to select an agency to filter by that particular Trading Partner. This allows you to select multiple agencies by clicking **Add** from the **Select Reporting Destinations** dialog.
Product Name/Generic Name	Enter the product name or generic name, as required.
Report Type	Select the report type, as applicable.
Transmit Date Range	Enter the range of the Transmit Date from the **From** and **To** fields. You can also select the range from the **Range** drop-down list.
Trading Partner	Displays the name of the Trading Partner of the case.

Field	Description
Initial / F/U / Null	The report version of the report ■ Initial: If the case received is an Initial Case. ■ Follow -up: If the case received is a Follow-up Case. ■ Nullification: If the case received is a Nullification Case.
World Wide Unique #	The worldwide unique number of the received case.
Sender Case #	Displays the case number of the sender.
Transmission Sent	Displays when the transmission was sent.
MDN Sent Date	Displays the date the MDN was sent.
Interchange Processed Date	Displays the date the interchange was processed.
Case Receipt Date	Displays the date the case was received.
Country of Incidence	Displays the country where the incident occurred.
Report Type	Displays the report type of the case.
Imported Case #	Displays the number of the imported case.
Product Name	Displays the product name.
Generic Name	Displays the generic name of the product.
Event PT	Displays the Primary Event and Verbatim as Reported.
Event LLT	Displays the Event LLT for the Event Information.
Is/Will be assigned to this site	Displays the site membership of the case.
Pat Initials	Displays the initials of the patient.
Study ID/Pat. ID	Displays the Study ID/ the ID of the patient in the case.
Reporter Type	Displays the primary reporter's Reporter Type.
Reporter	Displays the first and last name of the Primary Reporter.

Button and Right-click Options The following table describes the different buttons and right-click options available on Incoming E2B Reports page.

Button	Description
ICSR Viewer	Select this right-click option to launch the E2B viewer. For details, refer to the ESM User Help. **Note:** At the time of generating an E2B report, some characters entered by the user in the case form may not be displayed the same in the E2B report. For example, the E2B report equivalent of the "&" character entered in the case form is &. Similarly, there are other such characters that are represented differently in the E2b report. The table below contains the list of such characters and their equivalent representations in the E2b report:
View Error/Warning Message	Select this right-click option to view all warning messages including M2 validation errors and Multiple E2b Codes log.
Duplicate Search	Select this right-click option to perform Duplicate Search for the case being imported with the case present in the system.

Button	Description
Accept ISCR	Selects the incoming E2B report Execute these steps to accept an E2B Case: 1. Click the Accept E2B Case button. The **Acceptance of Initial Report Confirmation** dialog opens. 2. Enter your user password, date, and select a justification from the pre-defined list of justifications. 3. Click **OK**.
Reject ICSR	Rejects the incoming E2B report Execute these steps to reject an E2B Case: 1. Click the Reject E2B Case button. The **Rejection of Initial Report Confirmation** dialog opens. 2. Enter your user password, date, and select a justification from the pre-defined list of justifications. 3. Click **OK**.
Reject ICSRs	Enables you to reject multiple ICSRs by selecting the checkbox against each ICSR to that needs to be rejected. You can select the type of report to be followed up from the **Follow Up Report Form** screen. This screen allows you to select a Follow-up Report format for a Report Form. Select the desired option and click **OK** to print out the CIOMS or the MedWatch Report Form as a PDF report whilst importing the cases.
Accept ICSRs	Enables you to accept multiple ICSRs by selecting the checkbox against each ICSR to that needs to be accepted. You can select the type of report to be followed up from the **Follow Up Report Form** screen. This screen allows you to select a Follow-up Report format for a Report Form. Select the desired option and click **OK** to print out the CIOMS or the MedWatch Report Form as a PDF report whilst importing the cases.

Pending Reports

When using **E2B Pending** reports, be aware of the following:

- The system uses the Oracle Text profile settings for the duplicate search in E2B Pending configured in the Argus Schema Creation Tool.
- The user can right click on the row and select the following:

Case Summary. This displays the Case Summary (current functionality)

Medical Summary. This displays the Medical Summary report, if the user has permission to access the Medical Review dialog.

Case Form Print. This launches the **Case Form Print** dialog to enable the user to print the case form in a new IE window.

Bulk Incoming E2B Reports

The **Bulk Incoming Reports** dialog allows the user to import multiple E2B reports that have been sent by the agency or trading partner.

Be aware of the following:

- The reports that are imported can be a combination of Initial, Follow-up and Nullification reports.
- The only pre-requisite for this dialogue is that Case numbering should be set to auto-numbering and not manually.
- Bulk Incoming Reports does not prevent the duplicate cases to be loaded into the system.

To view Bulk Incoming Reports:

1. Select multiple reports from the **Incoming E2B Reports** screen and click **Accept ICSRs**.
2. The system opens the **Bulk Incoming Reports** screen.

The following table lists and describes the fields in the **Bulk Incoming Reports** dialog box.

Field	Description
Agency Name	This drop down list contains unique trading partner from the E2b reports have been received. You can select a particular agency/trading partner to filter the E2b reports.
Product Name	This drop down list contains unique suspect Product Names extracted from the received E2b reports. Select a particular suspect product to filter the E2b reports. If an Agency Name is selected, the Product Name list contains all suspect products belonging to that agency name.
Follow Up Output Format	This drop down list contains CIOMS-I, MedWatch and Case Form. You can print all E2b reports in CIOMS-I, MedWatch or Case Form format only if the Follow Up checkbox has been selected.
Source Count	Displays the total number of E2b reports with breakdown in 'Initial' 'Follow Up' and 'Nullification' category.
Report Type	Displays the report type.
Selected Count	Displays the number of E2b selected by the user to load the E2b reports in Argus Safety. Selected count can be changed by checking the 'Initial' or 'Follow Up' or 'Nullification' checkbox.
Import	Imports all the reports. **Note:** For the Import process, if the system receives an E2B report with the Medically Confirm field set to 1, the Primary reporter is marked as HCP.
Cancel	Removes the Import E2B reports window.

Duplicate Search

The **Duplicate Search** dialog for an E2B report enables you to search for possible duplicate cases in the Argus Safety system. You can select different combinations of search criteria. When more than one criterion is selected, only cases that satisfy all criteria are listed. By default, only the fields that are present in the E2B Report are checked for the Duplicate Search.

Duplicate Search Dialog Box Fields and Field Descriptions

The following table describes the fields present in the **Duplicate Search** dialog.

Field	Description
Agency	The name of the primary agency.
Original Case Number	The original case number.
Message Number	The message number of the case.
Product Name	The product name that caused the adverse event.
Generic Name	The generally known, popular name of the product.
Report Type	The type of report.
Study ID	The Study ID.
Receipt Date	The date the report was received by Argus and saved in the system.
Center ID	The ID of the center.
Sal.	The salutation such as Mr. or Mrs.
Suffix	The suffix, if applicable, that follows the name.
First Name	The first name of the patient.
Last Name	The last name of the patient.
Country of Incidence	The country where the incident occurred.
State	The state where the incident occurred.
Postal Code	The postal code of the area where the incident occurred.
Patient Name	The name of the patient.
Event Desc.	A description of the adverse event.
Initials	The initials of the patient.
Onset Date	The date from when the first reaction or adverse event occurred.
Pat. ID	The ID of the patient.
Age/Units	The age of the patient.
Pat. DOB	The date of birth of the patient.
Gender	The gender of the patient.
Reference #	National Regulatory Authority's Report Number, used as a Reference Number.
Journal	The journal name related to the adverse event.
Nullification Reason	The reason why the case was nullified.
Accept Initial E2B as Follow-Up	Enables you to accept initial E2B as a follow-up
Search	Finds results matching the specified search criteria.
View E2B	Enables you to view the E2B report.
Accept E2B Case	Enables you to accept an E2B case.
Reject E2B Case	Enables you to reject an E2B case.
View Warning	Enables you to view warnings associated with the case.

Field	Description
View Differences	Allows viewing differences between the current XML to be imported (a message that is not yet imported into the database), the current case data in the database, and if a case has been imported before, the last imported case. **Note:** This button is available only for follow-up and nullification reports.
Case Number	Displays the case number of the case matching the search criteria.
Pat. Initials	Displays the initials of the patient in the case matching the search criteria.
Action	Enables you to view the Case Summary dialog.
Project ID	Displays the Project ID of the case matching the search criteria.
Study ID	Displays the Study ID of the case matching the search criteria.
Date	Displays the date of the case matching the search criteria.
Country	Displays the country name of the case matching the search criteria.
Product	Displays the product name involved with the case matching the search criteria.
Event	Displays the event involved with the case matching the search criteria.
Report Type	Displays the report type of the case matching the search criteria.
Reporter	Displays the reporter involved with the case matching the search criteria.

Tip: The system displays the search results the **Total Number of Rows** section. Click the **Action** icon to view the case summary dialog.

Duplicate Search for Incoming Review

The Duplicate Search in Argus Central Incoming review enables you to search on Reference ID and Keyword field in Argus cases.

The following table lists and describes the fields on the **Duplicate Search** screen.

Field	Description
Product Name	The product name that caused the adverse event.
Report Type	The type of report.
Receipt Date	The date the report was received by Argus and saved in the system.
Generic Name	The generally known, popular name of the product.
Study ID	The Study ID.
Reference ID	Enables you to search for a duplicate case based on reference ID.
Keyword	Enables you to search for a duplicate case based on a keyword.
Sal.	The salutation such as Mr. or Mrs.
Suffix	The suffix, if applicable, that follows the name.
First Name	The first name of the patient.
Last Name	The last name of the patient.
Country of Incidence	The country where the incident occurred.

Field	Description
State	The state where the incident occurred.
Postal Code	The postal code of the area where the incident occurred.
Initials	The initials of the patient.
Pat. ID	The ID of the patient.
Age/Units	The age of the patient.
Gender	The gender of the patient.
Onset Date	The date from when the first reaction or adverse event occurred.
Event Description.	A description of the adverse event.

Be aware of the following:

- The Reference ID field searches on the following fields in the Argus case:
  - Additional Info | Case Reference ID
  - Reporters | Reporter's Reference #
  - Argus Case Number
- By default the system populates the Keyword field with the first value from the incoming affiliate event.

View Differences Report

The **View Differences Report** enables you to view differences between the current XML to be imported (a message that is not yet imported into the database), the current case data in the database, and if a case has been imported before, the last imported case.

Note: View Differences is available for follow-up reports only. This option is enabled only when an initial case or case number is selected in the duplicate search output section.

Click **View Differences** from the **Duplicate Search** screen to view the View Difference report. This displays the **E2B Difference Report**.

The following table describes the fields in the report.

Field	Description
Trading Partner	Allows you to view the Trading Partner name from whom the E2B report is received. **Note:** The Lock/Archive icon displayed with this field denotes the status of the case.
DTD Version	Allows you to view the DTD version of the follow-up E2B report.
Case Number	Displays the original case number of the E2B report.
Follow Up #	Displays the sequence number of the follow-up for the E2B report.
Total Number of Rows	Allows you to select the type of E2B Difference to view from: Current E2B vs. Current Case in Database ■ Current E2B vs. Last Imported E2B ■ Current Case in Database vs. Last Imported E2B
Import	Select this check box to highlight import differences.

Field	Description
E2B Element	Select this check box to highlight E2B differences.
Current E2B	Select this check box to highlight differences in the current E2B.
Current Case in Database	Select this check box to highlight differences in the current case in the database.
Last Imported E2B	Select this check box to highlight differences in the last imported E2B.
Accept Follow-up	Allows you to update the corresponding fields for the selected E2B elements in the Argus case.
Reject Follow-up	Does not update the corresponding fields for the selected E2B elements in the Argus case.
Print List	Provides the difference report in a PDF format.

Displaying Differences

The system displays the differences in the E2B reports as follows:

- **Addition** -- New elements are highlighted in grey.
- **Deletion** -- Deleted elements are highlighted in red.
- **Modification** -- Modified elements are highlighted in yellow.

Accept Initial E2B Cases As Follow-Up This option is enabled **only** when an initial case or case number is selected in the duplicate search output section.

1. Click this button to add an ICSR as a follow up to the Case Number, which you have highlighted in the duplicate search output section.
2. A pop-up dialog appears: "Do you want to add this ICSR as a Follow-up to the Case Number<Num>?"
3. Click **OK** to proceed.

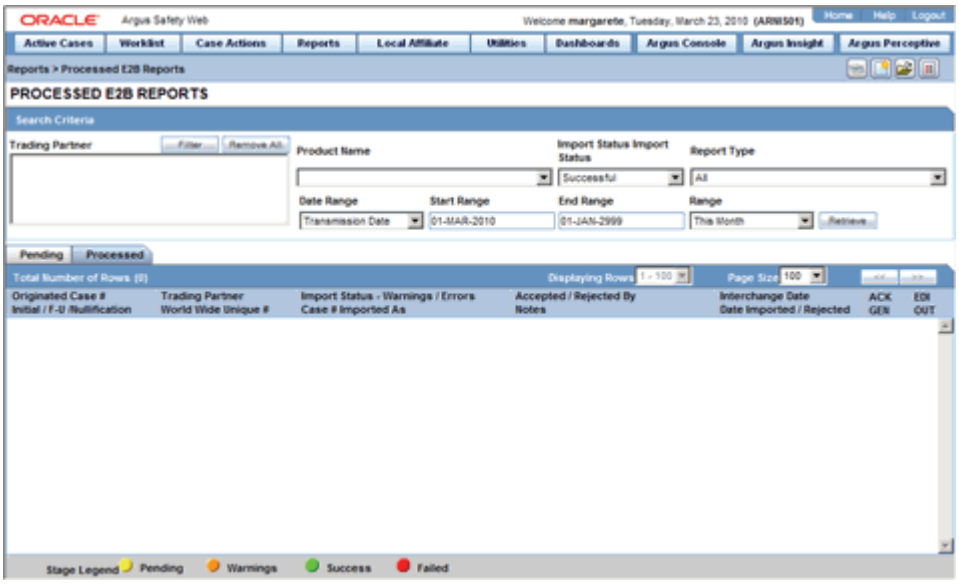
   Tip: Click Cancel to return back to the duplicate search screen.

4. The Argus application attaches the incoming ICSR as a follow-up, to the selected case number highlighted in the duplicate search screen.

Processed E2B Reports

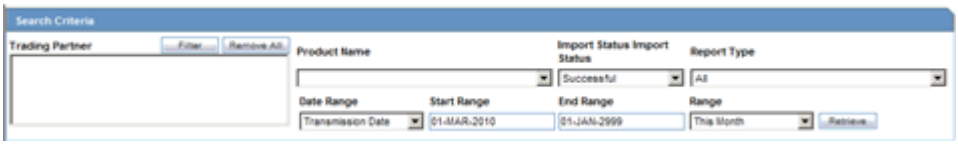
The **Processed E2B Reports** page contains a list of all the processed E2B Reports.

Click the Processed E2B Reports tab on the Incoming Reports screen to view the Processed E2B Reports screen.



Search Criteria Section

The system enables you to enter search parameters in the **Search Criteria** section.



The following table lists and describes the fields in the **Search Criteria** section.

Field	Description
Trading Partner	Enter the trading partner. Click **Filter** to select an agency to filter by that particular Trading Partner. This allows you to select multiple agencies by clicking **Add** from the **Select Reporting Destinations** dialog.
Product Name	Enables the user to select a Product Name as a search criterion.
Import Status	Enables the user to select Import Status as a search criterion.
Report Type	Select the report type, as applicable.
Date Range	Enables the user to select and specify the Date Range as the search criteria.
Start Date	Enables the user to enter the start date for the search.
End Date	Enables the user to enter the end date for the search.
Range	Enables the user to select a Range as a search criteria.
Retrieve	Enables the user to retrieve any stored search criteria.

Total Number of Rows Section

The system places the search results in the **Total Number of Rows** section.

The following table describes the columns in the **Total Number of Rows** section.

Field	Description
Originated Case#	Displays the Originated Case Number of the case.
Initial/F-U/Nullification	Displays the Initial/F-U/Nullification status.
Trading Partner	Displays the name of the trading partner.
World Wide Unique#	Displays the World Wide Unique # of the case.
Import Status	Displays the import status of the case.
Warnings / Errors	Displays warnings/errors associated, if any.
Accepted / Rejected By	Displays who accepted or rejected the case.
Notes	Displays the notes for the case, if any.
Interchange Date	Displays the Case Number with which the case has been imported on the specified interchange date.
Date Imported/Rejected	Displays the date the case was imported/rejected.
ICK/ACK Sent	Displays the status of the ICK/ACK. ■ Yellow is displayed if it is still pending. ■ Orange is displayed if it is accepted by warnings / errors. ■ Red is displayed if Rejected by user or system. ■ Green denotes successful import in the system.
EDI Out	Displays the EDI Out status. ■ Yellow is displayed if it is still pending to send the report out of the EDI / XML or PHY out folders. ■ Green is displayed if it is already sent out of the EDI / XML or PHY out folders. ■ Red denotes that the EDI gateway failed to send the report out of the EDI / XML or PHY out folders.

PMDA Reports

You can view or print a submitted report from the Submitted Reports dialog box. Select Reports-->Compliance-->Submitted Reports to access the Submitted Reports.

Expedited Reports

This section contains information about regulatory reports and includes discussions of the following:

- General Usage Information
- Scheduling Expedited Reports
- Viewing Submitted Reports
- Faxing or E-mailing Reports
- Viewing Blank Report Forms

General Usage Information

This section provides general usage information for expedited reports and includes discussions of the following:

- Paper Reports
- Report Generation Rules
- Case Deletion
- Changes to Cases
- Manually Schedule Nullification Reports
- Downgrading a Report
- Draft Reports

Paper Reports The system enables you to generate and submit 12 expedited paper reports: six (6) for marked drugs and six (6) for Investigational Drugs.

- PMDA Forms for Marketed Drugs
  - Drug AE/Infection Case Report -- Form 1
  - Drug AE/Infections Case -- Form 2 (5 pages)
  - Surveillance Report on Drug, Quasi, Drug, Cosmetic Case Report -- Form 3
  - Surveillance Report on Drug, Quasi Drug, Cosmetic Case Report -- Form 4
  - Surveillance Report on Measures Taken for Drug Outside Japan such as Product Termination, Recall, Rejection, etc. -- Form 5
  - Surveillance Report on Measures Taken for Drug Outside Japan such as Product Termination, Recall, Rejection, etc. -- Form 6
- PMDA Forms for Investigational Drugs
  - Investigational Product A/E Infection Case Report -- Form 1
  - Investigational Product AE/Infections Case -- Form 2 (5 pages)
  - Surveillance Report on Investigational Product Research Report -- Form 3
  - Surveillance Report on Investigational Product Research Report -- Form 4
  - Surveillance Report on Measures Taken for Investigational Product Outside Japan such as Product Termination, Recall, Rejection, etc. -- Form 5
  - Surveillance Report on Measures Taken for Investigational Product Outside Japan such as Product Termination, Recall, Rejection, etc. -- Form 6

The following table shows the relationship between the reporting category and the paper form.

Category Identifier	E2B Value	Reporting Category	Paper Report
A	1	Domestic/Infection Report (marketed drug)	Marketed: Form 1, 2 (5 pages)
B	2	Domestic/ADR Report (marketed drug)	Marketed: Form 1, 2 (5 pages)
C	3	Overseas/Infection Report (marketed drug)	Marketed: Form 1, 2 (5 pages)
D	4	Overseas/ADR Report (marketed drug)	Marketed: Form 1, 2 (5 pages)
E	5	Research/Infection Report (marketed drug)	Marketed: Form 3, 4
F	6	Research/ADR Report (marketed drug)	Marketed: Form 3, 4
G	7	Measures in foreign countries including discontinuing manufacture, recall, and withdrawn (marketed drug)	Marketed: Form 5, 6
H	8	Domestic Infection Report (investigational drug)	Investigational: Form 1, 2 (5 pages)
I	9	Domestic/ADR Report (investigational drug)	Investigational: Form 1, 2 (5 pages)
J	10	Overseas/Infection Report (investigational drug)	Investigational: Form 1, 2 (5 pages)
K	11	Overseas/ADR Report (investigational drug)	Investigational: Form 1, 2 (5 pages)
L	12	Research/Infection Report (investigational drug)	Investigational: Form 3, 4
M	13	Research/ADR Report (investigational	Investigational: Form 3, 4
N	14	Measures in foreign countries including discontinuation of the manufacture, recall, and withdrawn (investigational drug)	Investigational: Form 5,6
O	15	Research Report (Quasi Drug)	Marketed: Form 3, 4
P	16	Research Report (Cosmetics)	Marketed: Form 3, 4

- The system displays the following PMDA form list in all the report listing sections of the application:
  - Marketed Drug Case Report Form 1 and Form 2
  - Marketed Drug Research Report form 3 and Form 4
  - Marketed Drug Measures in Foreign Countries Report Form 5 and Form 6
  - Investigational Drug Case Report Form 1 and Form 2
  - Investigational Drug Research Report Form 3 and Form 4
  - Investigation Drug Measures in Foreign Countries Report Form 5 and Form 6
- Reports are grouped according to their characteristics. For example, market report 1 and 2 will be generated together on the same PDF.

- The names of Japanese forms display in both Japanese and English.
- The report form list appears in the following locations in the application:
  - Console J: Expedited Report Rules, Form Section
  - Console J: Code List/Batch Report Generation Case Form Regulatory Reporting Tab, Draft
  - Schedule New Expedited Report Dialog Box: Form Section
  - Utility Blank Report Form UI
  - E2B Viewer Report Form Listing UI
  - Medical Review: Preview of Expedited Report
  - Create Unscheduled Report
  - View Submitted Report
  - Worklist Report Filter
  - Bulk Report by Form

Regulatory Reporting Rules Algorithm The regulatory reporting rules and algorithm enable you to create and schedule reports based on the regulatory specifications.

Reporting Rules Configuration Fields

The reporting rules algorithm schedules reports for Japan based on the License caegory and Reporting category fields.

Japanese Aware Date

The reporting rules algorithm caulates the due date for Japanese reports based on the Japanese aware date as follows:

- For a domestic case, the Japanese aware date is the same as the latest significant follow-up date or the Initial Receipt date (from the PMDA tab) whichever is latest.
-
- In a foreign case, the Japanese aware date is the same as the Japanese significant follow-up date of the Japanese Receipt Date (from the PMDA tab) whichever is latest.

Multiple Reports for a Case

The reporting rules algorithm schedules multiple report for a cased based on PMDA requirements. PMDA requies submitting multiple reports for multiple marketed and investigational licenses. The number of reports submitted is determined based on the following:

- The system submits reports for valid (not withdrawn) marketing or investigational licenses in Japan only for the suspect company products in the case.
- The system submits a separate report for each suspect company product with a license in Japan as defined in Argus Console in the "allow multiple reports for single case for Marketed and Investigation" parameter.
- The system display a single row for each report on the Case Form Analysis-->PMDA-->General tab.

- If the "Allow multiple report for Maketed" parameter is set to No, auto scheduling schedules a report with a direct Japanese license. If there are multiple direct Japanese licenses, the system selects the licese with the earliest award date.

Report Generation Rules Be aware of the following report generation rules.

- You can manually schedule with any available report forms. When the system generates the report form, it checks the association between the reporting category and the report forms If the report forms don't match the selected reporting category, the system presents the following message: "This case does not have a matching reporting category for the selected report forms."
- The expedited reports retrieve report data from the E2B XML file. If the system encounters errors during this process it presents an error message.

Nullification Report Scenarios The following scenarios describe how the nullification reports are scheduled.

- Case Deletion
- Changes to Cases
- Manual Scheduling

Case Deletion

If you delete a case that has submitted rpeorts to the Japanese authority, the system prompts you to provide a justicfication for deleting the case and opens the Action Justification dialog box. the system requires you to enter data in eevery field in the dialog box. You can select the justification from the drop-down list or enter the justification manually. However, if you choose to enter the justification manually, you must enter the justification in both Japanese and English.

Changes to Cases

The application automatically schedules a nullification report when you do any of the following to a case:

- Delete a company product
- Modify a company product in such a way that it is no longer a company product
- Recode a company drug to another company drug
- Make a change to patient exposure for a study drug
- Change a drug so that it is no longer a suspect drug

Manual Scheduling

You manually schedule and E2B nullification report. This function is available only to Japanese users.

To manually schedule a nullification report

1. Select Report-->Compliance-->Submitted-->Search Case or select Report-->Unsubmit submitted E2B Report.
2. Click the Submitted icon to open the Unsubmit Report menu and click Unsubmit Report.
3. Select Nullification to open the Justification dialog box.
4. Enter the justification information and click OK.

5. The system schedules the nullification report.

Downgrading a Report The application permits you to downgrade a report if necessary. You must perform this action manually using the New Expedited Report dialog box.

To downgrade a report

1. In the New Expedited Report dialog box, select Downgrade Report from the Report Information drop-down list.
2. Enter the appropriate information in the fields and click OK.
3. When the system opens the Justification dialog box, enter the reason for downgrading the report and click OK.

Draft Report The system enables you to print a draft version of a report as follows:

- Click the Draft button on the Regulatory Reports tab.
- Click the Draft icon on the Toolbar.
- Print a draft version from the Medical Review tab.

Scheduling Expedited Reports

You can go to Case Form --> Regulatory Reports to manually schedule expedited reports from the Expedited Reports dialog box.

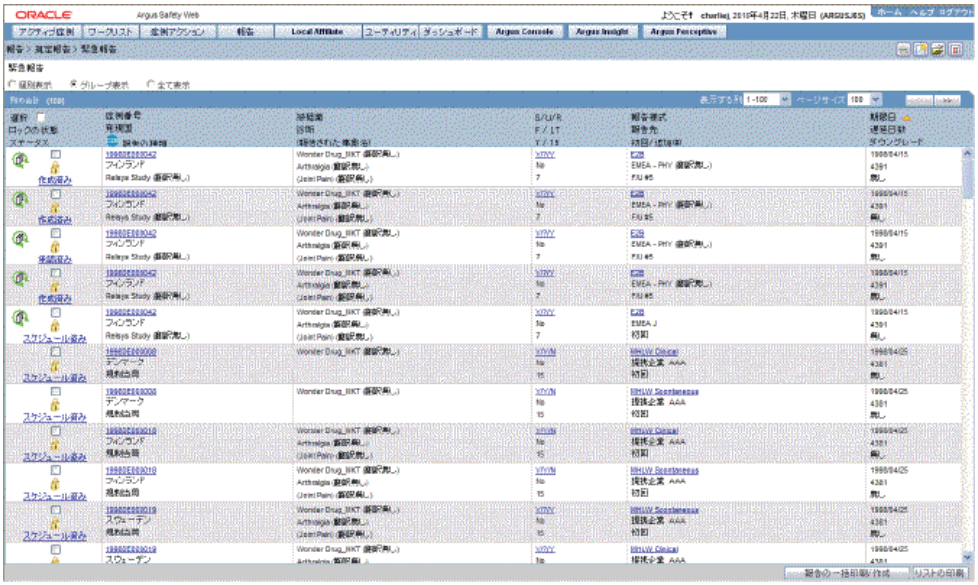
The following table lists and describes the fields in the Expedited Reports dialog box.

Field/Control Name	Description
View Individual	Click to view an individual report.
View Group	Click to view a group of reports assigned to a specific group.
View All	Click to view all reports.
Total Number of Rows	The total number of rows in the list.
Displaying Rows	The number of rows that display at the same time.
Page Size	The number of rows that display on a single page.
Selected	Click this checkbox to select a report.
Lock State	Identifies the status of the report. Report status can be one of the following: ■ Scheduled ■ Overdue ■ Non-submit ■ Generated ■ Disapproved ■ Approved ■ Submitted
Case Number	The unique value that identifies a specific case. If the report does not have a Japanese value, the system displays the English value followed by "no translation."
Country of Incidence	The name of the country where the adverse event occurred.If there is not a Japanese value for this field, the system displays the English value followed by "no translation."

Field/Control Name	Description
Report Type	Identifies the type of report. This information is from the Case form.
Suspect Product	The name of the product suspected to have caused the adverse event.
Diagnosis	The diagnosis for the adverse event.
Event Verbatim	Can be one of the following: ■ S-U-R ■ F/LT ■ 7/15
Report Form	The name of the form used for the report.
Destination	The name of the agency the report is being sent to.
Initial/Follow-up	Indicates whether the report is the initial report (I) or a follow-up (F/U) report.
Due Date	The date the report is due in YYYY/MM/DD format.
Days Past Due	The number of days the report is past due.
Downgrade	
Batch Print or Create Report	Enables you to create a batch for printing or print a single report.
Print List	Click this button to print a list of reports.

Scheduled Expedited Reports

You can go to the ARgus Main Menu-->Reports-->Compliance-->Expedited to view scheduled reports. This provides access to the list of previously scheduled and generated, but not submitted, expedited reports. You can also schedule a new expedited report from this dialog.



Periodic Reports

This section provides information about Period Reports and includes discussions of the following:

- PSR/ReSD Reports
- Clinical Study Periodic Safety Reports
- Scheduled Periodic Reports
- Unscheduled Periodic Reports

PSR/ReSD Reports

The system enables you to define Periodic Safety Reports (PSR) for specific products. The purpose is to define a fixed set of PSR reports for a Primary Agency and associate products with the reports. Once defined, you can have the system schedule automatic delivery of these reports.

The system provides a configuration screen that enables you to define a PSR. Select Reports-->Periodic Reports-->PSR/ReSD to open the Periodic Safety Report window.

Select Reports-->Periodic Reports-->PSR/ReSD to open the Periodic Safety Report Library screen. From this screen, you can open the configuration window that enables you to define a PSR. You need to choose New to create a new configuration or Modify to modify an existing configuration. The system provides a list of reports that includes the following information:

Field/Control Name	Description
Category	Identifies the category the report belongs to.
Subcategory	Identifies the subcategory the report belongs to.
Report Name	Indicates the name of the report.
Inclusion Start Date/Stop Date	Identifies the date range for the report.
Draft/Final	Indicates whether this is a draft or final version of the report.
Author Created	The name of the person who created the report.
Author Modified	The name of the person who modified the report.
Date Created	The date the report was created.
Date Modified	The date the report was modified.
Justification	The reason for creating or modifying the report.

When viewing this page, be aware of the following:

- This page shows a list of PSRs stored in the system. You can do the following:
  - Click New Report to create a new report.
  - Click Copy to make a copy of an existing report.
    - When you copy an existing PSR, the system copies the entire report including the timeframe rows.
    - The name of the copy has "Copy of" before the report name.

    * When you copy the report, the system copies the past dates in the schedule frequency, JAD, IBD, and the assigned date as read-only text. You can modify other sections of the report
    * When you copy an unsubmitted PSR report, the system copies the entire report including the timeframe rows. Because the report was unsubmitted, the timeframe rows, JAD, IBD, and Assigned are editable or non-editable depending on their configuration in the original report.
  - Click Modify to display the report definition.
  - Click Delete to delete a report. The system presents the confirmation message. Click "Yes" to delete the report.
  - Click Print to print the report. The system presents a dialog box to enable you to select from several preview or direct export options.
- The Delete function is available only if no final reports have been generated. Clicking Delete hides the report but does not delete it from the system.
- In the Periodic Report section, a link is available for the last executed report only if the report is still available on the report server.
- When you click New or Modify, the system opens the PSR Configuration window.
- When the state of the report changes to "Submitted," the system disables the OK button to prevent you from updating the PSR configuration.
- When a report has a Submitted status, the system only prints the configuration page.
- You can copy a report as long as the configuration for the report is available.
- Before the system permits you to save a PSR configuration, you must enter a value in the Report Name, Primary Agency, Product Selection and time frame fields.
  - If you fail to enter a Report Name, the system presents the following message: "Report Name is not entered. It is necessary to enter the above information in order to save the configuration."
  - If you fail to enter the Primary Agency, the system presents the following message: "Primary Agency is not entered. It is necessary to enter the above information in order to save the configuration."
  - If you fail to select a product, the system presents the following message: "Product is not selected. It is necessary to enter the above information in order to save the configuration."
  - If you fail to enter at least one time frame, the system presents the following message: "Investigation time frame is not configured. It is necessary to enter the above information in order to save the configuration."
  - If you fail to enter multiple parameters, the system presents the following error message:

    " <Parameter> is not entered.

    Parameter> is not entered.

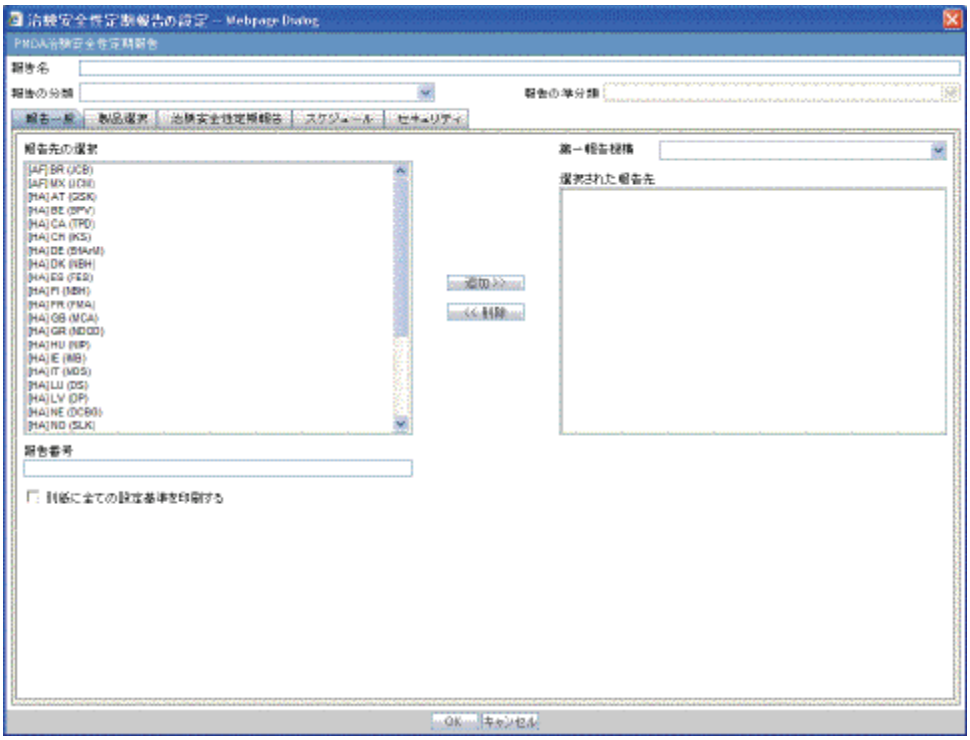
    It is necessary to enter the above information in order to save the configuration."
- If you click the Modify, Copy, Delete, or Print buttons without selecting a report, the system presents the following error message: "Please select a report." Click OK.

PSR Main Window

Once you select a report, the system opens the PMDA Reports window. The window has the following tabs:

- Subject of Report
- Product Selection
- Periodic Safety Report/ReSD
- Scheduling
- Security

Subject of Report tab The Subject of Report tab enables you to define a periodic report. The following is an illustration of the Subject of Report tab.



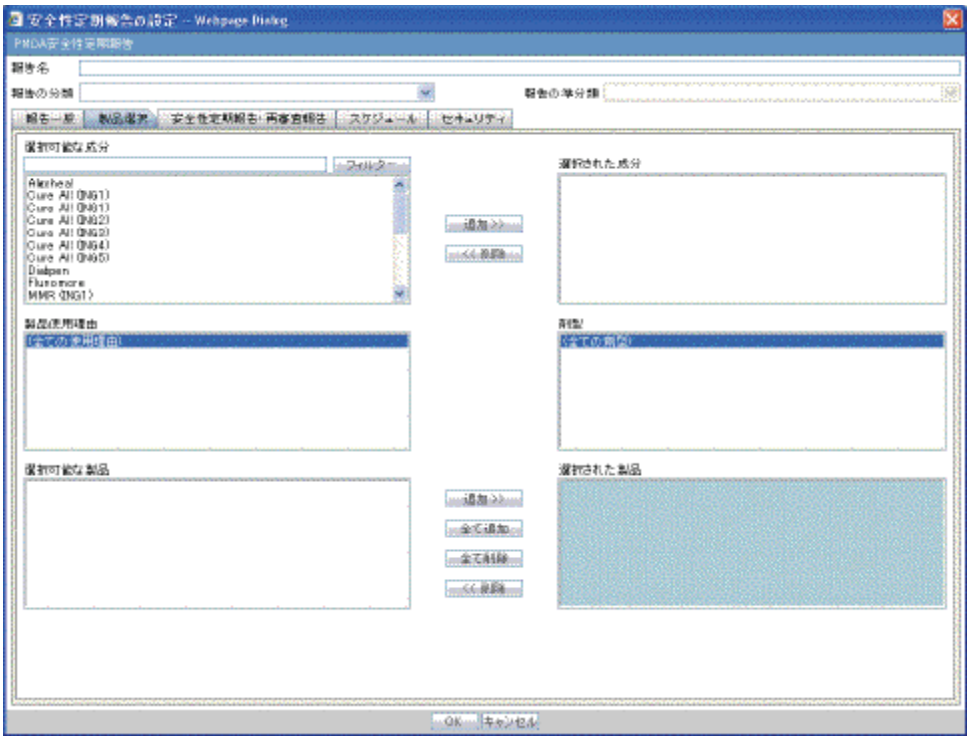
The following tables lists and describes the fields on the Subject of Reports tab.

Field Name	Description
Report Name	Enter the name of the report. The name you enter in this field displays on the Reports-->PSR Reports dialog box.
Report Category	Enter the report category name in this field. The name you enter here displays in the Reports-->PSR Reports dialog.
Report Subcategory	Enter the report subcategory name in this field. The name you enter here displays in the Reports-->PSR Reports dialog.
Selection of Reporting Destination	This is a list of the Regulatory Authorities configured in List Maintenance. If there is no Japanese authority name configured, the system lists the English name. You can select multiple agencies from the list to enable simultaneous submission to multiple agencies.

Field Name	Description
Primary Reporting Agency	Select the Primary Agency from the drop-down list. If a message profile is not defined for the Primary Agency, the system presents the following message: "Selected Primary Agency doesn't have configured Message Profile (I or J) in Argus Console/Reporting Destination/EDI. When you click OK, the Primary Agency reverts to the previous selection.
Selected Reporting Destination	The list of Regulatory Authorities that receive the report.
Report Number	Enter the unique value that identifies the report in this field.
Print all configuration criteria on separate cover page	When checked, the system prints the report configuration when it prints the report. The system prints the configuration page at the beginning of the PSR/ReSD report. Page numbering for the report does not include the configuration page.

Product Selection Tab

The Product Selection tab enables you to select the products to include in the report. The following is an illustration of the product selection tab.



The following table provides information about the fields on the Product Selection tab.

Field Name	Description
Ingredient	When you select a product, the application displays a list of ingredients for the selected product. You can filter the ingredients in the list of available ingredients by entering the Ingredient name and clicking Filter.

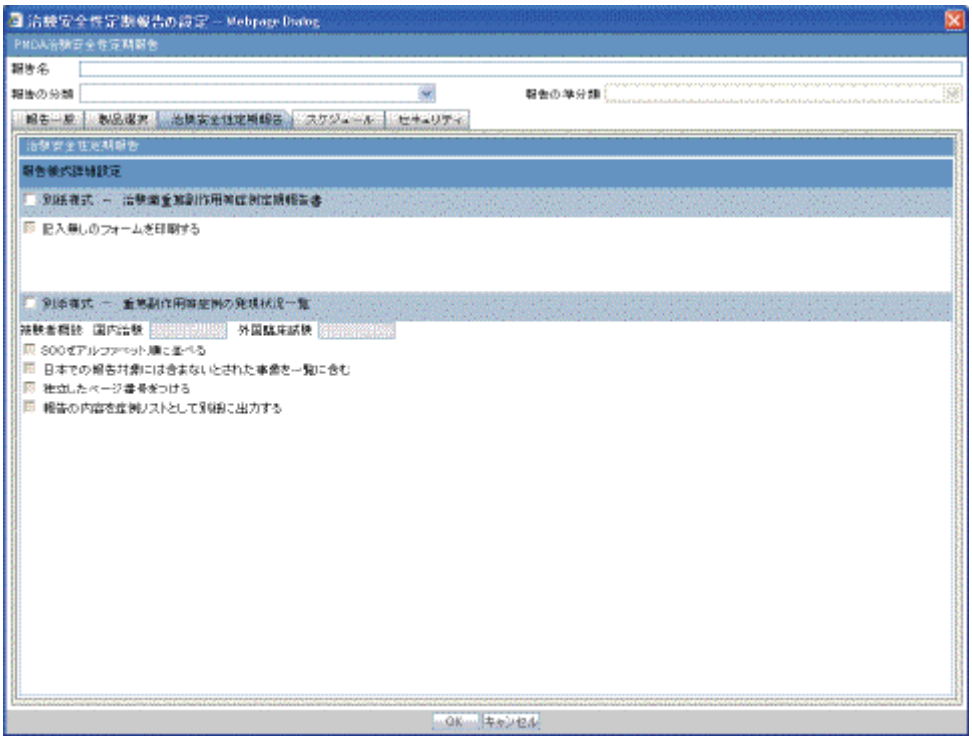
Field Name	Description
Selected Ingredients	The list of selected ingredients for the PSR product family.
Indication	A list of indications configured for the product containing the selected ingredient. To select multiple indications, hold CTRL and click each ingredient you want to include. If a Japanese name is not available for the indication, the system displays the English name.
Formulation	A list of formulations configured for the product using the selected ingredient. To select multiple formulations, hold CTRL and click each ingredient you want to include. If a Japanese name is not available for the formulation, the system displays the English name.
Available Products	The system displays a list of products containing the selected ingredient. If a Japanese name is not available, the system displays an English name.
Selected Products	A list of products you selected from the Available Products list. When a product is selected, the field has a blue background.

When a new product containing the same ingredient is released, you must set up the new configuration. Be aware of the following:

- If a Japanese ingredient, indication, or formulation is not configured, the system displays the English name.
- If you add or delete a product in the product selection field before the PSR/ReSD status is "Submitted," the system displays the following error message: "If the content of the selected product is changed, IBD, JAD, and Assigned date can possibly be changed. Do you want to proceed?"
- If you add or delete the products in the Product Selection field before the first PSR report is submitted, the system updates the IDB Japan award date, and the Assigned Date based on the new product set.
- If you copy an existing submitted PSR, and the JAD, IBD, and assigned dates are read-only, the subject dates do not change and the system displays the following error message: "Because the configuration has the record of past investigation period, JAD, IBD, and Assigned Date for scheduling configuration will not be changed by modifying the Selected Products. It is necessary to use the "Reset" button and re-configure the investigation period if new PSR needs to be created based on modified product selection."
- All forms printed as PSR and ReSD contain only the information about the selected product.

Periodic Safety Report/ReSD Tab

This tab enables you to select and configure either a PSR or an ReSD. The tab contains two radio buttons that enable you to select the type of report you wish to configure. Click Periodic Report to configure a PSR or click ReSD to configure an ReSD report. The following is an illustration of the tab.



The following table lists and describes the fields on the tab.

Report Section	Field Name	Field Description
PMDA		
Forms Configuration		
	Periodic Safety Report	Enables you to choose whether to create a PSR or and ReSD report.
	Re-examination Submission Dossier	Enables you to choose to create a PSR or and ReSD report.
Data Counting Configuration		
	Count Configuration	

Report Section	Field Name	Field Description
	Exclude events which don't meet the condition from the past data	Enables you to eliminate events from the report. Reasons for not including an event in a report include the following: ■ Event was deleted ■ Event was downgraded ■ The report was nullified ■ When this occurs, the system presents the following message: "One of the cases in the nth report nullified during this investigation time frame." ■ The default for this field is unchecked.
	Exclude events which were reported on the Paper Report Form	■ Enables you to exclude events reports on the paper form during the investigation phase from the report. ■ The default for this field is unchecked.
	Exclude Incompletion report from output.	■ Enables you to exclude events reported on the incompletion report from the report. ■ The default is unchecked.
PSR Report Form 3		
	Form 3 Selection	■ Check this checkbox to print the PSR Form ■ The default is checked.
	Print Only the Term	■ Enables you to select whether PT or LLT will be printed on Form 3. ■ Click Preferred Term to print the PT (preferred term) on the form. ■ Click Lower Level to print LLT (lower level term) on the form.
	Classify based on SOC	■ Check this checkbox to group the PSR Form 3 PT/LLT section by SOC. ■ The default is checked.
	Print the report content as Case Listing in a separated report.	■ Check this checkbox to print a separate version of the report. ■ The default is unchecked.

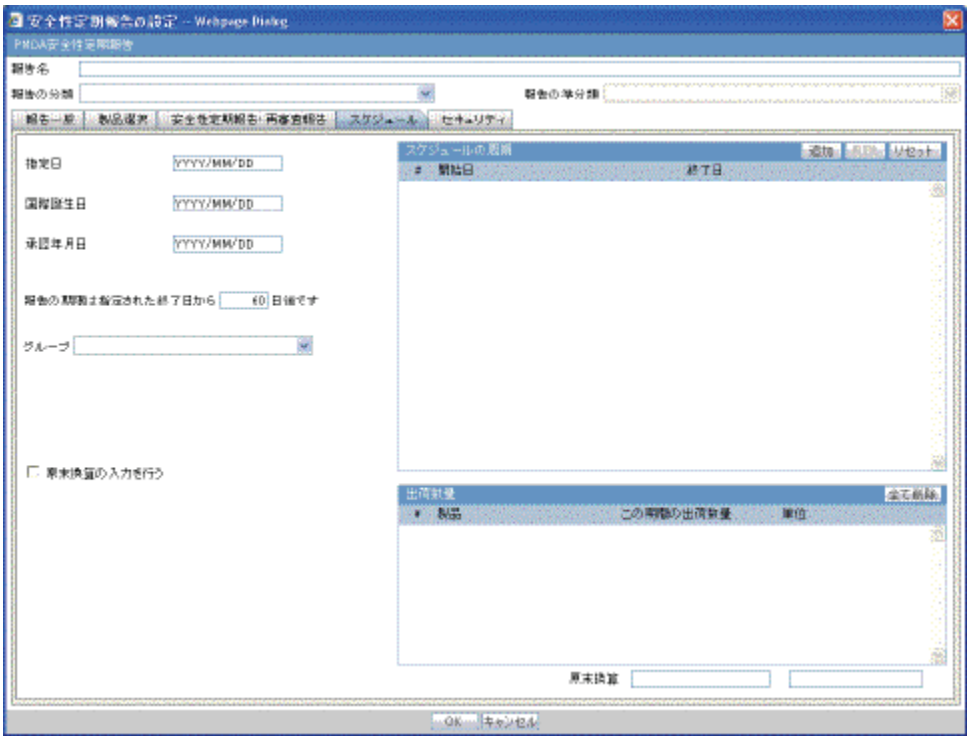
Report Section	Field Name	Field Description
PSR Report FORM 4		
	Form 4 Select	■ Check this checkbox to print the PSR Form 4. ■ The default is checked.
	Print only the term	■ Enable you to choose which term (PT or LLT) to print on the report. ■ PT is the default.
	Order SOC Alphabetically	■ Click this checkbox to print the SOC in alphabetical order. ■ If this is unchecked, the system prints the report in the MedDRA order. ■ The default is unchecked (MedDRA Order).
Non-Serious Unlisted PSR Report		
	Paper Report	Click Paper Report to generate the paper report format. This is the default.
	FD Report	Click FD Report to generate the report in CSV report format.
PSR Report Form 7-1		
	Form 7-1	■ Click this checkbox to print PSR Form 7-1. ■ This is the default.
	Print a Blank Form	■ Click this checkbox to print a blank form. ■ The default is unchecked.
PSR Report Form 7-2		
	Form 7-2 Selection	■ Click this checkbox if you want to print PSR Form 7-2 ■ The default is unchecked.
	Print a separate Case Listing report.	■ Click this check box to print a separate Case Listing report. ■ The default is unchecked.
	Separate Page Numbering	■ Click this checkbox to start each form with page 1. ■ Checked is the default.
ReSD Report Form 4		
	Form 4	■ Click this checkbox to print an ReSD Form 4. ■ The default is checked.

Report Section	Field Name	Field Description
	Print Only the Term	■ Click Preferred Term to print PT on ReSD Form 4. ■ Click Lower Level to print LLT on ReSD Form 4. ■ PT (Preferred Term) is the default.
	Classify based on SOC	■ Click this checkbox to group the PT?LLT section on PSR Form 3 by SOC. ■ This is the default.
	Print a separate Case Listing Report.	■ Click this checkbox to print a separate Case Listing report. ■ The default is unchecked.
ReSD Report Form 5		
	Form 5	■ Click this checkbox to print ReSD Form 5. ■ The default is checked.
	Print Only the Term	Enables you to select which term (PT or LLT) to print on the form. ■ Click Preferred to print PT on the report. ■ Click Lower Level to print LT on the report. ■ The default is PT.
	Order SOC Alphabetically	■ Click this checkbox to print the SOC in alphabetical order. ■ If left unchecked, SOC is printed in MedDRA order. ■ The default is unchecked.
ReSD Report Form 7		
	Form 7	■ Click this checkbox to print ReSD Form 7. ■ The default is checked.
ReSD Form 8		
	Form 8	■ Click this checkbox to print ReSD Form 8. ■ The default is checked.
ReSD Form 9		
	Form 9	■ Click this checkbox to print ReSD Form 9. ■ The default is checked.
Report Tabulations		

Report Section	Field Name	Field Description
	Tabulations	■ Click this checkbox to include all tabulations in the section in the printed report. ■ The default is checked.
	Tabulation for Unlisted Events	■ Click this checkbox to include the tabulation for unlisted events in the report. ■ Check ed is the default.
	Tabulation for Listed Events	■ Click this checkbox to include the tabulation for listed events in the report. ■ Check ed is the default.
	Case Overview Tabulations	■ Click this checkbox to include case overview tabulations in the report. ■ Check ed is the default.
	Overdose Tabulation	■ Click this checkbox to include the overdose calculation in the report. ■ Check ed is the default.
	Accident Exposure Tabulation	■ Click this checkbox to include the accident exposure tabulation in the report. ■ Check ed is the default.

Scheduling Tab

This tab enables you to configure report scheduling. The following is an illustration of the Scheduling tab.



The following table lists and describes the fields on the scheduling tab.

Field/Control Name	Description
Assigned Date	The system automatically populates this field. with the report date based on the values in either the International Birth Date field or the Japan Award date field. ■ When the first report is still unsubmitted, you can manually change the assigned date and the system automatically repopulates the date in the Frequency of Schedule field based on the assigned date. ■ If you try to change the assigned date after the report has been submitted, the system presents the following message: "The assigned date is different from the dates in the IBD and JAD. Do you want to change the date?" Click OK to modify the date. Click Cancel to replace the new date with the original date in the field. ■ When you create a copy of an existing report and click Reset to remove all previous periods, you can modify the Assigned Date. The system puts the new date in the Frequency of Schedule field. ■ If the modified assigned date is earlier than the IBD, the system displays the following message: "Assigned date cannot be earlier than the IBD" and resets the date to the original value. ■ If either the JAD or IBD is unavailable, the system does not populate the Assigned Date and Start Date fields. You must manually enter the Assigned Date. ■ You can edit the Assigned Date field if the report has not been submitted and does not have any read-only time frames. Once the report has been submitted, you cannot edit the Assigned Date.

Field/Control Name	Description
International Birth Date (IBD)	This is the date the product was first licensed. ■ When you select an ingredient and a product, the system automatically populates this field based on the earliest product license date. ■ If you modify this date and the new date is later than the JAD, the system displays the following message: "IBD cannot be later than JAD." ■ If you change the IBD, the system displays the following message: "If you change the IBD, the Assigned date will be changed. Do you want to proceed?" If you click "Yes," the new date remains in the field. If you click "Cancel" the system replaces the new value with the old date. ■ You can modify the IBD if the report has not been submitted and does have any previous, non-editable timeframes. ■ Once you submit the report, you can no longer modify the IBD field.
Japan Award Date (JAD)	The date the product was licensed in Japan. ■ When you select an ingredient and a product, the system automatically populates this field. ■ If you select multiple products, the system populates this field with the earliest award date. ■ If you change this date and it is earlier than the IBD, the system presents the following message: "JAD cannot be earlier than IAD." ■ If you modify the JAD, the system presents the following message: "If you change the JAD, the Assigned date will also be changed. Do you want to proceed? If you click OK the new value remains in the field. If you click Cancel, the system replaces the date you entered with the old date. ■ If the JAD is not configured for one or more products, the system leaves the field blank so you can enter the JAD manually. ■ You can edit the JAD if the report has not been submitted and does not have any previous non-editable timeframes. Once you submit the report, you can no longer edit this field.
Report is due xx after the selected end date	This field enables you to set the PSR due date a specific number of days after the end date for the scheduling period. The system adds the value you enter in this field to the current end date and identifies it in the printed report as the report due date.
Group	This field enables you to specify which Argus group is responsible for the Periodic report after the application schedules it. This information appears on the group's Report worklist.

Field/Control Name	Description
Start Date	The date the reporting timeframe began. You can enter the start date for each report timeframe starting period. ■ The first report timeframe start date is the same as the Assigned Date. ■ Start date is a read-only field. ■ If you need to enter additional rows for start/end date, you must enter them one at a time. ■ The system auto populates the Start Date and resets it to the Assigned Date value only if the first start and end dates are modifiable. ■ If the system auto populates the start date and the end date is already specified, the system displays the following message: "The Start Date for the reporting period has changed. Please update the Ed Date accordingly." ■ If you enter a start date that is older than the latest end date, the system presents the following message: "The start date must be the same or later than the end date." When you click OK, the system removes the incorrect start date.
End Date	The day the reporting timeframe ended. You can enter the end date for each report timeframe.If you enter an End date that is earlier than the start date, the system presents the following message: "End date must be after the Start date." When you click OK, the system removes the incorrect end date.
Reset	Click Reset to delete all the existing timeframe rows (editable and non-editable). Clicking "Reset" also enables you to enter values in the Assigned Date, JAD, and IBD fields. The system presents the following message: "Clicking Reset removes all previous data. Do you want to proceed?" Click OK to continue with the reset. If you click Cancel, the system leaves the past data in the table.
Add	Click Add to add a timeframe row. ■ A new report (unsubmitted, uncopied) does not have a timeframe row. You must click Add to add one. ■ When you generate a report, the system generates it based on the last timeframe row. ■ Once you submit a report, you can no longer edit the timeframe rows.
Delete	Click Delete to delete an editable timeframe row. The system does not permit you to delete a timeframe row that cannot be edited. When you click Delete, the system presents the following message:" Do you want to delete the highlighted row?"

Configuring Delivery Quantity

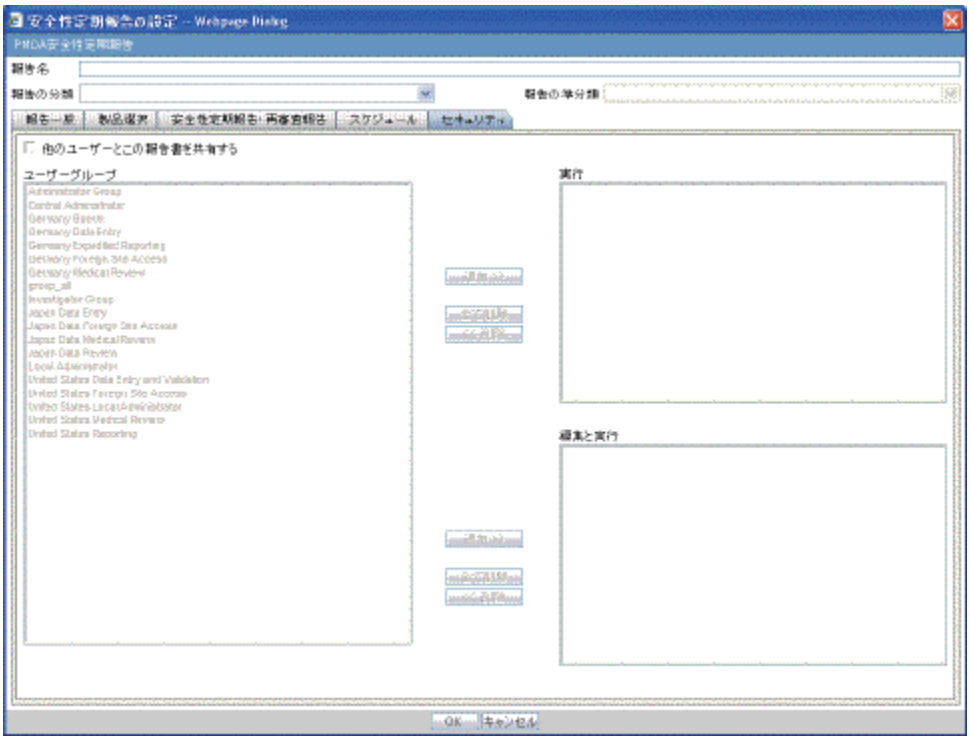
The Scheduling tab includes a Delivery Quantity section to enable you to specify the number of reports to print.

The following table lists and describes the fields in the Delivery Quantity section on the Scheduling tab.

Field Name	Description
Clear All	▪ When you click this button, the system clears the delivery quantity and delivery unit information from all fields ▪ The system presents the following message: "If you continue, the entered information will be erased. do you want to continue?" Click OK to delete the information.
Products	▪ The system displays the product names in the PSR by default. ▪ You can change the names only the first time the report is generated. Otherwise the names are read-only. ▪ You can enter a maximum of 70 characters in this field.
Delivery quantity during this period	▪ Enter the number of reports to print. ▪ You can enter up to 12 characters (including the decimal point and the numbers) in this field.

Security Tab

The Security tab enables you to share a report with other users. The following is an illustration of the Security tab.



The following tables lists and describes the fields on this tab.

Field Name	Description
Share this report with others?	When clicked, the system shares the reports with selected users and/or user groups.
User Groups	Contains a list of users you can share the report with.
Selected User Groups	Contains a list of users you selected to share the report with.
Modify & Execute	Enables you to modify the members of the groups.

Printing a PSR/ReSD

The system enables you to print batches of reports. You define the batch print parameters in the Report Batch Printing dialog box . The following table lists and describes the fields in the Report Batch Printing dialog box.

Field Name	Description
Run at	Enables you to specify the date and time to run the report. Date and time entry must be in the following format: YYYY/MM/DD 00:0. If you fail to enter a date in this field, the system presents the following message: "Please enter a run date." Click OK and enter a run date in the field.
Print As	Enables you to specify how you want the report to print. Available options are Final, Draft, Internal, or Other. If you specify Other, you must enter a value in the associated text field.
Due Date	Automatically populates the this field based on the due days entered on the scheduling tab.

To print a report

1. Select Reports-->Compliance-->Periodic Reports-->View Report.
2. Check out the report from the "View and edit PSR/ReSD popup.
3. Edit the document as necessary and check it in.
4. Publish the resulting PDF file.

Printing Requirements Be aware of the following printing information

- You can print the report and use Word to update the resulting document.
- You can change the configuration for the investigational timeframe multiple times **before** you submit the report. However, once you submit the report, you cannot change the configuration.
- You can view the report by selecting Reports-->Compliance-->Periodic Reports-->View Report.

The following table lists and describes the fields on the Periodic Report list.

Field Name	Description
View All	Enables you to view a list of all periodic reports.
Total Number of Rows	Indicates the total number of rows the system displays in the window.
Page Size	Enables you to select the number of rows to display on each page of the list.

Field Name	Description
Trade Name	The trade name for the drug. If a Japanese name is available, it displays here. If a Japanese name is not available, the system displays the drug's English trade name.
Destination	Displays the destination for the report. If Japanese data is available, the system displays it. If it is not available, the system displays English data. If a destination is not available, the system displays the following: "No specific receiver."
Due Date	The date the report is due. The system displays this information in YYYY/MM/DD format.
Status	Identifies the status of the report. Status can be one of the following: ■ Deleted ■ Scheduled ■ Generated ■ Approved ■ Not Approved ■ Submitted ■ New Data Available ■ No Longer Required

- Report output is in a Word document to enable you to edit the report before generating a final version. You must check the Word documents in and out.
  - When you generate a report, the system displays the Check Out button to enable you to revise the document. The "Publish" button is disabled.
  - Only one user at a time can check a document in or out.
  - When you check out a document, the button label changes to "Check In." Click this button to check a file in.
  - You can check a document in and out multiple times. However, more than one user cannot check out the same document simultaneously.
  - You can check out and check in unpublished documents. Once a document is published, you can no longer check it out.
  - The system enables the Publish button the first time a document is checked in.
  - When you check in a document, the system opens a dialog box to enable you to specify a file name.
  - The system disables the publish button when a document is checked out.
  - Once a document is published, it cannot be checked out.
  - When you Publish a document, the system converts the document to PDF format and the Word version of the document is no longer available to you.

Note: If the generated report has a row spanning the whole height of the page and there seems to be data missing in that row, the user needs to select the table, do a right click, select Table Properties and in the Rows tab in the properties dialog, check the checkbox for “Allow row to break across pages”. This will allow the row to span across multiple pages and the truncated data will be shown on the next page.”

Deleting a PSR/ReSD

The system enables you to delete a PSR/ReSD. When you select a report and click Delete, the system presents the following message: "Are you sure you want to remove this report configuration?" Click "Yes" to continue with the delete operation; otherwise, click No.

Scheduling Periodic Reports

The system enables you to schedule Periodic Reports from the Periodic Reports window. Select Reports-->Regulatory Reports--> Periodic Reports to open the window.

The following table lists and describes the fields on the Periodic Reports window.

Field/Control Name	Description
View All	Click this checkbox to view a list of all periodic reports
Total Number of Rows: 150	The maximum number of rows that display in the window.
Displaying Rows	Identifies the rows currently being displayed.
Page Size	Indicates the number of rows that display on each page.
Trade Name	The name of the drug. If there is not a Japanese name for the drug, the system displays the name in English followed by "no translation."
Destination	The name of the agency receiving the report.
Description	The generic name of the drug.
Due Date	The date the report is due in YYYY/MM/DD format.

Field/Control Name	Description
Status	The status of a report. This can be one of the following: ■ Scheduled ■ Overdue (scheduled) ■ Non-submit ■ Generated ■ Overdue (generated) ■ Disapproved ■ Overdue (disapproved) ■ Non-submit (disapproved) ■ Approved ■ Non-submit (approved) ■ Submitted
Create Unscheduled Report	Click to create an unscheduled periodic report.
Print List	Click to print the report list.

Creating Unscheduled Periodic Reports

The system enables you to create the following kinds of unscheduled periodic reports:

- ICH PSUR
- IND
- NDA
- CTPR
- PSR/ReSD
- Clinical Study PSR (CSPSR)

To create an unscheduled periodic report

1. Select Reports-->Compliance-->Periodic to review the list of scheduled periodic reports.
2. Click Create Unscheduled Report.
3. When the system opens the dialog box, select the type of report to create.
4. Enter the appropriate information in the dialog box and click OK.
5. When the system opens the scheduling dialog box, enter the appropriate information and click OK.

Clinical Study Periodic Safety Reports (CSPSR)

You can configure and generate Clinical Study Periodic Safety Reports for various products. Once you define a fixed set of CSPSR for a Primary agency, you can associate products in the reports and schedule the CSPSR so the system generates them automatically.

Configuring CSPSR Reports You can define a CSPSR by selecting Reports-->Periodic Reports-->Clinical Study Periodic Safety Report. The system opens the window that displays a list of all CSPS Reports stored in the system.

When you configure a CSPSR, you must, at a minimum, provide the following information:

- Report Name
- Primary Agency
- Time frame

The following table lists and describes the fields and controls in the Clinical Study Periodic Safety Report window.

Field/Control Name	Description
Category	Identifies the report category.
Sub Category	Identifies the sub category the report is associated with.
Report Name	The name of the report.
Inclusion Start Date/Stop Date	The date range for the report. The date is in the following format: YYYY/MM/DD -- YYYY/MM/DD.
Draft/Final	Indicates whether the report is in a draft or final state.
Author Created	The name of the person who created the report.
Author Modified	The name of the person who modified the report.
Date Created	The date the report was created in the following format: YYYY/MM/DD.
Date Modified	The date the report was modified in the following format: YYYY/MM/DD
Justification	The reason for creating/modifying the report.
Search	Enables you to search for a report.
Clear	When clicked, clears all data from the fields on the screen.
Total Number of Rows	The total number of rows of report information.
Page Size	The number of rows of data that display on each page.
New Report	Click this button to create a new CSPSR. The system opens the CSPSR Configuration window.
Copy	Click this button to copy a selected CSPSR. When you copy a CSPSR, the system copies all report configuration information, including timeframe rows. The name of the copied report is Copy of <Report Name>. If you copy a submitted report, the following information is read-only ■ Past Schedule Frequency Dates ■ Clinical Study Plan Submit Date ■ Clinical Trial for Partial Change Submit Date ■ Assigned Date If you copy an unsubmitted CSPSR, the system copies all the configuration information, including timeframe rows. Depending on how they were configured in the original report, the configuration information may be editable.

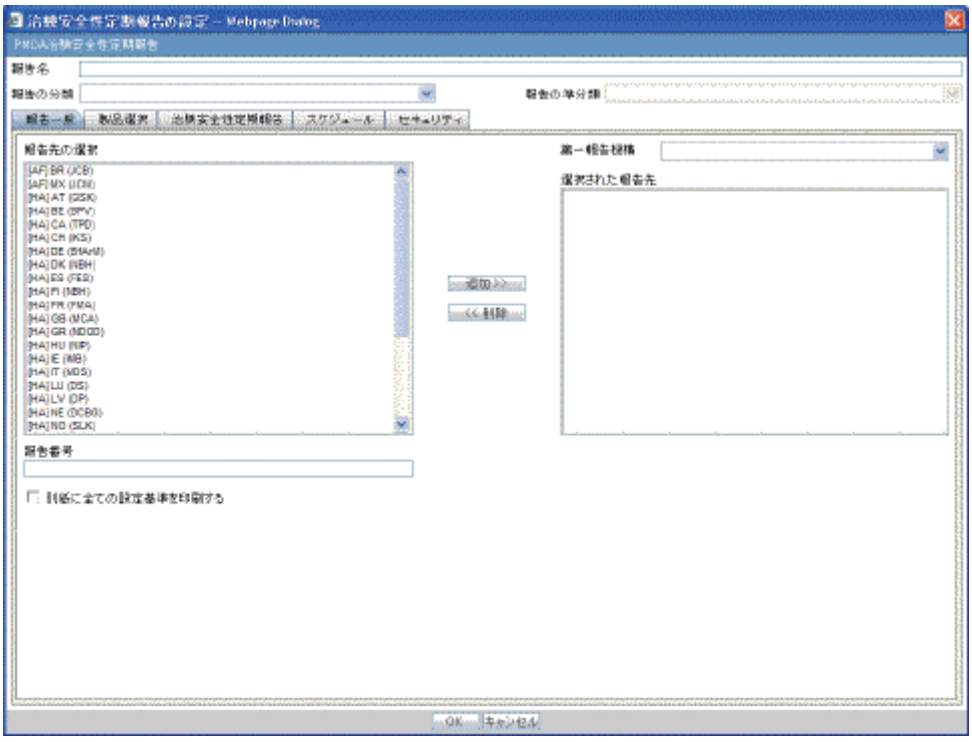
Field/Control Name	Description
Modify	Click this button to modify a selected CSPSR. The system displays the report definition. When you open a report that is currently in use, the system presents the following message: "The report which is selected is being used by <*User Name*> and cannot be modified."
Delete	Click this button to delete a selected CSPSR. The system presents a confirmation dialog box to enable you to confirm or cancel the delete operation. The delete option is available only if no Final Reports have been generated. The delete operation removes the report from the list, but does not delete it in the database.
Print	Click this button to print a selected CSPSR.

Submit Status When you submit a report, the system changes the status of the report to "Submitted." Once the status has been changed, you cannot modify the CSPSR configuration. If you try to modify a submitted report, the system presents the following error message: "This configuration is not modifiable because the status of this Clinical Study Periodic Report is Submitted. If you wish to modify a submitted report, you must unsubmit it.

Entering CSPSR Parameters You define a Clinical Study Periodic Safety report by entering report information on the following tabs:

- Subject of Report
- Product Selection
- CSPSR
- Scheduling
- Security

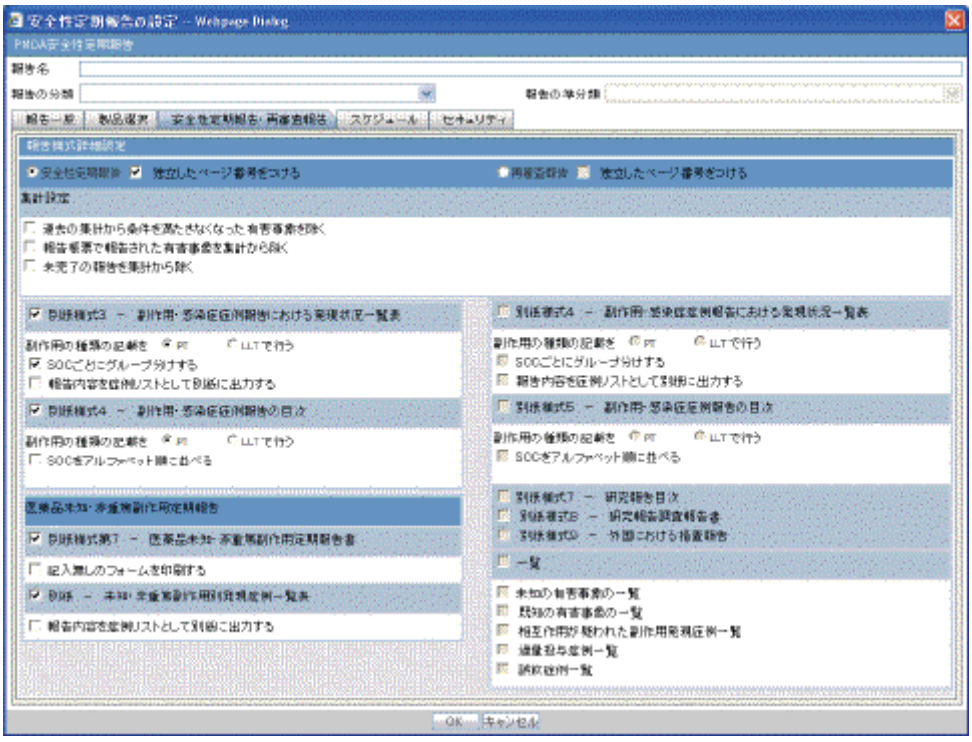
Subject of Report Tab The system permits you to enter information about the report and its recipients on this tab.



The following table lists and describes the tab fields/controls.

Field/Control Name	Description
Report Name	Enter the name of the report in this field.
Report Category	Enter the Report Category name in this field.
Report Subcategory	Enter the name of the Report Subcategory in this field.
Agency	Select the name of the agency that is to receive the report from the list.If there is no Japanese authority, the system lists the English name. Select the agency from the list and click >> to move it to the Selected Agencies list on the right.
Multiple Agencies	If you need to submit the report to more than one agency, select them from the drop-down list.
Report Number	Enter the report number in the field.
Print all configuration criteria on separate cover page.	Click the checkbox to print the report configuration at the beginning of the CSPSR.
Allow access to report cases through Hit List	Click this checkbox to place a final report on a Hit List. This enables you to retrieve the report from other areas of the application using advanced conditions functions.

Product Selection Tab This tab enables you to select ingredients, indications, and product formulations to include on the CSPSR. The following is an illustration of the Product Selection tab.



The following tables lists and describes the fields/controls on the Production Selection tab.

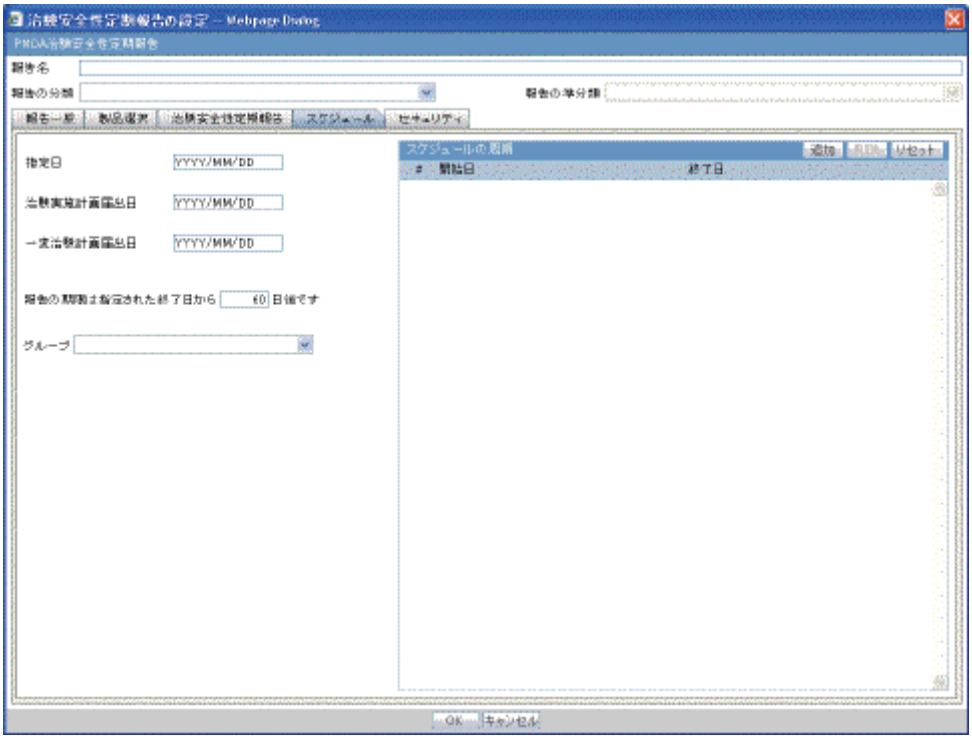
Field/Control	Description
Available Ingredients	Select a list of ingredients to include in the report. Click >> to move the selected ingredients from the Available Ingredients list to the Selected Ingredients list.
Indication	Select the appropriate indications from the list.
Formulation	Select the appropriate formulations from the list.
Available Products	The system populates this field with a list with all products that contain the selected ingredients. Select one or more products from this list and click >> to move them to the Selected Products list on the right.
Selected Products	This field contains a list of products selected from the Available Products list on the left.

Be aware of the following:

- The system displays English names if Japanese ingredients, indications, or formulations are not configured in the Console.
- If you move a product without a compound number to the Selected Products field, the system displays the following error message: "Selected product does not have a clinical compound number. The study product license must have at least one clinical compound number in order to include it in the report."
- If you move a product without a matching study to the Selected Products field, the system displays the following message: "Studies that have the selected product's clinical compound number doesn't exist. Do you want to include the product in

the report." If the user selects "Yes," the system places the product in the Selected Products field.

Clinical Study Periodic Safety Report Tab This tab enables you to configure the CSPSR. The following is an illustration of the tab.

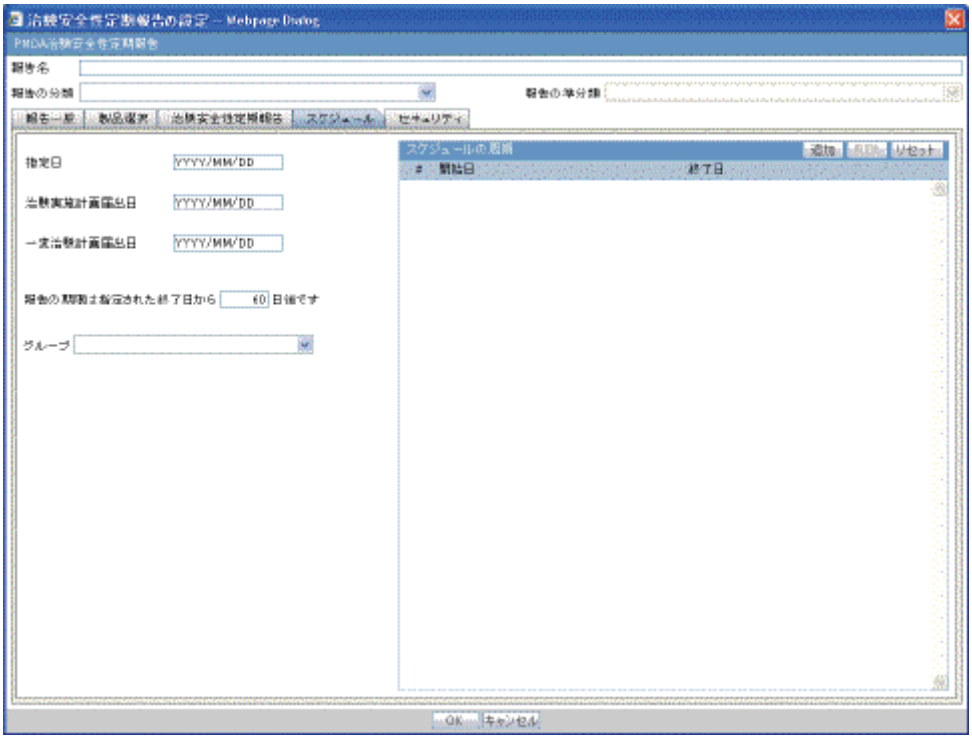


The following table lists and describes the fields on the tab.

Field/Control Name	Description
Report Form -- Clinical Study Serious AE Case Periodic Report	Click this checkbox to configure a report with this name.
Print Blank Form	Click this checkbox to print a blank report form.
Report Form -- Serious AE Case Occurrence Status Listing	Click this checkbox to print a report with this title.
Number of Subject: Domestic Study __ Foreign Study	Enter the total number of subjects for the entire clinical study, domestic and foreign. You can enter a maximum of seven (7) digits in each field.
Order SOC Alphabetically	Click this checkbox to print the SOC in alphabetical order based on their English names. If you leave this box unchecked, the system prints the SOC in MedDra browser order.
Include Foreign AE marked as "Not include for the report in Japan"	Click this checkbox to include AEs in foreign cases with flags for "Not include for the report in Japan."
Separate Page Numbering	Check this checkbox to start page numbering at 1 for each CSPSR Line Listing.

Field/Control Name	Description
Print the content of the report as case listing on separate page.	Click this checkbox to print the case listing on a separate page.

Scheduling Tab This tab enables you to schedule reports. The following is an illustration of the Scheduling tab.

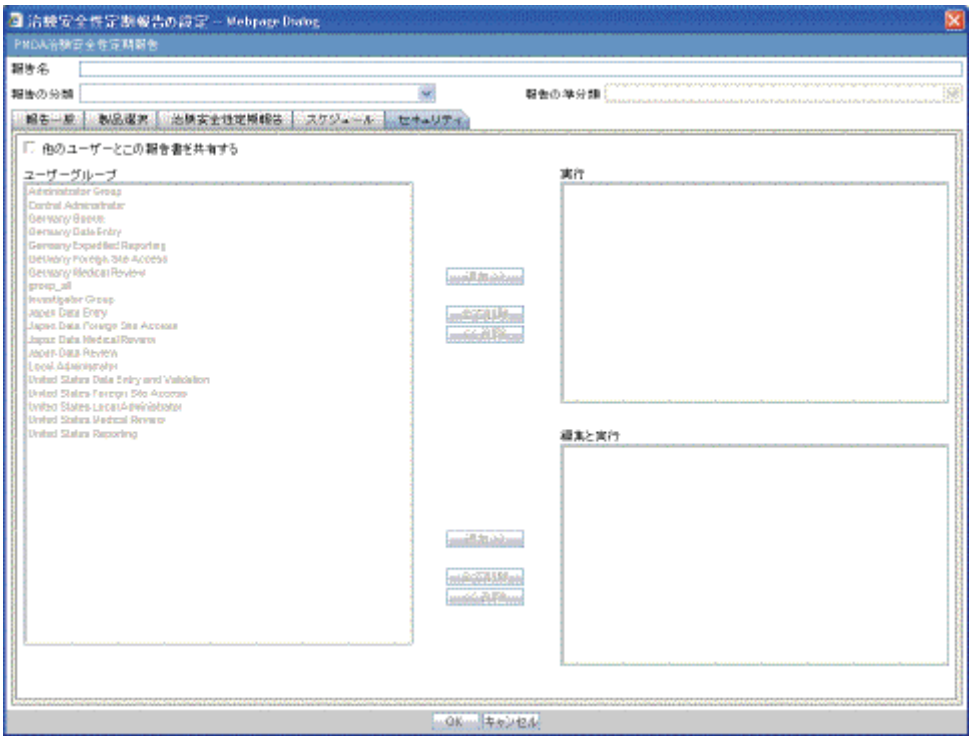


The following table lists and describes the fields on the scheduling tab.

Field/Control Name	Description
Assigned Date	The system automatically populates this field.
Clinical Study Plan Submit Date (CSPSD)	Enter the date the Clinical Study Plan was submitted. If the date you enter in this field is greater than the date for the Clinical Trial for Partial Change Plan Submit Date, the system presents the following error message: CSPSD cannot be after CTPCSD. If you change the Clinical Study Plan Submit Date, the system presents the following message: "If CSPSD is changes, assigned date will be changed. Do you want to proceed." If you click OK, the new value remains in the field. You can edit this field only if the a CSPSR is unsubmitted. Once submitted the field is read-only.

Field/Control Name	Description
Clinical Trial for Partial Change Plan Submit Date (CTPCSD)	If you change this date to a date earlier than the CSPSD, the system presents the following error message: "CTPCSD cannot be earlier than CSPSD." If you change this date the system presents the following message: "If CTPCSD is changed, the assigned date will be changed. Do you want to proceed?" If you click "OK," the new value remains in the field. You can edit this field only if the CSPSR has not been submitted and does not have previous non-editable timeframes.
Report is Due xx Days after Selected End Date	Enter the due date of the CSPSR to be xx number of days after the end date specified for the scheduling period.
Group	Select the name of the Argus group to be responsible for the Periodic report.
Start Date	The date the CSPSR reporting period begins. If you enter a date that is earlier than the most current end date, the system presents the following message: "Start date must be the same day or after the latest end date." When the system auto-updates the start date, it presents the following message: "Start date for the reporting period has changed. Please update the End date accordingly."
End Date	Enter the date the reporting period ends. If you enter an end date that is earlier than the start date, the system presents the following message: "End date must be after the start date.
Reset	Click Reset to delete all existing timeframe editable and non-editable time frame rows. When you click Reset, the system presents the following message: "By using Reset, all past data will be removed. Do you want to proceed? If you click "OK' the system proceeds with the reset.
Add	Click Add to add a single editable row.
Delete	Click Delete to delete an editable row. You cannot use this button to delete a non-editable row.

Security Tab The security tab enables you to share a report with other users. The following is an illustration of the Security tab.



The following table lists and describes the fields on the Security tab.

Field/Control Name	Description
Share this report with other users	Click this checkbox if you want to share the report with other users.
User Groups	Select the user groups you want to sent the report to and click Add to move the selected users to the Selected Users field.

Printing a CSPSR After you configure the CSPSR, click OK to print the report. The system opens the following dialog box.

The following table lists and describes the fields on the Report Batch Printing dialog box.

Field/Control Name	Description
Run at	Enter the date and time to run the report in the following format: YYYY/MM/DD 00:00
Run Now	Click this button to run the print now.
Print As	Click the appropriate button to print a Final report, a Draft report, an Internal report, or Other report.
Due Date	The system populates this field with report due date.

When printing a report, be aware of the following:

- You can print a report and update the Report output in a Word document.

- When you select Draft, Internal, or Other, the system prints a watermark on the report.

Viewing Periodic Reports You can view a report by selecting Reports-->Compliance-->Periodic Reports-->View Reports. The system put the report in an uploadable Word document.

If an English user has permission to access the CSPSR, the user can perform check-in/check-out, publish, and upload operations. The application UI displays in English. The following table lists and describes the fields on the Periodic Report List screen.

Field/Control Name	Description
View All	Click to view all reports.
Total Number of Rows	Indicates the total number of rows to display on the page.
Displaying Rows	Lists the number of rows that display on the page.
Page Size	The number of rows that display on each page.
Trade Name	Displays trade names for a list of selected products. If the selected product does not have a Japanese trade name, the system displays the English trade name.
Destination	Display the destination for the report.
Description	Displays a description of the report
Due Date	Displays the due date for the report.
Status	Displays the status of the report. This can be one of the following: ■ Scheduled ■ Generated ■ Approved ■ Disapproved ■ Submitted ■ New Data Available ■ No Longer Required
Create Unscheduled Report	Enables you to create an unscheduled report.
Print List	Click this button to print the Periodic Report List.
View Report	Click this button to view the Periodic Report List.
Report Details	Click to display detailed information about a selected report.

When viewing Periodic Reports, be aware of the following:

- The system outputs the report in a Word document. This enables you to edit the document outside the system and publish a final Word document.
- You must check out a report in order to revise it.
- The system enables the Publish button after a document has been revised and checked in.
- After the final Word document is created, the system saves the document in the repository.

- When you click Publish a document, the system creates a PDF file.

You can view a report, check in a report, check out a report, or publish a report from the View and Edit CSPSR dialog box.

- Click View to see a report.
- Click Publish to publish the report.
- Click Check-Out to check out a report.
- Click Check-In to check in a report.

The following table lists and describes the fields/controls in the dialog box.

Field/Control Name	Description
View	Click View to look at a Periodic Report.
Check In/Check Out	Click Check In to check in a checked out file. Once the document is checked in, the button label changes to Check Out.
Publish	Click Publish to convert the checked in document to a PDF.

Checking a Report In or Out When you click Check In, the system presents the CSPSR Check In dialog box.

To check in or check out a report

1. Click Check in on the View and Edit PSR/ReSD dialog box.
2. When the system opens the Check In/Check Out dialog box, Enter the name of the file to check in/check out in the File name field.
3. Click OK.

Deleting a CSPSR When you delete a CSPSR, the system opens the confirmation dialog box. Click Yes to continue with the Delete operation.

11

Dashboards

This chapter describes the dashboards in the Argus Safety application.

Dashboards Options

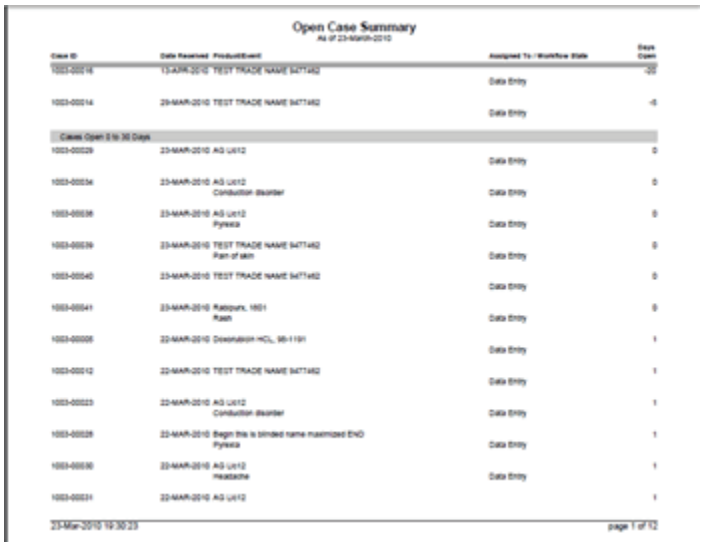
Dashboards option is available on the menu bar. Place the cursor over **Dashboards** in the menu bar to view the options available in it.

The following is list of available dashboard options.

- Open Case Summary Reports
- Open Action Items Reports
- Quick Signal Reports
- Increased Frequency Reports
- Expedited Report Status
- Workflow Status
- Reports Due Soon
- Personal Argus Status
- Case Workload

Open Case Summary Reports

The **Open Case Summary Report** displays a summary of all open cases sorted in ascending order according to the number of days the case has been open.



To view the Open Case Summary Report

1. Select Dashboards --> Open Case Summary.
2. The system displays the **Open Case Summary Report** in PDF format.

When using the **Open Case Summary Report**, be aware of the following:

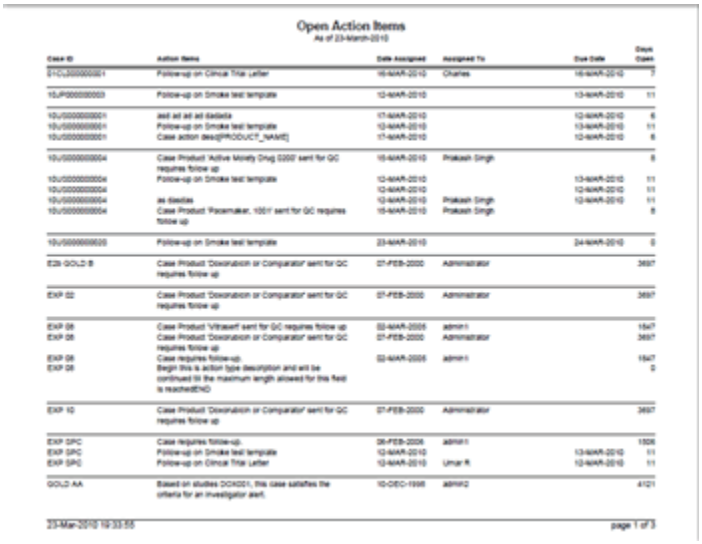
- The **Date Received** column prints the initial receipt date or the latest follow-up date for the case.
- If there are no follow-ups for a case, the system calculates open cases based on the initial receipt date.
- If there are follow-ups for a case, the system calculates the days open based on the most recent follow-up in the case. If the latest follow-up date is older than the previous follow-up, it considers only the last follow-up.
- The system also calculates days open based on the latest follow-up date for the case.

The following table lists and describes each field in the **Open Case Summary Report**

Field	Description
As of (date)	Displays the report as per the current date (in dd-mmm-yyyy format).
Case ID	Displays the Case ID of each listed case.
Date Received	Displays the date when the case was received.
Product	Displays the Product Name.
Event	Displays the Event Info/Preferred Term.
Assigned To	Displays the Workflow/Case Owner.
Days Open	Displays the number of days since the initial receipt date.
Status	Displays the Case Status.
Total Cases	Displayed at the end of the report, it shows the total number of cases listed in this Open Case Summary Report.

Open Action Items Reports

The **Open Action Items** Report displays all outstanding action items. This report is sorted as per the Case ID of the listed cases.



Open Action Items

As of 23-March-2010

Case ID	Action Items	Date Assigned	Assigned To	Due Date	Days Open
01CL0000000001	Follow-up on Clinical Trial Letter	16-MAR-2010	Charles	16-MAR-2010	7
10JP0000000003	Follow-up on Smoke test template	12-MAR-2010		13-MAR-2010	11
10US0000000001	asd ad ad ad dadada	17-MAR-2010		12-MAR-2010	6
10US0000000001	Follow-up on Smoke test template	13-MAR-2010		13-MAR-2010	11
10US0000000001	Case action desc[PRODUCT_NAME]	17-MAR-2010		12-MAR-2010	6
10US0000000004	Case Product 'Active Moiety Drug 0200' sent for QC requires follow up	16-MAR-2010	Prakash Singh		8
10US0000000004	Follow-up on Smoke test template	12-MAR-2010		13-MAR-2010	11
10US0000000004		12-MAR-2010		12-MAR-2010	11
10US0000000004	as dasdas	12-MAR-2010	Prakash Singh	12-MAR-2010	11
10US0000000004	Case Product 'Pacemaker, 100Y' sent for QC requires follow up	16-MAR-2010	Prakash Singh		8
10US0000000020	Follow-up on Smoke test template	23-MAR-2010		24-MAR-2010	0
E2b GOLD B	Case Product 'Doxorubicin or Comparator' sent for QC requires follow up	07-FEB-2000	Administrator		3697
EXP 02	Case Product 'Doxorubicin or Comparator' sent for QC requires follow up	07-FEB-2000	Administrator		3697
EXP 05	Case Product 'Vitrasert' sent for QC requires follow up	02-MAR-2005	admin1		1547
EXP 08	Case Product 'Doxorubicin or Comparator' sent for QC requires follow up	07-FEB-2000	Administrator		3697
EXP 08	Case requires follow-up.	02-MAR-2005	admin1		1547
EXP 08	Begin this is action type description and will be continued till the maximum length allowed for this field is reachedEND				0
EXP 10	Case Product 'Doxorubicin or Comparator' sent for QC requires follow up	07-FEB-2000	Administrator		3697
EXP SPC	Case requires follow-up.	06-FEB-2006	admin1		1526
EXP SPC	Follow-up on Smoke test template	12-MAR-2010		13-MAR-2010	11
EXP SPC	Follow-up on Clinical Trial Letter	12-MAR-2010	Umar R	12-MAR-2010	11
GOLD AA	Based on studies DOX001, this case satisfies the criteria for an investigator alert.	10-DEC-1998	admin2		4121

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To view the Open Action Items Report

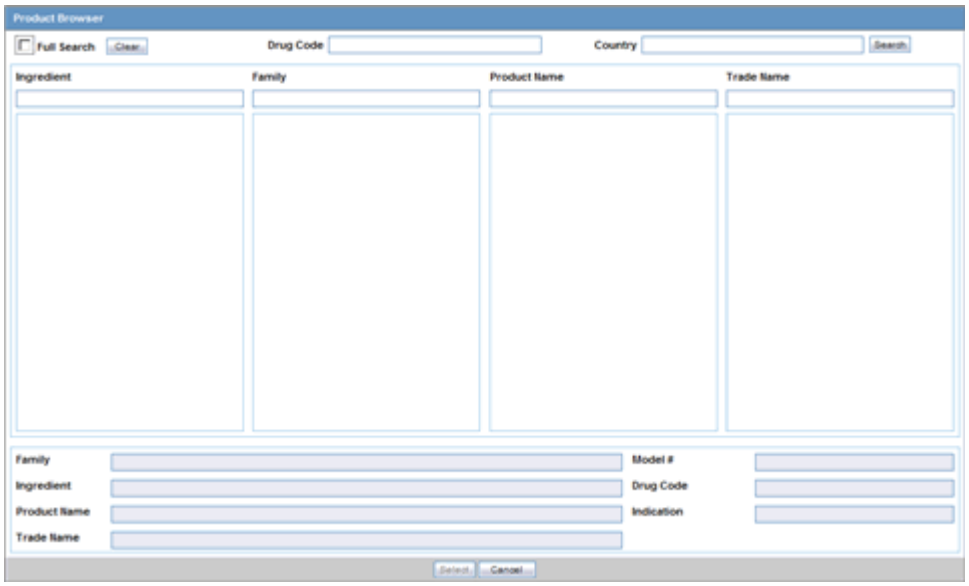
1. Select Dashboards --> Open Action Items.
2. The system displays the **Open Action Items Report** in PDF format as shown in the following illustration.

The following tables lists and describes the fields in the **Open Action Items Report**.

Field	Description
As of (date)	Displays the report as per the current date (in dd-mmm-yyyy format)
Case ID	Displays the Case ID of each listed case.
Action Item	Lists the status of the case and the action that needs to be taken.
Date Assigned	Displays the date when the case was opened/assigned.
Assigned To	Displays the Workflow/Case Owner.
Date Due	Displays the date when the action item was due.
Days Open	Displays the number of days that have lapsed since the date when the case was opened.

Quick Signal Report

The **Quick Signal Report** displays the changes in numbers of events over the past year. This report is a summary listing of events, which have triggered signals.



Click the following link for information about the information in the fields on the report.

Quick Signal Report Fields

The following table lists and describes the fields in the **Quick Signal Report**.

Field	Description
Product	Displays the Product Name.
As of	Displays the report as per the current date (in dd-mmm-yyyy format).
Term	Displays the Event Information in alphabetical order Body system and sort them within the body system in descending order.
Last 6 Months (Selected Drug)	Displays the number of cases received in the past 6 months for the selected drug.
All Cases (Selected Drug)	Displays the total number of cases recorded for the selected drug.
Last 6 Months (All Products)	Displays the number of cases received in the past 6 months for all the drugs.
All Cases (All Products)	Displays the total number of cases for all the drugs.

To enter information in the Product Browser

1. Select Quick Signal Report from Dashboards.

2. This displays the **Product Browser** dialog.

To search through the Product Browser dialog

1. Click the entities being displayed in the dialog.

   The hierarchy above and below the entity being searched is also displayed. For example, if Product Name is searched, it displays the Product Name as well as the Family Name and Trade Name.

2. Search for Products based on the following criteria:

- Ingredient - Displays the ingredients of the product
- Family - Displays the family of the product
- Product Name - Displays the Formulation (Dosage Form), Concentration (Strength) and Indication to aid in the selection of the correct product.
- Trade Name - Searches the License Trade Name, Country fields.

3. When the system displays the results, select the appropriate Product.
4. Click **Select** to view the Quick Signal Report that matches the entered criteria.

Memorized Reports

The system enables you to recall a previously memorized case listing or case data analysis report for printing. In addition to the reports for a specific user, the system displays a list of reports whare are shared by all users.

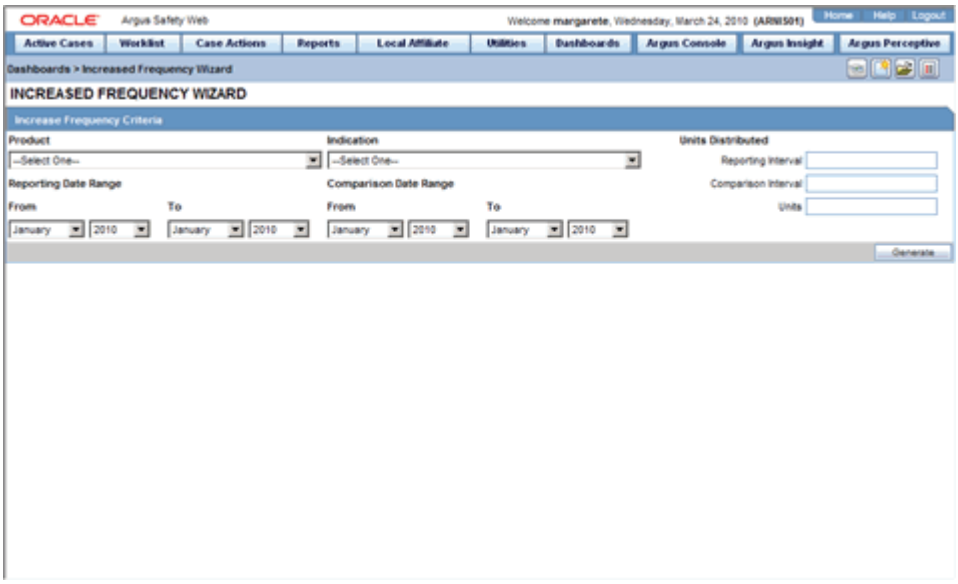
You can select a memorized report from the dialog box. When you select the report, the system enables the Open button to permit you to open the selected memorized report. Click Cancel to close the dialog box. Click Delete to delte the selected ememorized report.

To memorize a configured report, click the Memorize button on the configuration dialog box for the Case Listing or Case Data Analysis report.The system opens the Memorized Report .

The system enables you to save the memorized report, make it available for , and Share the report with other users.

Increased Frequency Reports

The **Increased Frequency Report** displays events that have occurred at increased frequency for a given product and indication, based on a FDA formula (modified t-test).



To generate an Increased Frequency Report

1. Select Dashboards --> Increased Frequency.

2. When the system opens the **Increased Frequency Wizard**, enter the appropriate information in the fields and click **Generate**.

Increased Frequency Criteria Fields and Field Descriptions

The following table lists and describes the fields in the **Increased Frequency Criteria** section.

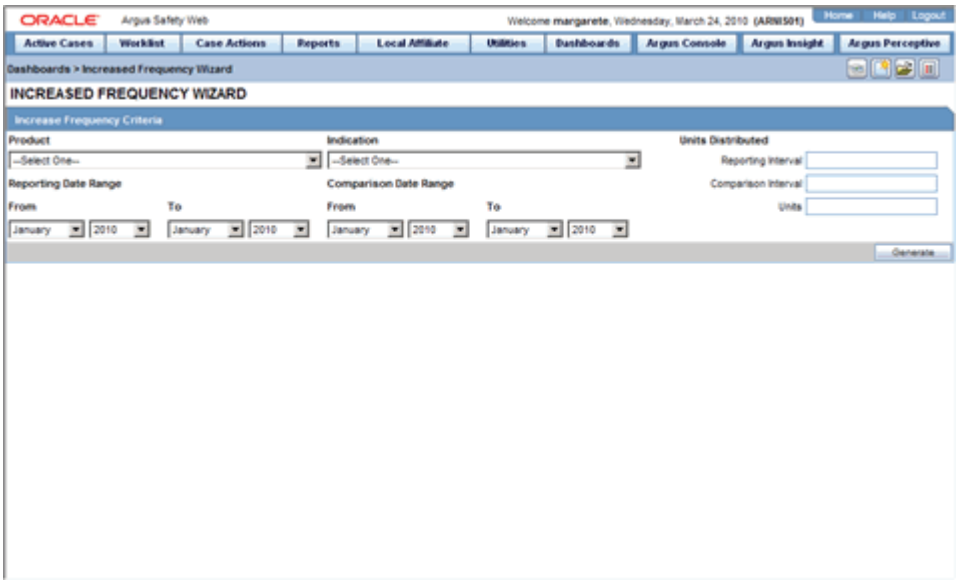
Field	Description
Product	Allows the user to select the product on which this report is to be based.
Indication	Allows the user to select an indication for this product.
Reporting Date Range From Date	Defines the starting date.
Reporting Date Range To Date	Defines the ending date.
Comparison Date Range From Date	Defines the starting date for the comparison period.
Comparison Date Range To Date	Defines the ending date for the comparison period.
Units Distributed in Reporting Interval	Allows the user to adjust the number of units distributed in the reporting interval.
Units Distributed in Comparison Interval	Allows the user to adjust the number of units distributed in the comparison interval.
Units	Allows the user to adjust the unit term as appropriate.
Generate button	Generates the Increase Frequency Report.

The following table lists and describes the information that appears in the **Increased Frequency Report**.

Field	Description
Adverse Event	Displays the name of the adverse event.
Number of Adverse Events	Displays the number of adverse events.

Increased Frequency Wizard

The Increased Frequency Wizard enables you to determine which events have occurred at increased frequency for a given product and indication based on an FDA formula (modified t-test).Select Utilities --> Increased Frequency Wizard to open the Increased Frequency Wizard dialog box shown in the following illustration.

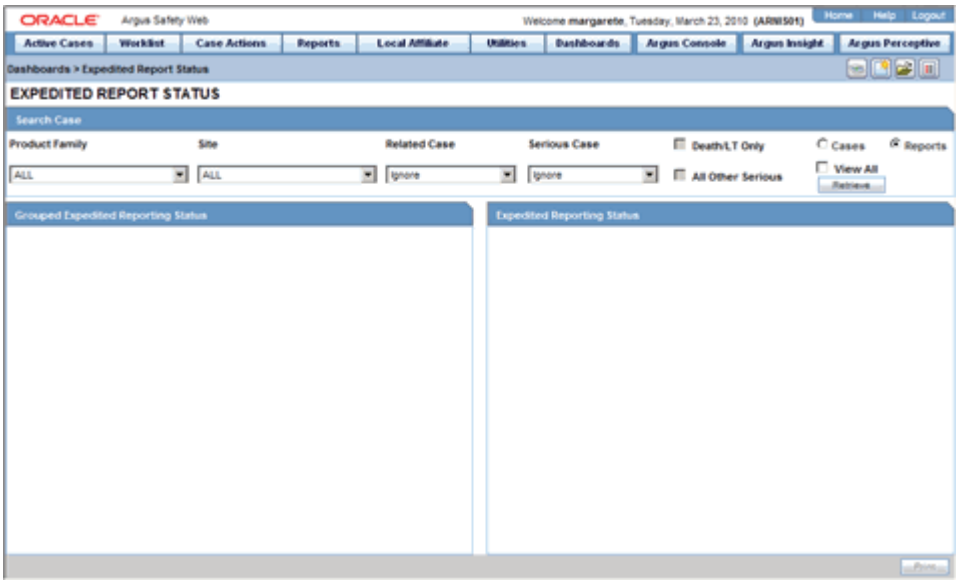


The following table lists and describes the fields on the Increased Frequency Wizard dialog box.

Field/IControl Name	Description
Product	Enables you to select the product on which this report is to be based.
Indication	Enables you to select an indication for the product
Reporting Date Range From	Enables you to define the starting date.
Reporting Date Range To	Enables you to define the ending date.
Comparison Date Range From Date	Enables you to define the starting date for the comparison period.
Comparison Date Range To DAte	Enables you to define the ending date for the comparison period.
Units Distributed in Reporting Interval	Enables you to adjust the number of units distributed during the reporting interval.
Units Distributied in Comparison Interval	Enables you to adjust the number of units distributed during the comparison interval.
Units	Enables you to adjust the unit term as appropriate.
Generate	Click Generate to generated the Increase Frequency Report.

Expedited Report Status

The **Expedited Reporting Status** page enables you to search for and field information about the status of expedited reports. **Expedited Reporting Status** also appears on the **Worklist Group** menu. Additionally, if you have access to **Expedited Report Status**, you wil also have access to the **Report Due Soon** dashboard. The following is an illustration of the **Expedited Report Status** screen.



1. Select Dashboards --> Expedited Report Status to open the Expedited Reporting Status screen.
2. When the system opens the **Expedited Report Status** screen, enter the appropriate information in the fields in the **Search Case** section and click **Retrieve.**
3. he system creates the report based on the search criteria you entered.

Expedited Report Status Fields and Field Descriptions

The **Expedited Report Status** screen contains the sections mentioned below:

- Search Case
- Grouped Expedited Reporting Status
- Expedited Reporting Status

Search Case Status This section enables you to enter the search parameters for the report

The following table lists and describes the fields

Field	Description
Product Family	Allows the user to select which Product Family to be included in the dashboard.
Site	Allows the user to filter the workflow statuses to the selected site.
Serious Case	Displays if the case is serious or not. If **Yes** is selected, the seriousness criteria are enabled. **Note:** A case that does not have a seriousness specified (i.e. blank) is treated as serious.

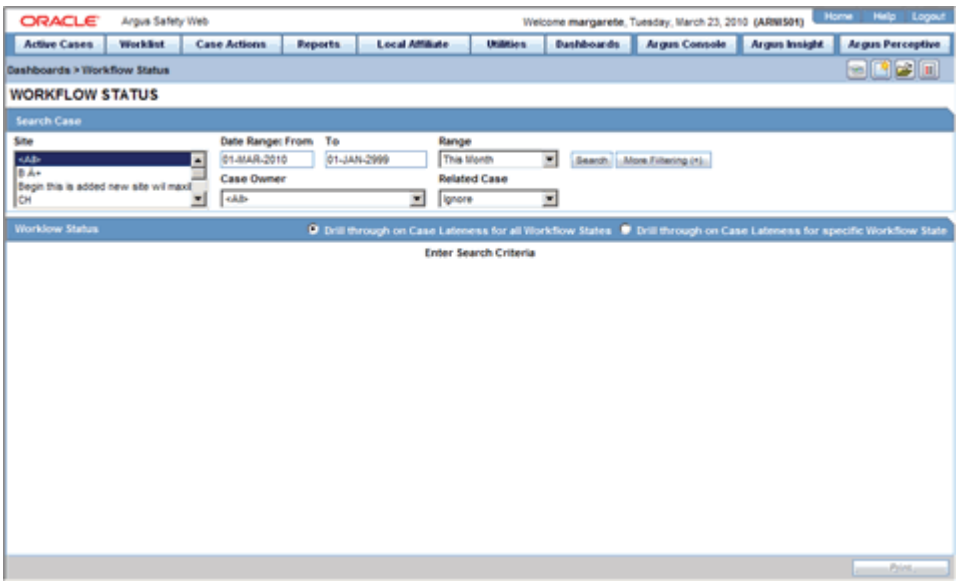
Field	Description
Related Case	Filters on the relatedness of the case. A case is only included if it meets the relatedness criterion.
Death/LT Only	Select this option to include any case that has any of the Fatal or Life-Threatening seriousness criteria.
All Other Serious	If this seriousness criterion is checked, the case only gets included if any of the following seriousness criteria of any event are checked: Hospitalized, Disability, Congenital Anomaly, Medically Significant, Intervention Required or Other.
Cases	Enables you to search for cases.
Reports	Enables you to search for reports.
View All	Enables you to view all.
Retrieve	Prints the currently selected dashboard, including filter criteria.

Grouped Expedited Reporting Status (Pie chart) Click on the Color Coded Areas of the pie to open all the Reports or Cases within that section instead of just the bar.

Expedited Reporting Status (Bars) Click on a bar to open the Worklist displaying the cases that belong to the reports or the actual reports. These reports belong to the specified timeframe.

Workflow Status

You can view the **Workflow Status** based on case owner, site, case seriousness, and other criteria. The following is an illustration of the **Workflow Status** screen.



To view the Workflow Status

1. Select Dashboards --> Workflow Status to open the Workflow Status Screen.
2. When the system opens the **Workflow Status** screen, enter the appropriate data in the **Search Case** fields and click **Search**.
3. The system displays the **Workflow Status** information.

General Usage Information

When using the **Workflow Status** screen, be aware of the following:

- Workflow Status appears on the Worklist Group menu.
- You can:

  Click on a bar graph and select from a dashboard menu to open the list of cases in the **Workflow Status Dashboards**.

  Click on the graphical bars to drill down on the specific workflow state details.
- If no updates are made to cases during case processing, the cases the system displays the number of cases you clicked during the drill down.
- If one or more cases change workflow state between loading the dashboard screen and loading the worklist-specific screen, a discrepancy in case numbers may occur.
- The system maintains user preferences once you return to the **Workflow Status Dashboard**.
- By default, the system displays only the first filtering results and makes other filters available when you click **More Filtering**.
- **Worklist Status.** This screen provides filtering capabilities by site, workflow state, product family, date range, advanced condition, serious or non-serious, study or non-study by clicking the **More Filtering** option. The **More Filtering** options also hide additional filtering elements.
- **Site Filter.** The Site Filter is a multiple selection screen that enables you to use the **CTRL** and **Shift** keys to select multiple sites. The default value is **All Product Family**. When you use the site filter, the system displays all active (undeleted) sites in the **Argus Code List**. However, the system **does not** display LAM sites.
- **Workflow State Filter.** The Workflow State filter is a multiple selection screen. You can select use the **CRTL** and **Shift** keys to select multiple groups.
  - The system displays all active (undeleted) workflow states, except archived/closed, in the **Argus Utilities - Configuration**.
  - The default selected value is **<All>Product Family**.
  - The **Product Family** filter is a type ahead field.
  - The default selection on the type ahead is blank (no filtering on Product Family). By default, the system displays a maximum of 25 rows.
  - The system displays all active (undeleted) product families configured in the **Argus Code List Product & Family** in the **Product Family Filter** results.
- **Date Range Filter.** In this module, the **Date Range** function works in the same manner as it does in other parts of the application.
  - The default value for range is last month.
  - The system automatically populates the values in the **From** and **To** fields with the dates based on the **This Month** option.
  - The date fields functions as they do in other parts of the application.
  - The system evaluates **Aware Date** to fall in between the date range specified in the **Date Range** filter.
- **Advanced Condition Filter**.The Advanced Condition functions as it does in other part of the application.

- **Serious or Non-Serious Filter.** Five (5) sub-filtering options are available.
  - All

    This is the default option. When you select this option, the report returns all cases whether serious or non-serious.
  - Serious

    When you select this option, the system returns only those cases that are serious. The system evaluates seriousness at the event level. If any event is serious, the system considers the case serious and returns it in the results.
  - Non-Serious

    When you select this option, the report returns only non-serious cases. All the events must be non-serious before the system returns the case in the search results.
  - Death/LT Only

    When you select this option, the report returns cases that have an event where Death or Life Threatening is checked. The system disables this check box when you select the non-serious option.
  - **Serious other than death or life-threateningFilter.**

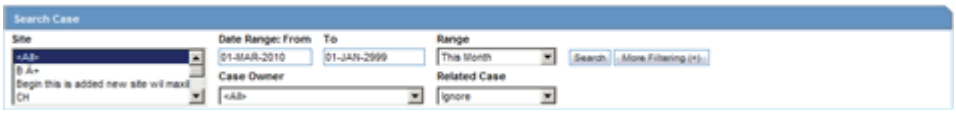
    When you select this option, the report returns only those cases that have an event with a seriousness criteria other than Death or Life Threatening.The system disables this check box when you select the Non-Serious option.
- **Report Type Filter.** The Report Type filter is a multi-selection screen that enables you use the **CTRL** and **Shift** keys to select multiple items. The default value is **All**.
- **Project ID Filter.** The Project ID filter is a multi-selection screen that enables you to use the **CTRL** and **Shift** keys to select multiple items. The default value is **All**. All active Project ID values are configured in the Argus Utilities Protocol ID Code List.
- **Default Report Configuration Filter.** When no other filters are used, the default report configuration returns all cases for the current month. The system uses the case **Aware Date** for evaluation purposes.
- **Search Filter.** When you click **Search**, the system displays the **Workflow Status** screen.
- When you click the **Bar Graph**, the system displays a menu. You can select **Late**, **Over Normal**, **Normal** or **All** to go to the worklist-specific screen. When you double-clicks the bar, the system displays the worklist-specific screen.
- **Print.** When you click **Print**, the system uses the standard **Argus Print** function to print the search results. This is the same as **CDA** print functionality.

Workflow Status Fields and Field Descriptions

The **Workflow Status** screen includes the following sections:

- Search Case
- Workflow Status

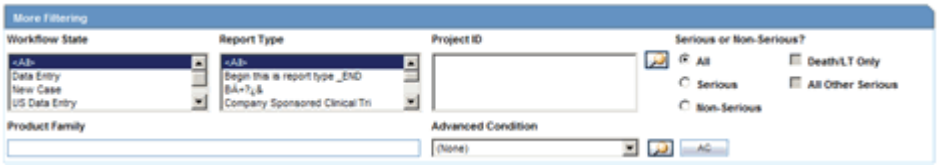
Search Case The **Search Case** section enables you to enter appropriate search criteria to search for workflow information.



The following table lists and describes the fields in the **Search Case** section.

Field	Description
Site	Allows the user to filter the workflow statuses to the selected site.
Date Range From/To	Enables you to filter workflow status based on a specific date range
Range	Enables you to filter workflow status based on a pre-define date range (e.g., last 30 days, etc.)
Case Owner	Enables you to filter the workflow status based on the case owner.
Related Case	Filters on the relatedness of the case. A case is only included if it meets the relatedness criterion.
Search	Click **Search** to search for the workflow status.
More Filtering	Click **More Filter** to display more filtering options on the **More Filtering** section
Print	Prints the currently selected dashboard, including filter criteria.

More Filtering Section The **More Filtering** section provides additional criteria for filtering cases. The following is an illustration of the **More Filtering** section.



The following table lists and describes the fields in the **More Filtering** section.

Field	Description
Workflow State	Enables you to filter the workflow status based on workflow state (e.g., data entry, medical review, etc.)
Report Type	Enables you to filter the workflow status based on the report type.
Project ID	Enables you to filter the workflow status based on the Project ID.
Serious or Non-Serious	Enables you to filter workflow status based on the Serious/Non-serious criteria as follows: ■ All -- Search for all workflow statuses ■ Serious -- Search for workflow status for serious cases ■ Non-Serious -- Search for workflow status for non-serious cases ■ Death/LT Only -- Search for workflow status for Death or life-threatening cases ■ All Other Serious -- Search for the workflow status for all serious cases other than death or life-threatening.
Product Family	Search for workflow status based on product family.
Advanced Condition	Search for workflow status based on a selected advanced condition

Field	Description
AC	Enables you to create an Advanced Condition.
Print	Prints the currently selected dashboard, including filter criteria.

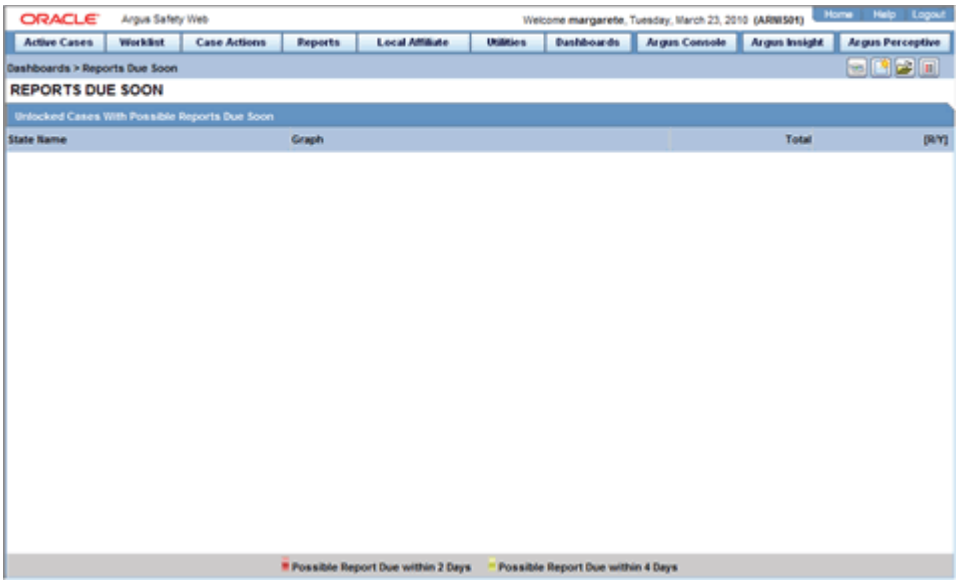
Workflow Status (Bars) Bar graph colors indicate the following statuses:

- Red -- Late Cases
- Yellow -- Outside of Normal Cases
- Green -- Normal Cases.

Click on the bar to view a Worklist with cases of the selected state (red, green or yellow).

Reports Due Soon

As report scheduling is commonly configured to be executed when significant changes are made to a case, it is possible that expedited reports may be delayed if a case never gets locked. You cannot know that a report is late if it has never been scheduled. In order to address this potential compliance issue Argus Safety assesses case reportability prior to formal report scheduling. Workflow and Expedited Status monitoring screens identify unlocked cases due soon.



To view a list of unlocked cases with reports due

1. Select Dashboards --> Reports Due Soon from Dashboards.
2. The system opens the **Unlocked Cases with Possible Reports Due Soon** screen is displayed.

The Workflow and Expedited status include another report with cases that have not had reports scheduled but that may generate a report with a due date in the near future. This graph is displayed below the graph detailing the actual case status.The reports included in this sub-dashboard are limited to the filter criteria specified for the main dashboard

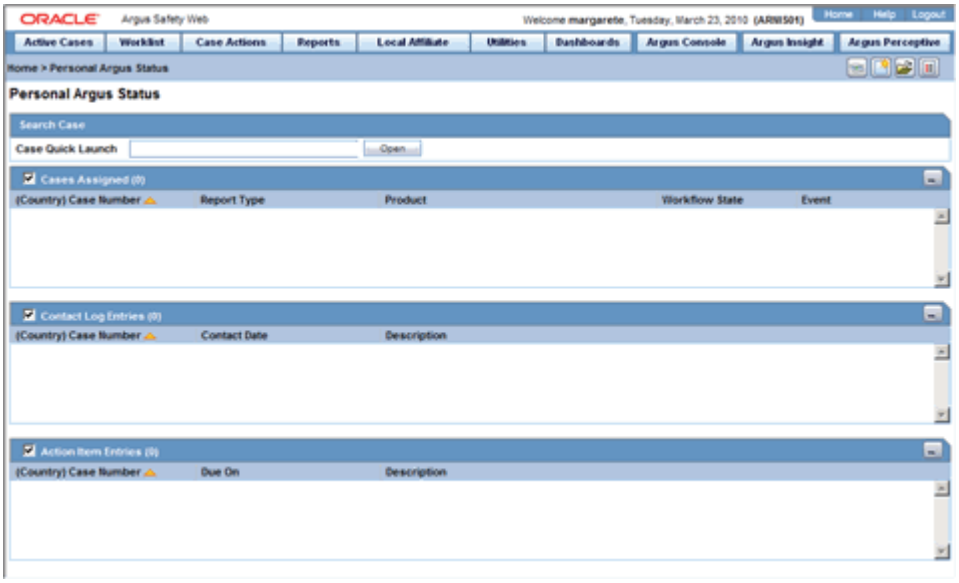
The following table lists and describes the fields on the **Reports Due Soon** screen.

Field	Description
State Name	Displays the workflow state of each listed case is.
Graph	Red bars indicate that the report is likely to be due within the next 5 days. Yellow bars indicate that the report is likely to be due in the next 10 days.
Total	Displays the number of cases within the displayed workflow state.
R/Y	Number of cases in Red/Yellow

Click the graphical bar to view a Worklist with cases of the selected state (red or yellow).

Personal Argus Status

The **Personal Argus Status** screen of the Argus Safety application displays a list of Cases Assigned, Contact Log Entries and Action Item Entries sections that are specific to the logged-in user. The following is an illustration of the **Personal Argus Status** screen.



To view the Personal Argus Status screen

1. Select Dashboards --> Personal Argus Status.
2. The system opens the **Personal Argus Status** screen

To search for a case

Use the following procedure to search for a specific case.

1. Type the case number in the **Case Quick Launch** field of the Home page and click **Open**.
2. Click the link displaying a case number to view the case details.

   By default, each section and header column is sorted by Case Number in ascending order.

3. Select the check box for any of the headers to enable that section.

   The sections in which the check box is not selected are displayed at the bottom of the screen.

Cases Assigned Section

The system displays the Workflow status for displayed cases in the **Cases Assigned** section. You can right-click on the case row and select the **Accept** option. This moves the cases to their Worklist Open list.

The following table describes the fields in the **Cases Assigned** section:

Field	Description
Country (Case Number)	Displays the name of the country to which the case belongs, with the Case Number listed in brackets.
Report Type	Displays the report type of the case.
Product	Displays the product name.
Event	Displays the event name

Contact Log Entries Section

The following table describes the fields in the **Contact Log Entries** section:

Field	Description
Country (Case Number)	Displays the name of the country to which the case belongs, with the Case Number listed in brackets.
Contact Date	Displays the contact date
Description	Displays the description of the case

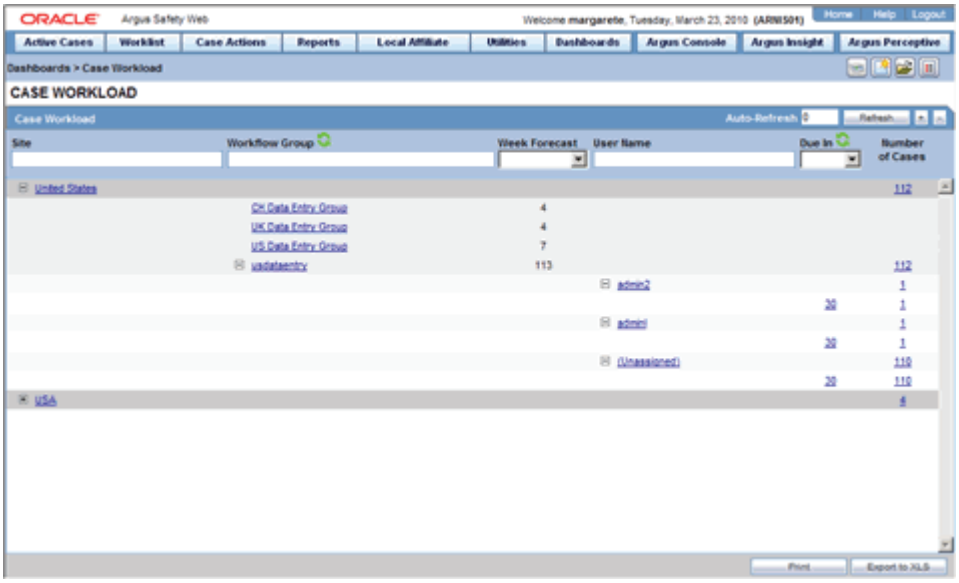
Action Items Entries

The following table below describes the fields in the **Action Items Entries** section:

Field	Description
Country (Case Number)	Displays the name of the country to which the case belongs, with the Case Number listed in brackets.
Due On	Displays the date when the case is due.
Description	Displays a description of the case.

Case Workload

The **Case Workload** feature enables an administrator to view the case workload for individuals and one or more sites. The Case Workload feature is available for only Workflow Managers. For example, if a user belongs to a group which has access to this menu option but is not a Workflow Manager, this option will not be displayed.



To view case workload information

1. Select Dashboards --> Case Workload.
2. The system opens the **Case Workload** screen.

The following table lists and describes the fields in th **Case Workload** screen.

Field	Description
Site	Enables you to view the Cases part of the site. Displays the specific Worklist where the user can view the case numbers. Click + to view the next level and expand either the Workflow State or Workflow Group.
Workflow State	Enables you to view the Workflow State of the Cases part of the site. Displays the specific Worklist where the user can view the case numbers. Click + to view the next level and expand to User Name. Click the Header to toggle between Workflow Group or Workflow States.
Workflow Group	Displays the Workflow Group of the Cases part of the site. Displays the specific Worklist where the user can view the case numbers. Click the Header to toggle between Workflow Group or Workflow States. Click + to view the next level and expand to User Name.
Week Forecast	Enables the user to view the number of cases projected in the next 5 days for the current workflow state or group. If a case is routed to multiple workflow states/groups, it is counted multiple times within the Week Forecast. The Projected Week Forecast is based on the Dynamic Workflow calculation for the entire case, as per the configuration settings.

Field	Description
User Name	Enables you to view the User Name to whom the cases are assigned. Displays the specific Worklist where the user can view the case numbers. Click + to view the next level and expand to Priority. Online Users can view the Online icon and their User Names appear in bold.
Priority	Enables you to view the Priority of the Cases part of the User. Click the link to view the specific Worklist where the user can view the case numbers.
Due In	Enables you to view the Due In of the Cases part of the User. Displays the specific Worklist where the user can view the case numbers. Due In is based on the Days remaining field, similar to the Worklist | New dialog.
# of Cases	Enables you to view the Total number of the Cases for the row entity. Click the link to view the specific Worklist where the user can view the case numbers.
Refresh	Enables you to only refresh the number and the entities but not the entire page. Enter a value in the text field for Auto-Refresh automatically refresh the dialog every N minutes up to a maximum of 99 minutes.
Expand All (+)	Enables you to expand all entities across the Summary Tabulation.
Collapse All (|)	Enables you to collapse all entities across the Summary Tabulation, leaving only the Sites Total.
Print	Enables you to print the Load Balancing Dashboard in PDF format.
Export to XLS	Enables you to export the Load Balancing Dashboard in Excel format.

12

Utilities

This chapter discusses the different utility functions to help you view, change, or retrieve case-related information.

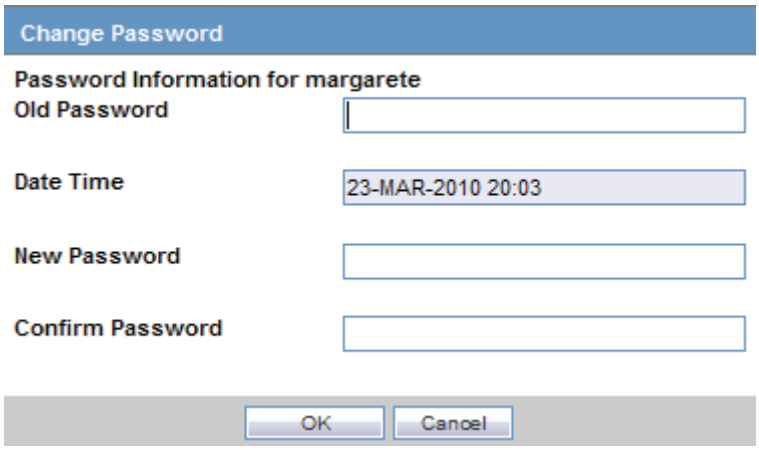
Utilities

To access the Utilities menu, place the cursor over the **Utilities** menu bar to view the available options.The following utilities are available to you.

- Change Password
- MedDRA Browser
- MedDRA J Browser
- User Login List
- Logs
- E2B
- Argus Reconciliation
- Undelete
- Batch Reports
- Blank Report Forms
- End of Study
- Clear Cache

Change Password

The Change Password functionality allows users to change the password that they use to login to Argus. When you log on to the system for the first time, change the password that has been assigned to you.



Note: LDAP users cannot change their passwords.

To change your password

1. Select **Change Password** from the **Utilities** menu.
2. When the system opens the **Change Password** dialog box:
   - Enter your current password in the **Old Password** field.
   - Enter your new password in the **New Password** field.
   - Re-enter your new password in the **Confirm Password** field to verify it.
   - Click **OK** to change your password,

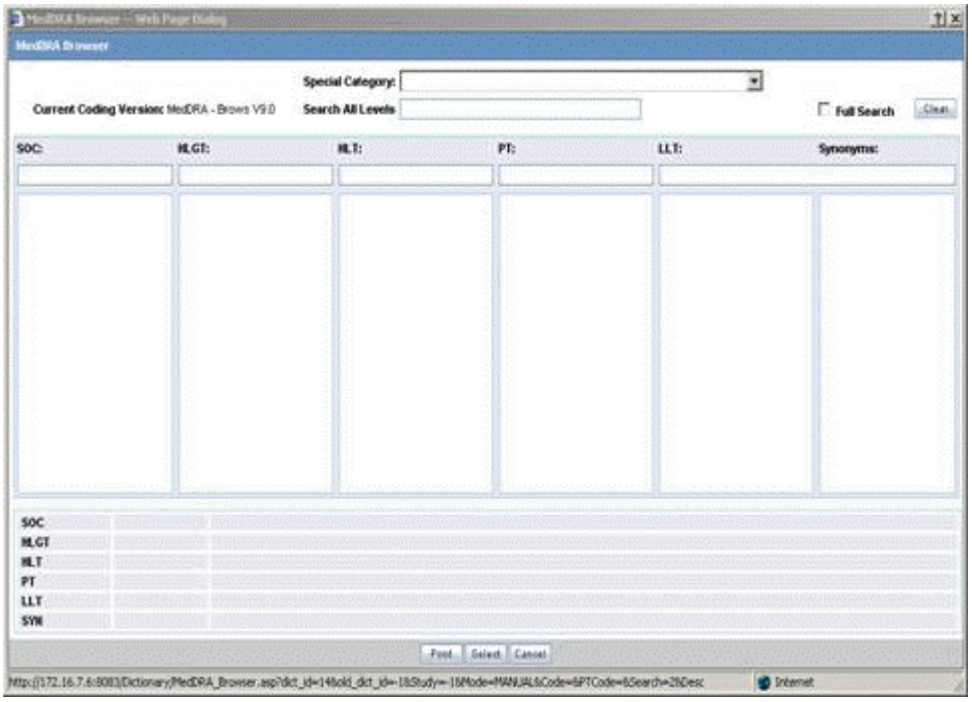
3. Your password has been changed.

Be aware of the following:

- If the system has difficulty confirming the password, it presents the Password Confirmation Failure dialog box.
- You cannot re-enter the password you are currently using when the system prompts you to change your password.
- When you update your password, the system displays the system date and time.

MedDRA Browser

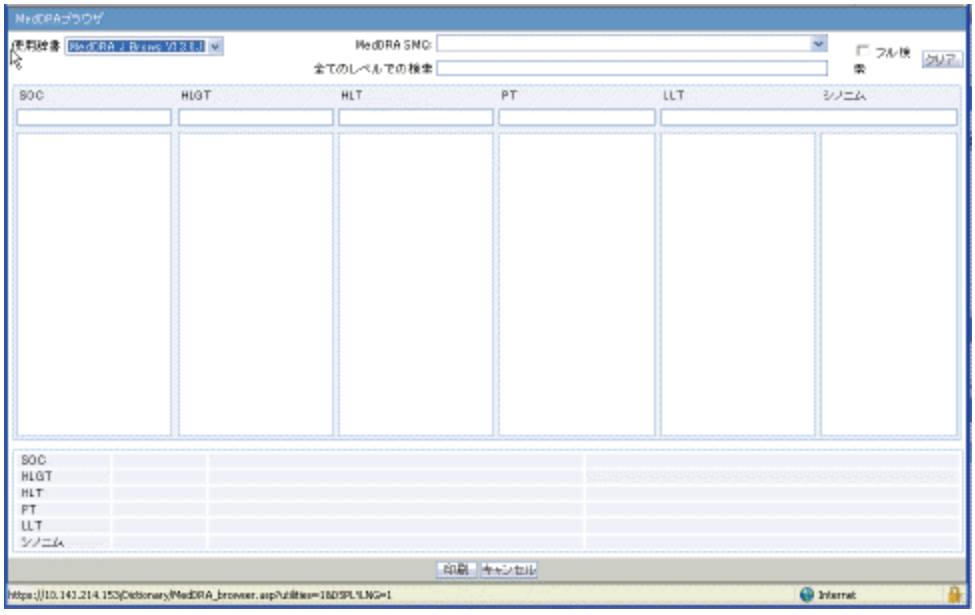
Use the Medical Dictionary for Regulatory Activities (MedDRA) to encode diseases, symptoms, signs, and so forth. In Argus Safety, the usage of such a dictionary provides consistency to the assignment of terms for adverse events.



1. Select Utilities --> MedDRA Browser.
2. The system opens the **MedDRA Browser** screen.

MedDRA J Browser

For all Japanese cases, use the MedDRA J to code all medical terms. The following is an illustration of the MedDRA J browser.



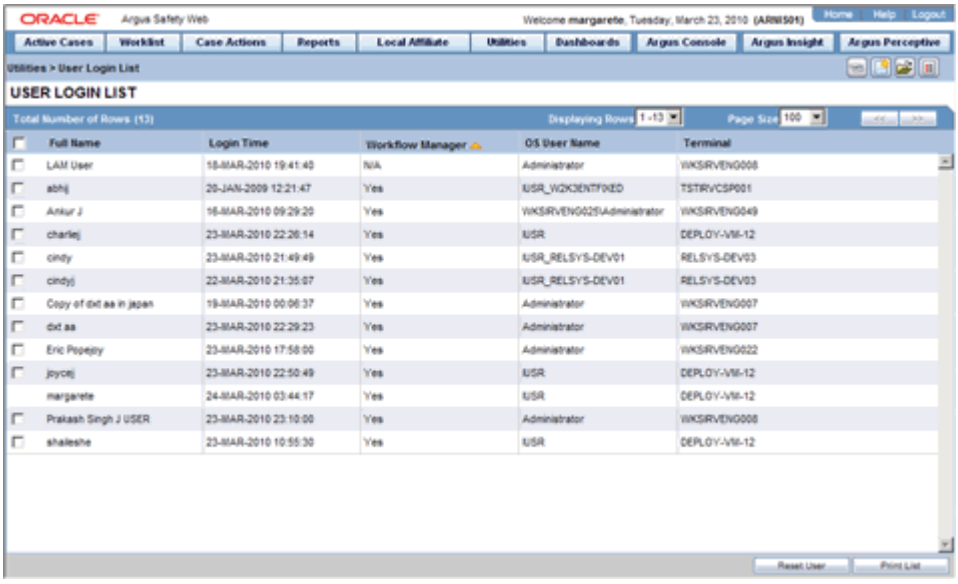
When using the MedDRA browser, be aware of the following:

- The system requires both MedDRA and MedDRA J data files to be loaded in the database.
- The application supports both MedDRA and MedDRA J, but only one can be active at a time.
- If you encode a MedDRA J term in Japanese, the system also encodes the equivalent MedDRA term. and put it in the English MedDRA data field with the corresponding LLT code.
- When you code MedDRA/MedDRA J terms, the coded terms could be non-current in the other language. The system identifies such terms with a special symbol as shown in the following illustration.

- After you perform the first coding, you can change the LLT coding in the same PT level only for that language without synchronizing the alternate language MedDRA coding.
- Changing the PT level or above from the MedDRA J browser updates MedDRA MedDRA. Changing the PT level or above from MedDRA updates the MedDRA J coding.

User Login List

The **User Login List** displays a list of all the current users and their security levels. It also displays a list of all the currently logged in users. The following is an illustration of the **User Login List**.



To view the User Login List

1. Select Utilities --> User Login List.
2. The system opens the **User Login List** screen.

General Usage Information

When using the **User Log List**, be aware of the following:

- You can click a column heading to sort the displayed records.
- By default, the system displays the **User Login List** in ascending order based on **Login Time**.

The following table lists and describes the fields on the **User Login List**.

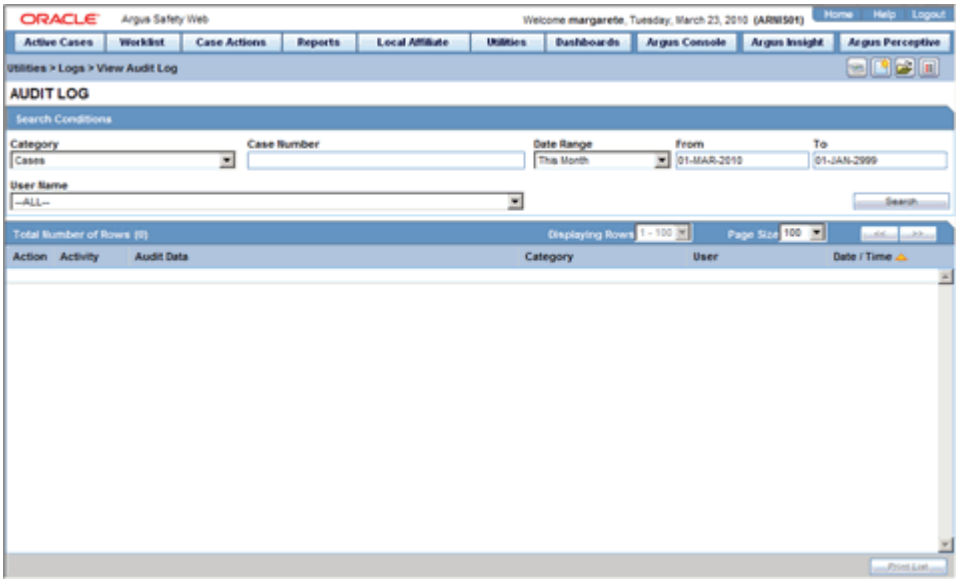
Field	Description
Full Name	Displays the full name of the user.
Login Time	Displays the login time.
Workflow Manager	Displays whether the user is a workflow manager or not.
OS User Name	Displays the Operating System user name.
Terminal	Displays the name of the terminal.
Print List	Allows you to print the user login list.

- You can configure the number of cases to display from the **Page Size** drop-down list in the **User Login List** dialog box. The **Page Size** drop-down list contains the following values:
  - 50
  - 100 (default)
  - 250
  - 500
  - 1000
  - 2000
- The system displays the number of cases currently in view and automatically updates the range as defined by the **Page Size** drop-down list. For example, if the user selects 100, the system separates the rows to display into groups of 100 cases.
- You can go directly to a range of cases by selecting a range from the **Displaying Rows** drop-down list.
- You can scroll through the **User Login List** search results in page-by-page increments.
- You can select multiple users or click the **All** users check box in the header.
- When you select a user and click **Reset User**, the system resets **all** selected users in the list.
- The system **does not** permit you to reset your login.

Logs

Logs are a repository of all the cases in the database, displaying the Activity, Audit Data, User ID, and Date/Time entries. Three (3) types of logs are available in Argus:

- View Audit Log
- LAM Audit Log
- View Error Log



To view a log

1. Select Utilities --> Logs --> <*Log Type*> to view a log.
2. The system open the selected log type.

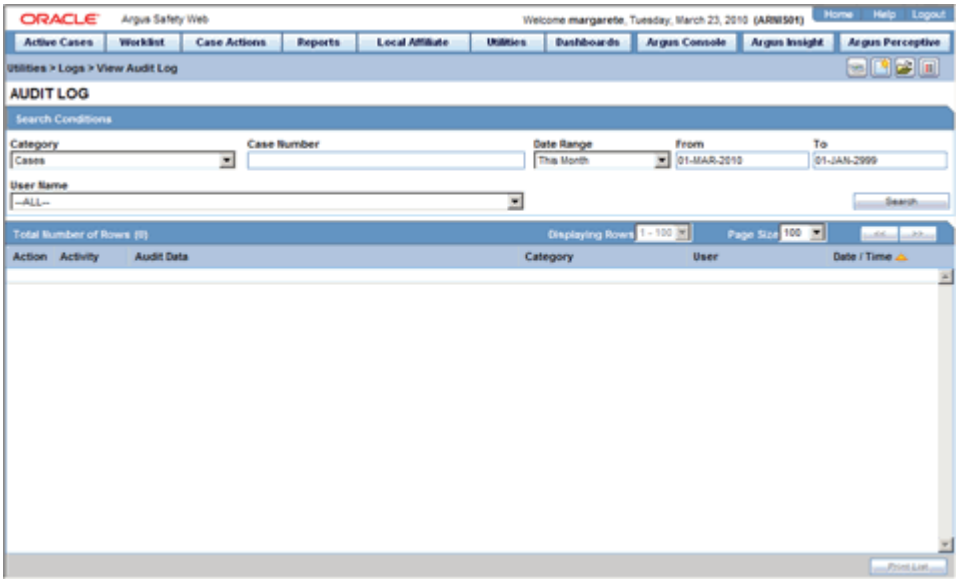
View Audit Log

The audit log is a chart that show modifications that have been made to a particular case since the case's inception.

It also shows which user made the changes, the date and time the changes were made, and the old and new field values. Run the AG Service Audit Log update to audit log all the cases.

To view an Audit Log

1. Select Utilities --> Logs --> View Audit Log.
2. The system opens the **Audit Log** screen.



Search Conditions Section

The **Search Conditions** section enables you to enter information about the logs you want to view.

The following table lists and describes the fields in the **Search Conditions** section.

Field	Description
Category	Select the category for the search criterion. **Tip:** You can also search for Advanced Conditions in this Application release. The system enables you to Select All to view all updates performed by a user. You can select a category and filter on a specific field elements, and you can view all revisions at the same time by clicking the checkbox near the Revisions column.
Case Number	Enables you to search for logs for a specific case number
Date Range	Select the date range from the given drop-down list. This selection automatically populates the **From** and **To** fields.
From	Enter the initial date of the time period to be searched.
To	Enter the end date of the time period to be searched.
User Name	Select the User Name for the search.
Search button	Displays the results of the specified search criteria.

Total Number of Rows Section

The system displays the search results in the **Total Number of Rows** section.

The following table lists and describes the fields in the **Total Number of Rows** section.

Field	Description
Action	Displays the **Audit Log Details** screen
Activity	Displays the status of the activity. Displays whether it has changed or not.

Field	Description
Audit Data	Displays the audit data in the following format: Name of the entity (such as Advanced Condition): deleted or changed (as applicable) in entity (such as Advanced Condition)
User	Displays the last user who made changes to the case.
Date/Time	Displays the last time the case was changed. **Note:** The time displayed is as per GMT.
Print List button	Prints the list of all the logs.

Audit Log Details Screen

The Audit Log functionality tracks all central coding activities for the code-able event and products.

Audit log for the case has the record of the central coding related changes. These changes display the Username as the associated Central Coding Username concatenated with **Central Coding**.

Multiple selections can be made to view the details of revisions.

To view the Audit Log Details screen

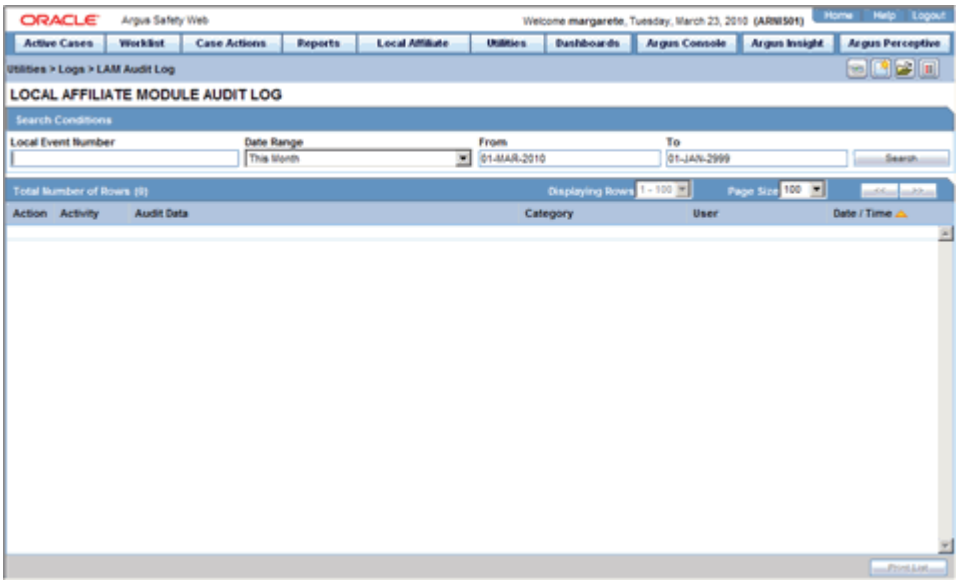
1. Click the **Action** icon to view the **Audit Log Details** screen.
2. 2. Click a row displaying a revision to display the details in the upper portion of the screen.

The following table describes the fields in the **Audit Log Details** screen.

Field	Description
Total Number of Rows	Displays the total number of rows in the list.
Parent	Displays the parent screen where the change has been made.
Field	Displays the field where the change has been made.
Old Value	Displays the previous value.
New Value	Displays the new, changed value.
Rev	Displays the revision number. The list is sorted in descending order of the revisions that have been made so the latest revision is displayed at the top.
User Name	Displays the name of the last user who made a change.
Revisions Date	Displays the last date when the change was made.
User	Displays the name of the user who last made the revision.

LAM Audit Log

The **LAM Audit Log** enables you to track changes made while using the LAM module.



To view the LAM Audit Log

1. Select Utilities --> Logs --> LAM Audit Log.
2. The system opens the **LAM Audit Log** screen.

General Usage Information

- When using the **Argus Safety Audit Log**, be aware of the following:
- In the **Argus Audit Log Options**, **Category** has an **<ALL>** option that enables viewing of all updates made by a user.
- If you select **All**, you must select the appropriate **User Name** from the drop-down to enable the **Search** button. The system updates the default **User Name** to the name of the user who is logged in.
- The system identifies the category on the UI.
- The print list displays the **Category**.
- The system updates the element field label based on the category selected by the user. If you **do not** enter an element value, the system returns the audit details as is does in the current system.
- You can view **All** revisions at the same time by selecting the check box near the revisions column. This system displays the entire audit trail for the elements.

Using the Argus Affiliate Audit Log When using the **Argus Affiliate Audit Log** be aware of the following:

- You can filter for a specific Affiliate event in the audit log.
- You can view **all** revisions at the same time by selecting the check box near the revisions column. The system displays the entire Audit trail for the elements.
- You can view **all** LAM user updates made for Argus Safety cases under the **LAM Audit Trial**. For example, the action Items which can be closed or local labeling performed by a Affiliate user is visible under the LAM audit trail.
- Central User updates **do not** display under the LAM audit trail.

- Any user who has access to **LAM Audit Log** can view **All** cases associated with that site.
- The audit trail detail print includes **only** the revisions the selected by the user.

Search Conditions The **Search Conditions** section enables you to enter information for retrieving the audit logs you want to view.

The following table lists and describes the fields in the **Search Conditions** sections.

Field	Description
Local Event Number	Enter the appropriate local event number.
From	Enter the initial date of the time period to be searched.
To	Enter the end date of the time period to be searched.
Search button	Displays the results of the specified search criteria.

Total Number of Rows The system puts the search results in the **Total Number of Rows** section.

The following table lists and describes the fields in this section.

Field	Description
Action	Displays the **Audit Log Details** screen.
Activity	Displays the status of the activity. Displays whether it has changed or has been added.
Audit Data	Displays the audit data.
Category	Displays the category data.
User	Displays the last user who made changes to the case.
Date/Time	Displays the last time the case was changed. **Note:** The time displayed is as per GMT.
Print List button	Prints the list of all the logs.

Audit Log Details The Audit Log functionality tracks all central coding activities for the code-able event and products.

Audit log for the case has the record of the central coding related changes. These changes display the Username as the associated Central Coding Username concatenated with **Central Coding**.

Multiple selections can be made to view the details of revisions.

To view the Audit Log Details screen

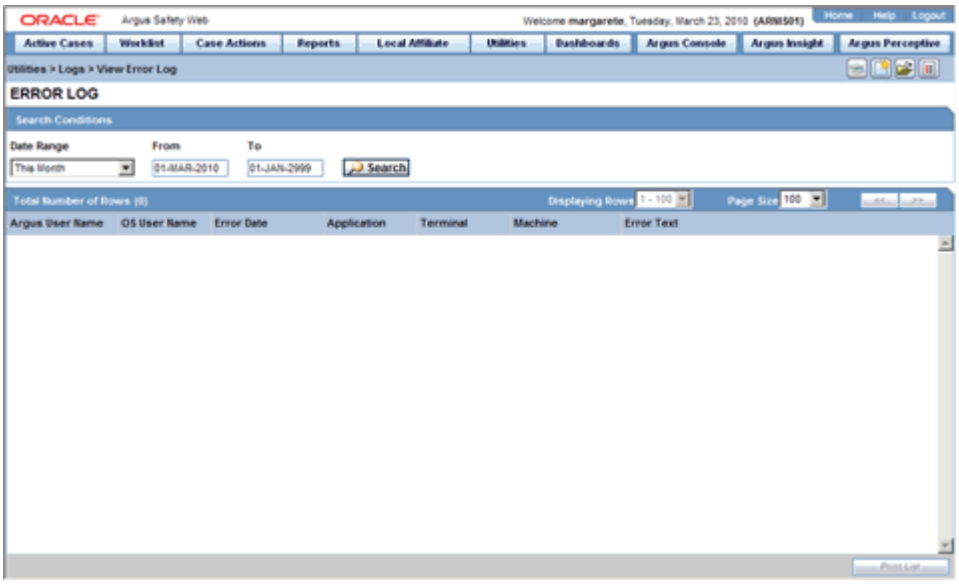
1. Click the **Action** icon to view the **Audit Log Details** screen.
2. Click a row displaying a revision to display the details in the upper portion of the screen.

The following table describes the fields in the **Audit Log Details** screen.

Field	Description
Total Number of Rows	Displays the total number of rows in the list.
Parent	Displays the parent screen where the change has been made.
Field	Displays the field where the change has been made.
Old Value	Displays the previous value.
New Value	Displays the new, changed value.
Rev	Displays the revision number. The list is sorted in descending order of the revisions that have been made so the latest revision is displayed at the top.
User Name	Displays the name of the last user who made a change.
Revisions Date	Displays the last date when the change was made.
User	Displays the name of the user who last made the revision.

Error Log

The **Error Log** screen provides information about errors that occurred during case processing.



To view the error log

1. Select Utilities --> Logs --> View Error Log.
2. The system opens the **Error Log** screen.
3. In the **Search Conditions** section, enter or select a date range and click **Search**.
4. The system displays the search results in the **Total Number of Rows** section.
5. Locate the error log you want to view and click to view the error message text.

Search Conditions Section

The **Search Conditions** section enables you to search for error logs based on pre-defined or custom date ranges.

The following table lists and describes the fields in the **Search Conditions** section.

Field	Description
Date Range	Select the date range from the given drop-down list. This selection automatically populates the **From** and **To** fields.
From	Enter the initial date of the time period to be searched.
To	Enter the end date of the time period to be searched.
Search button	Displays the results of the specified search criteria.

Total Number of Rows Section

Total Number of Rows

The system retrieves the error logs for the specified date range and places the results in the **Total Number of Rows** section.

The following table lists and describes the fields in the **Total Number of Rows** section.

Field	Description
Total Number of Rows	Displays the total number of rows in the list.
Argus User Name	Displays the Argus User Name of the user who got the error.
OS User Name	Displays the OS User Name of the user who got the error.
Error Date	Displays the date and time of the error.
Application	Displays the name of the application where the error occurred.
Terminal	Displays the name of the terminal where the error occurred.
Machine	Displays the name of the machine where the error occurred.
Error Text	Displays the text of the error. **Note:** click the Zoom icon to view the complete text.
Print List button	Prints the list of all the errors.

E2B Screens

The purpose of the **E2B Transmit Status** and **E2B Receive Status** screens is to monitor the incoming and outgoing messages and acknowledgments. E2B screens are categorized as:

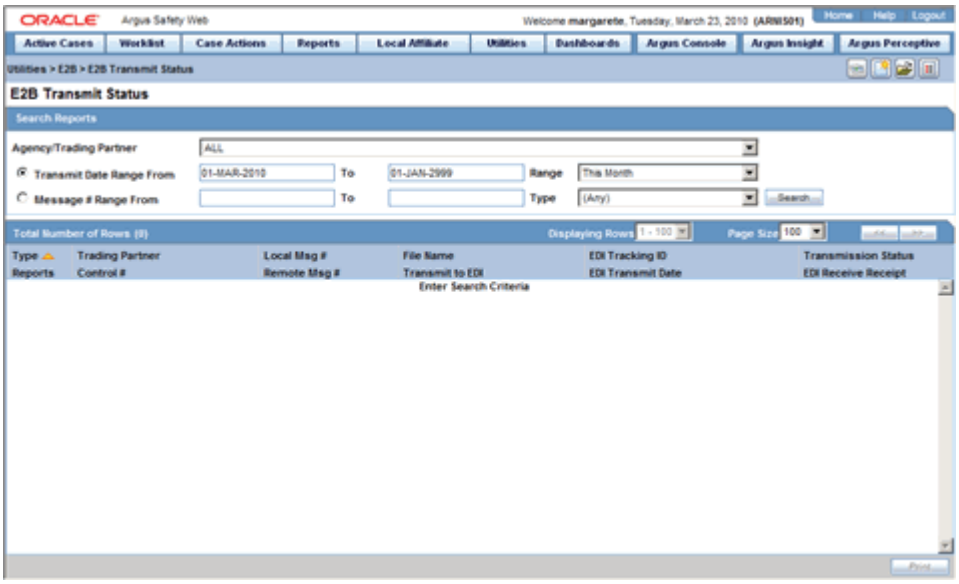
- E2B Transmit
- E2B Receive Status

To view the E2B screens

1. Select Utilities --> E2B --> *<E2B Category>*.
2. The system opens the appropriate **E2B** screen.

E2B Transmit Status Screen

The **E2B Transmit Status** screen enables you to track outgoing messages. The following is an illustration of the **E2B Transmit Status** screen:



To view E2B transmit status data

1. Select Utilities --> E2B --> E2B Transmit Status.
2. When the system opens the **E2B Transmit Status** screen:
   - Enter the appropriate search criteria in the **Search Reports** section.
   - Click **Search** to display the search results in the **Total Number of Rows** section.

Search Reports The **Search Reports** section enables you to enter information for retrieving transmission information.

The following table lists and describes the fields in the **Search Reports** section.

Field	Description
Agency/Trading Partner	Select the agency/trading partner as the receiver from this list.
Search button	Displays all the E2b messages and acknowledgments only for the specified receiver. **Note:** If 'Any' is selected as the Agency, the search results display all messages and acknowledgements for all receivers.
Transmit Date Range	Select this radio button to specify the date range for all transmissions.
From	Enter the initial date of the specified period
To	Enter the end date of the specified period.
Message # Range	Select this radio button to specify the date range for all messages.
From	Enter the initial date of the specified period.
To	Enter the end date of the specified period.
Range	Select the desired range from the list.
Type	Select the desired type from the list.

Total Number of Rows The system displays the search results in the **Total Number of Rows** section as shown in the following illustration.

The following table lists and describes the fields in this section.

Field	Description
Total Number of Rows	Displays the total number of rows that displayed in the list, as shown in the parenthesis.
Type	Allows the user to view the type of entity transmitted. Click the Details icon to view the attachment as a PDF.
Reports	Allows the user to view the number of attachments transmitted.
Trading Partner	Allows the user to view the Reporting Destination to which the attachment is transmitted.
Control #	This field is left blank for attachment transmission only.
Local Msg#	Displays the local message number.
Remote Msg#	Displays the remote message number.
File Name	Allows the user to view the filename transmitted by EDI Gateway.
Transmit to EDI	Allows the user to view the date and time when the attachment was transmitted to the EDI Gateway.
EDI Tracking ID	Allows the user to view the EDI Tracking ID.
EDI Transmit Date	Allows the user to view the EDI Transmit Date and Time from the gateway.
Transmission Status	Allows the user to view the Transmission Status of the attachment file transmitted from EDI Gateway such as Failure / Success / Pending.
EDI Receive Receipt	Allows the user to view the date and time of the EDI MDN Acknowledgement date.
Print button	Prints the list.

Type Icon Options Click the **Type** icon to view these options:

- Any - Displays all the E2B messages and acknowledgments
- MSG - Double-click on MSG to view messages in the E2B Viewer.
- ACK - Double-click on ACK to view the acknowledgement.

When you click these options, the system opens the **Message Acknowledgement** screen shown in the following illustration. This screen contains all the safety report detail information such as, if the report is loaded or not loaded with error and enables you to monitor message acknowledgements.

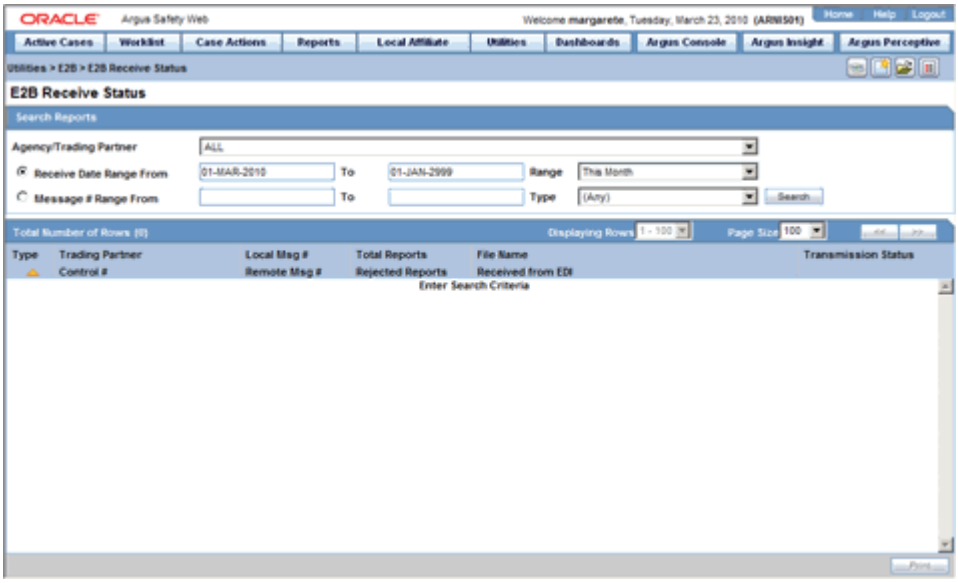
The following table lists and describes the fields in the **Message Acknowledgement Status** dialog box.

Field	Description
ICSR Message Number	Displays the ICSR Message Number.
ICSR Message Receiver ID	Displays the ICSR Message Receiver ID.
ICSR Message Sender ID	Displays the ICSR Message Sender ID.
Sender Acknowledgement Message #	Displays the acknowledgement message number of the sender.

Field	Description
ICSR Message Date	Displays the ICSR Message Date.
Acknowledgement Message Initiated On	Displays when the acknowledgement was initiated.
Transmission Acknowledgement Code	Displays the Transmission Acknowledgement Code.
Case #	Displays the Case #.
Message	Displays the message.
Authority #	Displays the Authority #.
Local Case #	Displays the Local Case #.
Other #	Displays the Other #.
Report Status	Displays the Report Status.
E2B Report Type	Displays the type of the E2B Report.

E2B Receive Status

The **E2B Receive Status** screen enables you to monitor incoming E2B messages. The following is an illustration of the **E2B Receive Status** screen:



Search Reports The **Search Reports** section enables you to search for received messages.

The following table lists and describes the fields in the **Search Reports** section.

Field	Description
Agency/Trading Partner	Select the agency/trading partner as the receiver from this list.
Receive Date Range	Select this radio button to specify the date range for all transmissions.
From	Enter the initial date of the specified period.
To	Enter the end date of the specified period.

Field	Description
Range	Select a predefined date range from the drop-down list.
Message # Range	Select this radio button to specify the date range for all messages.
From	Enter the initial date of the specified period.
To	Enter the end date of the specified period.
Type	Select the desired message type from the list.
Search	Initiates the search and displays all the E2b messages and acknowledgments only for the specified receiver. **Note:** If 'Any' is selected as the Agency, the search results display all messages and acknowledgements for all receivers.

Total Number of Rows The **Total Number of Rows** section contains the search results.

The following table lists and describes the columns

Field	Description
Total Number of Rows	Displays the total number of rows that displayed in the list, as shown in the parenthesis.
Type	Displays the Type icon containing options.
Trading Partner	Displays the name of the trading partner.
Control #	Displays the control number.
Local Msg#	Displays the local message number.
Remote Msg#	Displays the remote message number.
Total Reports	Displays the total number of reports.
Rejected Reports	Displays the number of rejected reports.
File Name	Displays the file name.
Receive from EDI	Displays the messages received from EDI.
Transmission Status	Displays the Transmission Status.
Print	Enables you to print the list.

Type Icon Options Click the **Type** icon to view these options:

- Any - Displays all the E2B messages and acknowledgments
- MSG - Double-click on MSG to view messages in the E2B Viewer.
- ACK - Double-click on ACK to view the acknowledgement.

When you click these options, the system opens the **Message Acknowledgement** screen. This screen contains all the safety report detail information such as, if the report is loaded or not loaded with error and enables you to monitor message acknowledgements.

The following table lists and describes the fields in the **Message Acknowledgement Status** dialog box.

Field	Description
ICSR Message Number	Displays the ICSR Message Number.

Field	Description
ICSR Message Receiver ID	Displays the ICSR Message Receiver ID.
ICSR Message Sender ID	Displays the ICSR Message Sender ID.
Sender Acknowledgement Message #	Displays the acknowledgement message number of the sender.
ICSR Message Date	Displays the ICSR Message Date.
Acknowledgement Message Initiated On	Displays when the acknowledgement was initiated.
Transmission Acknowledgement Code	Displays the Transmission Acknowledgement Code.
Case #	Displays the Case #.
Message	Displays the message.
Authority #	Displays the Authority #.
Local Case #	Displays the Local Case #.
Other #	Displays the Other #.
Report Status	Displays the Report Status.
E2B Report Type	Displays the type of the E2B Report.

Argus Reconciliation

The Argus Safety Reconciliation module enables you to configure and edit/reconcile records as per requirements.

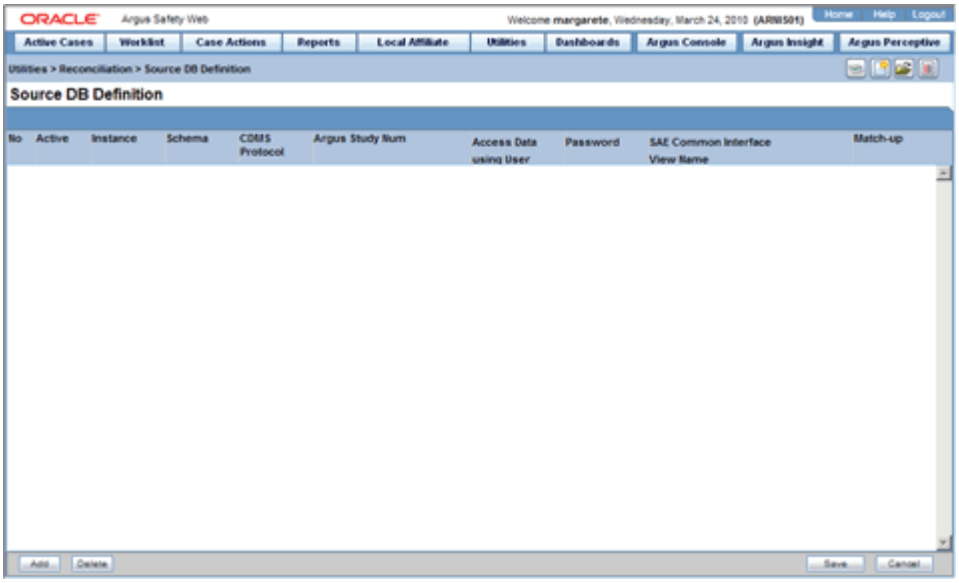
Select **Reconciliation** from the **Utilities** menu to view the options available under Argus Reconciliation.

Source Database Definition

This **Source DB Definition** screen enables you to define the mapping of the Reconciliation databases to the Common Interface of the CDMS.

To open the Source DB Definition screen

1. Select Utilities --> Reconciliation --> Source DB Definition.
2. The system displays the **Source DB Definition** screen.



The following table lists and describes the tables on the **Source DB Definition** screen.

Field	Purpose
No	Displays the serial number of the row
Active	Enables you to include the reconciliation source in the next reconciliation run
Instance	Displays the name of the instance
Schema	Displays the name of the database schema
CDMS Protocol	Displays the CDMS Protocol
Argus Study Num	Enables you to select a study from the Study Lookup dialog
Access Data using User	Displays the username used to access the data
Password	Displays the password used to access the data
SAE Common Interface View Name	Enables you to specify the view name to be accessed that returns the expected reconciliation fields
Match-up	Enables you to configure a match-up

Editing Source Database Definition Use the following procedure to edit the source database definition.

To edit the source database definition

1. Click the **Active** check box, as required.
2. Click **Select** in **Argus Study Num** to configure a study that has been set up in Argus Safety.
3. Click Select on the Source DB Definition screen.
4. When the system opens the **Clinical Trial Selection** dialog box:
   - Enter the appropriate study information (i.e., Project, Study, Center) and click **Search**.

Tip: Enter specific search criteria to refine the search results.

- When the system displays the search results in the **Total Number of Rows** section, locate and click the row containing the study information to be configured.
- Click **Select** to configure the selected information.

5. Click Select in **SAE Common Interface View Name** to configure a view name to be accessed that will return the expected reconciliation fields.
6. When the system opens the **Reconciliation Database Connection** dialog, modify the database connection details as appropriate and click **OK.**

Reconciliation Database Connection Fields and Field Descriptions The following table lists and describes the fields in the **Reconciliation Database Connection** dialog box.

Field	Description
Database	Enables you to enter the Database Name for fetching the data for the view.
View Schema Owner Name	Enables you to enter the Schema Owner Name.
View Schema Owner Password	Enables you to enter the Schema Owner Name password for connection to the database.
Connect to CDMS Database	Enables you to check if connection is successful or parameters entered are incorrect.
Create New View	Enables you to create a new view for the Database and the corresponding Schema Owner.
Use Existing View	Enables you to select an existing view from the Database and the corresponding Schema Owner.
CDMS View Definition	Enables you to enter SQL statement for the view definition.
Create Public Synonym for View	Enables you to create a Public Synonym for the CDMS View in the CDMS Database.
Grant "SELECT" on View to User / Role	Enables you to grant "Select" permission to the specified User and Role for the CDMS View in the Schema Owner.
Create/Update View	Enables you to create or update the View in the Schema Owner.
Drop View and Public Synonym	Enables you to drop the View and Public Synonyms in the Schema Owner after Creating / Updating / Deletion of the View.
OK	Enables you to return back to the **Reconciliation Sources Database Definition** dialog.

- 7. Click Select in **Match-up** to configure a match-up behavior per study.
- 8. When the system opens the **Reconciliation Match-up Configuration** dialog box:
  - Select an **Argus Tab** as required, from the **Argus Tab** drop-down list for the corresponding **Reconciliation Field**.
  - Select an Argus field as required, from the **Argus Field** drop-down list for the corresponding **Reconciliation Field**.
  - Click the **Only Reconcile if present in CDMS** checkbox to reconcile a field, only if it is also present in CDMS.

– d. Click **OK** to save the changes made to the section.

Sample SQL for Creating Views The following is sample SQL code to use when creating views.

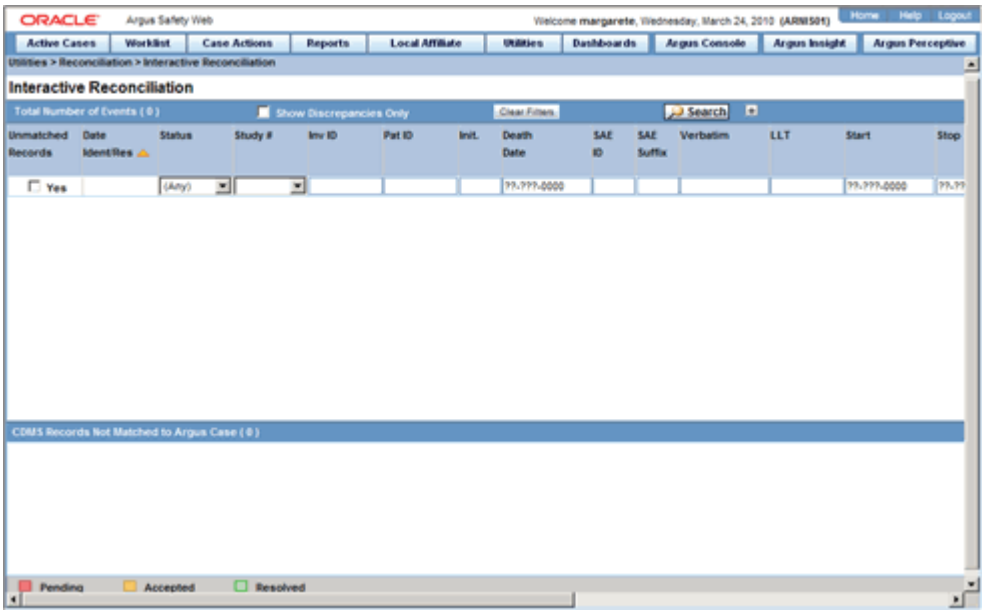
```
create or replace view RECON_STUDY_A as
SELECT ct_recid, saeid1, saeid2, saeid3, saeid4, saeid5, saesuffix1, saesuffix2,
saesuffix3, saesuffix4, saesuffix5, tracknum, firstaetrack, subpage,
study, pid, ptinit, treatnone, treatdrug, treatnondrug, ae, llt_code,
aestartdd, aestartmm, aestartyy, aestopdd, aestopmm, aestopyy, deathdd,
deathmm, deathyy, severity, appraisala, appraisalb, appraisalc,appraisald,appraisale,
outcome, entry_datetime
FROM A.ae_all
WHERE NVL (status, -1) IN (0, 1)
```

Interactive Reconciliation

This **Interactive Reconciliation** screen enables you to view and configure an interactive reconciliation report.

To open the Interactive Reconciliation screen

1. Select Utilities --> Reconciliation --> Interactive Reconciliation.
2. The system opens the **Interactive Reconciliation** screen.



Interactive Reconciliation Screen Fields and Field Descriptions

The following table lists and describes the fields on the **Interactive Reconciliation** screen.

Field	Purpose
Show Discrepancies Only	Displays only those reconciliation records that contain discrepancies.
Unmatched Records	Displays only unmatched Argus and CDMS records.
Date Ident/Res	Displays the date of resolution.
Status	Displays the status of the record.
Study #	Enables you to select the study number of the record. **Note:** It is mandatory to select a **Study #** to perform a search. The default value is the first study in the list.
Inv ID	Displays the Investigator (Reporter) ID of the record.
Pat ID	Displays the Patient ID of the record.
Init.	Displays the event initials.
Death Date	Displays the event death date in the record.
SAE ID	Displays the SAE ID of the record.
SAE ID Suffix	Displays the SAE ID Suffix of the record.
Verbatim	Displays the verbatim of the event for the record.
LLT	Displays the LLT for the record.
Start	Displays the event start date for the record.
Stop	Displays the event stop date for the record.
Intensity	Displays the event intensity level of the record.
Treatment	Displays the event status on treatment of the record.
Outcome	Displays the event outcome of the record.
Causality	Displays the event causality status for the record.
Search	Enables you to search for cases that match the specified filter criteria.
Print List	Prints the displayed list as a PDF.

Editing Interactive Reconciliation Reports

The **Interactive Reconciliation Report** screen enables you to edit and configure interactive reconciliation reports.

Be aware of the following:

- You can search for records by entering a filter criterion below the header row.
- If multiple filter criteria are specified, only those records that meet all the specified criteria are displayed. For example, select the filter criteria for **Status** as **Approved**, enter **Pat ID** as 1234 and click **Search**.
- Only the record with Patient ID 1234 and Status as Approved, will be displayed in the search results.

> **Tip:** Click **Clear Filters** to remove all the search criteria entered under different headers such as **Unmatched Records**, **Status**, **Study #**, etc.

Applying a Filter Use the following procedure to apply a filter.

To apply a filter

Right-click on any column header to display the filtering criteria.

Filter on Reconciliation Status Filtering Options The following table lists and describes the **Filter on Reconciliation Status** options.

Filtering Option	Purpose
No Discrepancy	Enables you to view only those records that do not have any discrepancy between Argus and CDMS records. This displays the selected filtering criteria in green.
Accepted	Enables you to view only **Accepted** records. The color associated with this filtering criteria is orange.
Pending	Enables you to view only **Pending** records. The color associated with this filtering criteria is red.
(Any)	Enables you to view all records, irrespective of their status. The color associated with this filtering criteria is blue.

Configuring an Interactive Reconciliation Report Use the following procedure to configure an Interactive Reconciliation Report

To configure an Interactive Reconciliation Report

1. In **Unmatched Records**, click the **Yes** check box to filter out any paired records and view only unmatched Argus and CDMS records.
2. Select the **Status** of the record such as **Pending** or **Accepted**, as required.
   - Click any cell within **Pending** records to display the **Reconciliation Options** menu, containing the **Accepted** and **Pending** options.
   - Select **Accept** to accept the discrepancy for the selected field and change the status to **Accepted**.
3. When the system opens the **Justification** dialog:
   - Enter a justification for changing the status in your own words in the **Please enter a justification for performing this action** text box

     OR

     Select a justification from the drop-down list containing pre-defined justifications.
   - Click **Add**.
   - Click **OK**.

     Tip: Alternatively, you can also click the orange/red icon denoting the status of a record to view the Justification dialog.
4. Enter other filter criteria such as **Study #**, **Pat ID**, **SAE ID**, etc., as required.
5. Click **Search**.
6. The results matching the specified filter criteria are displayed in **Total Number of Rows**.

Manually Matching Unmatched Records Unmatched records are CDMS records that do not match with Argus cases. These records are listed in the **CDMS Records Not Matched to Argus Case** section.

To manually match unmatched records

1. Select the record to be matched from the **CDMS Records Not Matched to Argus Cases** section.
2. Select **Attach** to the desired Argus record.
3. The system matches the record to Argus.

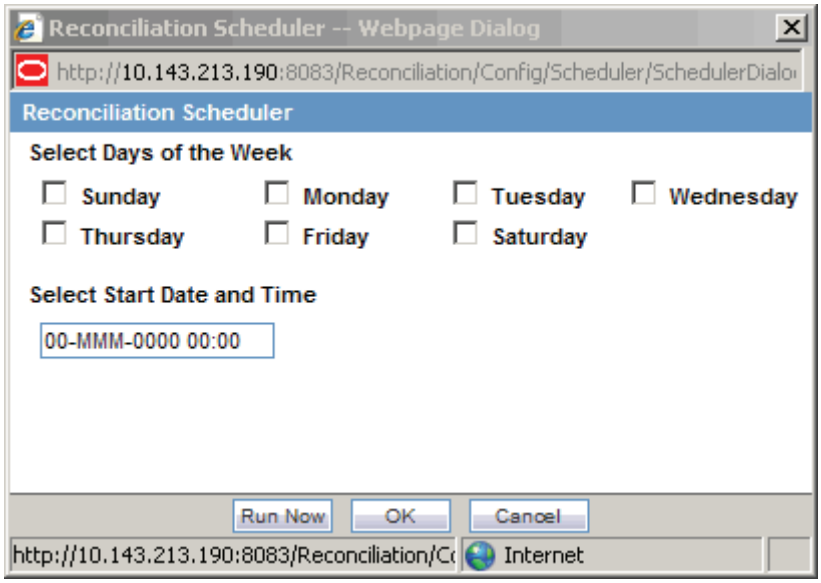
> **Note:** The icon in the **Status** column of a record denotes that it has been matched manually.

Reconciliation Scheduling

Reconciliation Scheduling enables you to run a reconciliation now or schedule a time for the reconciliation for a later date.

To open the Reconciliation Scheduler dialog box

1. Select Utilities --> Reconciliation --> Reconciliation Scheduling.
2. This displays the **Reconciliation Scheduler** dialog box.



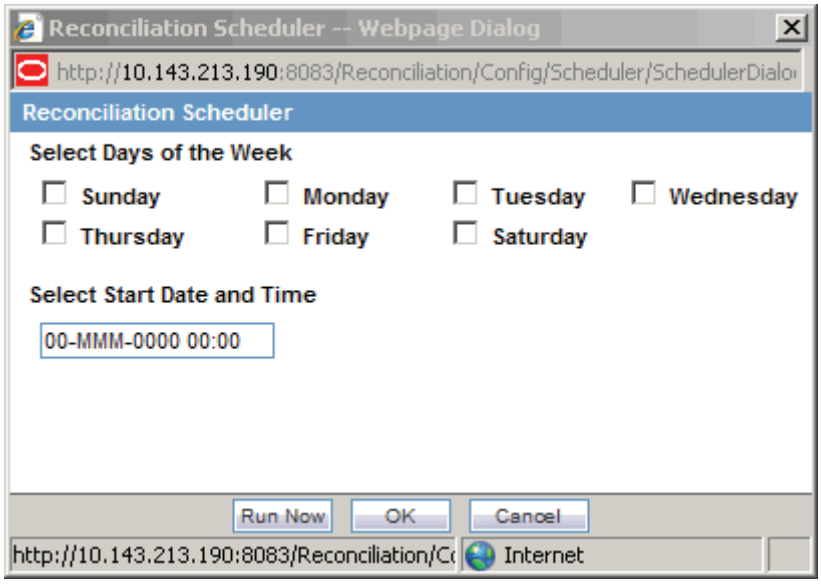
Reconciliation Scheduler Dialog Box Fields and Field Descriptions

The following table lists and describes the fields in the **Reconciliation Scheduler** dialog box.

Field	Purpose
Select Days of the Week	Enables you select the days of the week when the scheduler will run.
Select Start Time	Enables you to specify the time when the scheduler will run.
Run Now	Runs the scheduling as soon as this button is selected.

Editing Reconciliation Scheduling

Editing the reconciliation scheduling from the **Reconciliation Scheduler** dialog box shown in the following illustration.



To edit reconciliation scheduling

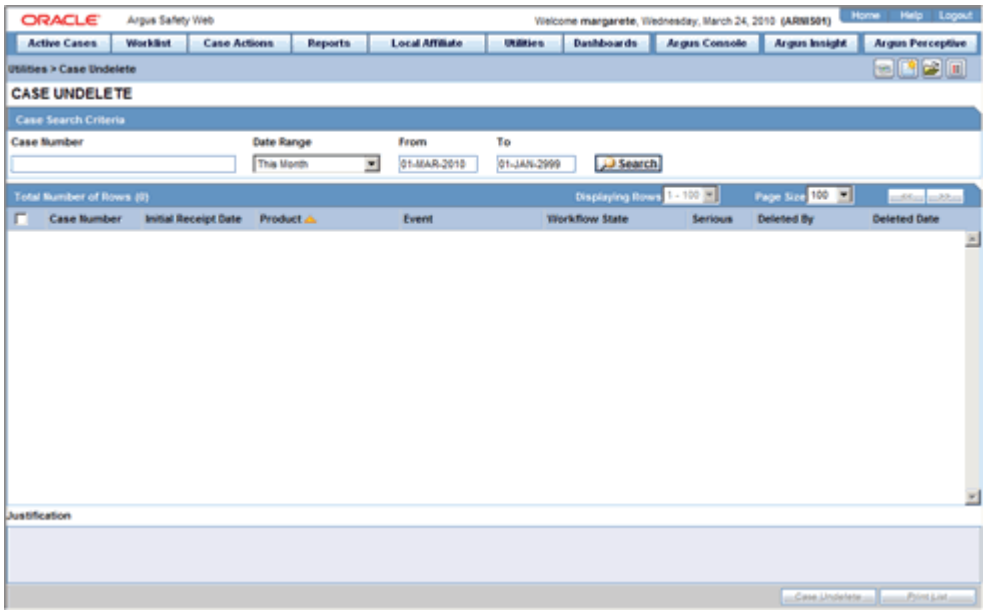
1. Select the days for which the reconciliation is to be scheduled in the **Select Days of the Week** section.
2. Specify the time (hh:mm:ss AM/PM format) for the reconciliation to start in the **Select Start Date and Time** section.
3. Click **OK**.
4. The system schedules the reconciliation for the specified days and time.

Case Undelete

The **Case Undelete** option enables you to restore deleted cases.

To restore deleted cases

1. Select Utilities --> Case Undelete.
2. When the system opens the **Undeleted Cases** screen, enter the appropriate information in the **Case Search Criteria** fields and click **Search**.



Case Search Criteria Fields and Field Descriptions

The **Case Search Criteria** enables you to enter information to help you retrieve deleted cases.

The following table lists and describes the fields in this section.

Field	Description
Case Number	Enables you to enter the number for a specific case.
Date Range	Enables you to select a date range from which cases may be selected. The selection made from the Date Range drop-down list automatically populates the **From** and **To** fields.
From	Displays the initial date of the search period
To	Displays the end date of the search period
Search	Click to display the Search results that match the specified search criteria

1. When the system displays the search results in the **Total Number of Rows** section:
   - Locate the case you want to restore and click the **check box** associated with its case number.
   - Click Case Undelete.

Total Number of Rows Fields and Field Descriptions

The system displays the search results in the **Total Number of Rows** section on the **Case Undelete** screen.

The following table lists and describes the columns in the **Total Number of Rows** Section

Field	Description
Total Number of Rows	Displays the total number of rows in the list
Check Box	Enables you to select the case to restore.
Case Number	Displays the case number of each deleted case.
Initial Receipt Date	Displays the initial receipt date of the case.
Product	Displays the product category that the belongs to.
Event	Displays the event related to the deleted case.
Workflow State	Displays the workflow state of the case.
Serious	Displays if the deleted case was serious or not.
Deleted By	Displays the name of the user who deleted the case.
Deleted Date	Displays when the case was deleted.
Justification	Displays the justification for deleting the case. **Note:** Click the check box corresponding to the case to view the justification for its deletion.
Case Undelete	Displays the Justification dialog box. Enables you to restore the selected case number.
Print List	Prints the current worklist for reference.

1. When the system opens the **Action Justification** dialog box:
   - Enter the justification manually in the Please enter a justification for performing this action field

     OR

     Select a preconfigured justification from the **Select a standard justification for this field** drop-down list.
   - Click **OK**.

General Usage Information

When using **Case Undelete** functions, be aware of the following:

- You can search for a specific case from the **Case Undelete** dialog shown in the following illustration.
- If you enter the **Case Number** to search for a specific case, the following apply:

The system disables the date range fields including **From** and **To**.

If you enter an invalid case number, the system displays the following message:

The Case Number entered is not valid. Please enter a correct Case Number and search again.

- You can configure the number of cases to display in the **Case Undelete** dialog box from the **Page Size** drop-down list.
- The **Page Size** drop-down list contains the following values:
  - 50
  - 100 (default)

  - 250
  - 500
  - 1000
  - 2000
- The system displays the number of cases currently in view and automatically updates the range as defined by the **Page Size** drop-down list. For example, if you select 100, the system separates the rows to display into groups of 100 cases.
- You can go directly to a range of cases by selecting a range from the **Displaying Rows** drop-down list.
- You can scroll through the **Case Undelete** search results in page-by-page increments as defined in the **Page Size** drop-down list.

Action Justification Dialog Box Fields and Field Descriptions

The following table lists and describes the fields in the **Action Justification** dialog box.

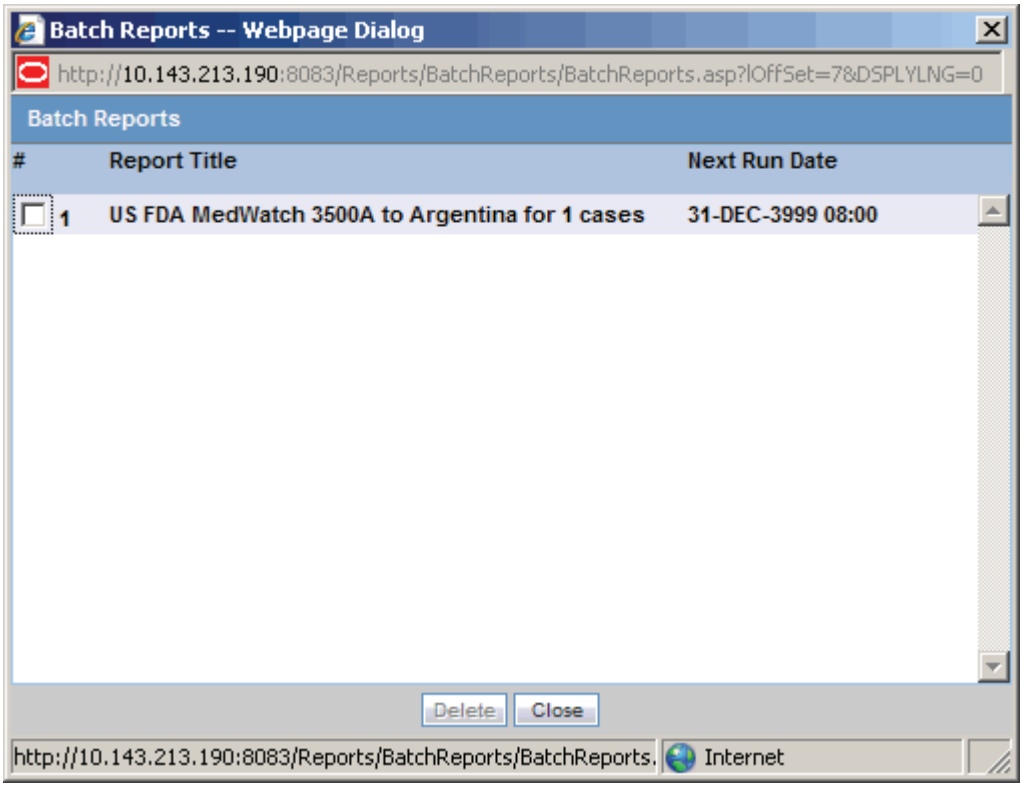
Field	Description
Please enter a justification for performing this action	Enter the text that justifies the need to un-delete a case.
Select a standard justification for this field	Contains standard, pre-configured descriptions of justifications for un-deletion.
Spell Check	Checks the entered/selected text for any grammatical errors.
OK	Saves the justification entered/selected for case un-deletion.
Cancel	Exits out of this dialog without saving any justification.

Batch Reports

The **Batch Reports** dialog displays a list of those batch reports that have been scheduled for generation.

To view a list of batch reports

1. Select **Batch Reports** from **Utilities** in the menu bar.
2. The system opens **Batch Reports** dialog box with a list of batch reports along with their report titles and next run dates.



To delete a batch report from the list

1. Select the check box corresponding to the batch report to delete.
2. Click **Delete**.

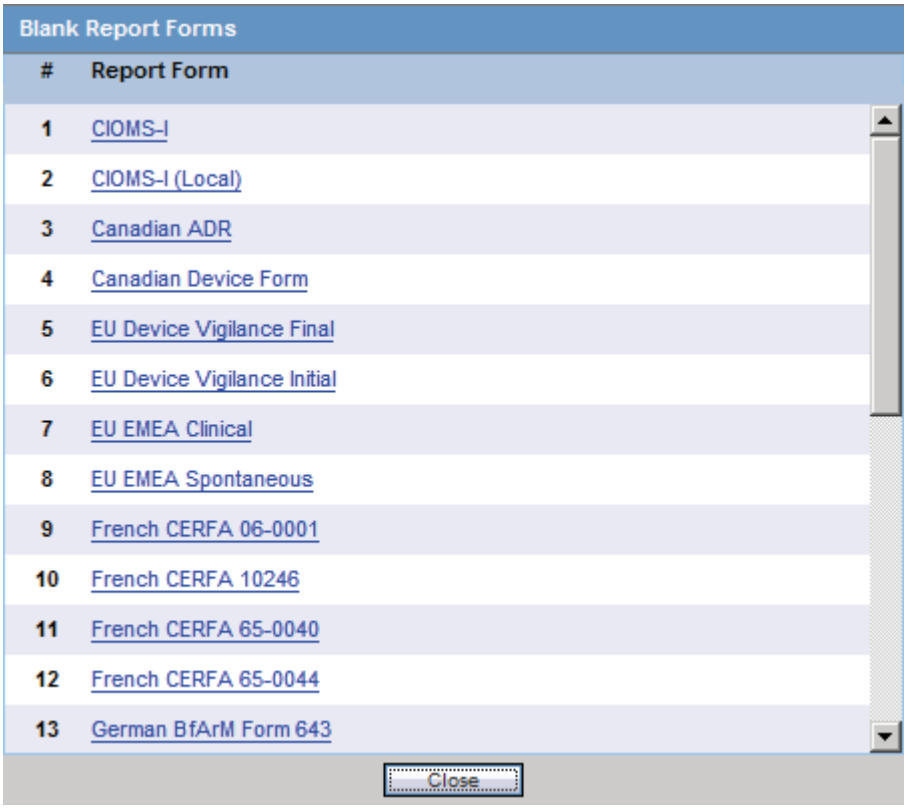
Blank Report Forms

The **Blank Report Forms** screen enables you to view and print blank report forms for the following reports:

- CIOMS-I
- US FDA MedWatch 3500A
- US FDA VAERS
- EU EMEA Clinical
- EU EMEA Spontaneous
- EU Device Vigilance Initial
- EU Device Vigilance Final
- German BfArM Form 643
- German PEI Form 643
- French CERFA
- MCA Clinical
- MCA Spontaneous
- US FDA MedWatch 3500A Drug
- MHLW Spontaneous
- MHLW Clinical
- CERFA 65-0044
- CIOMS-I (Local)
- CERFA 65-0040
- Spanish Clinical
- Spanish Spontaneous
- Canadian Device Form
- Canadian ADR
- Case Form

To view and print blank report forms

1. 1. Select Utilities --> Blank Report Forms.
2. 2. When the system opens the **Blank Report Forms** screen, locate the form you want to view or print and click its **Name**.



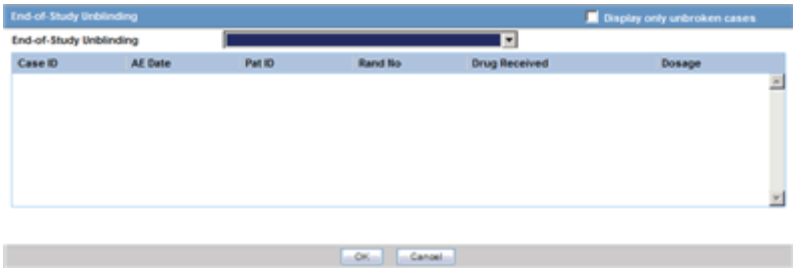
3. 3. The system opens the selected form in PDF format.

End of Study

When a study is complete, use the **End of Study** utility to unblind all the cases associated with the study at the same time instead of unblinding them one by one.

To unblind a study

1. Select Utilities --> End of Study.
2. The system opens the **End of Study Unblinding** dialog box.



End of Study Unblinding Dialog Box Fields and Field Descriptions

The following table lists and describes the fields in the **End of Study Unblinding** dialog box.

Field	Description
Display only Unbroken cases	Enables the user to view only unbroken cases
End of Study Unblinding	Only those studies that are "Eligible for unblinding" (as determined via List Maintenance) are displayed in this list. Select a study from this list. This populates the list of cases based on the study chosen.
Case ID	Displays the ID of each case.
AE Date	Displays the Associated Event Date for the case.
Pat ID	Displays the Patient ID.
Rand No	Displays the Randomization Number of the case.
Drug Received	Displays the name of the drug received.
Dosage	Displays the Select button to view the Dosage Regimens screen.

1. Select the appropriate study from the **End-of-Study Unblinding** drop-down list.
2. When the system displays the selected information, locate the appropriate study and click **Select** in the **End of Study** dialog.
3. When the system opens the **Dosage Regimens** dialog box, enter the drug dosage information as required.
4. Click **OK** to save the changes, update the cases, and close this dialog.

> **Note:** For each case that is unblinded by this method, the Blinding Status is adjusted to "Broken After Study" if the study type is single or double blinded and fills information about the Unblinding Date, Study Drug, Follow-up Received Date, Mark case as Significant, and Dosage Regimen.

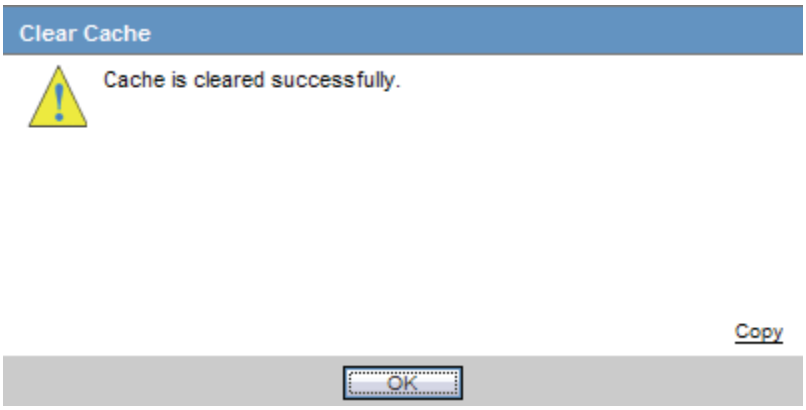
Clear Cache

A cache contains a record of the items you have seen or downloaded from the Web, including images, logs of Web pages, etc. Typically these items are stored in the Temporary Internet Files folder.

Storing these files in your cache can make browsing the Web faster because it usually takes your computer less time to display a Web page when it can call up some of the page's elements or even the entire page from your local Temporary Internet Files folder. If you believe that you have a less than current version of a page, you can clear the cache in your browser to avoid viewing the same page again. Clearing your cache can significantly improve the speed and performance of your browser.

To clear your cache of previously stored information

1. Select Utilities --> Clear Cache.
2. The system clears the cache and displays the following message in the **Clear Cache** dialog box.



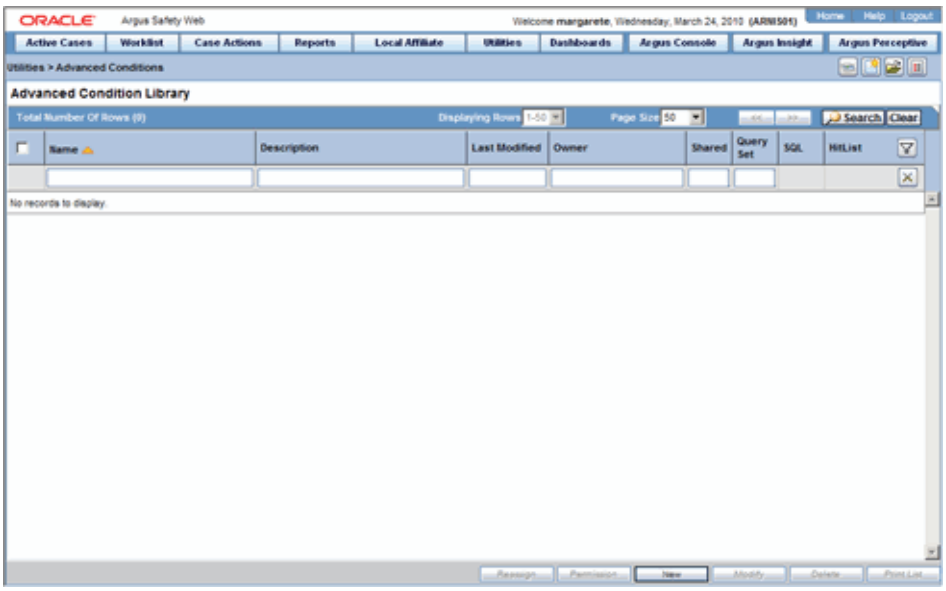
Advanced Condition Library

The **Advanced Condition Library** option enables you to access the advanced condition library and do the following:

- Create a new advanced condition
- Reassign an advanced condition
- Set advanced condition permission levels
- Modify an existing advanced condition
- Delete an advanced condition
- Print a list of advanced conditions

To open the Advanced Condition Library

1. Select Utilities --> Advanced Condition Library.
2. The system opens the **Advanced Condition Library** screen.



For further information about Advanced Conditions, see chapter 6 of this document.

13

About dsNavigator

The **dsNavigator** application interfaces with the centralized MedDRA database for MedDRA coding in the Argus Safety system.

dsNavigator

The centralized coding process is conducted between the following:

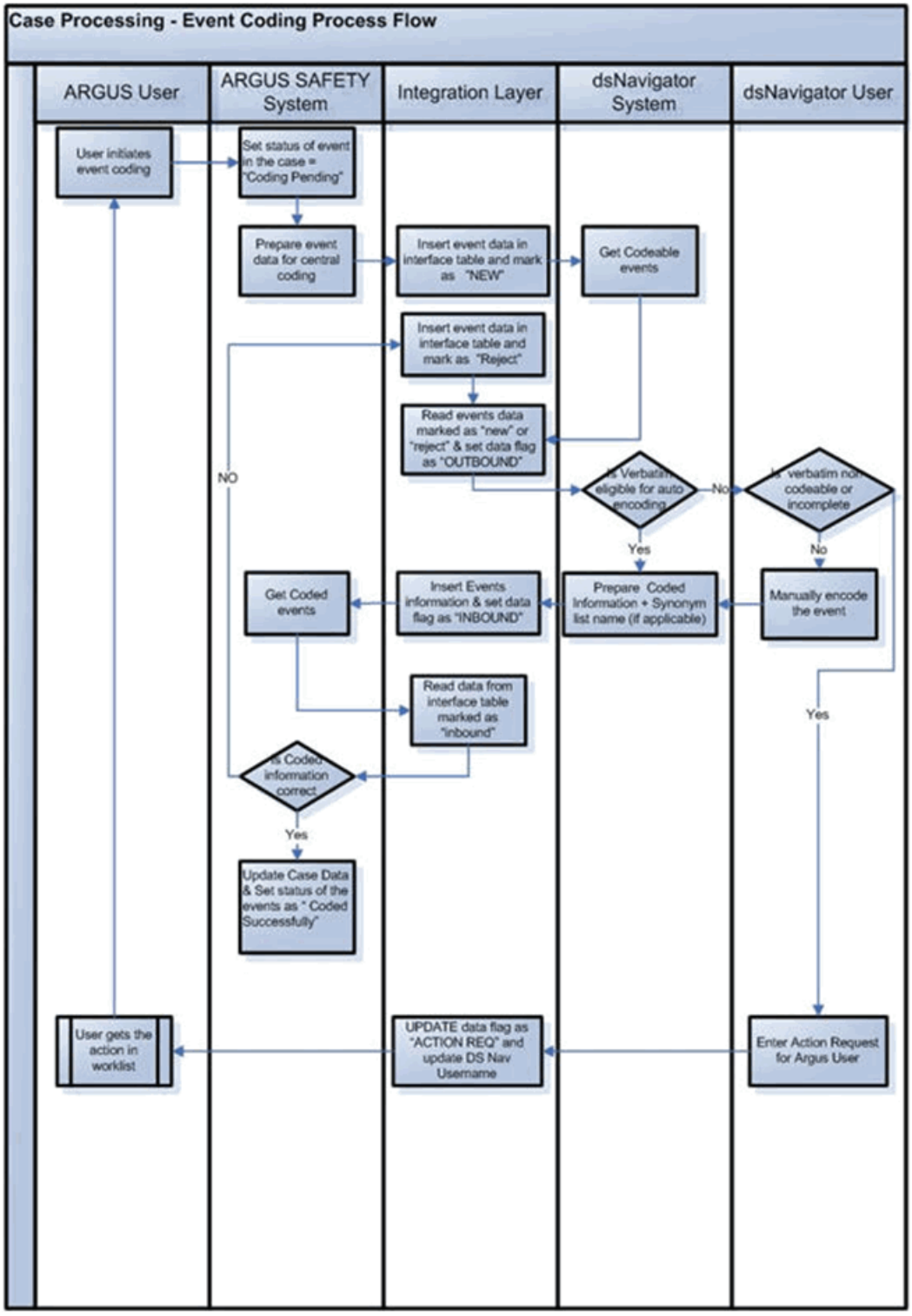
- Argus Safety User
- Argus System
- Coding Integration Layer
- dsNavigator Application
- dsNavigator User

dsNavigator Coding Process

The complete coding process can be divided into several steps.

Case Processing - Event Coding Process Flow

This is the first step of the coding process and is initiated as soon as the need for coding an event is determined.



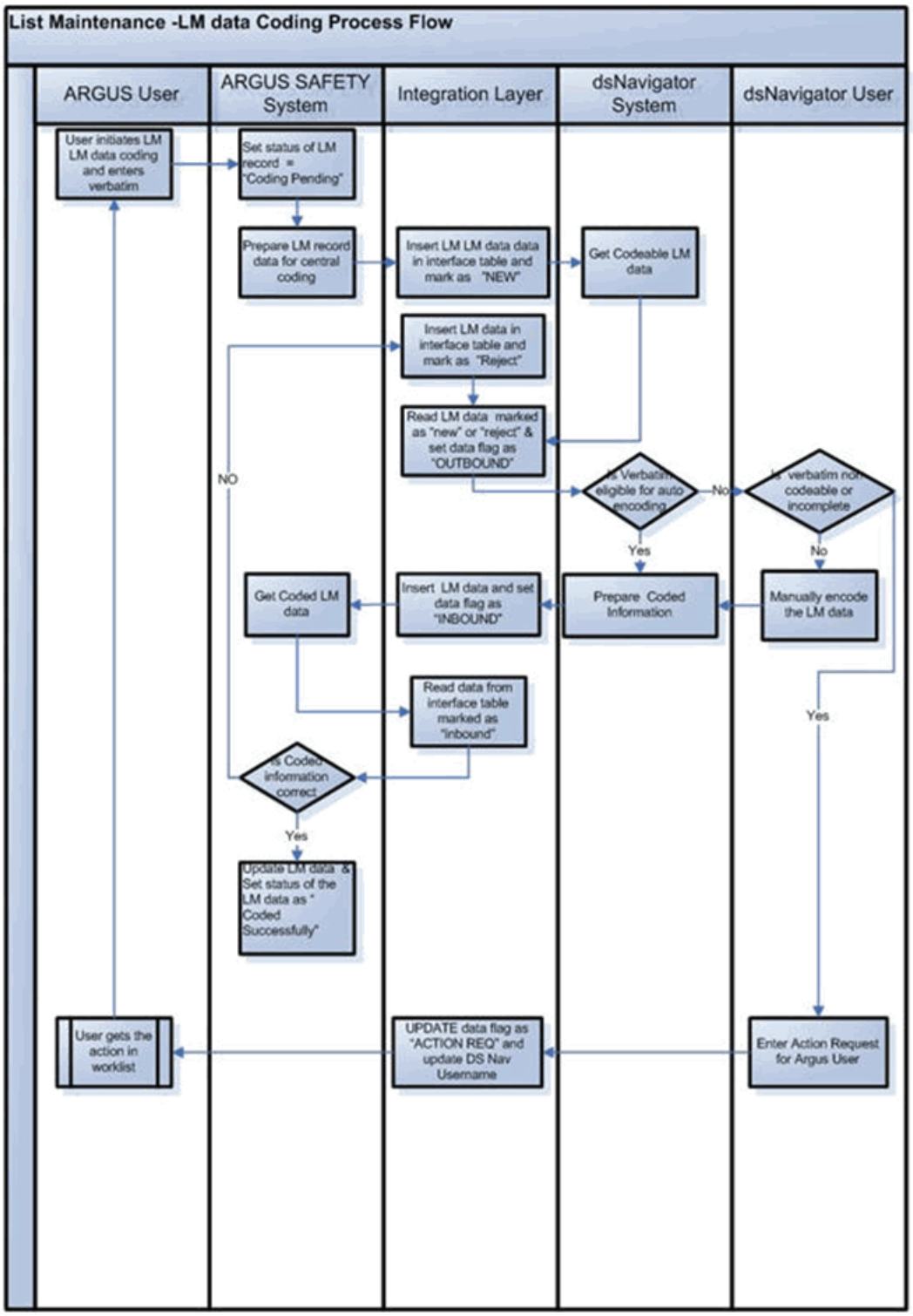
The following event related fields in the case form are eligible for the central coding process:

- Parent Tab - Other Relevant History | Description (Multiple)
- Products Tab - Primary Indications (Multiple)
- Analysis Tab - Company Diagnosis / Syndrome

- Event Tab
  - Description to Reported
  - Description to be Coded
  - Cause of Death (Multiple)
  - Autopsy Results (Multiple)
- Patient Tab
- Other Relevant History - Description (Multiple)
- Lab Test Data (Multiple)

List Maintenance Coding Process Flow

The illustration shows the business process supported by the dsNavigator.



Central Coding Process Management

This process is defined for Argus Safety only. It includes the following:

- Managing Verbatim Modification
- Coding Status Reporting

- Audit Trail

Manage Verbatim Modification Verbatim as reported in the Argus might change because of the request by the DsNavigator User, Quality Control review, follow up reports or for any other significant business reason. Once the verbatim is modified, the application does the following:

1. Initiates the same process as if a new event or product has been entered
2. Changes the status of the event / product in Argus to "Pending Coding."

The status of the coding has no impact on the process if the previous coding status is in pending and verbatim has been changed

Coding Status Reporting Argus institutes additional reports to determine the status of the coding with regard to the items sent to the central coding interface, turnaround time and aging of the pending items.

Audit Trail Argus provides for the logging of the central coding transactions to maintain history of data transfers and to audit changes made to coding records outside of the safety database system.

Configuring through dsNavigator

The following features are available after configuring them through dsNavigator. Click the links to access configuration information

- Central Coding Options
- Coding Review and Coding Status Role

Configuring Central Coding Options

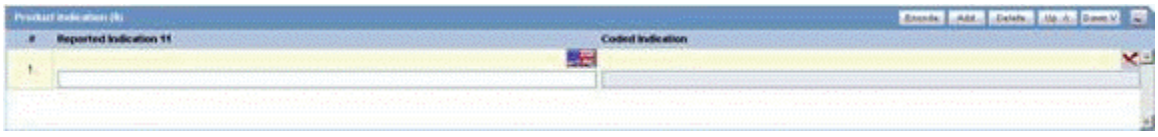
The Administrator can configure central coding options through **dsNavigator**. The configuration is a one-time process and enables the following:

- Central Coding in the Case Form
- Clicking Encode to send event terms to the central coding interface

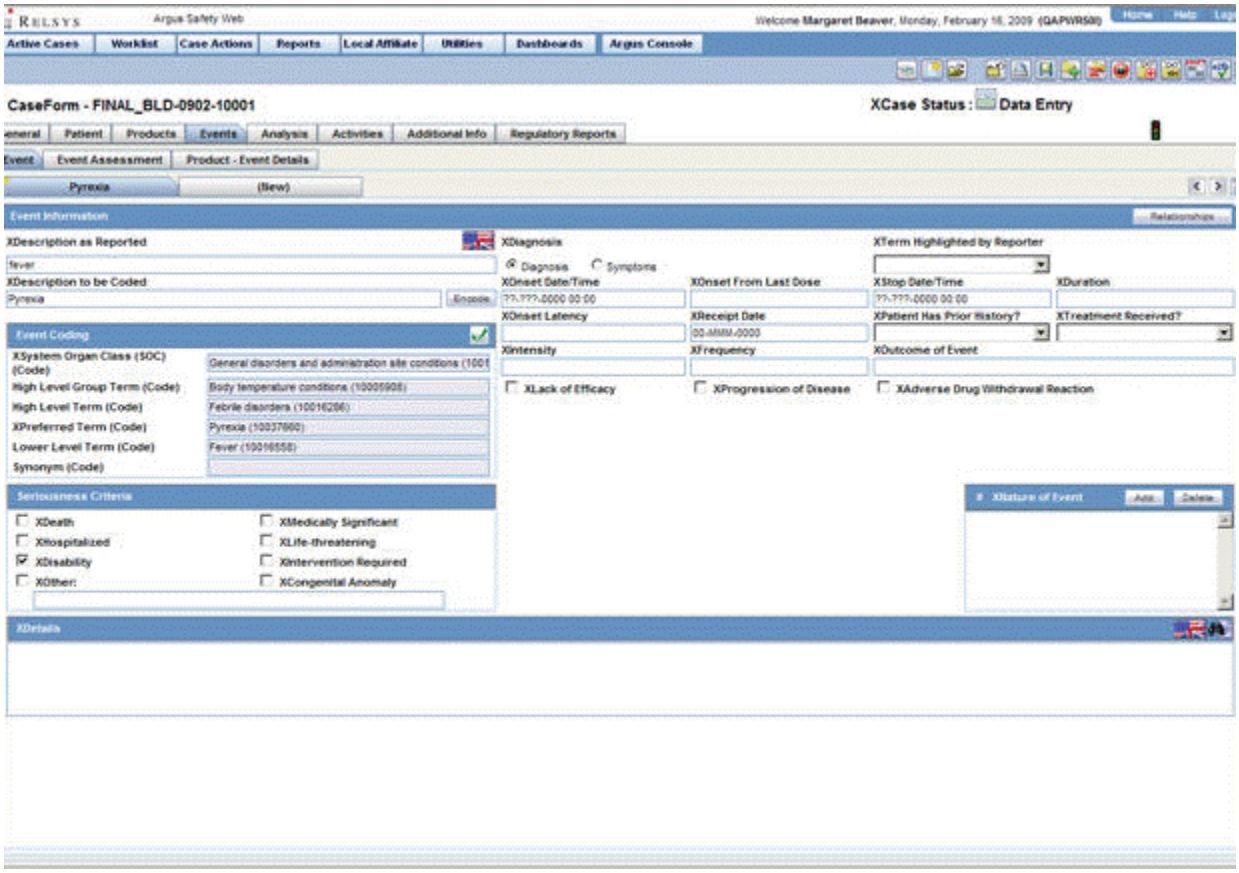
Configuring central coding also enables users to make dictionary selections.

Configuring Sections of the Case Form The Administrator can configure the following sections of the Case Form for Central coding.

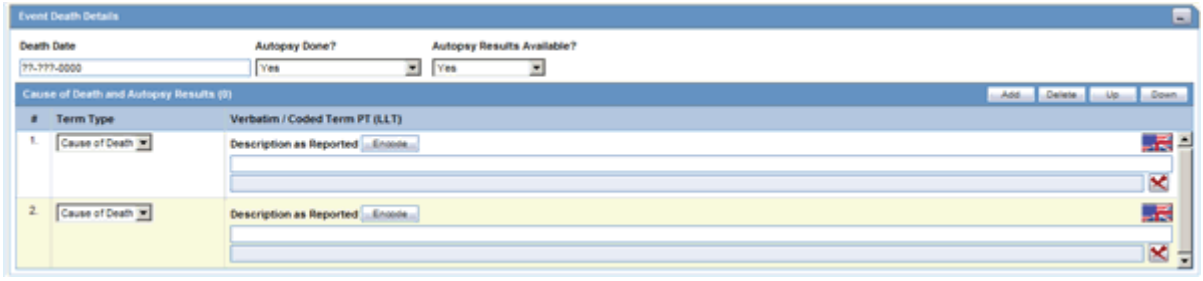
Products Tab - Primary Indication



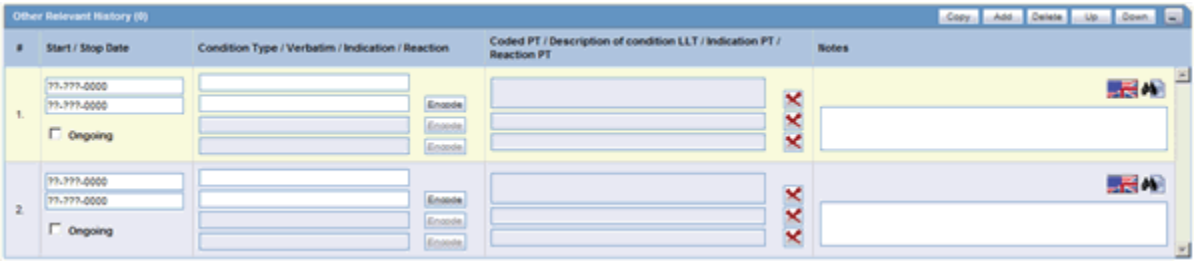
Events Tab - Description to be Coded



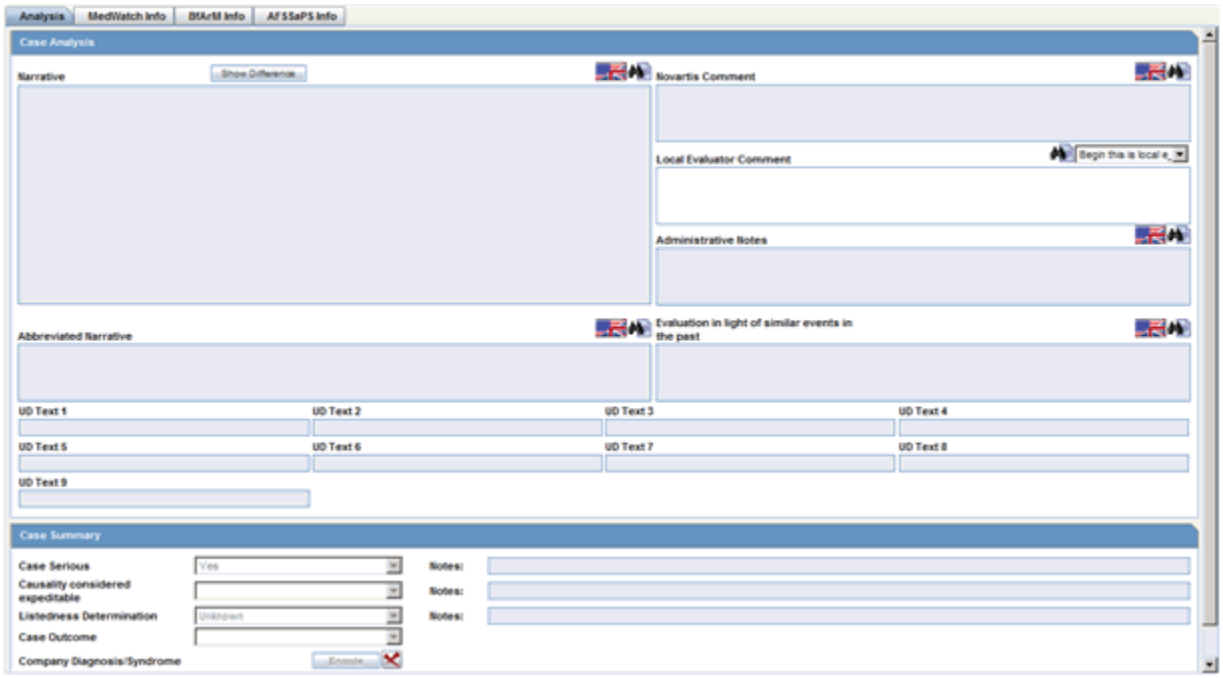
Events Tab - Death Details Section



Patient and Parent Tab - Other Relevant History



Analysis Tab - Company Diagnosis



Configuring Encode

The Administrator can configure **Encode** to enable users to manually send event terms to the central coding interface when they click the button.

Configuring Coding Review and Coding Status Role

The **Modify Group** screen enables you to configure User Groups to enable access to the coding review screen and coding status screens.

Select the Enabled or Disabled radio button to allow or deny access to users.