Oracle Argus Safety

English Administrator's Guide

Release 7.0.3

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Oracle Argus Safety English Administrator's Guide Release 7.0.3

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Preface

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

Intended Audience

This document is intended for administrators of the Argus Safety system for configuring Argus Safety.

Documentation Accessibility

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About This Book

This guide contains the following chapters:

Chapter 1, "Introduction"

Chapter 2, "Access Management"

Chapter 3, "Business Configuration"

Chapter 4, "System Configuration"

Chapter 5, "Code List Configuration"

Chapter 6, "Accessing Tools"

Chapter 7, "Using Advanced Conditions"

Chapter 8, "Multi-Tenancy Best Practices"

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.

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Introduction

Introduction

Argus Safety assists manufacturers of pharmaceuticals and devices by providing a simple and efficient way to comply with international and domestic regulatory safety reporting requirements. It also facilitates internal company safety surveillance by providing tools for signal detection and for analyzing the overall safety profile of both investigational compounds and marketed products.

Argus Safety Configuration Process Overview

To configure Argus Safety, the Administrator must follow a particular sequence of steps. Steps that fall later in the sequence might depend on those that appear earlier. It is, therefore, important for the Administrator to use the following flowchart as a guideline for configuring Argus Safety.
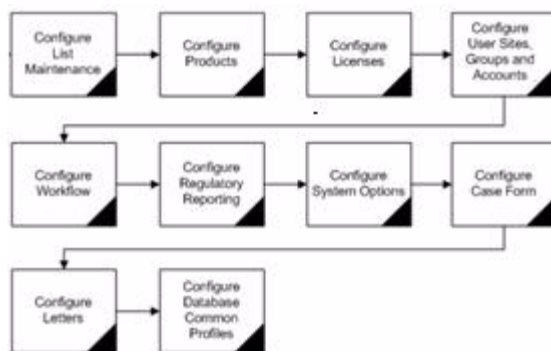
Task	Purpose
Configure User Sites, Groups and Accounts	Enter user sites, create user groups and user accounts, configure group and individual user access rights
Configure Products	Configure Manufacturers, Ingredients, Formulations, Dosage Units, Product Families, and Data Sheets
Configure Licenses	Enter license information, countries and products associated with the license

Task	Purpose
Configure Code List Items	Configure list maintenance items that are not covered in other topics, like Action Taken, Clinical Studies, Study Centers, etc.
Configure Workflow	Configure case workflow states and rules that determine the transition of cases between states
Configure Regulatory Reporting	Configure Regulatory Agency information and expedited reporting rules
Configure System Options	Configure miscellaneous system items like Auto-numbering, Field Labels, etc.
Configure Case Form	Configure Case Form dictionaries, duration calculations, etc.
Configure Letters	Create letter templates by using template placeholders
Configure Database Common Profiles	Configure the Common Profiles Table to customize the Argus Safety application

Usage Conventions

The following conventions are used throughout this document to help you identify specific kinds of information.

Usage Convention	Description
Bold	User interface elements 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: Text	Information that should be noted before proceeding with the instructions.
Important! Text	Important information that must be noted to ensure accurate, reliable, or safe behavior of the system.
Tip: Text	Information that enables easier completion of the current task or helps in completing other tasks.
ALL CAPITALS	Keyboard keys
Initial Capitals	Names of user interface elements, modules, applications, proper nouns, etc.

Getting Started

This section introduces the basic tasks for configuring Argus Safety. To get started with the configuration process, the person responsible for configuring Argus Safety must log on as Administrator to configure the Argus Console.

Refer to the following sections for information pertaining to:

Section	Topics Covered
Administrator Login	■ Logging in and out of the Argus Console
	■ Changing the Administrator password
	■ Accessing the Home Page and Online Help

| Understanding Argus Console user interface | Read this section for an overview of the Argus Console user interface components. |

Argus Console Architecture

The Argus Web Administration Console has been designed to enhance ease of navigation for the Argus end-users.

The following illustration shows the design and location of the individual components under the main **Argus Console** Menu.

> **Note:** The menu items that you can access depend on the security permissions that are defined for your account by the administrator
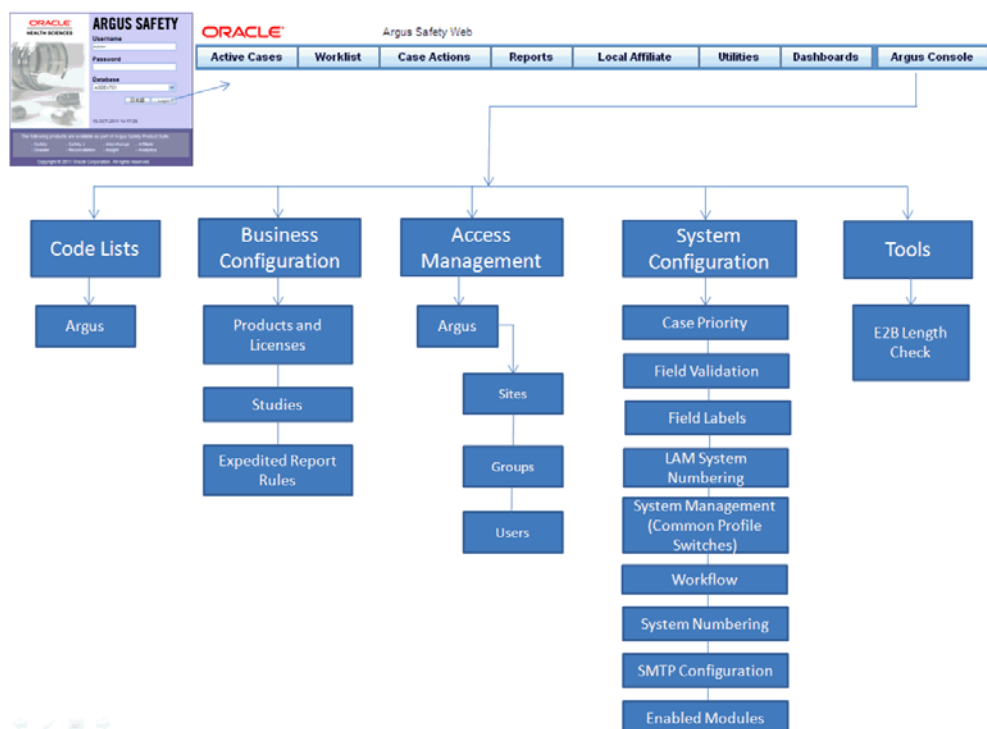
Required Fields

Fields that are marked with a red flag image and associated with an orange boundary are required fields. These fields must be filled in, to proceed with the configuration requirements.

Standard Buttons

The standard buttons used in this console are described in the following table:

Button	Description
Save	Use this button to save changes associated with a section
Cancel	Use this button to cancel changes associated with a section

Button	Description
Print	Use this button to print information associated with a sub-section in a PDF.
Delete	Use this button to delete an item associated with a section
Copy	Use this button to create a new editable copy of an item within a section
OK	Use this button to confirm an action associated with a section
Yes	Use this button to confirm an action associated with a section
No	Use this button to cancel an action associated with a section
Help	Use this button to launch the online manual for the Argus Console
Add New	Use this button to add a new item associated with a section

Standard Icons

The standard icons used in this console are described in the following table:

Icon	Identifies
	A required field
	An item placed inside a folder in the tree-view
	A closed folder containing sub-folders or nodes
	An open folder displaying sub-folders or nodes
	An open folder that does not contain sub-folders or nodes
	A closed folder that does not contain sub-folders or nodes
	An expandable or collapsible browser tree view
	An option to sort columns alphabetically (when placed next to a column header)

Icon	Identifies
	An item appearing under multiple categories (e.g. a user name appearing under multiple groups)
	A withdrawn license in the tree-view of licenses.

Administrator Login

When Argus Safety is installed, an account for the Administrator is automatically created. The installation program assigns "admin" as both the User Name and Password for this account.

Before logging in to the Argus Console, be aware of the following:

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

  The login button has been disabled due to 3 consecutive incorrect entries of Username or Password. Please refresh the page to enable the Login button.

- The Date/Time format 24-hour used by the Web server: DD-MMM-YYYY HH:MM:SS.

Logging In as an Administrator:

1. Enter the **Argus URL** in your web browser, to launch Argus Safety. The login screen appears as shown:

Tip:

- The modules displayed in bold text identify the modules you have permission to access.

- Your login user ID and password are valid for all accessible Argus modules.

2. Enter the **User Name** and **Password** to login to Argus Safety.

Note: The password is case-sensitive.

3. Select the database name from the **Database** list.

4. Press **Enter** or click **Login**.

5. When the window opens, click **Yes** to proceed with the login.

Note: If the window does not appear, verify that your brower's Pop-Up blocker is disabled.

6. Click **Argus Console** to launch the Argus Console Administrator screen.
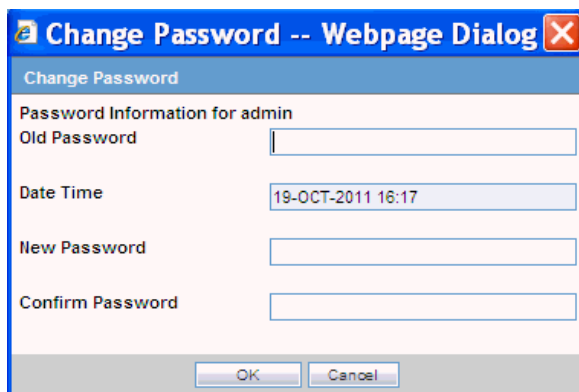
Note: If the window does not appear, verify that your brower's Pop-Up blocker is disabled.

Changing the Administrator's Password

1. Select **Utilities** -> Change Password in Argus Safety.

2. The **Change Password** dialog opens.

3. Enter the current password and the new password.

Note: In case of a Single Sign On user, the Change Password option is not supported in Argus Safety.

4. Confirm the new password and click **OK**.

Logging out

1. Click **Close** to leave the Argus Console application.

2. To log out at any time from Argus Safety, click **Logout**.

Accessing the Home Page

To go back to the Home page, click **Home**. The default Home page appears.

Launching Online Help

To launch online help click **Help**.

Understanding Argus Console GUI

This section broadly categorizes the sections of the Argus Console GUI with their associated descriptions.

Section	Sub-Section	Description
Getting Started	~	This section provides information about new keyboard navigation features for the Argus Console.
Access Management	Sites	This section enables the administrator to enter and configure new user sites.
	Groups	This section enables the administrator to enter and configure new user groups.
	Users	This section enables the administrator to configure user accounts.
Business Configuration	Product and License	This section helps in capturing Product Details (product specifics, product licenses, products involved in the studies.
		These can be the products marketed, or under investigation, by the company.
	Studies Configuration	This section helps in capturing Study information (study specifics, products involved in the study licensed countries associated with the study and the clinical references used in the expedited reports.
	Expedited Reporting Rules	This section helps in capturing Expedited Reporting Rule configuration.
		The Reporting Rules configuration feature enables the administrator to define the reporting rules or criteria for the cases to be qualified for expedited reporting.

Section	Sub-Section	Description
System Configuration	Case Priority	This section enables the administrator to configure rules to determine the priority of new cases that are entered into the system.
	Field Labels	This section enables the administrator to change field labels, hide and unhide fields in Case form.
	Field Validation	This section enables the administrator to configure field level validations for the case form fields.
	LAM System Numbering	This dialog enables the administrator to specify the case numbering preferences for LAM cases.
	System Management Common Profile Switches	This section enables the configuration of Common Profile Switches that affect the behavior of the Argus application.
	Workflow	The section enables the configuration of workflow states and rules, within the safety department starting from initial case receipt to case closure.
		The system enables tracking of the progress of cases between users and states of activity.
	System Numbering	This section enables the administrator to specify the case numbering preferences.
	SMTP Configuration	This screen enables the user to configure SMTP settings.
Code Lists	Code Lists Argus	This section helps in capturing Code List information. Code lists appear as drop-downs in the Argus application.
Tools	E2B Length Check	This screen enables the user to view the E2B Length Check report in PDF format.

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Access Management

Access Management

Site, group, and user configuration takes place in the **Access Management** section of Argus Console. Here you can add, copy or delete users, groups or sites.

Each user must be assigned to at least one group in order to determine their security level. Each group is assigned a specific security level. This security level enables members of the group to view, modify, or restrict access rights to various sections of the Case Form, and so on.

The first set of steps in configuring Argus safety is to create the following **exactly in the listed order**:

- Sites

- Groups

- Users

> **Note:** The configuration must occur in the **exact order** specified above.

Configuring User Sites

Addition of Sites is necessary in order to create Users because every user must be assigned to exactly one Site. Site information can also be used in automatic numbering of case IDs.

To configure Sites, use the **Access Management --> Argus --> Sites** section. The following is an illustration of that section.

Field Descriptions

The following table lists and describes the fields on the screen.

Field/Control Name	Description
Description	Enter a description of the site.
Abbreviation	Enter an abbreviation of the site name. A one to four character abbreviation is required for each site.
Site Type	Select the Site Type Argus or LAM (Local Affiliate Module).
Protect Patient Confidentiality - Default	Protects or reveals Patient Confidentiality for the specific site.
Protect Reporter Confidentiality - Default	Protects or reveals Reporter Confidentiality for the specific site.
Bulk report By form (Approved reports) - Default	Allows or protects availability of the Bulk Reports by Form for the specific site.
LAM Sites	Select and add previously created LAM sites.
Site Printers	The Site Printers section is used to configure site printers.

Adding User Sites

This screen helps in capturing Site information (such as user site description, abbreviated term, site type and LAM site configuration).

Use the following procedure to add a user site.

1. Click **Access Management->Argus->Sites**.

2. In the left panel, select **User Sites**. The User Sites are listed in the right panel.

> **Tip:** You can alternatively click **Modify** to modify an existing site.
>
> Use **Copy** to make an editable copy of an existing user site**.**
>
> Use **Delete** to delete a user site.

3. Select a **User Site** and click **Add New**.

4. Enter the user site **Description**.

5. Enter the user site **Abbreviation**.

> **Note:** A maximum four-character abbreviation is required for each user site.

6. Select a **Site Type**.

> **Note:** Each Argus Safety user must be assigned to exactly one user site.
>
> You cannot change the site type from LAM to Central if the current central site has an association with a LAM site, the current site is associated with any user, or the current LAM site has any events assigned to it.

7. Select the following options as required:

   - Select the **Protect Patient Confidentiality - Default** to protect or reveal *Patient Confidentiality* for this specific user site.

   - Select the **Protect Reporter Confidentiality - Default** to protect or reveal *Reporter Confidentiality* for this specific user site.

   - Select the **Bulk Report by Form (Approved Reports) - Default** to enable availability of the *Bulk Reports By Form* for this specific site.

8. Add or remove any **LAM Sites** information.

> **Tip:** To add more **LAM Sites** to the Lam Sites list, use the **Add>>/Add All** .options.
>
> To delete the **LAM Sites** from the Lam Sites list, use the **Remove>>/Remove All** options..

9. In the **Site Printers** section, click **Add** to add a site printer.

10. Enter the **Name** of the printer that will be displayed in the application when referring to the printer. The name can have up to 20 characters.

11. To delete a site printer, select the printer and click **Delete**.

12. Click **Print** to print the site information, as shown below:

Site Information					
Description	LAM Site 1				
Abbreviation	LAM1		**Site Type**		LAM
Intake File Path					
☐ Protect Patient Confidentiality-Default		☒ Protect Reporter Confidentiality-Default		☐ Bulk Report Report By Form (Approved Reports)-Default	

Site Printers		
#	**Name**	**Path**
1	Printer 1	Printer 1 Path
2	Printer 2	Printer 2 Path

13. In the **Path** textbox, enter the full path of the printer on the network. This path name can have upto 256 characters. The specified path should be accessible from the machine where Argus Safety Service is installed.

14. Click **Save** to save the information and return to the Code List Maintenance dialog.

About Filtering Criterion The *filtering criterion* is essential as it helps you to search for specific items. The Argus Console provides this option for the Access Management section. The filtering browser is displayed as the **Code Filter List**

Argus Console helps you to filter information further for the Access Management section. Using the **Code Filter List** you can specify whether your search should contain or start with specific alphabets.

For Example: The following filtering criteria enables the system to search for all User Sites that contain A in the abbreviated term.

User Sites Filter				
Field			Value	
Description ▾	Starts with ▾		A	Filter
Description				
Abbreviation				
Site Type	...ation		Site Type	
Intake File Path	Description		Argus	

The right panel now displays the list of User Sites based on the filtering criterion.

Configuring Groups

Each user of Argus Safety can be a member of one or more user groups. The access rights of each user group to the menus in the user interface and specific sections of the Case Form can be configured when the group is created.

Configuration of the user site is done using the **Access Management-->Argus --> Groups** section.

Field Descriptions

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

Field/Control Name	Description
Group Name	Enter a unique name for the group.
Email	Add the group email, used for case priority notification and workflow routing notification.
Supervisor Email	Add the Group's Supervisor Email as applicable. This e-mail address is used to send notifications when the maximum time of a case for a particular workflow state is exceeded.
Menus	Lists the menus and sub menus within a Case Form and allows you to enable or disable each of them.
Case Form	Lists the sections and sub sections within a Case Form and enables you to assign the group Modify; View (Read Only); or No Access (not visible) to each area.
Listedness Determination - Countries	Assigns Argus users to the group that has rights to change the listedness determination for licenses originating in the selected countries.
Restrictions - Products	Limits the number of products that can be viewed in the trade name lookup and non-study cases.
Restrictions - Studies	Limits the number of studies available for selection and the study cases that can be viewed. 1. Click the **Studies** checkbox to enable the **Select** button 2. Click this button to view a security configuration containing a tree view list of available items 3. Select a study family to select all its constituents
Default report (LAM only)	Lists the expedited report forms in the drop-down list.

Adding User Groups

This section enables the Administrator to configure the security levels for each work group.

Radio buttons enable you to view the group and assign access rights for several specific sections of the case form, menu, case workflow, and report workflow.

If a user belongs to multiple groups, the access rights for the user will be the sum-total of the individual group access rights. Consider the following example:

John Smith is an Argus User and his profile has been added to 2 user groups with different access level permissions for each group.

- John has access rights to the **Patient** Tab in one group and access rights to the **General** Tab in another group.

- In this case, John will be able to access both the **Patient** and the **General** tabs of Argus

Use the following procedure to create a user group

1. Click **Access Management->Argus->Groups**.

2. Select the filtering criterion to display the list of Groups or Users in the left panel.

3. Select a **Group** and click to view the group details in the right panel.

Tip:

- You can alternatively click **Add Group** to create a new group.

- Use **Copy** to make an editable copy of an existing group.

- Use **Delete** to delete a group.

4. Enter the **Group Name**. This should be a unique name associated with this Group.

5. Enter the **Email** address, if applicable.

6. Enter the **Supervisor Email** address, if applicable.

7. In the **Case Form** section, select the desired access right option ("Modify", "View", or "No Access") for the group's access to each of the listed items of Case Form.

> **Note:** The following fields are required in order to save a case: **Initial Receipt Date**, **Country of Incidence**, **Report Type**, **Suspect Product**, and **Event Description as Reported**. Therefore, the group responsible for initial case entry must have access to these fields in order to save new cases.

8. In the **Menus** section, enable or disable access of the group, to particular items in the Argus Safety menu.

> **Tip:** Refer to the Argus Safety User Guide for information about the functions of the Case Form sections and the menu items in the Argus Safety user interface.

9. In the **Listedness Determination** section, select a list of countries. This enables the end user to override the listedness determination in the **Event Assessment** section of the Case Form for product licenses that match the countries selected in this step.

10. In the **Advanced Conditions** section, select **No Access to Create Advanced Condition**, **No Access to Share Advanced Conditions**, and/or **No Access to View and Edit SQL**.

   Tip:

   - If you select **No Access to Create Advanced Condition**, **Advanced Conditions** does not appear as an option for that user group.

   - If you select **No Access to Share Advanced Conditions**, the user group does not have access to share Advanced Conditions.

   - If you select **No Access to View and Edit SQL**, the **SQL...** button will not appear as an option for that user group.

11. In the **Restrictions** section, select **Products**.

12. Click **Add Product**, to open the **Available Products** dialog box.

13. Select each product you want to add and click **OK**.
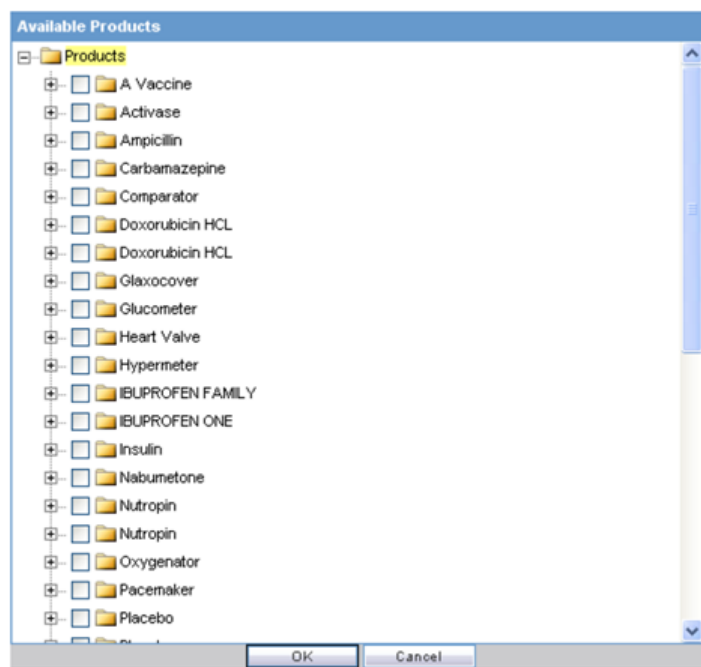
14. In the **Restrictions** section, select **Study**.

15. Click **Add Study**, to open the **Available Studies** dialog box.

16. Click the appropriate checkboxes to select the required studies and click **OK**.
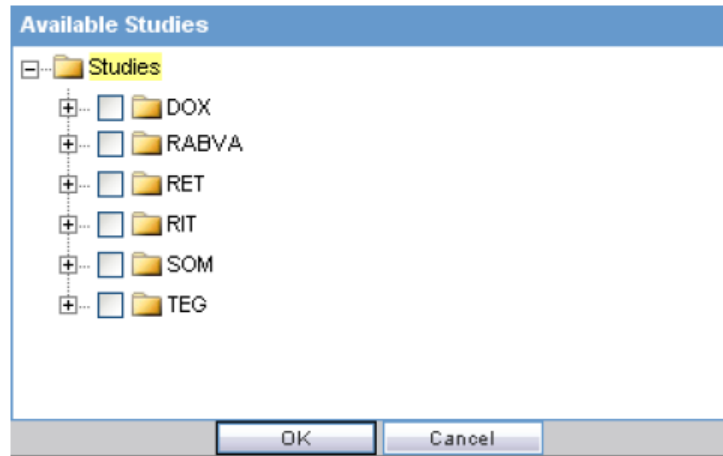
17. Click **OK** to save the group.

Groups Included with the Factory Data The following table lists and describes the groups included with the factory data.

Group	Description
Administrator	This group has access rights to all areas and all the functionality of Argus Safety.
Investigator	Receives an e-mail alert that can be set up during Clinical Study Configuration.

About Filtering Criterion The filtering criterion is essential as it helps you to search for specific items. The Argus Console provides this option for the Access Management section.

Using Organized by

The system displays the filtering browser in the top-left corner of the left panel. You can filter based on either of the two combination shown in the following illustration.

Consider the following.

- If you enable **Organized by Groups**, the generated output displays in a tree-format in the left panel. The structure is based on the entire categorization of Groups and Users

- If you enable the **Organized by Users**, only the User list is available in the tree view in the left panel.

Using **contains or starts with** enables you to specify whether your search should contain or start with specific alphabetic characters. For example, filtering criterion shown in the following illustration enables the system to for all Groups that contain the word "administrator."
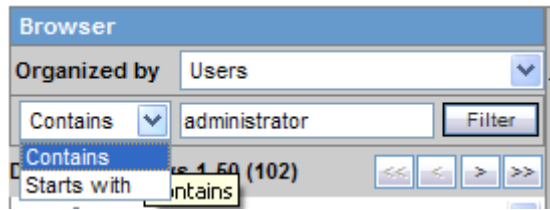
Printing a User Group

Use the following procedure to print a user group.

1. Select **Access Management->Argus->Groups**.

2. Select the filtering criterion to display the list of Groups or Users (based on the filtering criterion) in the left panel.

3. Select a **Group** and click to view the group details in the right panel.

4. Click **Print** to display a **Print** dialog that enables the user to choose to print the entire window or to print only the text covered by the current selection.
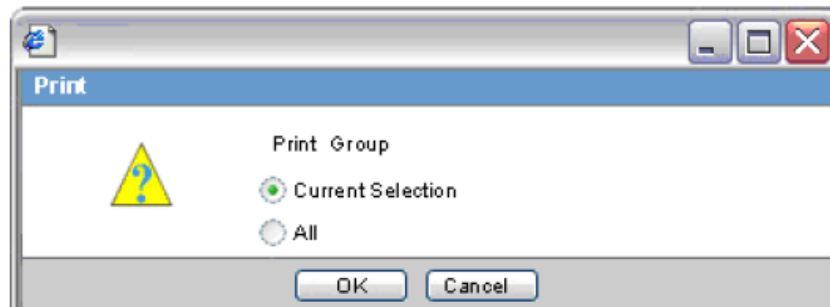
5. Select the appropriate options and click **OK**.

6. The system opens the **Print Groups** to enable the user select the sections to be printed in the **Group Configuration** printout.

    By default, the **Group Information** checkbox is selected and disabled so that it always gets printed.

7. Select the appropriate checkboxes, and click **OK**
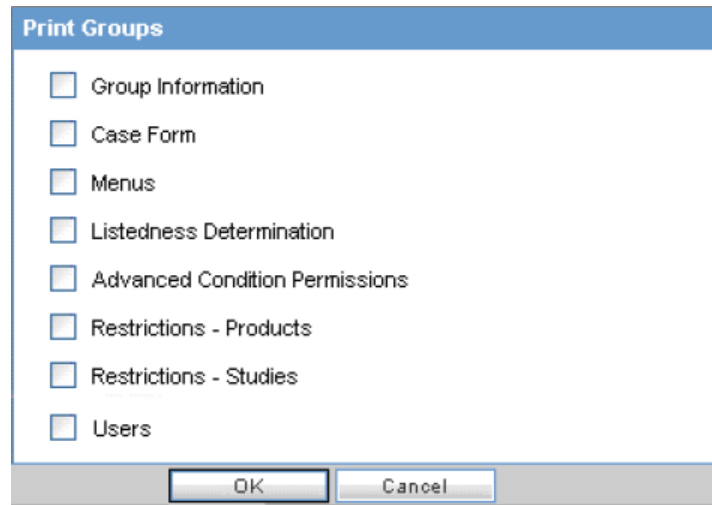
Group Configuration Print Out The following is an illustration of the **Group Configuration** printout.

■ It lists the users which are configured to the groups.

■ User are sorted alphabetically by **User Full Name** in the report section

About Filtering Criterion The filtering criterion is essential as it helps you to search for specific items. The Argus Console provides this option for the Access Management section.

Using Organized by

The system displays the filtering browser in the top-left corner of the left panel. You can filter based on either of the two combinations.

Consider the following.

■ If you enable **Organized by Groups**, the generated output displays in a tree-format in the left panel. The structure is based on the entire categorization of Groups and Users

■ If you enable the **Organized by Users**, only the User list is available in the tree view in the left panel.

Using **contains or starts with** enables you to specify whether your search should contain or start with specific alphabetic characters. For example, filtering criterion

shown in the following illustration enables the system to for all Groups that contain the word "administrator."

Configuring Users

User Maintenance enables you to add, copy, or delete users for the system.

- Each user must be assigned to at least one group in order to determine security level.

- Each group is assigned a specific security level that defines whether group members can view, modify, or have no access rights to various sections of the case form, etc.

Configuration of the users is done using the **Access Management->Argus->Users** section. If the Enable LDAP Login checkbox is not checked, you can specify a password when creating or modifying an individual user account. When updating user records, be aware of the following:

- If you enter a value in the **Password** field, the system uses this password to authenticate at login.

- The **Reset Password** field is available **only** when you select **Reset Password**. The new password can be up to 30 characters.

- If you leave the value blank, the system uses the default password as defined in the **Common Profile** for the system.

- When you save the user configuration, the system saves the default password you enter.

- During entry, the system displays the password you type.

The following illustration shows the fields associated with this section.

Field Descriptions

The following table lists and describes the fields in the **Administrator** section

Field/Control Name	Description
User Name	Enter the full name.
User ID	Enter a unique user identification (ID).
Reset Password	Reset the password of a user to a default value specified in the common profile section.
Email Address	Enter the user's e-mail address.
Site	Assigns the user to a site.
	The values in this field are populated from the codelist item **User Sites**.
User Group - Select	Attaches the user to pre-configured user groups.
User Type	Select the type of user, such as an Argus J user from the drop-down list.
User Roles - Select	Attaches the user to pre-configured user roles such as Global Admin. By default, a Global Admin role is granted to only an Administrator, who can grant/revoke this role to other Argus users. Such a user role should be assigned to users who need access to the Argus Global application. Similarly, you can also select from other roles present within User Roles.
Application Access	Configure user access settings for Argus Console and Argus Safety.
	The default application access for the user can be selected from the list.
Worklist to display at login	Configure users to see their worklists immediately upon login. The options are:
	■ None (default) - Does not open any worklist when the user logs into Argus. Displays personal Argus status on login.
	■ Action Items - Opens Worklist - Action Items screen for the user on login into Argus
	■ New - Opens Worklist - New screen for the user on login into Argus
	■ Open - Opens Worklist - Open screen for the user on login to Argus.
	■ Reports - Opens Worklist - Reports screen for the user on login into Argus
Enable site security	If *Enable Security* is checked, the site-based data security will be enabled for the user.
	If the box is not checked, the user will have full access to data from all sites.
Enable LDAP Login	Authenticates users against the active directory server.
	When **Enable LDAP Login** is selected, all fields inside the **Access** section are disabled, excluding the **Account Disabled** option.
Account Disabled	When this option is selected, the user account is temporarily disabled to prevent users from logging in. This option is different from deleting a user as it enables the Administrator to re-activate the account at a later date.

Field/Control Name	Description
Security Disabled Account	■ When **unchecked**, the login procedure keeps track of the number of consecutive unsuccessful attempts at logging into the system. If the count reaches three, the login procedure will always fail the password validation to lock the user out. Administrators with rights to user maintenance can reset the login attempts for the user to unlock the account. ■ When **checked**, the login procedure that tracks the consecutive unsuccessful attempts at logging into the system do not apply.
Force password change at login	If this check box is selected, the users must change the password the first time user logs on to the system after the checkbox is checked.
Force password to expire every	Enables the Administrator to force the user's password to expire in the specified number of days.
Days	Enables the Administrator to enter the number of days after which the password should expire.
__ Days remaining	The field displays the number of days remaining for the password change.
Allow unblinding of cases	Enables the user to unblind a study case. For example, a user **without** unblinding rights will not see the Study Drug field. A user with unblinding rights sees a yellow *Unblind* tag next to concentration of product field and the *Broken by Sponsor* option in Blinding Status drop-down list is enabled. User will have to enter password when user selects Broken by Sponsor' option.
Protect from unblinded information	When checked, the user cannot view any unblinded information.
Protect from printing unblinded information	When checked, the user cannot print any unblinded information.
Allow locking of cases	Enables the user, to lock/unlock the cases.
Allow closing of cases	Enables the user to close the cases.
Route on close case	Opens a routing dialog when the user closes the case.
Enable Checklist on Route	By default, this checkbox is selected. If this checkbox is not selected, the checklist for the Workflow is not displayed to the user while routing the cases, even if the rule that is being used has a checklist.

Printing Users

Use the following procedure to print users.

1. Select **Access Management > Argus > Users**.

2. Select a **User** and click to view the user details in the right panel.

3. Click **Print** to display the **Print User** dialog.
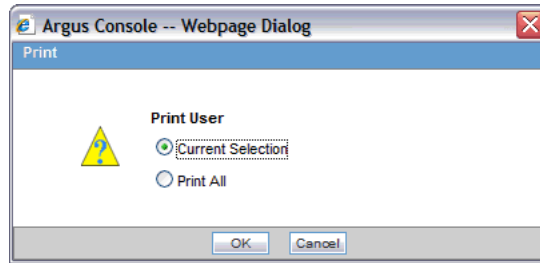
4. Click OK to display list of Print User options.

5. Select the appropriate option(s) and click **OK**.

3
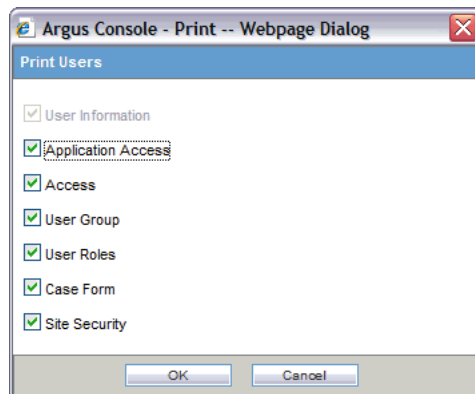
Business Configuration

About Business Configuration

This section explains the Business Configuration of the Argus Console, categorized into the following modules:

Section	Sub-Section	Description
Business Configuration	Products and Licenses:	This section helps in capturing Product Details such as product specifics, product licenses and products involved in the studies.
		These can be the products marketed, or under investigation, by the company.
		Refer to the following sections for further information on:
		■ Configuring Product Families
		■ Configuring Products
		■ Configuring Licenses
	Studies	This section helps in capturing Study information such as study specifics, products involved in the study licensed countries associated with the study and the clinical references used in the expedited reports.
	Expedited Report Rules	This section helps in capturing Expedited Reporting Rule configuration.
		The Reporting Rules configuration feature enables the administrator to define the reporting rules or criteria for the cases to be qualified for expedited reporting.

Editable and Non-editable Business Configuration Sections

Each of the three Business Configuration sub-sections supports various views for efficient access to data. Each view consists of a hierarchical tree-structure comprising various nodes such as Family, Product, Licenses, and Countries.

The following table list which nodes can be edited and which cannot.

Business Configuration Sub-Section	Organized By	Node	Editable
Products and Licenses	Family / Product / Licenses	Family	Yes
		Product	Yes
		Licenses	Yes
	Product / Licenses	Product	Yes
		Licenses	Yes
	License / Products	License	Yes
		Products	Yes
	Countries / Licenses	Countries	No
		Licenses	No
	Countries / License Type / Licenses	Countries	No
		License Type	No
		Licenses	No
Studies	Projects / Studies / Products	Projects	No
		Studies	Yes
		Products	No
	Studies / Products	Studies	No
		Products	No
	Products / Studies	Products	No
		Studies	No
	Countries / Projects / Studies	Countries	No
		Projects	No
		Studies	No
Expedited Report Rules	Country / License Type / Reporting Rule	Country	No
		License Type	No
		Reporting Rule	Yes
	License Type / Reporting Destination / Reporting Rule	License Type	No
		Reporting Destination	No
		Reporting Rule	Yes
	Responsible Group / Reporting Rule	Responsible Group	No
		Reporting Rule	Yes
	Inactive Rules	Country	No
		License Type	No
		Reporting Rule	Yes
	Active Rules	Country	No
		License Type	No
		Reporting Rule	Yes

Type Ahead Fields

Some fields in the Business Configuration section of Argus Console are enabled with Type Ahead-input. This means that these fields are equipped with the ability to guess what the user is typing.

Based on the text being entered, this feature provides suggestions for the user to choose from.
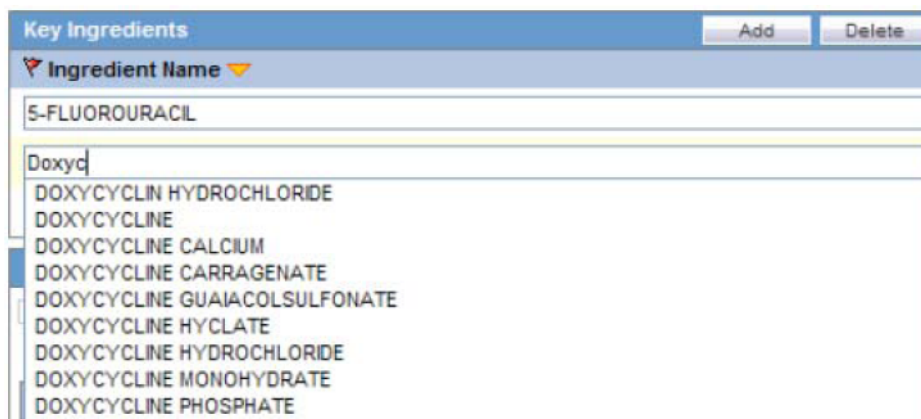
The following fields have the type-ahead feature:

- Clinical Reference Type (Under **ClinicalStudies Configuration**)

- Ingredients (Under Product Family Configuration)

- Manufacturers (Under Product and License Configuration)

- Project ID (Under Clinical Studies Configuration)

- Reporting Destination (Under **Expedited Reporting Rules**)

Additional Comments Fields

Be aware of the following:

- The system has a **Comments** field that accommodates a maximum of 1000 characters on the **Product Family**, **Product**, and **License and Study** configurations.

- The **Product Configuration** permits a maximum of 50 characters in the PSUR Group Name field. Multiple blank spaces between words will cause the generation of unusable report templates.

- The **License Configuration** permits a maximum of 50 characters in the CTPR Group Name. Multiple blank spaces between words will cause the generation of unusable report templates.

- The **Business Configuration** report prints the **Comments** field, and the system tracks any changes made to these fields in the audit log.

Configuring Product Family

Each company has a set of products to sell and a set of processes unique to its business. The Administrator should be aware of the company business processes and/or workflow rules. The manner of product configuration in Argus Safety will depend on how the company handles its internal workflow related to the release of a product.

Details of the company's products can be added in Argus Safety using the Business Configuration section. This feature helps end-users to retrieve details of company products, without entering significant product information for each case.

Every company product should belong to a product family. Each product within a product family shares the same key ingredient and data sheets but can have a different concentration for the key ingredient.

Configuration of the product is done using the **Business Configuration->Products and Licenses** section.

The following illustration shows the fields associated with this section.

Field Descriptions

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

Field	Description
Product Family Name	Enables the user to enter a new product family name.
Product Group	Enables the user to select a product group name.
Ingredient Name	Enables the user to select the multiple key ingredients for the product family ■ The user can sort the field alphanumerically. ■ Sorting on the ingredient name in the Product Family Configuration updates the sort order in all the products which are part of the same family ■ A maximum of 25 items are displayed as the search results in the drop-down list. ■ The Key Ingrediens drop-down list enables the user to enter up to 20 active ingredients for a product family.

Adding Product Families

The screen helps in capturing the Product Family information. As per the Argus data model, the Product Family adds the Ingredients, Data Sheets, and the Product group.

Products are associated with Product families and are created using the Data Sheets, Dosage form, Strength and unit of the corresponding Product Family. The **Product Group** field in the Product Family configuration screen enables the Argus administrator to group the product families into various Product Groups.

Use the following procedure to add a product family.

1. In the Business Configuration section, select **Product and Licenses**.

2. In the left panel, select a filtering criterion. The left panel now displays the tree view of the **Family** based on the filtering criterion.

3. Select a Product Family and click to view the product family details in the right panel.

    > **Note:** Ensure that you select the top-level folder to view the details of the product family.

    Product family details appear in the right panel.

Tip:

- You can alternatively click **Add Family** to create a new family of products.

- Use **Copy** to make an editable copy of an existing product family.

- Use **Copy with Datasheets** to make an editable copy of an existing product family, along with all associated datasheets.

4. Enter the **Product Family Name** as applicable.

5. Select the **Product Group** from the drop-down list. This helps you to group the product families into various product groups.

6. Select the required **Ingredient Name(s)** displayed under the **Key Ingredients** section

7. Select the required Datasheet configuration.

8. Click **Save** to save the changes made to the Product Family.

> **Tip:** If you have added a new Product Family, click **Add Family** to save the new **Product Family**.

About Filtering Criterion The filtering criterion is essential as it helps you to search for specific items. The Argus Console provides this option for the Business Configuration section.

Using Organized by

The filtering browser is displayed in the top-left corner of the left panel. The Products and Licenses section can be filtered based on any of the three combinations shown in the following illustration. Consider the following:

- If you enable **Organized by** Family/Product/License, then the generated output will be visible in a tree-format in the left panel.

- If you enable the **Organized by** Product/License, only the Product and License views are available in the tree view in the left panel.
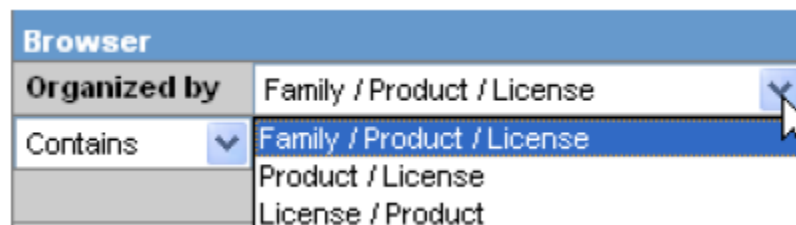
The Argus Console helps you to filter information further for the Business Configuration section. Once you have selected the **Organized by,** you can specify whether your search should contain or start with specific alphabets.

The filtering criterion shown in the following illustration, enables the system to search for all Family/Product/License data that contains the term Cure.
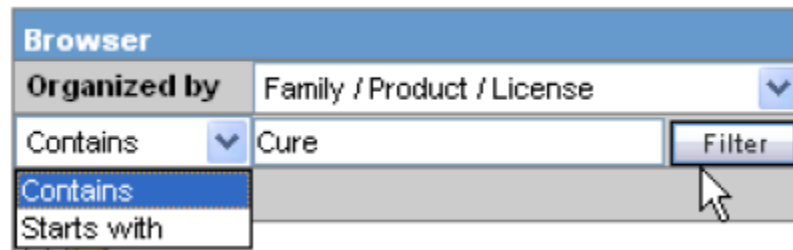
Tip: The number displayed next to the folder indicates the number of Products in the product family.

Creating Data Sheets

Packaged medications (like prescriptions) are marketed with an insert sheet that lists the known contraindications (side-effects) that may occur as a consequence of taking the product. These inserts are also referred to as data sheets. It is important to list these effects in order to ensure accuracy in reporting. An inaccurate report could result in the wrong action taken or bring harm to a patient.

The Listed Events & Indications from the data sheet determine the listedness of the adverse event(s) for the case. Depending on the configured regulatory report rules, the listedness determination will automatically schedule the expedited reports .

The data sheet in the Product Family is configured using the **Business Administration -> Products Family** section.

Field Descriptions

The following table lists the Field Descriptions for this section.

Field/Control Name	Description
Datasheet Name	Enables the user to rename the datasheet.
Activate Data Sheet	Enables the user to activate the current data sheet. Be aware of the following:
	■ When you click the checkbox, the system enables the radio buttons next to Activate Data Sheet.
	■ You can either select the option to activate the data sheet with Terms added on the current dates or on another date entered in the Other Date field.
	■ Once the datasheet is activated, the system disables the Activate Datasheet text box.
	■ If you enter a date greater than the current system date, the system permits you to enable the activation date.
Core Sheet	The Core Sheet checkbox enables the user to indicate that this data sheet is the central data sheet. This checkbox is disabled if another data sheet is marked as the core data sheet.

Include	The Include checkbox enables the user to indicate that this data sheet includes the particular datasheet selected in the drop-down list. Be aware of the following:
	■ The system populates the drop-down list with the list of datasheets that do not include other data sheets.
	■ The system enables the drop-down list only when the include checkbox is checked.
	If a product family has a single datasheet that is marked 'Core', the system disables the Include checkbox.
Other Date	This radio button is enabled if the current date is not to be selected. Select this checkbox and enter any other date, as required.
Global /No local labeling assessment required	Checking this option automatically marks any license using this data sheet, as assessed, and the license does not require any local labeling assessment.
Notes	On clicking the notes icon, a pop-up appears to enable users to enter notes while entering the details of the Datasheet.
Listed Term	This field displays the listed terms (Preferred Term) for the datasheet.
View Revisions	Enables users to view a list of term that were added or removed with the added date.

The View Revisions dialog displays the datasheet revisions, as shown below:

> **Note:**   In order to facilitate optimum system performance, you can configure a limit on the number of revised terms that get displayed. If, for example, this value is set to 1000, the datasheet will display only 1000 revised terms in the list. This value is configurable in web.config by using the keyname **DataSheetRevisionTermCount**. The default value is 1000.
>
> Click **Print** to view all other revised terms.

Use the following procedure to create a datasheet.

1. In the **Datasheet** section of the **Product Family** section, click **Activate Datasheet** to activate the data sheet associated with the Product Family.

> **Note:**   If you want to make a copy of the datasheet, click **Copy.** Ensure that you enter a new name for the datasheet, if you are making a copy of another datasheet.

2. Select the **Core Sheet** check box, if this data sheet is required to be the core data sheet. Only one core data sheet is allowed per product.

3. Select the **Include** check box and select the value from a drop-down list. This helps you to indicate that this data sheet includes the particular datasheet selected in the drop-down list.

4. Select **Global/No local labeling assessment required** to automatically mark any license using this data sheet as assessed.

5. Click **Add Term** to select the listed terms (Preferred Term) for the datasheet. The MedDRA browser appears.

6. The MedDRA Browser available for Datasheets enables the administrator to select either multiple or all Preferred Terms (PTs) in the following way:

   ■ Click the required High Level Term (HLT) and select multiple PTs by clicking on each required PT.

   OR

   ■ Right-click the HLT to select all entities available under PT.

7. Select the Preferred term from the MedDRA browser and click **Select**.

   > **Tip:** You can alternatively click **Select and Close,** in the MedDRA browser to save and exit the Product Family screen.
   >
   > You can use **Delete Term** to delete the selected listed term(s) from the datasheet.

8. Click **Select** from the **Event Groups** tab of Datasheet to select an event group. The **Event Group Selection** window appears.

9.

10. Press **Save** to save the data sheet. The Data Sheet name displays in the **Data Sheets** list.

    > **Tip:** To view the revision history associated with a Datasheet, click **Revisions**. A pop-up appears containing the following information:
    >
    > ■ **Rev. No**: Displays the revision number of the datasheet. This number is updated each time the data sheet is activated
    >
    > ■ **Terms**: Displays all the terms that were added / removed. In case a term has been deleted, it is marked with * against the term name.
    >
    > ■ **Added On**: Displays the date when the terms were added in the datasheet
    >
    > ■ **Active On**: Displays the date when the datasheet was made active for that revision

Configuring Products

Each company has a set of products to sell and a set of processes that are unique to its business.

The manner of product configuration in Argus Safety depends on how the company handles its internal workflow, related to the release of a product. Therefore the Administrator should be familiar with the business processes or workflow rules of the company.

Configuration of the product is done in the **Business Administration -> Products and Licenses** section.

When configuring a product, be aware of the following:

■ When the user clicks the **Notes** link on a data sheet, he/she can enter a maximum of 2000 characters in the **Preferred Terms** section of a data sheet as shown in the following illustration.

■ When the user clicks the **Notes** link, he/she can enter one note for each term.

- The user can use the standard spell check function.

- If notes have been entered for the term, the system displays the Notes icon to indicate that notes are present.

- The system also prints the notes on the **Product Family** details.

- A comments field that can contain up to 1000 characters has been added to the **Product Family/Product/License** and **Study** configuration elements.

- The **Product** configuration also has a 50 character PSUR Name.

- The **Business Configuration** reports print the contents of the **Comments** fields.

- The system tracks any updates made to the datasheets in the audit log.

The following illustration shows the fields associated with this section.

Field Descriptions

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

Field Name	Description
Product Family Name	Enables the user to enter the unique family name for the product. The Product Family Name must be of at least five (5) characters.
Product Group	Select the product group for the product.
Ingredient Name	Displays the Ingredients of the Product Family to which the Product belongs.
	The user can alphanumerically sort the field.
	Sorting on the ingredient name in the Product Configuration updates the sort order in the corresponding Product Family and all the other products which are part of the same family.

Field Name	Description
Datasheet	To view the description of the fields of this section, see Creating Data Sheets.
Preferred Terms	Displays the Listed Term (Preferred Term) for the product, as described in the field description table under Creating Data Sheets.
Event Groups	The Event Group, selected from the **Select** button > **Available Event Groups** dialog, is displayed as follows:
	Event Group Name in English
	The event group name is displayed in the following format for Japanese users: Event Group Name in English (Event Group Name in Japanese)
	The count of the total number of Event Group Names present for the case is displayed on the header of the Event Groups tab.
	For more details about Event Groups, see the section Event Groups tab under Configuring Event Groups.

Adding Products

This screen helps in capturing Product Details (product specifics, product licenses, products involved in the studies. These can be the products marketed, or under investigation, by the company. Every company product should belong to a product family. Each product within a product family shares the same key ingredient and data sheets but can have a different concentration for the key ingredient. This data is reflected in multiple expedited and periodic reports and case form-general information section.

Use the following procedure to add a product.

1. In the Business Configuration section, select **Product and Licenses**.

2. In the left panel, select a filtering criterion.

3. Select a Product and click to view the product details in the right panel.

   > **Note:** Ensure that you select the second-level folder to view the details of the product.

4. The details of the product appear in the right panel.

   Tip:

   - You can alternatively click **Add Product** to create a new product.

   - Use **Copy** to make an editable copy of an existing product.

   - Use **Copy with Licenses** to make an editable copy of an existing product, along with all associated licenses.

5. Enter the Product Name and Product Abbreviation.

6. Enter the **Dose** information associated with the Ingredient Names in the **Key Ingredients** section.

7. Select the **Unit** information from the drop-down list, associated with the Ingredient Names in the **Key Ingredients** section.

8. Enter the **Generic Name**.

> **Tip:** To copy all the Key Ingredients entered in the previous section, click **Copy From Ingredients**. This helps you to modify the list as required, instead of entering all the names manually

9. Enter the Dosage Formulation.

10. Enter the **Strength** of the dosage and select the **Units** from a drop-down list.

11. Click **Encode** to enter the **Primary Indication**. This enables you to display a primary indication for the product using either the MedDRA or the ICD-9 Dictionary.

12. Enter the **Model #** number associated with the product.

13. Select the **Manufacturer** from the drop-down list.

14. Click Select icon to select the **WHO Drug Code** associated with the product.

15. Enter the **Company Code** allotted for the product.

16. Enter the **Lot#** and **Date** associated with the Product.

> **Tip:** You can click **Add** to add new **Lot#** numbers. If you wish to add the current date in the **Date** field, use the **=** sign on your keyboard as a short-cut.

17. Click **Save** to save the product details.

> **Tip:** If you have added a new Product, click **Add Product** to save the new **Product**.

About Filtering Criterion The filtering criterion is essential as it helps you to search for specific items. The Argus Console provides this option for the Business Configuration section.

Using Organized by

The filtering browser displays in the top-left corner of the left panel. The Products and Licenses section can be filtered on the basis of any of the three combinations displayed below. Consider the following:

- If you enable **Organized byFamily/Product/License**, the generated output is visible in a tree-format, in the left panel.

- If you enable **Organized byProduct/License**, only the Product and License views are in the tree view in the left panel.

The Argus Console helps you to filter information further for the Business Configuration section. Once you have selected the **Organized by,** you can specify whether your search should contain or start with specific alphabets.

For example, the filtering criterion defined in the following illustration searches for all Family/Product/License data that contains the term Cure.

The left panel now displays the tree view of the **Product Family->Product** based on the filtering criterion.

> **Tip:** The number displayed next to the folder signifies the number of licenses within that product.

Configuring Licenses

Once product configuration is complete, you must create product licenses. Licenses are issued for pre-market and post-market release of a drug, device, or vaccine. Investigational (pre-market) licenses are issued for studies done at study centers and marketed licenses are issued for release of product. Configuration of licenses related to a product is a key step in the configuration of Argus Safety.

Configure licenses in the **Business Administration -> Products and Licenses** section. When configuring product licenses, be aware of the following:

- The user can enter Medical Device Information in the licenses as shown in the following illustration.
- The user can enter the following values in the Medical Device Information:
  - AIMD Active Implants
  - MDD Class III
  - MDD Class IIb
  - MDD Class lla
  - IVD Annex II List A
  - IVD Annex II List B
  - IVD Devices for Self-testing
  - IVD General
  - Blank (default)
- The user can enter up to 20 characters in the **PMA?510(k) #** field. By default, the field is empty.
- The user can enter a five-digit **Nomenclature Code**.
  - This **must** be a numeric value.
  - By default, the field is empty.
- The system tracks license updates in the audit log.
- These values display on the **License** report.

The following illustration shows the fields associated with this section.

Field Descriptions

The following table lists the Field Descriptions for the License configuration section.

Field/Control Name	Description
Trade Name	Enables the user to enter the Trade Name under which this product(s) is (are) authorized by this license.
Award Date	Enables the user to enter the license award date for this license.
Withdrawn Date	Enables the user to enter the license withdrawal date for this license. The withdrawn date cannot be less than the award date.
Market Authorization Holder	Enables the user to select a manufacturer or co-marketing partner for this license of the product.
Biologic / Vaccine	Whether the license is for a Biologic/Vaccine (this can impact reporting rule).
	If this is option is checked MedWatch will print PLA# not NDA# in section G5. It is included to support the Biologic License Application (BLA) and the Product License Application (PLA) requirements.
Not in Tradename lookup / Not Auto-scheduled	An option to indicate that this license name should not appear in the filter criteria for Auto Scheduling of Reports or trade name lookup browser.
	When this checkbox is checked, the trade name will not appear for this license in the Trade Name Lookup dialog and this license will not be evaluated or allowed for auto scheduling of the reports, but will be available for manual scheduling of reports.
	The license will be displayed in event assessment.
Labeled for Single Use	Whether the drug is for single use (such as disposables)
	If this option is selected it will mark YES in section H5 of the MedWatch device form, otherwise it will mark NO.
OTC Product	This enables the user to specify if the Product has been bought as an Over-the-Counter Product.
Datasheet URL	User can enter a hyperlink to a site giving information about the datasheet of the product.
Countries List	Enables the user to select all the countries in which the same license was issued.

Field/Control Name	Description
Authorization Country	This enables the user to select the Country for which this license applies.
	The chosen country does not impact the reporting rules algorithm. This field maps to the Country' field in the Reporting rules configuration.
License Type	The user can select one of the possible six types:
	Investigational Drug/Device/Vaccine or Marketed Drug/Device/Vaccine
	The chosen license type maps to the License type field under each country on the Reporting rules configuration.
Datasheet Name	The datasheet drop-down enables the user to associate a datasheet with the License.
	The field lists the datasheets for all the product families of the added products.
	The Data Sheet drop-down is enabled when one or more products have been added to the Products list.
License #	Enables the user to enter the License Number which will be referred in the regulatory reports like NDA, IND.
Company Item Number	Enables the user to enter the Company Item number corresponding to the license.
Countries List	Enables the user to select all the countries in which the same license was issued. The system adds the authorization country to the Countries Lise and updates the list when the user updates the authorization country.
Product Name	The Product List box displays the list of products (product name, dosage form and strength) that this associated license covers for regulatory reporting purposes.
Hide	When a product is marked as non display, it will not appear in the Trade Name Product lookup dialogue associated with the license tradename.
PMA/510(k)#	This field is associated with medical device information and prints in expedited reports.
Nomenclature Code	This field is associated with medical device information and prints in expedited reports.
Medical Device Information	This field is associated with medical device information and can contain the following values:
	■ AIMD Active Implants
	■ MDD Class III
	■ MDD Class IIb
	■ MDD Class IIa
	■ MDD ClassI
	■ IVD Annex II List A
	■ IVD Annex II List B
	■ IVD Devices for self-testing
	■ IVD General
	■ Blank (default)
CTPR Group Name	This value is used in Argus Safety when filter periodic report data.
Comments	Enables the user to enter information about the element configuration.

Adding Product Licenses

This screen helps capture License information (License specifics, associated with the License, Countries where the product is marketed or is under investigation). This data is reflected in multiple expedited and periodic reports and in case form-product information section.

Use the following procedure to add a product license.

1. In the Business Configuration section, select **Product and Licenses**.

2. In the left panel, select a filtering criterion.

3. Expand the folders till you reach the license associated with a product.

4. Select a license and click to view the license in the right panel.

5. The system opens the following screen:

1. Enter the **Trade Name** of the license.

2. In the **Manufacturer** list, select the manufacturer of the product.

3. Select the **AuthorizationCountry** in which the license was issued.

4. Select the **License Type.** This is the type of license.

5. Enter the license number in **License#**.

6. If this license is to be reported under the PLA# and not the NDA# select the **Biologic/Vaccine** checkbox. If this checkbox is selected, the PLA# (and not the NDA#) will be printed in section G5 of the MedWatch form.

7. Specify if the drug is **Labeled for Single Use** or not.

8. Specify if the drug has been bought as an Over-the-Counter (**OTC**) **Product**.

9. Under **Award Date**, enter the date the license was granted to the manufacturer.

10. Enter the **Withdrawn** date, if applicable.

11. Enter the Company item number in **Company item number**.

12. Enter a URL reference for the license under **Data Sheet URL** (A URL reference might be a link to product label or product information).

13. A world wide web address or an appropriate network path (For example: http://anydomainname/anypath or \\FILESERVER\LOCATION) can be entered in this field.

14. Select **Not in Tradename lookup/Not Auto-Scheduled** if this license is not to be involved in reporting.

15. In the **Countries List**, select the countries that define whether the case will be classified as domestic or foreign for regulatory report scheduling algorithm.

    Tip: To modify this list, use the **Modify** option (placed next to the Countries List).

16. Select the **Data Sheet Name** associated with the license, from the drop-down list.

17. Click **Add** in the **Product Name/Dosage Form/Strength** to add a product to the License

    Tip: You can alternatively click **Add License** to create a new license.

    Use **Copy** to make an editable copy of an existing license.

6. The **ProductBrowser** dialog opens.

7. Enter the name (partial or full) of the product and select **FullSearch**.

8. Select the appropriate product in the search results and click **Select**. Enter all the required products in this manner. Click here for more information on Product Browser.

Using the Product Browser

1. Click on **Add Products** to add products.

2. The **Products Browser** window opens:.

   ■ Enter the **Ingredient** key word for the search. The ingredient is displayed in the first column.

   ■ Select the **Ingredient** to obtain the **Family** it is associated with.

   ■ Select the **Product Name** to view the associated Trade Names.

   ■ Select the **Trade Name** required.

3. **Select** is now enabled at the bottom of the window.

4. Click **Select** to add the product details under the **Product Name** section. The Product Name is displayed in under the Product Name section.

5. The product browser available for datasheets, enables the administrator to select either multiple or all Product Names as follows:

   ■ Click the Family name and select multiple Product Names by clicking on each required Product Name.

   OR

   ■ Right-click the Family name to select all entities available under Product Name.

6. Click **Save** to save the changes.

   Tip: If you have added a new License, click **Add License** to save the new **License.**

Configuring Clinical Studies

It is important to configure clinical studies in the Argus Console because it helps the system categorize the source of information for the cases that have been registered. This screen helps in capturing Study information (study specifics, products involved in the study licensed countries associated with the study and the clinical references used in the expedited reports.

Configuration of the product is done using the **Business Administration->Studies** section.

The following illustration shows the fields associated with this section.

Field Descriptions

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

Field/Control Name	Description
Study ID	This is the Study ID.
Project ID	This is the project ID for the study.
Other ID	Enter any other ID associated with this study.
Observe Study Type (E2B)	This enables the user to select the study type from a drop-down list.
	■ This element is populate from the Case From Clinical Study section of the application.
	■ The value selected in Study Configuration, "Observe Study Type (E2B)" is populated in the the Case Form Study section when the user selects the Clinical Study.
	■ The system updates the standard E2B profiles (EMA, FDA, and ICH) to populate the tag.
Template Only	Select this checkbox to select only a template for the study.
Study Development Phase	Enables you to choose the study phase.
Arms	
Study Name	Enter the name of the study. This is a mandatory field. You can add upto 99 Arms to a study.
Study Type	Enter the type of study.
	Note: The Study Name and the Study Type fields must be unique for a study.
Product License	Select the applicable product license from the list of licenses available in this drop-down list. These licenses are displayed as per the products that have been selected for the Arm. This drop-down list is displayed as blank for a new Arm.
Copy	Click this button to copy a selected Arm.
Delete	Click this button to delete a selected Arm.

Field/Control Name	Description
Products	
Product Name	This is the Product Name.
Dosage Form	This is the Product formulation.
Strength	This is the Product Concentration.
Units	This is the Product Units.
Blinded	Check this checkbox to configure a blinded study. You cannot check this checkbox if the Study Type for that Arm is not blinded.
	Note: A **Study is eligible for Unblinding** checkbox is enabled when a study has at least one Arm with Study type as Blinded (Single/Double).
Product Type	Allows you to select a Product Type from the drop-down list comprising options of 'Investigational Product', 'Placebo', and 'Comparator'.
Products -Add WHO Drug	Opens Search Screen for selecting a non-company product.
Products -Add Product	Opens Search Screen for selecting a company product.
Products -Delete	Deletes the selected product row.
Clinical References	
Reference Type	Shows the various reference types that can be setup for this study.
Country	Enables the user to select a country for the clinical reference type.
Reference Number	Captures the reference number that will be reflected on the regulatory reports.
Add	Enables the user to add another clinical reference.
Delete	Enables the user to delete the selected clinical reference.
Countries	Enables the user to select a country for the clinical reference type.
Product License	This is the license of the primary (company) product participating in the study.
Product Abbreviation	This enables the user to enter an up to 5 character abbreviation of the study name which would be used in Case numbering when Product' is selected in the system numbering configuration in case of study cases.
Centers	The system displays the selected study centers for the study.
Study Description	Enables the user to enter a brief description of the study.
	Opens the study description in zoom mode and provides a spell check dialog.
	Opens the multi lingual dialog allowing the user to choose the language by clicking on the relevant flag of the country.
Investigator Alert	Enables the user to select an existing Advanced Condition. Under Investigator alert, an advanced condition can be created / selected. When this condition is satisfied, the system automatically sends an e-mail to the investigator group associated with this study.
Investigator Alert - select	Opens up the Advance Condition browser.

Field/Control Name	Description
Study is eligible for Unblinding	Check this box if the study can be unblinded. If the Study Type selected is Not Blinded", this field is disabled. This checkbox is enabled when a study has at least one Arm with Study type as Blinded (Single/Double).
Enable Study Specific Encoding	User checks this box if Study specific Auto encoding has to be enabled.
Autoencoding : Drugs(dict)	If unchecked (default state) the study will use the dictionaries configured using the Case form Configuration options. If checked, the Auto encoding button is activated.
Autoencoding : Events & Indications	Select this field to enable the system to encode Events & Indications using the dictionary the user selects from the list.
Study Reporting	
Products -Add Product	Opens the Search screen for selecting a company product.
Products -Delete	Deletes the selected product row.
Inherent Reporting Rules Form	This drop-down list is populated from all the Study templates which are configured for SUSAR Reports. Users can use the pre-defined SUSAR reports by selecting the applicable template from the drop-down list.
Always report	Usually the study-specific reporting is configured to handle reporting requirements for non-company products, e.g. Placebo or a comparator, as the company-based reporting is taken care by the license based reporting logic utilized in Argus. However, checking this checkbox will force Argus to check for qualifying expedited reporting rules based on the country, license type and reporting destination specified even if no non-company products are identified as study drugs. If the checkbox is unchecked then expedited reports based on the study-specific reporting rule will only be scheduled if there is a non-company product identified as a study drug.
Country	Specifies what country's reporting rules the console should consider. The list includes countries for which the expedited reporting rules exist.
License Type	Specifies what license type to consider for the specified country. Only applicable license types, i.e. Marketed Drug, Device, Vaccine or Investigational Drug, Device, Vaccine are displayed in this drop down list. For example if a country Germany" only has reporting rules for investigation drugs, then Investigational Drug" is the valid drop-down element.
Reporting Destination	This field is optional and by default will have the value All. Specifying any value in this list limits the reporting rules to be evaluated to the selected country, license type and reporting destination. The drop-down list is filled with valid destinations (regulatory authorities) for the country and license type selected based on the expedited reporting rules. For example, if the user has selected Germany, Investigation Drug and there are reporting rules for Germany with destinations of BfArM" and Drugs R us" then only these two destinations (LM: regulatory authorities) are displayed.
Time Frame	This field cannot be searched or altered, but is included for informational purposes. Based on the country, license type and reporting destination selected, the system determines and displays all possible time frames in ascending order separated by a comma.

Field/Control Name	Description
Possible Report Forms	This field cannot be searched or altered, but is included for informational purposes.
	Based on the country, license type and reporting destination selected, the system should determine and display all possible report forms in alphabetical order separated by a comma.

Adding Clinical Study Configurations

This screen helps capture study information (study specifics, products involved in the study licensed countries associated with the study and the clinical references used in the expedited reports). Study Information is required if a case has been reported while conducting a study and the participating product(s) belong to the company. This data is reflected in multiple expedited and periodic reports and case form-general information section.

Be aware of the following:

- The IND Reference Number drop down displays only those reference numbers (license numbers) associated with a product with a License Type of Investigational.

    – Console **-->** Business Configuration **-->** Studies **-->** Clinical Reference section (in middle of screen).

    – The **Reference Number** drop down field should be limited to IND (Investigational) US Licenses Number only.

- The Study Name on the Study Configuration can be a maximum 70 Characters (same as the Product name).

Use the following procedure to add a study:

1. In the Business Configuration section, select **Studies**.

2. In the left panel, select a filtering criterion.

3. Select a Study and click to view the study details in the right panel.

    > **Note:** Ensure that you select the study-level folder to view the details of the study.

4. The details of the study appear in the right panel.

Tip:
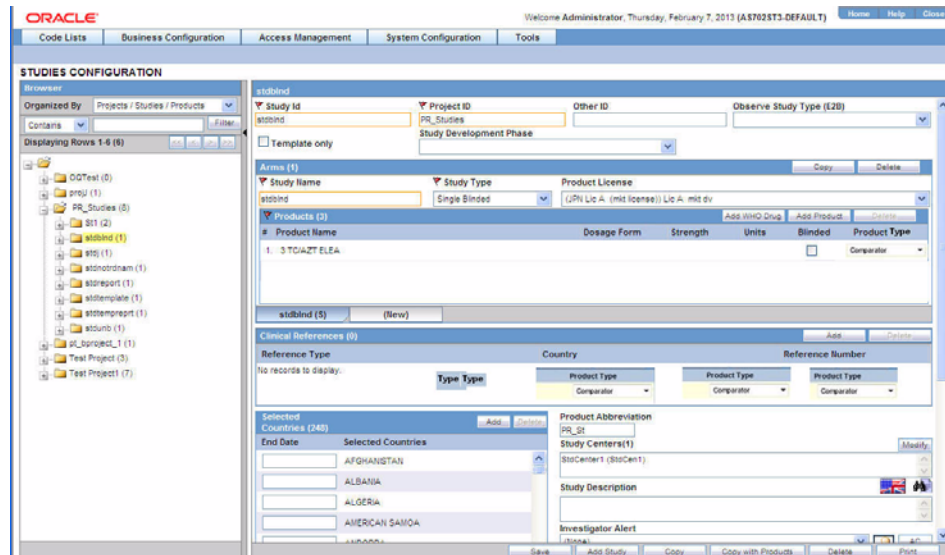
■ You can alternatively click **Add Study** to create a new study.

■ Click **Copy** to copy of the Study Name and the Study Type data to the new Study.

■ Click **Copy with Products** to copy the Study Name and the Study Type data, as well as to copy the blinded and open products.

5. Enter the **Study ID** and **Study Name** associated with the Study.

6. Select the **Project ID** for the Study, from the drop-down list.

7. Select the **Study Type** associated with the Study, from the drop-down list.

8. Enter the **Other ID**. This will be an alternative id for the Study.

9. Select **Template** to associate a template with the Study.

10. Select the **Observer Study Type(E2B)** from the drop-down list.

About Filtering Criterion The filtering criterion is essential as it helps you to search for specific items. The Argus Console provides this option for the Business Configuration section.

Using Organized by

The filtering browser displays in the top-left corner of the left panel. The studies section can be filtered based on of any of the three combinations shown in the following illustration. The generated output is visible in a tree-format, in the left panel, based on the entire categorization of Projects, Studies, Products.
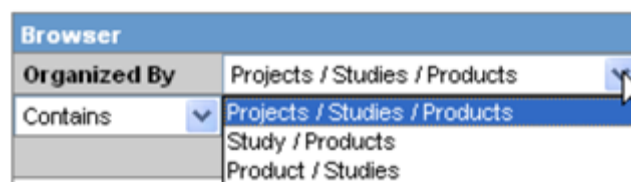
If you enable the **Organized by** Study/Products, only the Study and Product views will be available in the tree view in the left panel.

The Argus Console helps you to filter information further for the Business Configuration section. Once you have selected the **Organized by,** you can specify whether your search should contain or start with specific alphabets.

The filtering criterion shown in the following illustration, enables the system to search for all Projects/Studies/Products data that contain the term Cure.

The left panel displays the tree view of the **Projects/Studies/Products** based on the filtering criterion.

> **Tip:** The number displayed next to the folder signifies the number of studies/products within that project/studies family.

Adding WHO Drug Details

Use the following procedure to add WHO Drug detail information.

1. Select **Add WHO Drug** in the Products section to add the WHO Drug details associated with the Study.

2. Click on **WHO Drug** to add WHO drug details (using the WHO Drug browser window) associated with the Study.

3. The system opens the WHO Drug browser window.

4. Select the **Trade Name** or the **Ingredient** radio-button, to search for the WHO Drug term associated with either the Trade Name or the main Ingredient of the drug.

5. Click **Search** to execute the search. The data is displayed as follows.

6. Select the required component/row (this can be the key **Trade Name** or **Ingredient**).

7. The row now appears highlighted and the **Drug Details** section displays the associated information.

8. Click **Select** to add this drug information in the **Product Name** section of the Studies Configuration window.

9. The WHO Drug browser window closes and the drug appears in the **Product Name** section.

Adding Product Details

Use the following procedure to add details about the Product in the Product Browser.

1. Select **Add Product** in the Products section to add the products associated with the Study.

2. Click on **Add Products** to add products. The Product Browser window appears.

3. Enter the **Ingredient** key word for the search. The ingredient is displayed in the first column.

4. Select the **Ingredient** to obtain the **Family** it is associated with.

5. Select the **Product Name** to view the associated Trade Names.

6. Select the **Trade Name** required.

7. **Select** is now enabled at the bottom of the window. Click **Select** to add the product details under the **Product Name** section. The Product Name is displayed in under the Product Name section.

> **Tip:** To delete a product, select the product and click **Delete** (placed next to Add Product). A pop-up appears asking you to confirm the action.

1. Select the **Reference Type** associated with this Study, from the drop-down list.

2. Select the **Country** associated with this Study, from the drop-down list.

3. Enter the **Reference Number** associated with the Reference Type in this Study.

   > **Tip:**
   >
   > ■ To add more **Reference Types** in the Clinical Reference section, simply click **Add** . A new row is added to this section.
   >
   > ■ To delete the **Reference Type,** select the Reference Type and click **Delete** (placed next to **Add**). A pop-up appears asking you to confirm the action.

4. The **Countries** field is a display only field. You can **Add** or **Delete** this list based on your requirements.

5. Select the **Product License** from the drop down list. This is the license of the primary (company) product participating in the study.

6. Enter the Product Abbreviation.

7. The **Centers** are displayed as per the centers you choose to associate with the Study. To modify this list, click on **Modify** (placed next to **Centers**). Using this option you can add and delete Centers associated with the Study.

   > **Tip:**
   >
   > ■ To add more **Centers** to the Study Center list, use the **Add>>/ Add All** .options.
   >
   > ■ To delete the **Centers** from the Study Center list**, use the Delete>>/Delete All** options.

8. Enter the **Study Description** associated with the Study.

9. Click **Select** placed next to **Investigator Alert** to select or create an Advanced Condition for this Study.

   > **Tip:** Click here for details on Advanced Conditions.

10. Select **Study is eligible for Unblinding** to enable the study to be unblinded.

11. Select **Enable Study Specific Encoding** to enable the study specific Auto Encoding.

Configuring Auto Encoding

The Auto Encoding features helps you to configure your own dictionary of encoded data. Using this enables you to:

■ Configure studies to use dictionaries different from the dictionaries configured using the Case Form configuration.

■ Retrieve coded Events, Drugs and Events & Indications and codes from the lists associated with this section.

■ Ensure that the expedited reports display the correct verbatim and coded terms

Use the following procedure to configure Auto Encoding.

1. Click Auto Encoding to open the Auto Encoding dialog. The Auto Encoding dialog opens.

2. Select the encoding options as required for **Drugs** and **Events & Indications**. Use the items in the list to encode. For Study Encoding, go to **Console -> Business Configuration -> Studies -> Study Encoding** to support Central Encoding for Events & Indications for study cases, in a similar way as for non-study cases. Checking the Central Encoding checkbox (next to the Event & Indications Checkbox) also ensures that Central Encoding also gets reflected (as configured here) in the Argus Case Form, for study cases.

3. Select **Prevent manual encoding for Events & Indications** , if you want to disable manual encoding by users.

4. Select the **Require event term encoding before case closure**, to ensure that the expedited reports display the correct verbatim and coded terms.

> **Note:** If this feature is not selected, then the study will use the dictionaries configured using the Case Form Configuration options.
>
> Cases where the report type does not include clinical trial cases, will always encode with the dictionaries configured through the Case Form configuration options.

5. Select **Inherit Reporting Rules From** using the drop-down list to configure study-based reporting requirements.

Configuring Study Reporting

Study Reporting is provided in the Study Configuration section to configure study-based reporting requirements.

The reporting rules are not directly defined in the study, but rather identify which reporting rules to check from the already configured expedited reporting rules.

The identification is based on specifying what set of reporting rules to evaluate, as per the criteria of:

- Country
- License Type
- Reporting Destination

Use the following procedure to configure study based reporting.

1. Click **Add** in the **Inherit Reporting Rules From** section. The Study Reporting dialog opens.

2. Select **Always Report** as required.

   > **Tip:** Select this checkbox to force Argus to check for qualifying expedited reporting rules. These rules are based on the country, license type and reporting destination specified. Refer to the Field Descriptions for details.

3. Select the **Country** from the drop-down list.

   > **Tip:** This field specifies which country's reporting rules should be included. The drop-down list includes countries for which the expedited reporting rules exist.

4. Select the **License Type** from the drop-down list.

   > **Tip:** This field specifies the license type to be considered for the specified country. Refer to the Field Descriptions for details.

5. Select the **Reporting Destination** from the drop-down list.

   > **Tip:** This field is optional.

6. The **Time Frame and Possible Report Forms** cannot be searched or altered, but is included for informational purposes.

Tip:

- To add information pertaining to inheriting reporting rules in the **Study Reporting** section, click **Add**

- To delete information pertaining to inheriting reporting rules in the **Study Reporting** section, select the reporting rule and click **Delete**. A pop-up appears asking you to confirm the action.

7. Click **Save** to save the changes made to the **Studies** section.

    Tip: If you have added a new Study, click **Add Study** to save the new **Study**.

Configuring Expedited Report Rules

This section describes the configuration of Expedited Reports using pre-defined rules. These reports are required by Regulatory Authorities. The Administrator is responsible for entering information about Regulatory Authorities to which regulatory reports will be submitted.

This information is entered in the **Regulatory Agency Information** screen. Information about the local company contact for a regulatory authority can also be entered in this screen.

Configuration of the expedited report rules is done using the **Business Administration -> Expedited Report Rules** section shown in the following illustration.

When configuring expedited reporting rules, be aware of the following:

- If the user **does not** have permission to access **Advanced Conditions** on the **Expedited Reporting Rules**, the system does the following:

- – Displays the advanced condition name instead of displaying a blank.

- – **Does not** permit the user to modify or view advanced condition details.

- – Disables the **Advance Condition** button.

- The system enables the user configure the **Blinding Study Products** option for those included in the case (default unchecked).

  - – The system track updates to this field in the audit log.

  - – The **Reporting Rules** reports print the new options

- For cases where expedited reports are due, the user can force-distribute expedited reports even if processing is incomplete.

- Due Dates for expedited reports differ from Country to Country regulations. For Group 1 countries, the Due Date is based on the Aware Date received globally for the case.
  For Group 2 countries, the Due Date is based on the Aware Date when the affiliate or a company representative of that country received information about the case. In that case, the Due date for these reports could be 15 days after the report was actually generated based on the aware date received globally.

- When reports are scheduled and generated, the Due Date for Group 2 countries is calculated. The Due Date for a Group 2 Country = Report Generation Date + Additional days for Group 2 countries.
  The Due Date for a Group 2 country can be adjusted as per the holidays and weekends, through the **Adjust Due Date for Group 2 countries by XXX days** checkbox.

- The reporting rules have a **Force Distribute XXX days before due** checkbox. The default is unchecked.

  - – If the user checks the **Force Distribute** option, the **# of days before due** field is entered and automatically checks the **Auto Distribute** checkbox on the reporting rule (grayed out).

  - – The user can enter the number of days from 0 - # of days defined within the time frame.

  - – If the user enters a value greater than the defined time frame, the system displays the following message:

    Please enter a value less than the Time Frame defined for the Reporting Rule.

  - – If the user has not checked **Force Distribute**, the system disables the days before due.

- The system tracks updates made to the new Argus Console fields in the audit log.

- The system prints an audit log and print out that shows the expedited report rules information as shown in the following illustration.

- A super rule is a rule that overrides other rules when it finds a match. Be aware of the following:

  - – The system executes a super rule before executing any other reporting rules.

  - – If a super rule matches, it executes all the super rules but does not execute other rules.

  - – If the super rule does not match, the application executes the other rules.

Field Descriptions

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

Field/Control Name	Description
Report Name	Enables the user to view or enter the name of the Report.
Report Destination	Enables the user to select the name of the agency to which the report will be scheduled.
Active	Enables the user to specify whether the configured rule is active or inactive. ■ Only active rules are considered for report scheduling. ■ Inactive rules are not checked when the report scheduling algorithm runs.
Auto Distribute Reports	Enables you to distribute reports automatically. Except the E2B Reports, all the Expedited Reports that are selected for auto-distribution are tracked under the **Worklist--> Bulk Transmit** screen. The E2B Reports which are transmitted automatically, are tracked from **Worklist--> Bulk Transmit E2B**.

Field/Control Name	Description

Protect Reporter and Patient Confidentiality	Enables the user to configure Protect Reporter and Patient Confidentiality
	
	■ If this option checked and a report is generated or draft is viewed, the Patient and Reporter information will be hidden.
	
	■ This option will override the check-boxes on the case form (for Protect Reporter and Protect Patient) if it is checked.
	
	■ If this option is unchecked, the Case Form check-boxes will take effect.
	
	■
	
	■ The Reports listed below will check for the Reporting Rule Confidentiality Flag:
	
	    ■ EU Device Initial
	
	    ■ EU Device Final
	
	    ■ French CERFA Report
	
	    ■ CIOMS Report
	
	    ■ MedWatch Report
	
	    ■ Vaers Report

HCP Case	When checked, the system check for any reporter in the case where HCP=Yes. This enables the report to be scheduled if other parameters for the reporting rules are satisfied. The default is unchecked.
Report on Study Drug not Administered	If this field is not checked and a study drug (any in case) has not administered checked then no report is scheduled.
Active Moiety	Enable this check-box to enable rule to act exclusively as an active moiety rule for that country. When this option is enabled the system will disable and ignore the county when evaluating the domestic/foreign causality sections. Listedness will be evaluated at the case level.
No Follow-up or Downgrade	The system **does not** schedule a follow up or a downgrade report for the case when the the initial report was scheduled based on the current rule.
Origin of Events to Include - Domestic	Enables the user to select the inclusion of domestic or foreign cases based on their country of incidence. ■ Domestic: The event is marked as Domestic, if the country of incidence appears in the list of selected countries. ■ This list is displayed in the Countries tab, in the List Maintenance Licenses (section) for the license(s) of the suspect product(s) under examination.
Origin of Events to Include - Foreign	Enables the user to select the inclusion of domestic or foreign cases based on their country of incidence. ■ Foreign: The event is marked as Foreign, if the country of incidence *does not* appear in the list of selected countries. ■ This list is displayed in the Countries Tab on List Maintenance License (section) for the license(s) of the suspect product(s) under examination.
Timeframe	This field specifies the report's scheduled due-date based on the number of days, after the initial receipt or significant follow-up date.

Field/Control Name	Description
Adjust due date for Group 2 countries by xxx days	This field allows the user to specify the number of days by which the due date for a report may need to be adjusted for a Group 2 country.
Form	This is the drop-down list of expedited report forms.
Local Comment Type	This field is used to extract the local evaluator comment from case data (French CERFA 65-0044, CIOMS-I (Local)). This field is only enabled for CIOMS-I (Local) form.
Clinical Reference Type	This field is used to get information from the study configured for a case. This field is enabled for CIOMS-I and other forms.
Language	Enables the user to select language type. ■ English is the default language of choice. ■ The system does not support other languages at this time. ■ Reports such as the German BfArM, German PEI, and French CERFA can utilize some field values in their corresponding language (For example: narrative).
Message Type	Enables you to select the message type.
Message Type	Enables the user to select the message type for E2B report forms.
Listedness	Enables the user to check if the license being evaluated for reporting is listed. The possible values are: ■ Listed ■ Unlisted ■ Ignore (default)
Seriousness - Fatal/Life Threatening	Enables the user to check if the case contains a Death' or Life Threatening' seriousness criteria for the current event being evaluated. The possible values are: ■ Yes ■ No ■ Ignore (default)
Seriousness - Serious (Case)	Enables the user to check if case level seriousness assessment is Serious'. The possible values are: ■ Yes ■ No ■ Ignore (default)
Seriousness - Serious (Event)	Enables the user to check if the event level seriousness assessment (for any event) is Serious. The possible values are" ■ Yes ■ No ■ Ignore (default)
Seriousness - Severity	Enables the user to select a term descriptive of the severity of the event. E.g. Mild, Moderate, severe, unknown.
Product Specific - Family Name	Enables the user to configure product specific reporting rules.
Product Specific - Product Group	Enables the user to configure product specific reporting rules. Product Group drop-down always lists the configured Product Groups".

Field/Control Name	Description
Causality - Most Conservative	If this checkbox is marked, the system will look at the event level reported causalities, event level determined causalities and case level causalities, and if any of these three causalities is Yes then the case will be considered Reportable.
	If checked, the following options are hidden and set to Ignore":
	■ Causality as Reported (Event)
	■ Causality as Determined (Event)
	■ Causality as Reported (Case)
	■ Causality as Determined (Case)
	■ Causality is ignored when scheduling reports for non - study cases. This only Study cases.
Causality - Include Non-Clinical Trial Cases	Enables you to include the Spontaneous Cases (Non Clinical Trial Cases) for causality assessments.
Causality - Causality as Reported (Event)	Assesses As Reported causality in conjunction with the Listed value (if any) specified in the rule for the license/event combination being assessed. *Ignored for non-study cases. Only applies to Study cases.* The possible values are
	■ Reportable
	■ Non-reportable
	■ Ignore (default)
Causality - Causality as Determined (Event)	Assesses As Determined causality in conjunction with the Listed value (if any) specified in the rule for the license/event combination being assessed. *Ignored for spontaneous, literature and regulatory authority cases.*
	Ignored for non - study cases. Only applies to Study cases.
	The possible values are:
	■ Reportable
	■ Non-reportable
	■ Ignore (default)
Causality - Causality as Reported (Case)	Most conservative of the As Reported causalities in event assessment for ANY event.
	Ignored for non - study cases. Only applies to Study cases.
	The possible values are:
	■ Reportable
	■ Non-reportable
	■ Ignore (default)
Causality - Causality as Determined (Case)	Case Level Causality, as observed on the Analysis tab for the Case Level Causality.
	Ignored for non - study cases. Only applies to Study cases.
	The possible values are:
	■ Reportable
	■ Non-reportable
	■ Ignore (default)
Advanced Conditions	This field enables the selection of an advanced condition to further restrict cases that meet the criteria for the rule.

Field/Control Name	Description
Advanced Conditions - Select	Enables the user to open the Advanced Condition Browser.
	You can click this button to open the Advanced Conditions browser to select / create an Advanced Condition.
Responsible Group	Enables the user to select a group to whom reports scheduled by this rule will be assigned.
Cover Letter	Enables the user to use letters that have been configured for reporting template use.
Comments	Enables the user to enter reporting rule comments, up to 2000 characters.

Adding Expedited Report Rules

The Reporting Rules configuration feature enables you to define the reporting rules or criteria for the cases to be qualified for expedited reporting.

Use the following procedure to add expedited report rules.

1. In the Business Configuration section, select **Expedited Report Rules**.

2. In the left panel, select a filtering criterion. The left panel now displays the tree view of the **Country/License Type/Reporting Rule** based on the filtering criterion.

3. Select a Reporting Rule and click to view the reporting details in the right panel.

    Note: Ensure that you select the reporting rule-level icon/folder to view the details of the reporting rule.

    Tip: ▪You can alternatively click **Add Rule** to create a new reporting rule.

    ▪ Use **Copy Rule** to make an editable copy of an existing reporting rule, along with all associated expedited reporting rule information.

4. Enter the **Report Name**.

5. Select the **Report Destination** from the drop-down list. This is the name of the agency to which the report will be scheduled.

6. Select **Auto Distribute Reports** to distribute reports automatically.

7. Select **Active** to specify if the configured rule is active or inactive.

    Note: Only active rules are considered for report scheduling

8. Select **Origin of events to include-Domestic** to include *domestic* cases based on the country of incidence OR Select **Origin of events to include-Foreign** to include *foreign* cases based on the country of incidence

9. Select **Report on Study Drug not Administered**. This option ensures that all study drugs that are not administered are reported.

10. Select **Active Moiety** if you want to enable this option.

11. Select the required **Form** from the drop-down list of expedited report forms.

12. Select the **Local Comment Type** from the drop-down list. This field is used to extract local evaluator comments from case data.

13. Select the **Clinical Reference Type** from the drop-down list. This field is used to obtain information from study configured for a case.

> **Tip:** This field is enabled only for CIOMS-I and other forms.

14. Select the **Language** and **Message Type** from the drop-down list.

15. Select the **Listedness** from the drop-down list. This ensures that the license being evaluated for reporting is listed.

16. Select the **Seriousness- Fatal/Life Threatening** option from the drop-down list. This field ensures that cases that contain *Death* or *Life Threatening* seriousness criteria for an event are evaluated.

17. Select the **Seriousness- Serious (Event)** option from the drop-down list. Enable this field to check if the event level seriousness assessment is *Serious*

18. Select the **Seriousness- Serious (Case)** option from the drop-down list. Enable this field to check if the case level seriousness assessment is *Serious*

19. Select the **Seriousness- Serious (Severity)** option from the drop-down list.

This enables you to define the Severity as Mild, Moderate, Severe and Unknown.

20. Select the **Product Specific - Group Name** from the drop-down list. This field enables you to configure product specific reporting rules.

21. Select the **Product Specific - Family Name** from the drop-down list. This field enables you to configure product specific reporting rules.

22. Select **Causality-Most Conservative.** This ensures that the system looks at event level reported causality, event level determined causality and case level causality.

23. Select **Causality-Include Non-Clinical Trial Cases**. This enables you to include the Spontaneous Cases (Non Clinical Trial Cases) for causality assessments.

24. Select **Causality - Causality as Reported (Event)** as required, from the drop-down list.

25. Select **Causality - Causality as Determined (Event)** as required, from the drop-down list.

26. Select **Causality - Causality as Reported (Case)** as required, from the drop-down list.

27. Select **Causality - Causality as Reported (Case)** as required, from the drop-down list.

28. Select or create the **Advanced Condition** to restrict cases to the advanced conditions defined here.

If any of these three causalities are confirmed, then the case will be considered as reportable.

> **Note:** Use the Advanced Conditions browser to select or create an Advanced Condition by clicking Select .

29. Select the **Responsible Group** from the drop-down list. This is the group to which the reports scheduled by this reporting rule will be assigned.

30. Select the **Cover Letter** from the drop-down list. Use this field to select cover letters that have been configured for reporting template use.

31. Enter any regulatory report comments under the **Comments** text box.

32. Click **Save** to save the changes made to this section.

> **Tip:** If you have added a new Reporting Rule, click **Add Rule** to save the new **Expedited Reporting Rule.**

About the Filtering Criterion The filtering criterion is essential as it helps you to search for specific items. The Argus Console provides this option for the Business Configuration section.

Using Organized by

The filtering browser is displayed in the top-left corner of the left panel. The Expedited Report Rules section can be filtered on the basis of any of the five combinations shown in the following illustration.
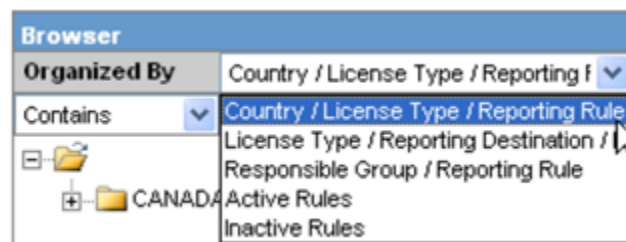
Consider the following examples:

- If you enable **Organized by Country/License Type/Reporting Rule**, then the output generated will be visible in a tree-format, in the left panel, based on the entire categorization of Country, License Type and Reporting Rule.

- If you enable the **Organized by Responsible Group/Reporting Rule**, then only the Responsible Group and Reporting Rule views will be available in the tree view in the left panel.

  > **Tip:**
  >
  > - Enable the **Organized By** filter for **Active Rules,** to obtain the list of active reporting rules.
  >
  > - Enable the **Organized By** filter for **Inactive Rules,** to obtain the list of inactive reporting rules

The Argus Console helps you to filter information further for the Business Configuration section. Once you have selected the **Organized by,** you can specify whether your search should contain or start with specific alphabets or words.

For example, the filtering criterion defined in the following illustration for all Country/License Type/Reporting Rule data that contain the term Canada.

4

System Configuration

This chapter provides information about configuring the system. It includes information about how to configure the following:

- Case Priority
- Field Validations
- LAM System Numbering
- Common Profile Switches
- Argus J
- Case Form
- Custom HTTP Header
- Case Processing
- Assessments
- Auto Archiving
- Case Numbering
- Lot Number
- MedDRA Browser
- WHO Drug
- Performance
- Documentum
- E2B
- Local Labeling
- Reports
- Workflow
- System Numbering
- Field Labels
- User-Defined Fields

System Configuration Overview

The following table describes how the system options are configured:

Section	Description
Case Priority	This screen enables the administrator to configure rules to determine the priority of new cases that are entered into the system.
Field Validation	This screen enables the administrator to configure field level validations for the Case Form fields.
Field Labels	This screen enables the administrator to configure field labels.
LAM System Numbering	This section enables the administrator to specify the case numbering preferences for LAM cases.
System Management (Common Profile Switches)	This screen enables the administrator to configure common profile switches.
Workflow	This screen enables the administrator to configure Workflow states and rules.
System Numbering	This screen enables the administrator to specify the case numbering preferences.
SMTP	This screen enables the administrator to configure SMTP for e-mails

Configuring Case Priority

Configure rules to determine the priority of new cases that are entered into the system. Based on these rules, the system assigns each case a priority that is displayed in the Worklist.

Each row in the Case Priority Configuration screen represents the priority level assigned to a case that meets the specific criteria selected for that level. This data is reflected in multiple expedited and periodic reports and case form-product information section.

■ The user can select the priority level for which the criterion is to be configured.

■ Select **System Configuration --> Case Priority** to view the Case Priority page.

Field Descriptions

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

Field/Control Name	Description
Priority	Enables the user to select the priority level whose criterion is to be configured.
	The user can disable only the last enabled priority. Example: If a user has priority 1-4 checked, the priority can be disabled only in the order of 4-1.
Case Assessment - Serious	Enables the user to configure the seriousness for case assessment.
	■ Select **Yes** from the drop-down list to give priority to cases that are serious.
	■ Select **No** for non-serious cases to be considered for this priority level. Seriousness is considered at the case level.
	■ Select **Ignore** from the drop-down list to ignore this condition when assessing the priority of this case.
Case Assessment - Unlisted	Enables the user to configure the priority level for unlisted case assessment.
	■ Select **Yes** from the drop-down list for unlisted cases to be considered for this priority level.
	■ Select **No** for listed cases to be considered for this priority level. Listedness criteria is considered at the case level.
	■ Select **Ignore** from the drop-down list to ignore this condition when assessing the priority of this case.
Case Assessment - Causal	Enables the user to configure the priority level for causal case assessment.
	■ Select **Yes** from the drop-down list for causal cases to be considered for this priority level.
	■ Select **No** for non-causal cases to be considered for this priority level. Causality criteria is considered at the case level.
	■ Select **Ignore** from the drop-down list to ignore this condition when assessing the priority of this case.
Report Due Date-Due Soon	Enables the user to configure the report date due soon.
	If this option is selected, the case is given the specified priority if at least one expedited report is due after the number of warning days specified from the current system date.
First Report Due Date - Ignore	Enables the user to configure the first report due date to ignore status.
	This option is used to ignore this parameter when assessing the priority.
No. of Warning Days Before Due	Enables the user to enter the number of days before a case's report due date when the priority is raised to Due Soon.
Advance Condition Drop Down List Box	Enables the user to select an existing advance condition from the drop-down list.
AC Button	Enables the user to create a new advanced condition set or modify an existing one.

Field/Control Name	Description
Run All Case Priority Determination on Middle Tier	Enables the user to run all case priority determination on Middle Tier. ■ If unchecked, the application assesses priority during every case save operation in Web . ■ If checked, the application does NOT assess priority during every case save operation in Web and Client/Server. The initial priority is calculated by the report scheduling and after that, all the priority updates are done by the AG Service Priority process.

Use the following procedure to configure Case Priority

1. Select the priority level whose criterion is to be configured.

2. Select the Case Assessment - **Serious.** The options in the drop-down list are **Yes, No, Ignore**.

3. Select the Case Assessment - **Listed.** The options in the drop-down list are **Yes, No, Ignore**.

4. Select the Case Assessment - **Casual.** The options in the drop-down list are **Yes, No, Ignore**.

5. Select First Report Due Date as Due Soon or Ignore. Enter the #Warning days for Due Soon.

6. Select the **Advanced Conditions** from the drop-down list.

7. Use the **AC** button to create a new Advanced Condition.

8. Select **Run All Case Priority Determination on Middle Tier** to ensure that the application *does not* assess priority when a case is saved in Web and Client/Server.

9. Click **Save** to save the changes made.

Configuring Field Validations

This screen enables you to configure field level validations for the Case Form fields. Be aware of the following:

■ These validation rules are expressed as an advanced condition, with their criteria marked as required or warning.

■ The field level validations feature helps in automatic checking of data as it is entered on the Case Form, to ensure consistency of data as per company requirements. Consider the following example:

Suppose that the year in the patient's date of birth is entered as 1860. The patient's date of birth probably could not have been prior to 1880; hence, a warning is issued to ensure the accuracy of the entered data.

■ A field level validation message such as this one is a "warning violation" and the user can therefore enter a justification and continue working on the case.

■ An example of a mandatory violation would be a dosage regimen stop date that occurs before the dosage regimen start date. Cases cannot be saved without correcting mandatory violations.

■ For dependent fields, Argus Safety is pre-loaded with several field level validations. Some of these validations are protected and cannot be disabled. Others can be disabled, if required by company policy.

- The system displays the Advance Condition Description for field validations on the case form after the Advanced Condition name in the following format: Field: *XXXX*:*YYYY***Reason**: *ZZZZ*

where:

XXXX	Is the Field Label Tree view followed by the field label as configured in the field label configuration.
YYYY	Is the Advance Condition name configured for the field validation.
ZZZZ	Is the advance conditions descriptions as configured for the Advance conditions.
	This text prints only if there is a description available for the Advanced Condition. Otherwise, the system disables the field label.
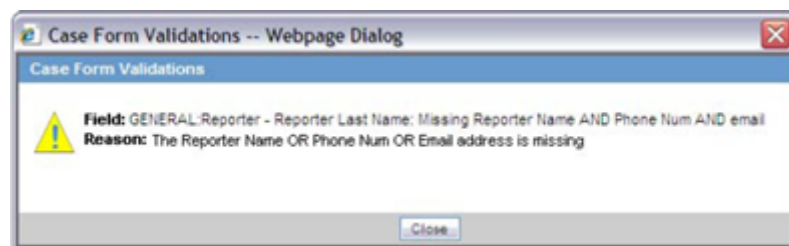
Select **System Configuration->Field Validation** to view the Case Form Field Level Validation screen. The following is an illustration of the screen.
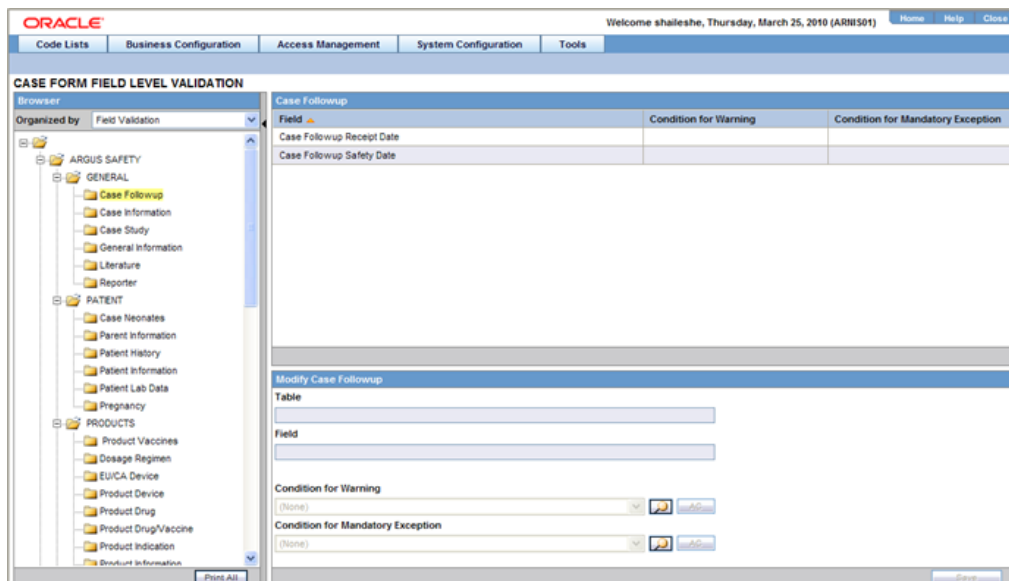
Tip: The Case Form tabs appear on the left panel and are categorized as folders. Each folder contains all the field labels associated with that section.

Consider the following example:

The General Tab in the Case Form contains sections such as Study, Follow-up, Case Literature, etc. To view the list of field names associated with the **Study** section, click **Study** in the left panel. The field names associated with **Study** appear in the right panel.

Field Descriptions

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

Field/Control Name	Description
Field	Displays the name of the field.
Condition for Warning	Displays the advanced condition for warning.
Table	Displays the name of the selected sub-folder as displayed in the browser tree view. This field cannot be edited.
Field	Displays the name of the selected field label in the browser tree-view. This field cannot be edited.
Condition for Warning	Displays the advanced condition for warning.
Condition for Mandatory Exception	Displays the advanced condition for mandatory exception.
Print All	Displays a list of validations on all tables, fields and advanced conditions of each Group in the Case Form as a PDF.

Modifying Field Validations

This section enables the user to edit the information already entered in fields.

Use the following procedure to modify a field validation.

1. Select the Case Form folder and field for which, the validation rule is to be modified.

   Tip: The information of the selected field is displayed in the **Modify** section.

2. Click **Select** icon to create/select advanced conditions for **Condition forWarning** and **Condition forMandatory Exception**.

   Tip: Click here for details on Advanced Conditions.

   Note:

   - If all validation rules are met, a green icon is displayed.

   - If a condition for warning is met during field validation, an orange icon is displayed.

   - If a condition for mandatory exception is met during field validation, a red icon is displayed.

3. Click **Save** to save the changes made.

   Note: Label Changes will not be reflected in Argus Case Form unless IIS is reset.

Configuring LAM System Numbering

This section enables you to specify the case numbering preferences for LAM cases. The system provides the ability to use multiple case numbering schemes for global use. For example, if site is used in the numbering, the system provides the option to keep separate sequences for each site.

Select **System Configuration->LAM System Numbering** to view the LAM System Numbering screen shown in the following illustration.

Field Descriptions

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

Field/Control Name	Description
Manually Number Cases	The option is used to enable the user to manually number the cases on booking or while copying the case, using the save as' option on the case form.
Automatically Number Cases	On selection, the system automatically numbers the cases as defined by the user in the numbering format.
Start at	Enables the user to initialize the counter of the sequence number.
Separate sequence for each site	Enables the user to separate the sequence numbering for cases on site by site basis. If there are cases being entered from two different sites then each site will have different sequencing of case numbers.
Separate sequence for each report type	Enables the user to separate the sequence numbering for cases by the report type of the case.
Separate sequence for each year	Enables the user to reset the sequence numbering for cases after each year, based on the initial receipt date of the case.
Separate sequence for each month	Enables the user to reset the sequence numbering for cases after each month, based on the initial receipt date of the case.
Separate sequence for each product abbreviation	Enables the user to reset the sequence numbering for cases for each different product abbreviation.
Numbering Format	Enables the user to select the numbering format by selecting the different placeholders. ■ Define the numbering format by typing in custom keywords to print on every case number and selecting different placeholders. ■ [YY][MM]-[###] is the default format.

Field/Control Name	Description
Placeholder	Enables the user to enter a placeholder.
	■ Placeholders are used to pickup values from the database to be used in the Case numbering format.
	■ The possible values populated in this list are:
	■ # - Number: defines the digits to be used as the sequence number in the format. The field is used to display the sequence number on the case numbers.
	■ CC- Country code: When selected, this uses the A2 code for the country of incidence for the case number.
	■ DD - Day: When selected, this uses the date of the Initial receipt date' field of the case.
	■ MM - month: When selected, this uses the month of the Initial receipt date' field of the case.
	■ P -When selected , this uses either of the two values:
	If report type is Spontaneous or other during booking: the system uses the value of the Product Abbreviation' field specified in the Product configuration for the selected Primary suspect product.
	■ SSS – User Site: When selected this uses the Site abbreviation of the site belonging to the user who booked in the case.
	■ TTT – Report Type: When selected this uses the report type abbreviation of the report type selected during bookin of the case.·
	■ YY- Year: When selected, this uses the year of the Initial receipt date' field of the case.

Use the following procedure to configure LAM Numbering.

1. Select the **Numbering** feature as required. This can be manual numbering or automatic numbering of cases.

2. Select the **Sequencing Options** as required.

> **Tip:** For the complete explanation of the sequencing option refer to the Field Descriptions.

3. Select the **Numbering Format**. Use **Placeholders** to enter the required format.

> **Tip:** To customize the **Numbering Format**, use the **placeholder** values. Consider the following example:

To select Country Code, Month and Year (as values to be incorporated from the database) as the Case numbering format, execute the following steps.

1. Click on *Country Code.* This appears in the **Numbering Format** field.
2. Click on *Month*. This appears in the **Numbering Format** field next to the Country Code.
3. Click on *Year*. This appears in the **Numbering Format** field next to the Country Code and Month.
4. The final data listed in the **Numbering Format** field is the Case Numbering Format.

4. Click **Save** to save the changes made.

Configuring System Management - Common Profile Switches

This section lists the configurable sections for Common Profile Switches.

Select **System Configuration**and then**System Management** to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

> **Note:** If any change is made in the System Management (Common Profile Switches) screen, the Argusvr2.exe and Argusvr2a.exe should be killed from each Web Server and the IIS on Argus Web / Report Servers must be reset, in order to reflect the changes made in the Argus application..

The following table provides the list of configurable sections associated with Common Profile Switches.

Section	Sub Section	Description
Advanced Conditions	~	The Advanced Conditions configuration screen enables you to specify the number of rows to be displayed on the Advanced Condition search screen.
Argus J	~	The Argus J Configuration screen enables you to modify the customizable fields on the Argus J form.

Section	Sub Section	Description
Case Form Configuration	~	This screen enables you to configure Common Profile Switches that affect the behavior of the Argus application
Case Processing	Assessments Auto Archiving Case Numbering Dictionary Browser Lot Number Processing Performance	This section enables you to configure the case processing fields and items.
Documentum	~	This screen enables you to configure the Documentum fields and items for Documentum.
Documentum Login	~	Enables the user to configure the Documentum login.
Enable Storage of E2B Reports in Documentum	~	Enables the user to indicate whether E2B reports should be stored in Documentum. The user selects Yes or No.
Enable Storage of Submitted Expedited Reports in Documentum	~	Enables the user to indicate whether submitted expedited reports should be stored in Documentum. The user selects Yes or No.
Enable Storage of Case Attachment Files in Documentum	~	Enables the user to indicate whether case attachment files should be stored in Documentum. The user selects Yes or No.
Enable Storage of Submitted Periodic Reports in Documentum	~	Enables the user to indicate whether submitted periodic reports should be stored in Documentum. The user selects Yes or No.
E2B	~	This screen enables you to configure the E2B fields and items for E2B.
Local Labeling	LAM	The Local Labeling Configuration screen enables you to modify the options available through local labeling.
MedWatch Configuration	~	The MedWatch Configuration screen enables you to modify the customizable fields on the MedWatch form.
Reporting	Expedited Expedited BfArM Expedited Canada Expedited CIOMS Expedited MedWatch Periodic Scheduling	The Reporting Configuration screen enables you to modify the options available for reporting.

Section	Sub Section	Description
Security	~	The Security Configuration screen enables you to modify the options available for security.
User Interface	~	The User Interface screen enables you to modify the options available for User Interface.
Workflow	~	The Workflow Items screen enables you to modify the options available for Workflow Items.

Configuring Advanced Conditions

Select **System Configuration --> System Management** to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the rows to display on each page of an advanced condition screen, click the **Advanced Conditions** folder in the left panel.
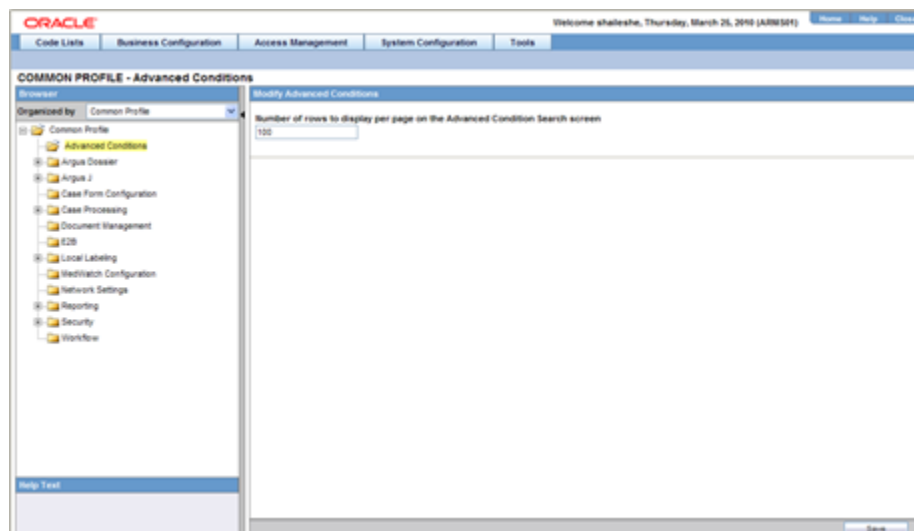
Field Descriptions The following table lists and describes the fields in **Advanced Conditions Configuration**.

Field/Control Name	Description
Number of rows to display per page on the Advanced Condition Search screen	Enables the user to specify the number of rows to be displayed on the Advanced Condition search screen.

Use the following procedure to configure Advanced Conditions.

1. Enter the Number of rows to display per page on the Advanced Conditions Search screen.

2. Click **Save** to save the changes made.

Configuring Case Form (System Management)

This screen enables you to configure Common Profile Switches that affect the behavior of the Argus application.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To view the list of field names associated with the **Case Form Configuration** section, click the **Case Form Configuration** folder in the left panel. The field names associated with **Case Form Configuration** appears in the right panel.

The Case Form Configuration dialog helps you customize the case processing activities in order to meet the company's requirements. The Administrator can configure the following items by using the Case Form Configuration dialog shown in the following illustration.

Auto Encoding / Central Encoding To enable the use of standardized medical terminology throughout the adverse event reporting process, dictionaries can be used to encode certain terms in the Case Form.

The dictionaries that will be used to encode drugs, Events & Indications, and events can be specified in the **Autoencoding** section of the **Case Form Configuration** dialog.

Field Descriptions

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

Field/Control Name	Description
Drugs	The Drugs dictionary list enables the selection of the WHO-DRUG dictionary. Select the **Drugs** check box and tab out of the product name field in the Case Form to search the company product followed by the license trade names. ■ If no matches are found, the WHO drug dictionary (drug names) is searched. ■ Tab out of the generic name field in the Case Form to search the product /product family ingredients (it displays the select dialog if more than one product is found with the ingredient). ■ If no match is found, the WHO drug dictionary (ingredients) is searched.
Events & Indications	Select **Events & Indications** to be prompted for the term as you enter it to be encoded on the **Events & Indications** tab. If an exact match is found in the dictionary, the term populates automatically. If an exact match is not found, the Event Coding dialog is displayed to select the desired event. Auto encodes primary indication for the drug encoding, Patient Condition description in Other Relevant History section and Death Details dialog.
Prevent manual encoding for Events & Indications	Prevents users from encoding the Events & Indications manually.
Require event term encoding before case closure	Ensures that users encode the events prior to formally closing a case.

Automation The **Automation** section enables the user to generate an Auto narrative based on one of the templates configured by the method described in this topic.

Field Descriptions

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

Field/Control Name	Description
Auto Regulatory Scheduling	This enables the user to configure the manner in which Argus Safety handles the Auto-scheduling of Regulatory Reports. The available options are: ■ None ■ Always ■ Significant ■ Manual Selecting Always will run the auto-scheduling algorithm when any field from a specific list of fields is modified on the Case Form and the case is saved.

Field/Control Name	Description
Report Generation	The Report Generation option helps you to configure how the system responds to new data when generating auto-scheduled regulatory reports.
	■ When new data is entered, the system re-runs the regulatory report-scheduling algorithm to determine which reporting rules apply to the case.
	■ If **Overwrite Existing Reports** is selected, the system updates the existing scheduled reports with the new data entered. This setting ensures that follow-up numbering is specific to each health authority.
	■ If a MedWatch report for the FDA has already been scheduled for this case, that report would then be updated with the new information entered.
	■ If **Create as Follow-up** is selected, the system uses the new data to create new reports marked as follow-up reports. This setting ensures that the same number would identify a follow-up report worldwide. Users will be unable to submit follow-up reports before one of the following events occur on the initial or previous follow-up report.
Case Locking for People	The Administrator has the option of indicating whether cases that are not locked can appear in periodic reports.
	■ If **Allow Unlocked cases to be included** is selected, then a check box on the periodic report configuration dialogs will allow unlocked cases to appear in periodic reports.
	■ To prevent unlocked cases from appearing in periodic reports, select **Prevent unlocked cases from appearing**.
Report On	Selecting **Diagnoses** will only list the events marked as diagnoses plus events unassociated with a diagnosis in Regulatory Reports.
	■ The Event Assessment section of the case form will only list diagnosis and unrelated events. If there are no diagnoses, all events are listed. You can configure a default setting for selecting the Diagnoses state at a system level.
	■ Selecting **All Events** will always list all events, regardless of their relationship in the Event Assessment section of the case form. The system will take into consideration both events marked as diagnoses and events marked as symptoms when running the regulatory report algorithm.
Diagnosis Default on Event	The options are **Yes** or **No**
	■ Selecting **Yes** will set the default Events Diagnosis to Yes whenever a new event is entered.
	■ Selecting No will set the default Events Diagnosis to No whenever a new event is entered.
Event Assessment On	The Event Assessment section of the case form will only list diagnosis and unrelated events. If there are no diagnoses, all events are listed. You can configure a default setting for selecting the Diagnoses state at a system level.
	■ Selecting **Diagnoses** will include in Event Assessment only those events that are associated with a diagnosis or symptoms that are not associated with any of the diagnoses.
	■ Selecting **All Events** will include all events when the Event Assessment is performed.
Prevent Modification to Autonarrative	Selecting the **Preventing Modification of Autonarrative** check box will prevent users from modifying autonarratives.

Field/Control Name	Description
Case Autonarrative	Selecting the **Case Autonarrative** check box enables the user to generate an Autonarrative based on one of the templates configured by the method described in this topic.

Templates Clicking the **Templates** button enables the Administrator to create a new Autonarrative template, modify/copy an existing template, or delete an existing template.

Use the following procedure to create a new Autonarrative template.

1. Click the **Templates** button in the **Case Form Configuration** dialog to open the Autonarrative Configuration dialog.

2. Click **New** to open the **Narrative Configuration** dialog.

3. Under **Template Name**, enter a name for this new template.

4. Click the **Add** button at the bottom of the dialog. A new row for entering a phrase and its associated logic will appear.

5. Enter a text phrase in the **Phrase** field. The text can include placeholders that will be substituted by the appropriate case data when the Autonarrative is generated.

   For example:A phrase might be entered as: "The patient was [age] at the onset of this event". When the Autonarrative is being generated, the "[age]" placeholder will be substituted for the actual age of the particular patient in the case.

6. Click the ellipsis button to the right of the **Logic** column. Select or enter an Advanced Condition for the logic section.

   This search will be used to determine whether or not the corresponding phrase will appear in a narrative for a particular case.For example:An advanced condition can be specified such that only cases involving children younger than five years old will have the phrase "

   The patient was [age] at the onset of this event" in the Autonarrative.

7. Repeat steps 4 through 6 to add other text phrases to the template. Click **OK** to save the template or **Cancel** to exit the dialog without saving the changes.

   Note: Selecting the **Preventing Modification of Autonarrative** checkbox in the Case Form Configuration dialog will prevent users from modifying autonarratives..

Creating a Template in Another Language Use the following procedure to create a template in another language.

1. Once a template is created, double-click the "Narrative Templates" folder to expand the template tree in the **Autonarrative Configuration** dialog.

    > **Tip:**   To open the Autonarrrative Configuration dialog, click the Autonarrative button in the Case Form Configuration dialog.

2. Expand the selected template folder to display the languages for this template. To configure this template in a language other than English, double-click the appropriate language icon.

3. Configure the foreign language template as described in steps 4 through 7 of the procedure for creating the Autonarrative template above.

4. Click Close to exit the Autonarrative Configuration dialog.

    > **Note:**   Autonarrative placeholders in a language other than English will get substituted by text from that particular language. If no text is available in that language, English language text will be used to substitute the placeholders.

Copying a Template to Another Language Use the following procedure to copy a template to another language.

1. Select the original language from which the target language copy is to be created. The original language can be selected in the tree-view of the **Autonarrative Configuration** dialog.

    > **Tip:**   To open the Autonarrrative Configuration dialog, click the Autonarrative button in the Case Form Configuration dialog.

2. Click **Copy**. The **Autonarrative Copy** dialog will appear.

    > **Note:**   In the **Autonarrative Configuration** dialog, the **Copy** button for a selected language template will only be available if a template has already been created in that language.

3. Select the language to which the narrative template is to be copied and click **Copy**.

4. The contents of the original language template will now be copied into the selected language template.

Deleting Templates Use the following procedure to delete templates.

1. To delete a language template, select the appropriate language icon for the template in the Autonarrative Configuration dialog and click **Delete**.

2. To delete the entire Autonarrative template, select the template folder icon in the Autonarrative Configuration dialog and click **Delete**.

Duration Calculations The following table lists and describes the fields associated with this section.

Field/Control Name	Description

Event	The **Duration Calculations** section is used to indicate whether the system should calculate event duration (the time from Event Onset Date to Event Stop Date) in an inclusive or an exclusive manner.
	For instance, select **Inclusive** to calculate a range from 01 January to 10 January as ten days. Select **Exclusive** to calculate a range from 01 January to 10 January as nine days.
	If the user has entered both the date and time, the exclusive/inclusive designation is ignored.
Drug	The Drug Duration Calculations section is used to indicate whether the system should calculate drug duration in an inclusive manner or an exclusive manner, as described under Event Duration Calculations.

Documentum Common Login The Documentum Common Login information is used to connect to the Documentum server to perform Documentum related activities to the case form. The system uses this information only if the common profile switch to use the common login is set. This option is only available if the system is configured to use Documentum.

The following table lists and describes the fields associated with this section.

Field/Control Name	Description
Username	This is the username associated with the Documentum Common Login.
Password	This is the password associated with the Documentum Common Login username.

Custom Routines The following table lists the Field Descriptions associated with this section.

Field/Control Name	Description
Custom Routine Before Save	The function behaves the same way as the Custom Routine Before Commit. The case ID is passed as a parameter to the function. The return value is a string format. If a null string is returned, the system assumes the procedure executed without any error, and continues with the case save operation. If any numeric/string value is returned, the case save routine is aborted and the system displays the returned string as an error message to the user.
Custom Routine Before Commit	This is the Custom routine to be called before case save. Ensure that the custom routine is present in the database, and the application has access to it.
Custom Routine After Commit	This is the after-save Custom routine to be called after case save. Ensure that the custom routine is present in the database, and the application has access to it.
	Select the **Table Config** button to select the tables that are being modified in the post-save script.
Custom Routine Before Lock	This is the Custom routine to be called before case lock Ensure that the custom routine is present in the database, and the application has access to it.
Attachment File Size Limit (in Megabytes)	The file size entered in this field enables you to specify the maximum size limit for attaching a file. The upload limit defined here can be seen in the **Attachments and References** section of the Bookin screen. The default size for uploading an attachment is 30 MB. You can also configure the file size as per your requirement, up to 300 MB.

Table Config Button The Table Config button enables you to fetch only the delta table data after post-save, so that the entire case is not reloaded. This button is enabled only when the **Custom Routine After Commit** checkbox is selected.

Use the following procedure to remove case tables.

1. Select the **Custom Routine After Commit** checkbox and click the **TableConfig** button. The following screen appears.
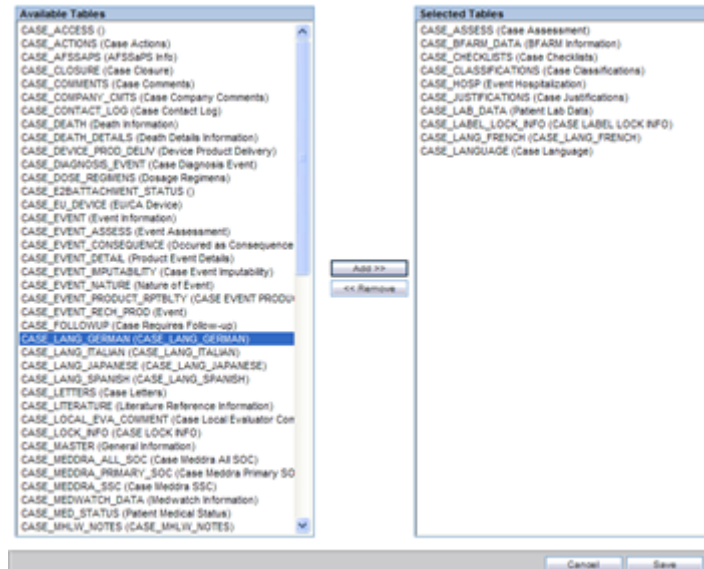
Initially, all case tables open under the **Available Tables** list box.

2. Select the required table(s) and click **Add>>** to include them to the **Selected Tables** list.

Alternatively, you can select the required table(s) and click **<<Remove** to exclude them from the **Selected Tables** list.

3. Click **Cancel** to close the screen without making any changes or click **Save** to save this configuration.

- The **Case Save** routine gets modified to retrieve only the table data from the **Selected Tables** in the configuration.

- If no **Post Save** is configured, the Case Save does not execute the Case Load routine.

Modify Data Lock Point This section is displayed only if the DLP_SETUP switch is set to ON in the database schema in the CMN_Profile_Global table.

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

Field/Control Name	Description
Enable Data Lock Point	Enables you to activate a data lock point by selecting this checkbox. If this checkbox is not selected, the Modify Data Lock Point section displays only this field as editable.
Use Last Completed Version	Enables you to use the last completed version.
Use Next Completed Version (Includes Data Cleaning)	Enables you to use the next completed version that includes data cleaning.

SMTP Configuration

The system enables you to attach a Custom SMTP Header along with the preconfigured text as the Header for every e-mail it sends.
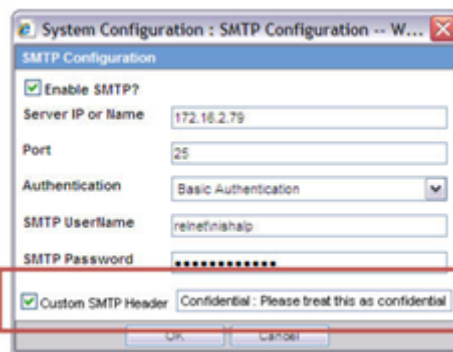
- The Custom SMTP Header text is enabled only when the Custom SMTP Header check box is checked.

  - The user can define the Header and the Header text in the Custom SMTP Header configuration by separating them with a colon (:).

  - The system does not validate the value for the Custom SMTP Header text.

- You can enter a maximum of 255 characters.

- All e-mail messages sent using the following processes are sent as Confidential:

  - AG Service : Bulk Transmit Email

  - AG Service : General Email

  - ESM Service : Business / User / IT Email

- The Audit Log tracks updates to this field.

Configuring Case Processing

This section enables you to configure the case processing fields and items. **Select System Configuration --> System Management** to view the Common Profile Configuration screen

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Tip: The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders.

Each folder contains all the field labels associated with that section.

To view the list of field names associated with the **Case Processing** section, click the **Case Processing** folder in the left panel.

The field names associated with **Case Processing Configuration** appear in the right panel.
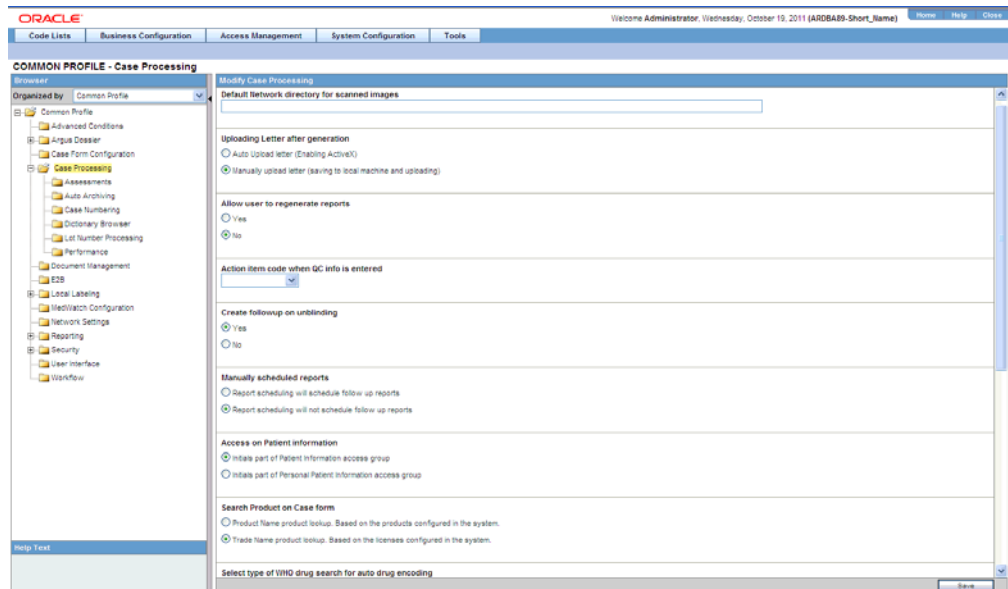
The Case Processing folder has been further categorized into the following sub-folders:

- Configuring Assessments
- Configuring Auto Archiving
- Configuring Case Numbering
- Configuring Dictionary Browser
- Configuring Lot Number Processing
- Configuring Performance

Field Descriptions The following table lists the fields available under **Case Processing Configuration:**

Field/Control Name	Description
Create follow-up on unblinding	The available options are Yes and No.
Allow User to regenerate reports	The available options are Yes and No.
Manually Schedule reports	The available options are: ■ Report scheduling will schedule follow up reports ■ Report scheduling will not schedule follow up reports
Events to Display on Assessment Tab	The available options are: ■ Event Assessment will display all Events ■ Event Assessment will display Diagnosis Events only

Field/Control Name	Description
Access on Patient Information	The available options are: ■ Initials part of Patient information access group ■ Initials part of Personal Patient Information access group
Search product on Case Form	The available options are: ■ Product Name product lookup. Based on products configured in the system. ■ Trade Name product lookup. Based on the licenses configured in the system.
Select Type of WHO drug search for auto drug encoding	The available options are: ■ Default WHO schema ■ Use alternate who tables
Action Item Code when QC info is entered	The available action item codes are listed in the drop-down list box.
Default Network directory for scanned images	Enter the path of the default network directory of scanned images in this text box. When the user selects **New Case from Image** from the Quick Launch toolbar, the **Windows Open** dialog opens, and displays the path specified in this textbox, by default.
Uploading Letter after generation	Select **Auto Upload Letter (enabling Active X)** to upload letters automatically through the Active X control. The Active X control supports the following versions of MS Office - Office XP, Office 2003 and Office 2007. Select **Manually upload letter** to manually upload a letter saved on the local machine.

Use the following procedure to configure the case processing options.

1. Select the required option in **Create follow-up on unblinding**.

2. Select the required option in **Allow User to regenerate reports**.

3. Select the required option in **Manually Schedule reports**.

4. Select the required option in Events to Display on Assessment Tab.

5. Select the required option in **Access on Patient Information**.

6. Select the required option in **Search product on Case Form.**

7. Select the required option in Select Type of WHO drug search for auto drug encoding.

8. Select the required action item code from the drop-down list box in **Action Item Code when QC info is entered**.

9. Enter the path of the default network directory of scanned images in the **Default Network directory for scanned images** text box.

10. Select whether to upload letters automatically or manually by making the required selection under **Uploading Letter after generation**.

11. Click **Save** to save the changes made to this section.

Configuring Assessments

This screen enables you to configure the case processing fields and items for assessments. **Select System Configuration --> System Management** to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To view the list of field names associated with the **Case Processing --> Assessments** section, click the **Assessments** folder in the left panel.

The field names associated with **Assessments Configuration** appear in the right panel.
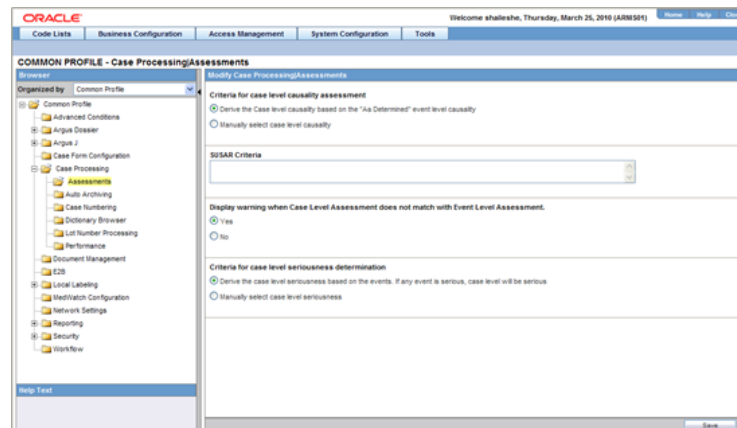
Field Descriptions The following table lists the fields available under **Assessments Configuration:**

Field/Control Name	Description
Display warning when Case Level Assessment does not match with Event Level Assessment	The available options are Yes and No.
Criteria for case level causality assessment	The available options are: ■ Derive the case level causality based on the As Determined event level causality. ■ Manually select case level causality.
Criteria for case level Seriousness determination	The available options are: ■ Derive the case level seriousness based on the events. If any event is serious, case level will be serious. ■ Manually select case level seriousness.
SUSAR Criteria	Enables you to enter an SUSAR criteria as an SQL query. An SUSAR is identified as a Serious, Unexpected, Related Case. **Note:** The SQL should not exceed 2000 characters.

Use the following procedure to Configure the Case Processing Options

1. Select the required option for Display warning when Case Level Assessment does not match with Event Level Assessment.

2. Select the required option for Criteria for case level causality assessment.

3. Select the required option for Criteria for case level Seriousness determination.

4. Enter the **SUSAR Criteria**.

5. Click **Save** to save the changes made.

Configuring Auto Archiving

This screen enables you to configure the auto-archiving. Select **System Configuration --> System Management** to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

The default rule requires that the following options must be completed before a case is auto-archived:

- All Action Items Closed

- All Reports Submitted or Marked required for Non-Submission

- All Events are encoded

- All Letters are sent

- All Cases are locked

Apart from this default rule, you can also configure additional rules/criteria for auto-archiving cases from this screen.

- Workflow State (Configurable by the user) - This option enables you to select Workflow States. Cases that fall in the specified workflow states can be auto-archived.

- Advanced Conditions selection (Configurable by the user) - This option enables you to specify advanced conditions. Cases that meet the specified advanced conditions, can be auto-archived.

This feature enables you to define rules for automatically archiving those cases that meet the defined rules.

To view the list of field names associated with the **Case Processing --> Auto Archiving** section, click the **Auto Archiving** folder in the left panel.

The field names associated with **Auto Archiving Configuration** appear in the right panel.
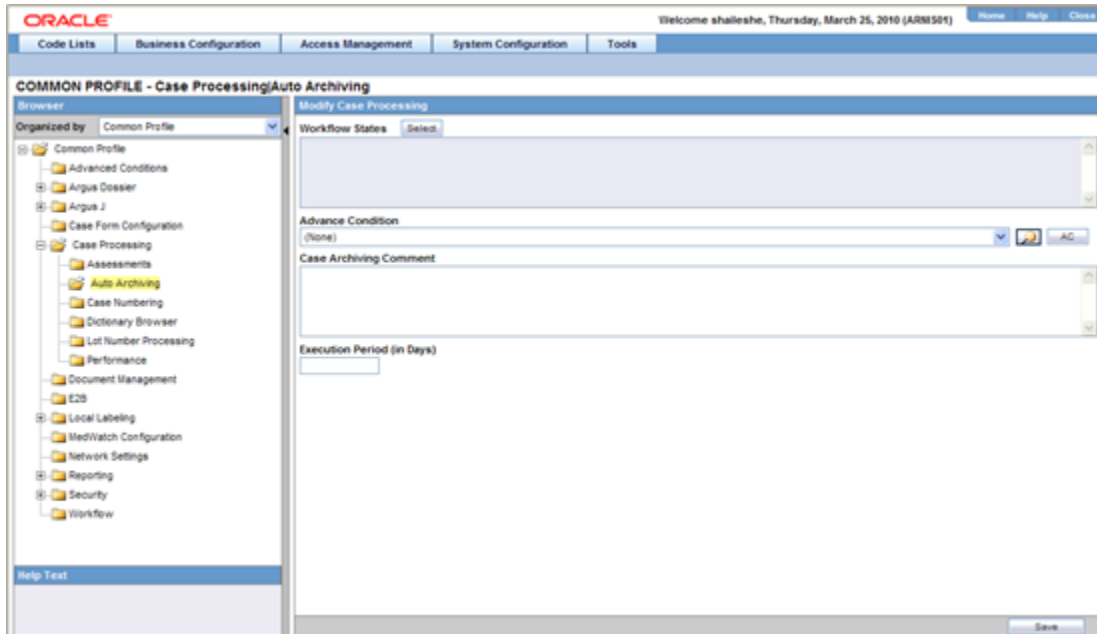
Field Descriptions The following table lists the fields available under **Auto Archiving Configuration:**

Field/Control Name	Description
Workflow States	The **Select** button enables you to select workflow states from a list of workflow states. The selected workflow states are displayed in the text box.
	Cases that belong to these workflow states are marked to be auto-archived.
Advanced Condition	Enables you to specify advanced conditions for auto-archiving cases. Cases that meet the advanced conditions are marked to be auto-archived.
	Refer to Advanced Conditions for details on creating advanced conditions.
Case Archiving Comment	Enables you to enter a pre-defined case close comment, of up to 200 characters. The information entered in this field is displayed in the Case Routing and Case Archive notes.
Execution Period (in Days)	Enables you to define how often the cases will be archived.
	Note: You can enter up to 99 days only.
	If no value is entered, the cases will not be auto-archived.

Use the following procedure to configure the auto archiving options

1. Select the workflow states for auto-archiving cases from **Workflow States**.

2. Create the advanced conditions for archiving cases in **Advanced Condition**.

3. Enter the **Case Archiving Comment** as a pre-defined case close comment.

4. Enter how often the cases will be archived, as per number of days, under **Execution Period**.

5. Click **Save** to save the changes made.

Configuring Case Numbering

This screen enables you to configure the case processing fields and items for case numbering. Select System Configuration **-->** System Management to view the Common Profile Configuration screen

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To view the list of field names associated with the **Case Processing --> Case Numbering** section, click the **Case Numbering** folder in the left panel. The field names associated with **Case Numbering** appear in the right panel.
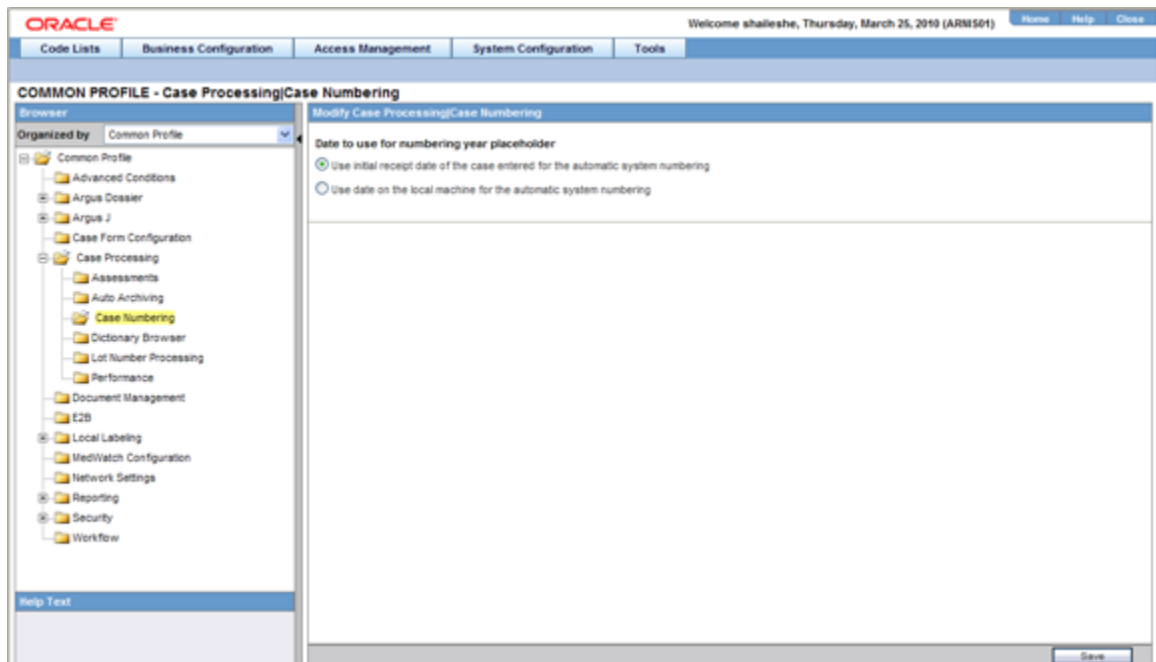
Field Descriptions The following table lists the fields available under **Case Numbering Configuration:**

Field/Control Name	Description
Date to use for numbering year placeholder	The available options are: ■ Use initial receipt date of the case entered for the automatic system numbering. ■ Use date on the local machine for the automatic system numbering.

Use the following procedure to configure the case numbering options.

1. Select the required option for Date to use for numbering year placeholder.

2. Click **Save** to save the changes made.

Configuring Lot Number

A common profile switch determines whether a user can override an un-validated lot number and enter them in the case form.
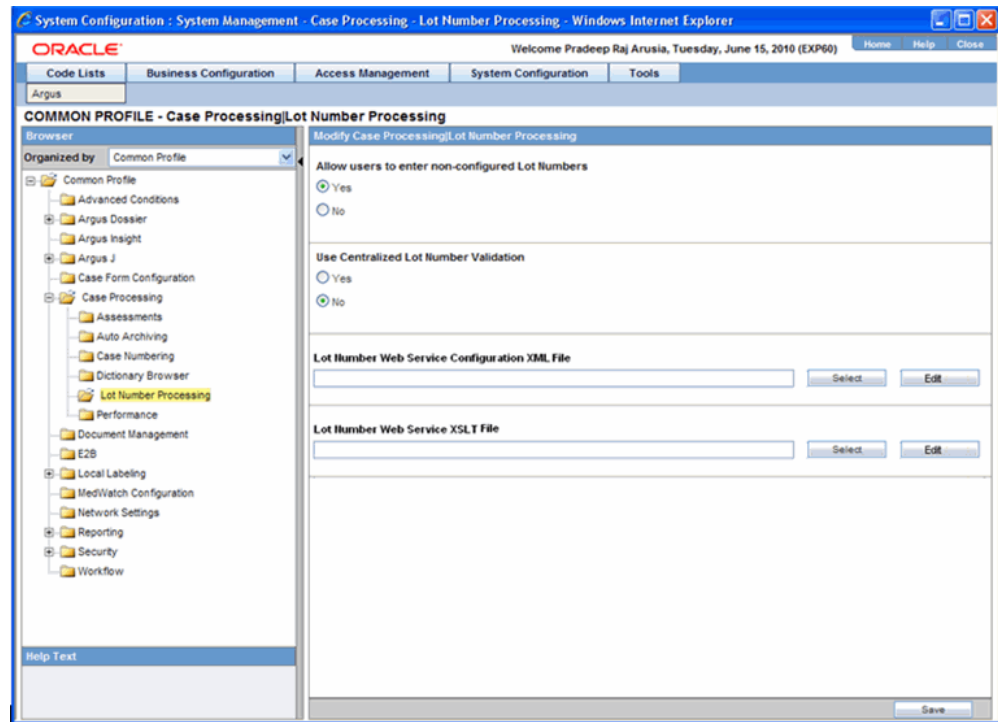
The following table lists and describes the fields available under **Lot Number Processing:**

Field/Control Name	Description
Allow Users to enter non-configured Lot Numbers	Enables you to select whether or not to allow users to enter non-configured lot numbers. Select Yes to allow, and No to diallow.
Use Centralized Lot Number Validation	Enables you to select whether or not to allow centralized lot number validation. Select Yes to use, and No to not use this option.
Lot Number Web Service Configuration XML File	Enables you to select and/or edit (if required) the Lot Number Web Service Configuration XML File. The file path textbox is a read-only field, which displays the path of the uploaded file. This field stores the configuration of the Centralized Lot Number Web Service in XML format. The Edit button is enabled only after the XML file has been successfully uploaded.
Lot Number Web Service XSLT	Enables you to select and/or edit (if required) the Lot Number Web Service XSLT File. This field stores the XSLT associated with the Centralized Lot Number Web Service. The file path textbox is a read-only field, which displays the path of the uploaded file. The Edit button is enabled only after the XSLT file has been successfully uploaded.

Yes is the default. This enables the user to select the options for the Lot Number Validation as current functionality This message box displays the following message:

No matching lot number was found.

If centralized lot search is used, the system hides the Lookup button since a list is automatically returned and displayed.

- No: The system does not permit the user to keep the existing value. The user can only obtain it from a Look up dialog that lists the available Lot Numbers.

- The system hides the Keep button.

  A common profile switch determines whether lot validation uses Argus or a centralized lot validation.

  - No (default): This enables the user to select the options for the Lot Number Validation as current functionality from within the Argus Product Families Lot Numbers

  - Yes: This enables the system to query outside the Argus Safety system through a web service return the following parameters for Lot Number Validation

    – Argus sends the user-entered lot number to central system for validation/look-up and retrieves a response to act on.

    – The message format for the retrieved lot is as follows:

  <Lots>

  <Lot>

  <Lot Number>: Lot number

  <Expiration>: Lot expiration date

  <Custom name=name metadata=text>: Custom data to a lot number

- If more than one lot number is returned, the system displays a lot selection dialog.

The Custom Node ■The metadata attribute is as labels in the selection dialog that displays the data. The name attribute is used to identify the case form field to be populated with the data in the node.

- Clients can use an XSLT document to map the custom data to case fields present on the active case form page.

If an error occurs during the web service transaction, a message box will appear with the proper error message.

Configuring MedDRA Browser

This screen enables you to configure the case processing fields and items for MedDRA Browser.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

- The existing MedDRA browser category has been renamed Dictionary Browser.
- A switch in Argus enables you to use either local MedDRA Coding or Central System MedDRA Coding (Web Service Method)
  - Local (Default): Current functionality of MedDRA browser using Local Dictionary within the Database
  - Web Services: Returns the MedDRA hierarchy via the configured Web Services.

This enables the User Local MedDRA if term is not found by Web Service" function.
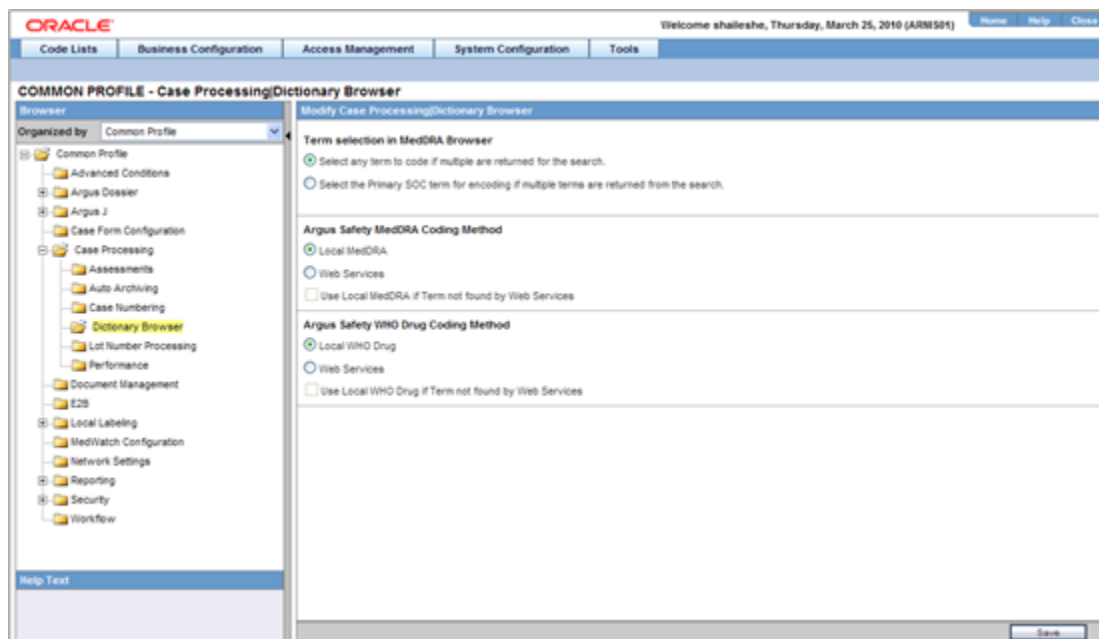
To view the list of field names associated with the **Case Processing --> MedDRA Browser** section, click the **MedDRA Browser** folder in the left panel. The field names associated with **MedDRA Browser** are in the right panel.

Field Descriptions The following table lists the fields available under **MedDRA Browser Configuration:**

Field/Control Name	Description

Term Selection in MedDRA Browser	The available options are:
	■ Select any term to code if multiple are returned for the search
	■ Select the Primary SOC term for encoding if multiple terms are returned from the search.

Use the following procedure to configure the MedDRA Browser.

1. Select the required option for Date to use for numbering year placeholder.

2. Click **Save** to save the changes made.

Configuring WHO Drug

Argus supports WHO-Drug encoding using a locally installed version of the WHO-Drug dictionary through the WHO-Drug browser.

■ A switch in Argus enables you to use either local WHO-Drug Coding or Central System WHO-Drug Coding (Web Service Method) under the Dictionary browser category

    – Local (Default): Uses the current functionality of WHO-Drug browser that uses the Local Dictionary in the Database

    – Web Service: Returns the WHO-Drug fields via the configured Web Services

    – The system enables the User Local MedDRA if term is not found by Web Service"

Configuring Performance

This screen enables you to configure the case processing fields and items for performance.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To view the list of field names associated with the **Case Processing --> Performance** section, click the **Performance** folder in the left panel. The field names associated with **Performance** appear in the right panel.
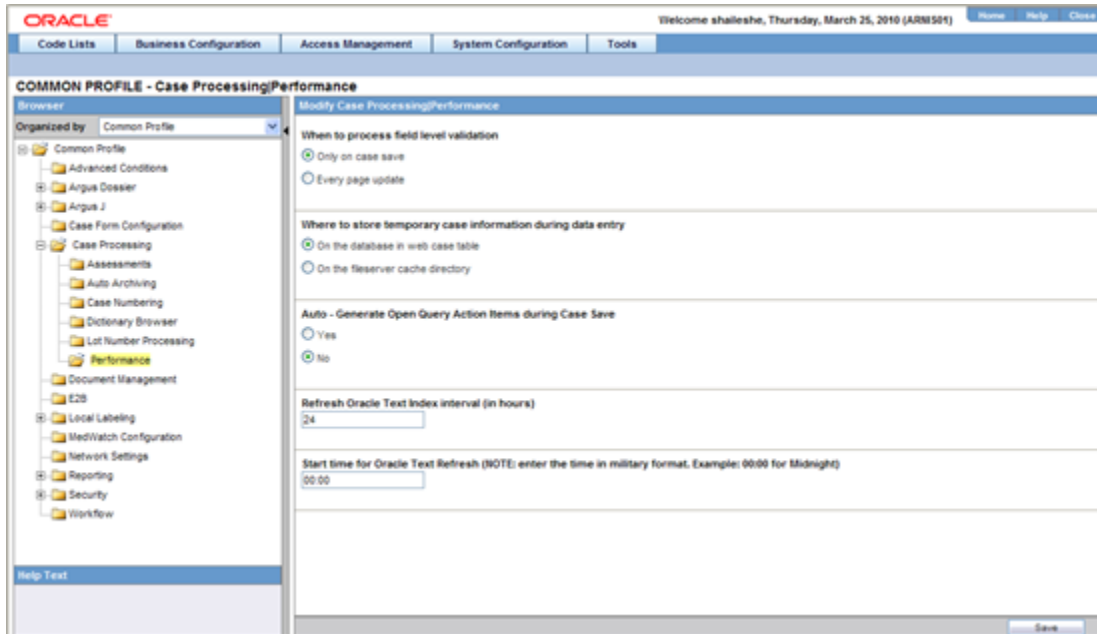
Field Descriptions The following table lists and describes the fields available under **Performance Configuration:**

Field/Control Name	Description
When to process field level validation	Enables you to configure the frequency of field level validation. Select **Only on case save** to validate only when a case is saved.
	Alternatively, select **Every page update** to validate fields whenever a page is updated.
Where to store temporary case information during data entry	Enables you to select the location where you can save the temporary case information during data entry.
	You can select the location to be On the database in web case table or On the fileserver cache directory.
Use Oracle Text for duplicate search querying	Enables you to select Oracle Text for duplicate search querying. Click **Yes** to enable this feature.
Refresh Oracle Text Index interval (in Minutes)	Enables you to configure the interval (in minutes) between each refresh of an Oracle Text Index.
	This feature is useful while searching for duplicate cases. It is advisable to enter a high interval for low number of cases and vice versa.
Start Time for Oracle Text Refresh	Enables you to specify the time when the Oracle text will be refreshed.

Use the following procedure to configure performance.

1. Select the required option for **When to process field level validation**, as applicable.

2. Select the required option for Where to store temporary case information during data entry, as applicable.

3. Select the required option for **Use Oracle Text for duplicate search querying**, as applicable.

4. Enter the time difference between each refresh (in minutes), under **Refresh Oracle Text Index interval (in Minutes)**.

5. Enter the time (in military format) when the Oracle text refresh will begin, under **Start Time for Oracle Text Refresh**.

6. Click **Save** to save the changes made.

Configuring Documentum

The system enables you to configure to choose Document Management from the Common Profile Switches: Document Management

- You may select from the following:

  – Documentum: Cabinet Name and Document Type textboxes are only enabled when the "Documentum" radio option is selected. These text boxes allow upto 255 characters.

- Docbase and Domain are textbox fields. These fields can be a maximum of 255 characters.

- Configure the following for Document Management:

  – E2B Reports

  – Expedited Paper Reports

  – Periodic Reports

- – Attachments saved within the cases

- – E2B Reports:

- ■ If the E2B switch is enabled and the user transmits an E2B Report (Before submission to the Gateway), the system stores the E2B XML Message in Documentum.

- ■ When the Report Submission is successful and the report is marked as submitted in Argus, the system updates a flag in the Documentum database to designate the same.

- ■ Expedited Reports

  - – If the Expedited switch is enabled and the user submits an expedited report, the Argus Safety Service inserts the report into Documentum as a PDF file.

  - – When the Report Submission is successful and the report is marked as submitted, the system updates a flag in the Documentum database to signify the same.

- ■ Periodic Reports:

  - – If the Periodic Switch is enabled and a Periodic Report is approved in Argus, an Argus Safety Service exports the report as a PDF file and saves it in the Documentum database.

  - – When the Report Submission is successful and the report is marked submitted, the system updates a flag in the Documentum database to indicate the same.

- ■ Attachments:

  - – When this switch is enabled, a new button is available on the Argus Attachments screen, **LAM Attachments Section label Attach Documentum Link**.

  - – The Argus Bookin dialog has an additional drop down option for attaching to Documentum.

  - – When the Links Switch is enabled, the system stores all Argus Attachments in the Documentum database.

  - – Clicking the Attach Documentum Link button opens a search dialog to enable the user to search the Documentum database for a document. This document is then linked as an attachment within Argus.

- – When the user clicks the Attach Documentum Link button, the following occurs:
- – The system presents a search dialog to enable the user to search for a document in the Documentum database.
- – The user must select a Table to Search. This list is a distinct Table List from the Documentum_table_info Table.
- – After the user selects a Table, the system populates the Column drop down with all the columns available for that table based on configuration from the same table.
- – When the user selects the Full Search option, the system performs a like search in Documentum.

- ■ If LDAP is enabled, the system automatically send the login information from Argus to Documentum.

- ■ After selecting a document from the Search results, the system saves the URL for the Argus attachment.

- ■ If the user clicks the URL, Argus automatically opens the document from Documentum.

- ■ Argus refers to two (2) that enables you to specify which tables/columns can be searched in Documentum and which Table Fields to display in the Search Results.

  - – documentum_table_info - This table holds the table / fields the user will be able to search.

    Type_Name - Table to Search

    Attribute_Name - Field in the Table to Search

    Attribute_Type - Type of field being searched.

  - – Documentum_display_info - This table stores the Return Search Parameters.

    Type_Name - Table to Search

    Attribute_Name - Field in the Table to Search

    Sort_Id - The order in which the fields will be displayed

  - – The Document Management (Central or Documentum) database gets a new document each time a document attachment is added as a new attachment. Existing documents are modified for changes.

  - – The system does not create a new document in the Document Management (Central or Documentum) database each time a case /event is saved in Argus or Affiliate

  - – When cases are copied, the document copy has the same DOC ID (Object ID) as the original case. If the Document is modified after the cases are copied, the system gets a new DOC ID only for the case attachments that were modified.

  - – The icon is similar to the Additional Info requirements for attachment types

  - – When the user clicks the attachment to open it, the system retrieves the attachment from Documentum

  - – When events from the Affiliate are accepted in Argus as Argus cases, the system keeps the DOC ID(Object ID) from the Affiliate Event

  - – Attachments can be entered to the case / affiliate event via

Affiliate Events

Bookin in Argus or Affiliate

Case Form / Affiliate Event Form

Intake WL

- Error Messages

  - If the system cannot connect to the document system, it displays the following message:

    Argus was unable to connect to the document management system. Please contact your Administrator for more details.

  - If the document system does not return any rows, the system returns a dialog with the following message

    No documents returned.

  - Select System Configuration **-->** System Management to view the Common Profile Configuration screen

    Tip: The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To view the list of field names associated with the **Case Processing --> Documentum** section, click the **Documentum** folder in the left panel. The field names associated with **Documentum** appear in the right panel.

Field Descriptions The following table lists the fields available under **Documentum Management:**

Section	Field	Description
Common Login	Use Common Login Password	Users use a common login password to access the system
	Docbase	The name of the document database.
	Domain	The name of the domain where the database resides.
Enable Storage of E2B Reports in Document Repository	Documentum	Enables the system to store E2B reports in the document repository.
	Argus	Enables the system to store E2B reports in the Argus document repository.
		This is the default.
	Cabinet Name	The storage location of the E2B reports.
	Document Type	The type of document that is being stored.

Section	Field	Description
Enable Storage of submitted expedited reports in Document Repository	Documentum	Enables the system to store submitted expedited reports in the Documentum document repository.
	Argus	Enables the system to store submittedd expedited reports in the Argus document repository.
		This is the default.
	Cabinet Name	The storage location of the submitted expedited reports.
	Document Type	The type of document that is being stored.
Enable storage of case attachment files in the Document Repository	Documentum	Enables the system to store case attachment files in the Documentum document repository.
	Argus	Enables the system to store case attachment files in the Argus document repository.
		This is the default.
	Cabinet Name	The storage location of the case attachment files.
	Document Type	The type of document that is being stored.
Enable storage of submitted periodic reports in the Document Repository	Documentum	Enables the system to store submitted periodic reports in the Documentum document repository.
	Argus	Enables the system to store submitted periodic reports in the Argus document repository.
		This is the default.
	Cabinet Name	The storage location of the submitted periodic reports.
	Document Type	The type of document that is being stored.

Use the following procedure to configure Documentum

1. Select the Common Login to configure the login for the user.

2. Select the option for Enable Storage of E2B Reports in Documentum.

3. Select the option for Enable Storage of submitted expedited reports in Documentum.

4. Select the option for Enable storage of case attachment files in Documentum and additionally the searching and attaching files already existing in Documentum to a case.

5. Select the option for Enable storage of submitted periodic reports in Documentum.

6. Click **Save** to save the changes made.

Configuring E2B

This screen enables you to configure the E2B fields and items for E2B. Select System Configuration **-->** System Management to view the Common Profile Configuration screen

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To view the list of field names associated with the **Case Processing --> E2B** section, click the **E2B** folder in the left panel. The field names associated with **E2B** appear in the right panel.
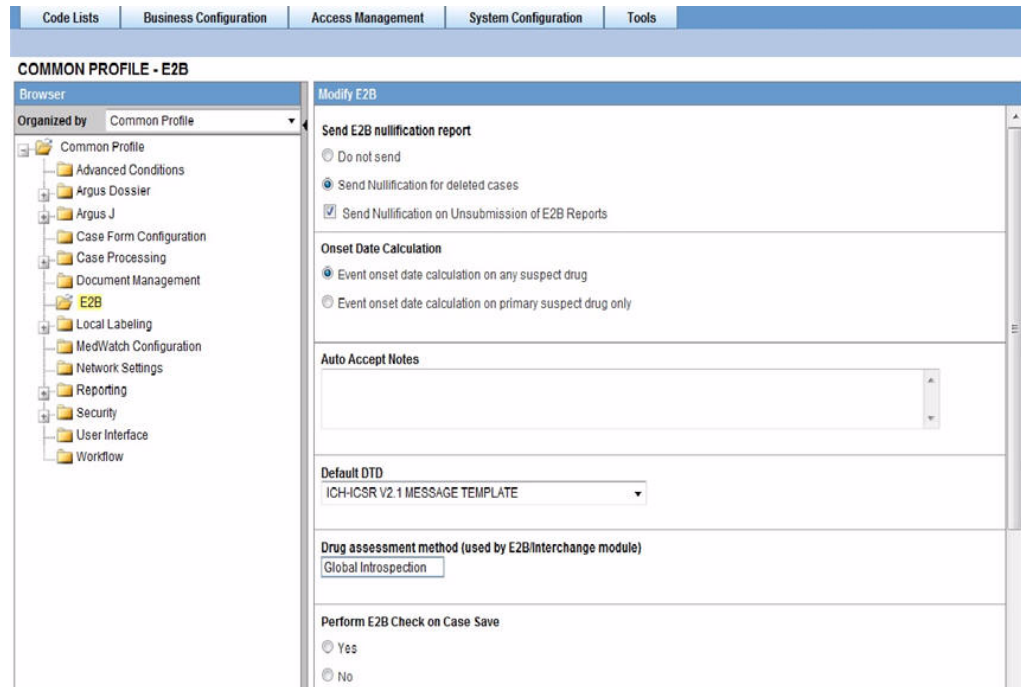
Field Descriptions The following table lists the fields available under **E2B:**

Field/Control Name	Description
Onset Date Calculation	This field enables the user to configure if the onset date is to be calculated based on any suspect drug or on the primary suspect drug only.
Drug assessment method (used by E2B/ESM module)	This field enables the user to incorporate the drug assessment method used by E2B/ESM module.
Blind status during E2B report generation	The available options are: ■ Blinded ■ Unblinded
Perform E2B Check on Save	Performs data check on Argus fields against E2B standard while saving the case. The available options are: ■ Yes ■ No
Default viewing format of the E2B report (used with Electronic Submission Module (ESM))	The available options are: ■ SGML ■ CIOMS ■ MEDWATCH ■ DECODED VIEW
Default DTD	This field enables the user to select the Default DTD from the drop-down list box.

Field/Control Name	Description
Send E2B Nullification Report	This field enables the user to configure whether to send the E2B nullification report or not.
Auto Accept Notes	Enables the user to enter notes (up to 190 characters). It is required for these notes to be entered for the acceptance of the E2B. The notes entered here, are automatically provided during E2B acceptance.

Use the following procedure to configure E2B

1. Enable the check-box option for **Drug assessment method (used by E2B/ESM module)**, if required.

2. Select the option for Blind status during E2B report generation.

3. Select the option for Perform length check of Argus fields against E2B standard.

4. Select the option for Default viewing format of the E2B report (used with Electronic Submission Module (ESM)).

5. Select the option for **Default DTD**.

6. Select the required radio button under **Onset Date Calculation**, as applicable.

7. Select whether to send the nullification report in **Send E2B Nullification Report**.

8. Enter the comments for the automatically generated notes, when an E2B is accepted, under **Auto Accept Notes**.

9. Click **Save** to save the changes made to this screen.

Local Labeling

This section enables you to configure the common profile switches for Local Labeling and includes discussions of the following:

- Configuring Local Labeling
- Configuring Local Labeling LAM

Configuring Local Labeling The Local Labeling Configuration screen enables you to modify the options available through local labeling. Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Local Labeling** section, click the **Local Labeling** folder in the left panel. The configurable fields associated with **Local Labeling** appear in the right panel.

Field Descriptions The following table lists and describes the fields available under **Local Labeling:**

Field/Control Name	Description
Number of Cases returned in local labeling dialog: default X	This field enables the user to configure the number of cases that are returned in the local labeling dialog. Example: If the value is entered as 20 then 20 cases are returned in the local labeling dialog.
Action to be taken after timeout	The available options are : ■ Discard ■ Submit
Timeout for assessment data lock (in minutes)	This field enables the user to enter the minutes after which the time-out for assessment data lock is applicable.

Use the following procedure to configure local labeling

1. Enter the number in Number of Cases returned in local labeling dialog: default.

2. Select the option for Action to be taken after timeout.

3. Enter the value in minutes for Timeout for assessment data lock (in minutes).

4. Click **Save** to save the changes made.

Configuring LAM The Local Labeling LAM Configuration screen enables you to modify the options available through local labeling for LAM.

Field Label Updates The **Argus Console Field Labels** option enables the user to modify the field labels for the **Argus Affiliate Event Information** form.

■ The existing Argus fields are under the **Argus Safety** folder structure.

- Please refer to the tables in the **LAM Information** section for the details about the Help Text for the fields.

- The system enables the user to hide the field on the LAM form.

- The system prints the Affiliate field labels.

- The system tracks all field label updates in the audit log.

Field Validation Updates Argus Affiliate enables the user to configure Field **Validations for Mandatory and Warning for the LAM Event** fields.

- The existing Argus fields are under the **Argus Safety** folder structure.

- Please refer to the table for **LAM Event Info** for the fields in the **Field Validations**.

- The Affiliate fields for advanced conditions are **only** visible for field validations. They are not visible to the rest of the application.

- The system prints the information for the configured field validations.

- The system tracks all updates to field validations in the audit log.

- The system displays the standard **Justifications** dialog to enable the user to enter the justifications for overriding the warnings, but **does not** permit the user to save the case for a mandatory error.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Local Labeling LAM** section, click the **Local Labeling** folder in the left panel.

- The **LAM** sub-folder is displayed in the left panel.

- Click on LAM sub-folder to configure the LAM options.

- The configurable fields associated with **Local Labeling Lam** appear in the right panel.

Field Descriptions

The following table lists and describes the fields available under **Local Labeling LAM:**

Field/Control Name	Description
Allow hiding of the Local Labeling dialog from Users	The available options are: ■ Local Labeling will be visible to users ■ Local Labeling will be hidden from users
Report Scheduling when Labeling Changes from the Local Labeling Screen	The available options are: ■ No Report Scheduling will not be executed when the Local Labeling is changed ■ Report Scheduling will occur for those Licenses where the Labeling has changed
Re-evaluate all scheduled and generated reports related to a case when the labeling is changed from the Local Labeling dialog.	The available options are: ■ The system will not re-evaluate generated reports ■ Re-evaluate general reports.

Use the following procedure to configure local labeling for LAM.

1. Select the option for Allow hiding of the Local Labeling dialog from Users.

2. Select the option for Report Scheduling when Labeling Changes from the Local Labeling Screen.

3. Select the option for Re-evaluate all scheduled and generated reports related to a case when the labeling is changed from the Local Labeling dialog.

4. Click **Save** to save the changes made.

Configuring MedWatch The MedWatch Configuration screen enables you to modify the customizable fields on the MedWatch form. Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To view the list of field names associated with the **MedWatch Configuration** section, click the **MedWatch Configuration** folder in the left panel.

The field names associated with **MedWatch Configuration** appear in the right panel.

Field Descriptions

The following table lists and describes the fields available under **MedWatch Configuration:**

Field/Control Name	Description
Firm Name as it Should Appear at the Top of Each Page	Enables the user to enter the name of the reporting firm on the MedWatch form.
Date of FDA Approval to appear on the first page	Enables the user to enter the FDA approval date of the manufacturer.
Disclaimer to appear at the bottom of the first page	Enables the user to enter a brief disclaimer.
Default text to appear on Block H10	Enables the user to enter default text.
Reset MedWatch Numbering	Enables the user to reset the sequence number that appears on the MedWatch form for the manufacturer.
Mfr. Site FDA Number	Displays the FDA number for the Manufacturer Site which submitted the MedWatch 3500 Device report in the year.
Year	Displays the year of report submission.
# of Reports	Displays the number of submitted reports for products associated with a Manufacturing Site in that year
Reset Number	Enables the user to reset the Sequence Number.

Use the following procedure to configure the MedWatch form options.

1. Enter the Firm Name as it Should Appear at the Top of Each Page.

2. Enter the Date of FDA Approval to appear on the first page.

3. Enter the Disclaimer to appear at the bottom of the first page.

4. Enter the Default text to appear on Block H10.

5. Click**Reset MedWatch Numbering** to reset the sequence number that appears on the MedWatch form, for the manufacturer as required.

User Interface

This section enables you to configure the common profile switches for User Interface.

Configuring User Interface

The User Interface Configuration screen enables you to configure the user interface, as per the options available. Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **User Interface** section, click the **User Interface** folder in the left panel. The configurable fields associated with **User Interface** appear in the right panel.
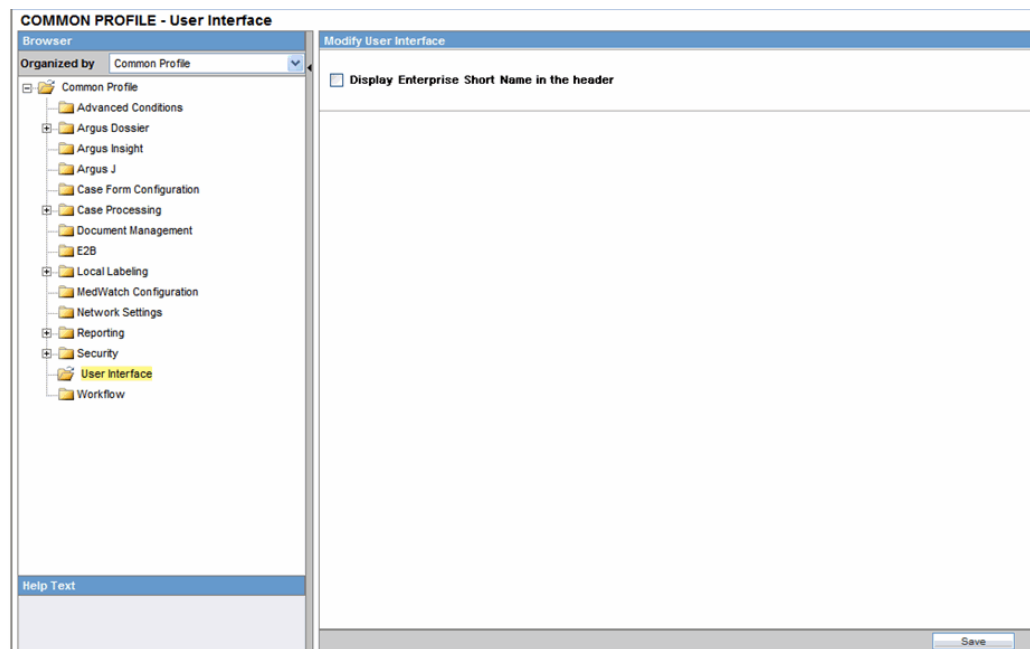
Field Descriptions

The following table lists and describes the fields available under **User Interface:**

Field/Control Name	Description
Display Enterprise Short Name in the header	This field enables the user to select whether to display the enterprise short name in the header. Check this checkbox to display the enterprise short name.

Configuring LAM

The Local Labeling LAM Configuration screen enables you to modify the options available through local labeling for LAM.

Field Label Updates The **Argus Console Field Labels** option enables the user to modify the field labels for the **Argus Affiliate Event Information** form.

- The existing Argus fields are under the **Argus Safety** folder structure.

- Please refer to the tables in the **LAM Information** section for the details about the Help Text for the fields.

- The system enables the user to hide the field on the LAM form.

- The system prints the Affiliate field labels.

- The system tracks all field label updates in the audit log.

Field Validation Updates Argus Affiliate enables the user to configure Field **Validations for Mandatory and Warning for the LAM Event** fields.
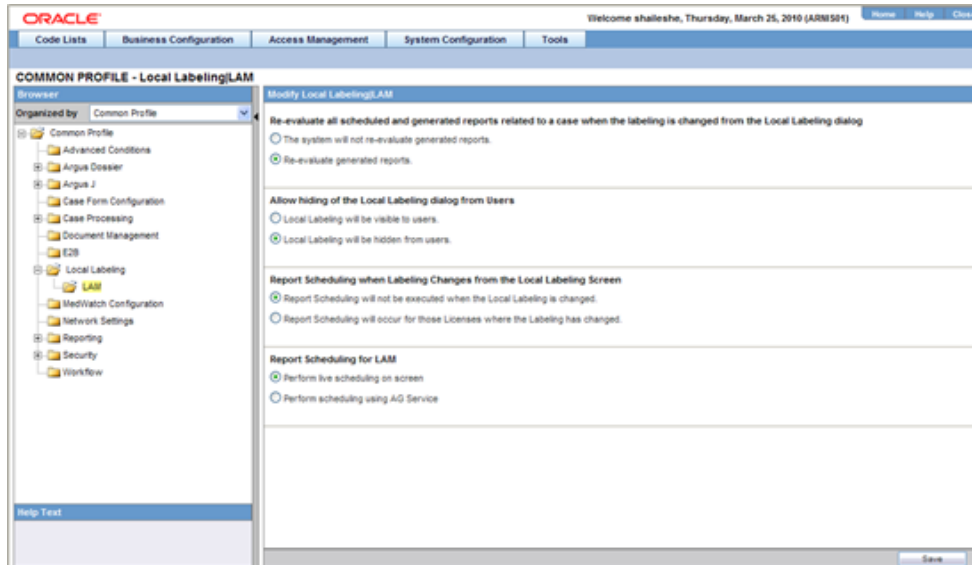
- The existing Argus fields are under the **Argus Safety** folder structure.

- Please refer to the table for **LAM Event Info** for the fields in the **Field Validations**.

- The Affiliate fields for advanced conditions are **only** visible for field validations. They are not visible to the rest of the application.

- The system prints the information for the configured field validations.

- The system tracks all updates to field validations in the audit log.

- The system displays the standard **Justifications** dialog to enable the user to enter the justifications for overriding the warnings, but **does not** permit the user to save the case for a mandatory error.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen

> **Tip:**   The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Local Labeling LAM** section, click the **Local Labeling** folder in the left panel.

- The **LAM** sub-folder is displayed in the left panel.

- Click on LAM sub-folder to configure the LAM options.

- The configurable fields associated with **Local Labeling Lam** appear in the right panel.

Field Descriptions

The following table lists and describes the fields available under **Local Labeling LAM:**

Field/Control Name	Description
Allow hiding of the Local Labeling dialog from Users	The available options are: ■ Local Labeling will be visible to users ■ Local Labeling will be hidden from users
Report Scheduling when Labeling Changes from the Local Labeling Screen	The available options are: ■ No Report Scheduling will not be executed when the Local Labeling is changed ■ Report Scheduling will occur for those Licenses where the Labeling has changed
Re-evaluate all scheduled and generated reports related to a case when the labeling is changed from the Local Labeling dialog.	The available options are: ■ The system will not re-evaluate generated reports ■ Re-evaluate general reports.

Use the following procedure to configure local labeling for LAM.

1. Select the option for Allow hiding of the Local Labeling dialog from Users.

2. Select the option for Report Scheduling when Labeling Changes from the Local Labeling Screen.

3. Select the option for Re-evaluate all scheduled and generated reports related to a case when the labeling is changed from the Local Labeling dialog.

4. Click **Save** to save the changes made.

Configuring MedWatch The MedWatch Configuration screen enables you to modify the customizable fields on the MedWatch form. Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To view the list of field names associated with the **MedWatch Configuration** section, click the **MedWatch Configuration** folder in the left panel.

The field names associated with **MedWatch Configuration** appear in the right panel.

Field Descriptions

The following table lists and describes the fields available under **MedWatch Configuration:**

Field/Control Name	Description
Firm Name as it Should Appear at the Top of Each Page	Enables the user to enter the name of the reporting firm on the MedWatch form.
Date of FDA Approval to appear on the first page	Enables the user to enter the FDA approval date of the manufacturer.
Disclaimer to appear at the bottom of the first page	Enables the user to enter a brief disclaimer.
Default text to appear on Block H10	Enables the user to enter default text.
Reset MedWatch Numbering	Enables the user to reset the sequence number that appears on the MedWatch form for the manufacturer.
Mfr. Site FDA Number	Displays the FDA number for the Manufacturer Site which submitted the MedWatch 3500 Device report in the year.
Year	Displays the year of report submission.
# of Reports	Displays the number of submitted reports for products associated with a Manufacturing Site in that year
Reset Number	Enables the user to reset the Sequence Number.

Use the following procedure to configure the MedWatch form options.

1. Enter the Firm Name as it Should Appear at the Top of Each Page.

2. Enter the Date of FDA Approval to appear on the first page.

3. Enter the Disclaimer to appear at the bottom of the first page.

4. Enter the Default text to appear on Block H10.

5. Click**Reset MedWatch Numbering** to reset the sequence number that appears on the MedWatch form, for the manufacturer as required.

Reporting Configuration

This section enables you to configure the common profile switches for Reporting. This topic has been divided into the following sub-topics:

Section	Sub-Section	Description
Reporting	Expedited Reports Configuration	The Expedited Reporting Configuration screen enables you to modify the options available for expedited reporting.
	Expedited BfArM	The Expedited BfArM Reporting Configuration screen enables you to modify the options available for expedited BfArM reporting.
	Expedited Canada	The Expedited Canada Reporting Configuration screen enables you to modify the options available for expedited Canada reporting.
	Expedited CIOMS	The Expedited CIOMS Reporting Configuration screen enables you to print fields such as Patient ID, Medically Confirmed and Worldwide Number in the "26. REMARKS" section of the CIOMS form.
	Expedited MedWatch	The Expedited MedWatch Reporting Configuration screen enables you to modify the options available for expedited MedWatch reporting.
	Periodic	The Periodic Reporting Configuration screen enables you to modify the options available for periodic reporting.
	Scheduling	The Scheduling Reports Configuration screen enables you to modify the options available for scheduling reporting.

Configuring Reporting

The Reporting Configuration screen enables you to modify the options available for reporting. Select System Configuration **-->** System Management to view the Common Profile Configuration screen

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Reporting** section, click the **Reporting** folder in the left panel. The configurable fields associated with **Reporting** appear in the right panel.
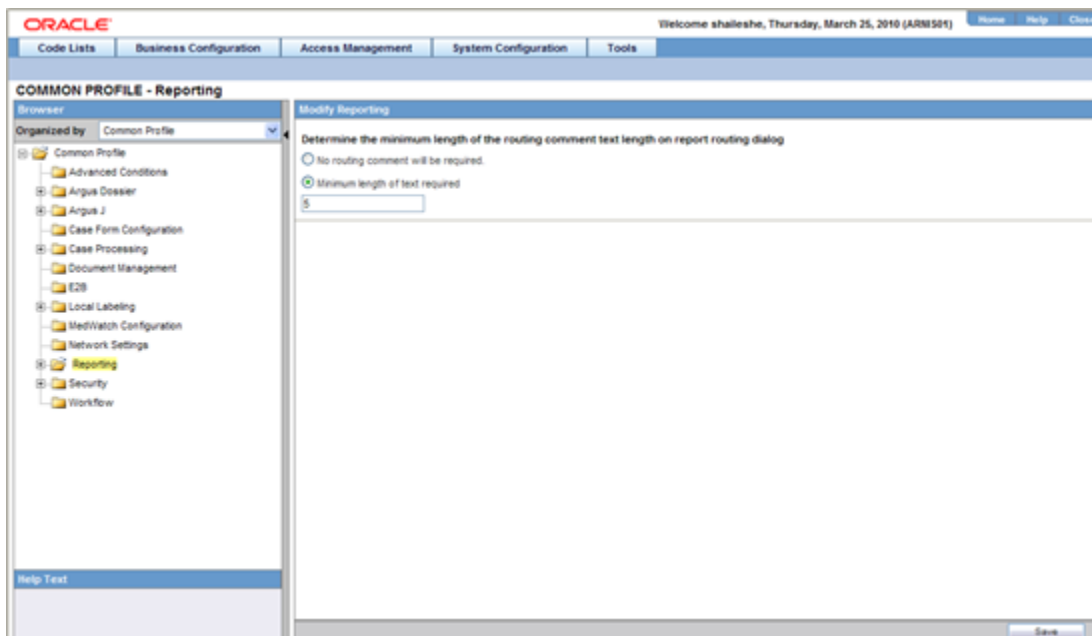
Field Descriptions The following table lists the fields available under **Reporting:**

Field/Control Name	Description
Determine the minimum length of the routing comment text length on report routing dialog	The available options are: ■ No routing comment will be required ■ Minimum length of text required

Use the following procedure to configure reporting.

1. Select the option for Determine the minimum length of the routing comment text length on report routing dialog.

2. Enter the numeric value in the **Minimum length of text required** text-box, if applicable.

3. Click **Save** to save the changes made to this screen.

Expedited Reports Configuration

The Expedited Reporting Configuration screen enables you to modify the options available for expedited reporting. When configuring expedited reporting rules, be aware of the following:

■ If the user **does not** have permission to access **Advanced Conditions** on the **Expedited Reporting Rules**, the system does the following:

– Displays the advanced condition name instead of displaying a blank.

– **Does not** permit the user to modify or view advanced condition details.

– Disables the **Adv Condition** button.

■ The system enables the user configure the **Blinding Study Products** option for those included in the case (default unchecked).

– The system track updates to this field in the audit log.

- The **Reporting Rules** reports print the new options

■ For cases where expedited reports are due, the user can force-distribute expedited reports even if processing is incomplete.

■ The reporting rules have a **Forced Distribute XXX days before due** check box. The default is unchecked.

- If the user checks the **Force Distribute** option, the **# of days before due** field is entered and automatically checks the **Auto Distribute** check box on the reporting rule (grayed out).

- The user can enter the number of days from 0 - # of days defined within the time frame.

- If the user enters a value greater than the defined time frame, the system displays the following message:

- Please enter a value less than the Time Frame defined for the Reporting Rule.

- If the user has not checked **Force Distribute**, the system disables the days before due.

■ The system tracks updates made to the new Argus Console fields in the audit log.

■ The system prints the new fields on the **Reporting Rules** report.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Reporting** section, click the **Reporting** folder in the left panel. The **Expedited** sub-folder opens in the left panel.

Click on **Expedited** sub-folder to configure the expedited reporting options. The configurable fields associated with **ExpeditedReporting** open in the right panel.
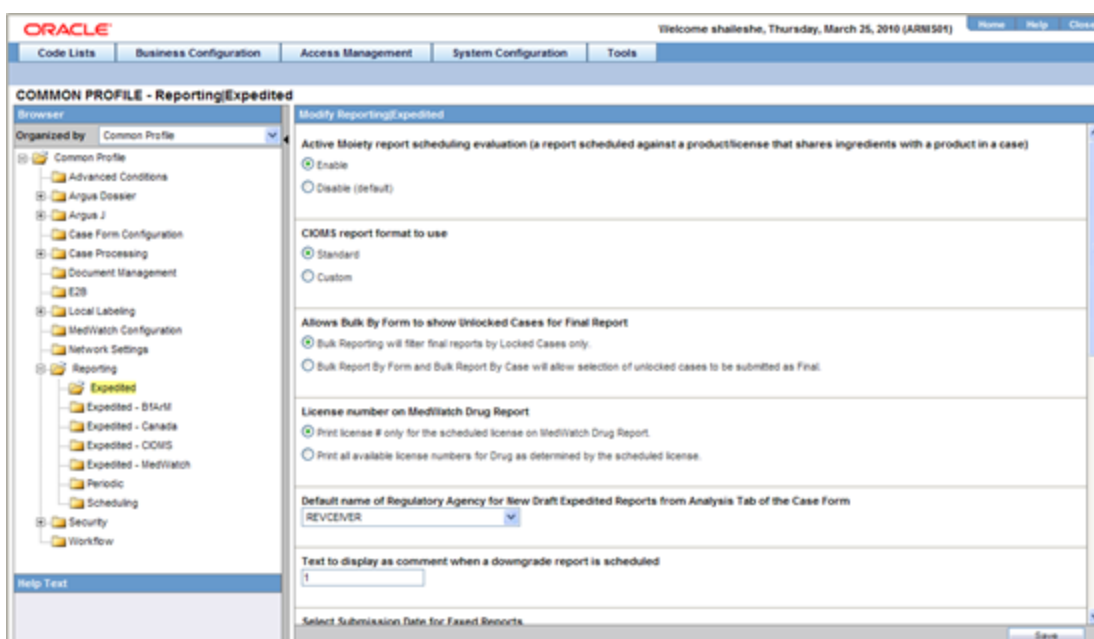
Field Descriptions

The following table lists and describes the fields available under **Expedited Reporting:**

Field/Control Name	Description
Active moiety report scheduling evaluation (a report scheduled against a product/license that shares ingredients with a product in a case)	The available options are: ■ Enable ■ Disable (default)
Allows Bulk by Form to show Unlocked Cases for Final Report	The available options are: ■ Report by Form and Bulk Report By Case will filter final reports by Locked Cases only ■ Bulk Report By Form and Bulk Report By Case will allow selection of unlocked cases to be submitted as Final
License number on MedWatch Drug Report	The available options are: ■ Print License # only for the scheduled license on MedWatch Drug Report ■ Print all available license numbers for Drug as determined by the scheduled license
Default name of Regulatory Agency for New Draft Expedited Reports from Analysis Tab of the Case Form	This enables the user to select the Default Name of the Regulatory agency from the drop-down list.
Text to display as comment when a downgrade report is scheduled	This enables the user to enter the text to display when a downgrade report is scheduled.
CIOMS report format to use	The available options are: ■ Standard ■ Custom When Custom is selected, a second version of the CIOMS form is used. This form is almost identical to the Standard form. The only difference is that the Custom form includes superscripts in the label text for boxes 15, 16, 18 and 19. The superscript is simply an asterisk (*) to draw the user's attention to the following footnote also included in the Custom form: *Boxes 15, 16, 18, and 19 on page 1 contain first dose regimen information for suspected product #1 and #2. Suspected Drug(s) information is continued on Additional Information page, if applicable. Thus, the Custom form simply provides the user the option to clearly identify fields that have overflow information on the Additional Information page.
CIOMS Form Selection	This enables the user to select the CIOMS form to be used across the application for Expedited Reporting / Periodic Reporting.
Auto Distribution Transmission Comments	Enables the user to enter transmission comments of up to 2000 characters, for Expedited Reports Transmission. These comments are auto-distributed, based on Expedited Reporting Rules or Reporting Destinations.

Field/Control Name	Description
Auto Distribution Submission Comments	Enables the user to enter submission comments of up to 2000 characters, for Expedited Reports Transmission.
	These comments are auto-distributed, based on Expedited Reporting Rules or Reporting Destinations.
Print Case Version of Expedited Reports (x.y.z)	This switch enables the user to enable or disable the printing of the case version of expedited reports.

Use the following procedure to configure expedited reports.

1. Select the option for Active moiety report scheduling evaluation (a report scheduled against a product/license that shares ingredients with a product in a case).

2. Select the option for enables Bulk by Form to show Unlocked Cases for Final Report.

3. Select the option for License number on MedWatch Drug Report.

4. Select the option for Default name of Regulatory Agency for New Draft Expedited Reports from Analysis Tab of the Case Form from the drop-down text-box.

5. Enter the text in the Text to display as comment when a downgrade report is scheduled text-box, if applicable.

6. Select the option for **CIOMS report format to use**.

7. Select the relevant CIOMS form, from **CIOMS Form Selection**.

8. Enter the transmission comments in **Auto Distribution Transmission Comments**.

9. Enter the submission comments in **Auto Distribution Submission Comments**.

10. Select whether to enable or disable printing the case version of expedited reports in **Print Case Version of Expedited Reports (x.y.z)**.

11. Click **Save** to save the changes made to this screen.

Expedited BfArM Reports Configuration The Expedited BfArM Reporting Configuration screen enables you to modify the options available for expedited BfArM reporting.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Reporting** section, click the **Reporting** folder in the left panel. The **Expedited- BfArM** sub-folder is displayed in the left panel.

Click on the **Expedited-BfArM** sub-folder to configure the expedited BfArM reporting options. The configurable fields associated with **Expedited - BfArMReporting** appear in the right panel.
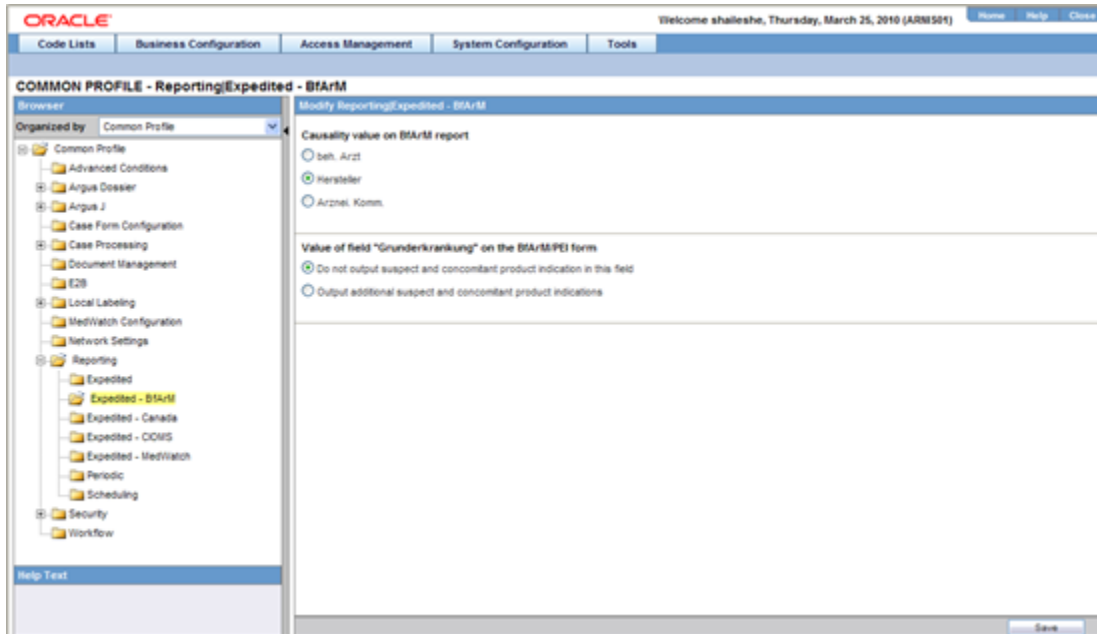
Field Descriptions

The following table lists and describes the fields available under **Expedited - BfArMReporting:**

Field/Control Name	Description
Causality Value on BfArM Report	The available options are: ■ beh.Azrt ■ Hersteller ■ Arznel.Komm
Value of field "Grunderkrankung" on the BfArM/PEI form	The available options are: ■ Do not output suspect and concomitant product indication in this field ■ Output additional suspect and concomitant product Events & Indications.

Use the following steps to configure the expedited BfArM reports.

1. Select the option for Causality Value on BfArM Report.

2. Select the option for Value of field "Grunderkrankung" on the BfArM/PEI form.

3. Click **Save** to save the changes made to this screen.

Expedited Canada Reports Configuration The Expedited Canada Reporting Configuration screen enables you to modify the options available for expedited Canada reporting.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Reporting** section, click the **Reporting** folder in the left panel. The **Expedited- Canada** sub-folder is displayed in the left panel.

Click on the **Expedited-Canada** sub-folder to configure the reporting options. The configurable fields associated with **Expedited** - **CanadaReporting** appear in the right panel.
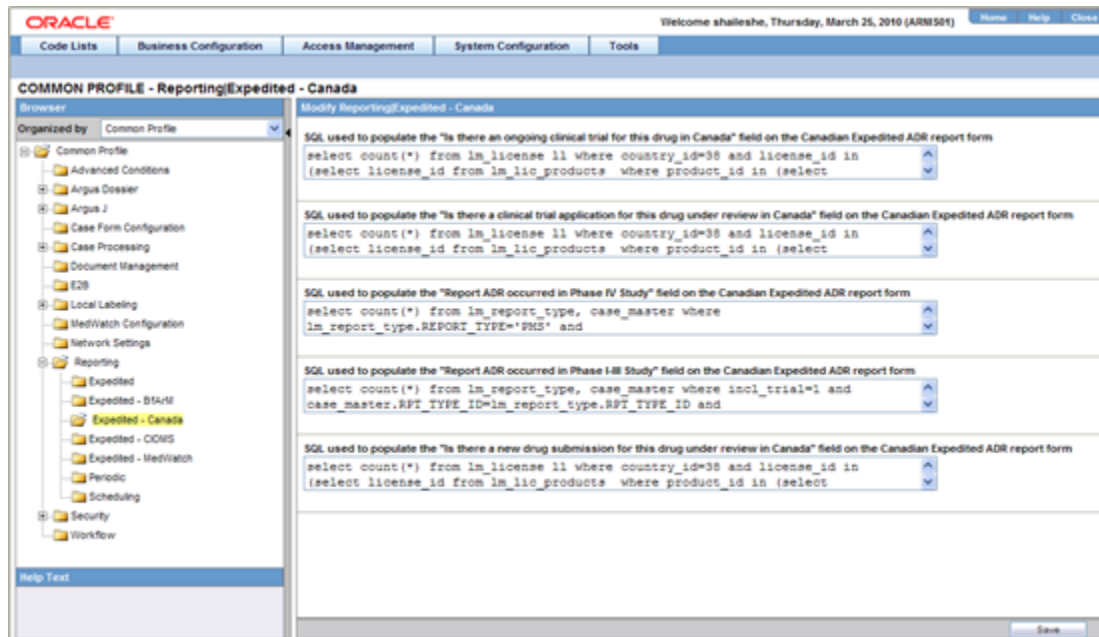
Field Descriptions

The following table lists and describes the fields available under **Expedited- Canada Reporting:**

Field/Control Name	Description
SQL used to populate the "Is there an ongoing clinical trial for this drug in Canada" field on the Canadian Expedited ADR report form	This field enables the user to enter the associated SQL syntax.
SQL used to populate the "Is there a clinical trial application for this drug under review in Canada" field on the Canadian Expedited ADR report form	This field enables the user to enter the associated SQL syntax.
SQL used to populate the "Is there a new drug submission for this drug under review in Canada" field on the Canadian Expedited ADR report form	This field enables the user to enter the associated SQL syntax.
SQL used to populate the "Report ADR occurred in Phase I-III Study" field on the Canadian Expedited ADR report form	This field enables the user to enter the associated SQL syntax.
SQL used to populate the "Report ADR occurred in Phase I-IV Study" field on the Canadian Expedited ADR report form	This field enables the user to enter the associated SQL syntax.

Use the following procedure to configure expedited Canada reports.

1. Enter the SQL syntax for SQL used to populate the "Is there an ongoing clinical trial for this drug in Canada" field on the Canadian Expedited ADR report form.

2. Enter the SQL syntax for SQL used to populate the "Is there a clinical trial application for this drug under review in Canada" field on the Canadian Expedited ADR report form.

3. Enter the SQL syntax for SQL used to populate the "Is there a new drug submission for this drug under review in Canada" field on the Canadian Expedited ADR report form.

4. Enter the SQL syntax for SQL used to populate the "Report ADR occurred in Phase I-III Study" field on the Canadian Expedited ADR report form.

5. Enter the SQL syntax for SQL used to populate the "Report ADR occurred in Phase I-IV Study" field on the Canadian Expedited ADR report form.

6. Click **Save** to save the changes made to this screen.

Expedited CIOMS Reports The Expedited CIOMS Reporting Configuration screen enables you to modify the options available for expedited CIOMS reporting. Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Reporting** section, click the **Reporting** folder in the left panel.

The **Expedited- CIOMS** sub-folder is displayed in the left panel. Click on the **Expedited-CIOMS** sub-folder to configure the expedited CIOMS reporting options.

The configurable fields associated with **Expedited** - **CIOMSReporting** appear in the right panel.
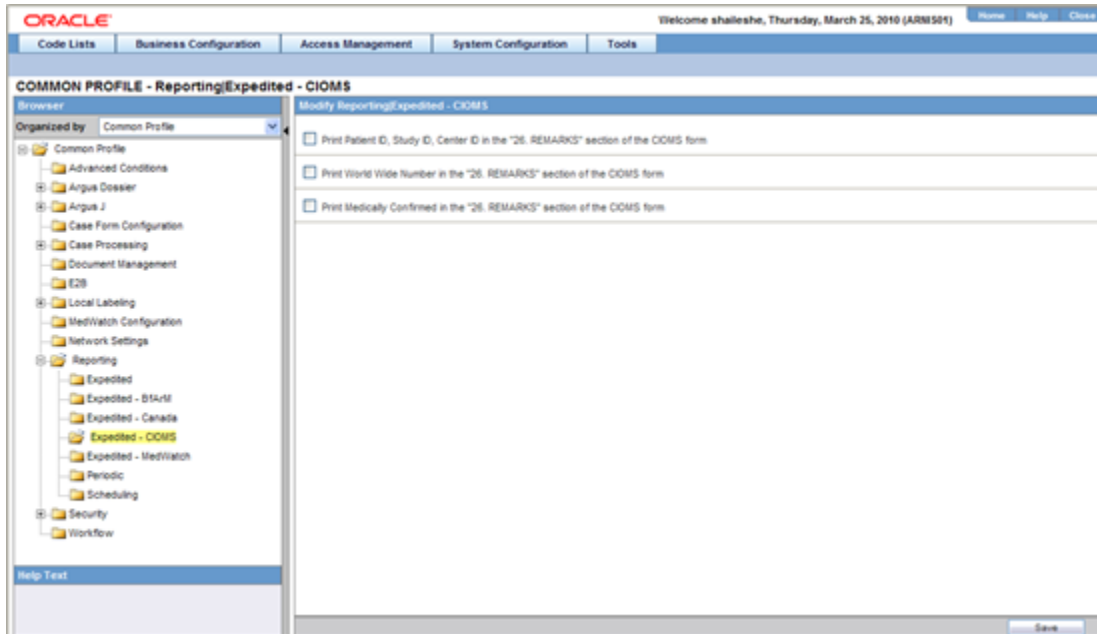
Field Descriptions

The following table lists the fields available under **Expedited- CIOMS Reporting:**

Field/Control Name	Description
Print Patient ID, Study ID, Center ID in 26. REMARKS section of the CIOMS form	Enables the user to print the Patient ID, Study ID and Center ID fields in the ”26. REMARKS" section of the CIOMS form.
Print Medically Confirmed in the 26. REMARKS section of the CIOMS form	Enables the user to print Medically Confirmed in the 26. REMARKS section of the CIOMS form.
Print World Wide Number in the 26. REMARKS" section of the CIOMS form	Enables the user to print World Wide Number in the ”26. REMARKS" section of the CIOMS form.

Use the following procedure to configure the expedited CIOMS reports.

1. Select the Print Patient ID, Study ID, Center ID in the ”26. REMARKS" section of the CIOMS form checkbox to print these fields in the CIOMS form.

2. Select the Print Medically Confirmed in the ”26. REMARKS" section of the CIOMS form checkbox to print this field in the CIOMS form.

3. Select the Print World Wide Number in the ”26. REMARKS" section of the CIOMS form checkbox to print this field in the CIOMS form.

4. Click **Save** to save the changes made to this screen.

Expedited MedWatch Reports Configuration The Expedited MedWatch Reporting Configuration screen enables you to modify the options available for expedited MedWatch reporting.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

Tip: The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Reporting** section, click the **Reporting** folder in the left panel. The **Expedited- MedWatch** sub-folder is displayed in the left panel.

Click on the **Expedited-MedWatch** sub-folder to configure the expedited MedWatch reporting options. The configurable fields associated with **Expedited** - **MedWatchReporting** appear in the right panel.
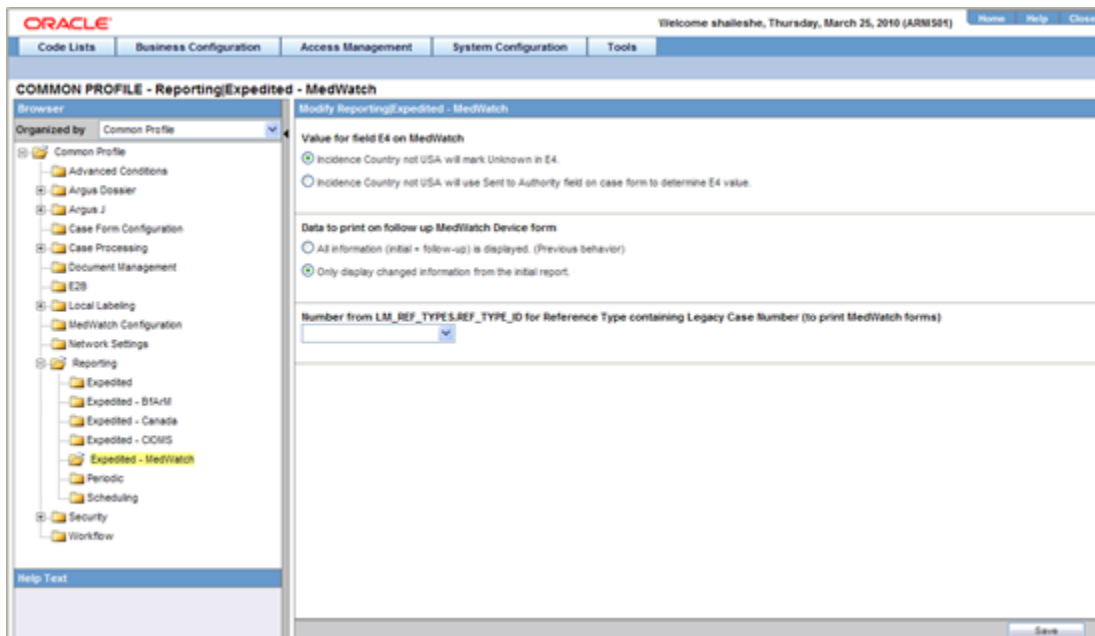
Field Descriptions

The following table lists the fields available under **Expedited- MedWatch Reporting:**

Field/Control Name	Description
Value for Field E4 on MedWatch	The available options are: ■ Incidence Country not USA will mark Unknown in E4. ■ Incidence Country not USA will use Sent to Authority field on case form to determine E4 value.
Data to print on follow up MedWatch Device form	The available options are: ■ All information (initial + follow-up) is displayed. (Previous Behaviour). ■ Only Display changed information from the initial report.
Number from LM_REF_ TYPES.REF_TYPE_ID for Reference Type containing Legacy Case Number (to print MedWatch forms)	This field enables the user to select the required option from the drop-down list.

Use the following procedure to configure expedited MedWatch reports.

1. Select the option for the **Value for Field E4 on MedWatch**.

2. Select the option for the Data to print on follow up MedWatch Device form.

3. Select the required option for Number from LM_REF_TYPES.REF_TYPE_ID for Reference Type containing Legacy Case Number (to print MedWatch forms) from the drop-down list box.

4. Click **Save** to save the changes made to this screen.

Periodic Reports Configuration The Periodic Reporting Configuration screen enables you to modify the options available for periodic reporting.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Reporting** section, click the **Reporting** folder in the left panel. The **Periodic** sub-folder is displayed in the left panel.

Click on the **Periodic** sub-folder to configure the periodic reporting options. The configurable fields associated with **Periodic Reporting** appear in the right panel.
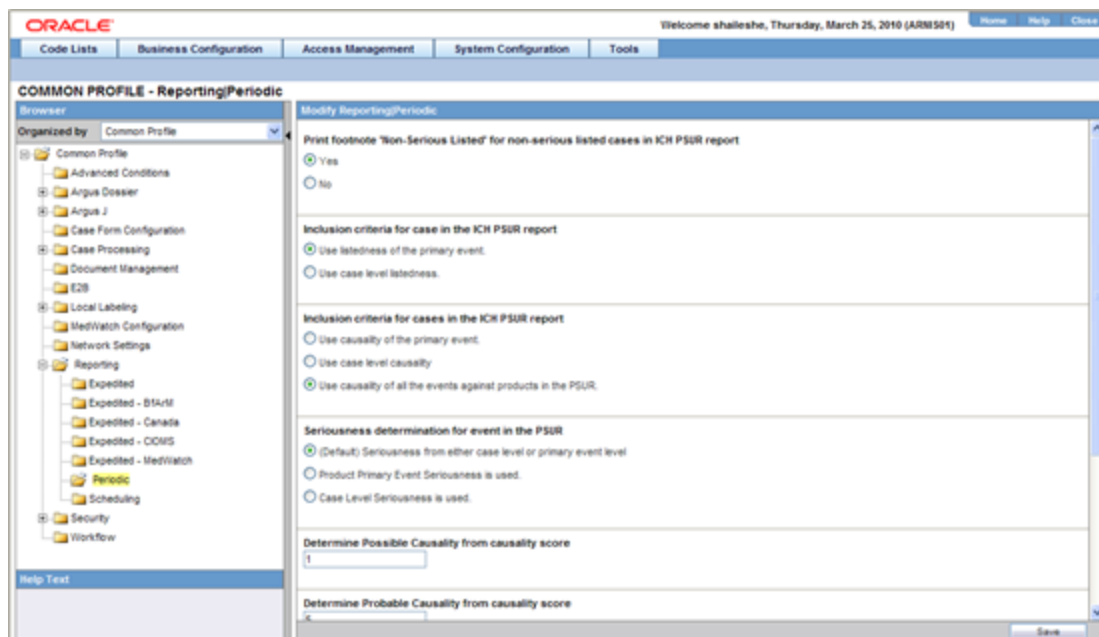
Field Descriptions

The following table lists and describes the fields available under **Periodic Reporting:**

Field/Control Name	DescriptionDescription
Inclusion Criteria for cases in the ICH PSUR report	The available options are: ■ Use Causality of the primary event ■ Use case level causality ■ Use causality of all the events against products in the PSUR
Print footnote Non Serious Listed for non-serious listed cases in ICH PSUR report	The available options are: ■ Yes ■ No
Inclusion criteria of event for a product in the PSUR	The available options are: ■ Primary Event (Left Most Diagnosis or the left-most Event if there is no Diagnosis on the case form) ■ Most Severe Event for the Product ■ Case Level Seriousness is used
Determine Possible Causality from the causality score	This field enables the user to enter a numeric value.
Determine Probable Causality from causality score	This field enables the user to enter a numeric value.
On PSUR, NDA, IND, Medical Review List Reports	The available options are: ■ Use Initial Receipt Date for report search date range ■ Do not see initial Receipt Date for report search date range
Inclusion Criteria for case in the ICH PSUR report	The available options are: ■ Use listedness of the primary event ■ Use case level listedness
Seriousness Determination for event in the PSUR	Enables the user to configure the seriousness determination for an event in the PSUR. The available options are: ■ (Default) Seriousness from either case level or primary event level ■ Product Primary Event Seriousness is used ■ Case Level Seriousness is used

Use the following procedure to configure periodic reports.

1. Select the option for Inclusion Criteria for cases in the ICH PSUR report.

2. Select the option for Print footnote "Non Serious Listed" for non-serious listed cases in ICH PSUR report.

3. Select the option for Inclusion criteria of event for a product in the PSUR.

4. Enter the value for Determine Possible Causality from the causality score.

5. Enter the value for Determine Probable Causality from causality score.

6. Select the option for On PSUR, NDA, IND, Medical Review List Reports.

7. Select the option for Inclusion Criteria for case in the ICH PSUR report.

8. Select the option for Seriousness Determination for event in the PSUR.

9. Click **Save** to save the changes made to this screen.

Scheduling Reports Configuration The Scheduling Reports Configuration screen enables you to modify the options available for scheduling reporting. Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Reporting** section, click the **Reporting** folder in the left panel. The **Scheduling** sub-folder is displayed in the left panel.

Click on the **Scheduling** sub-folder to configure the scheduling report options. The configurable fields associated with **Scheduling Reports** appear in the right panel.
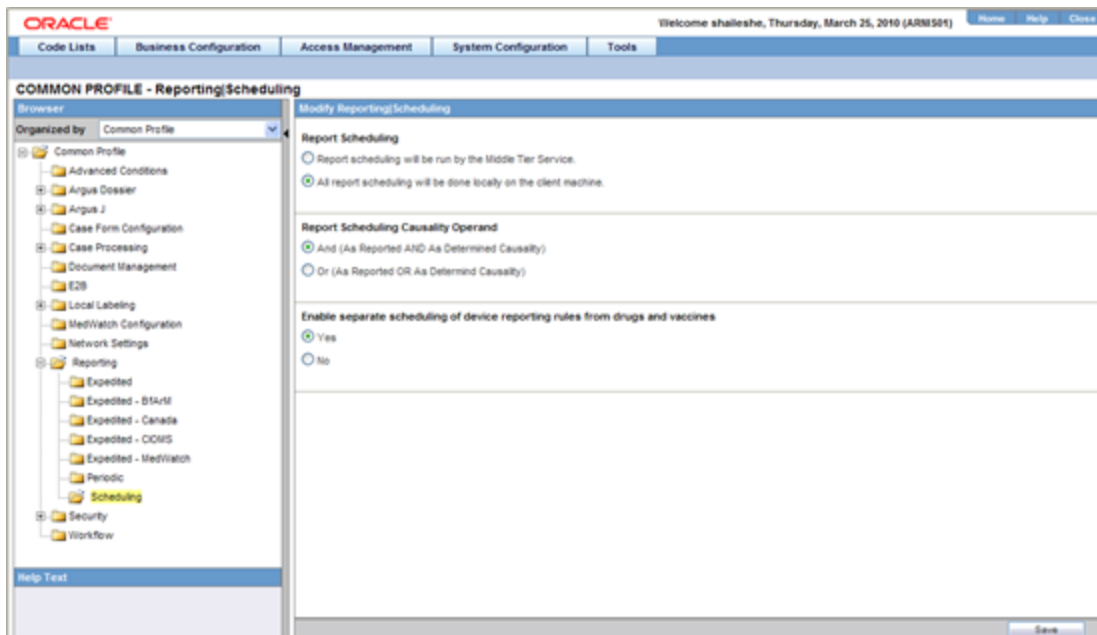
Field Descriptions

The following table lists and describes the fields available under **Schedule Reports:**

Field/Control Name	Description
Report Scheduling	The available options are:
	■ Report Scheduling will be run by the Middle Tier Service
	■ All report scheduling will be done locally on the client machine
Enable separate scheduling of device reporting rules from drugs and vaccines	The available options are:
	■ Yes
	■ No
Report Scheduling Causality Operand	Enables the user to select from the causality operands AND/OR to use for scheduling a report.

Use the following procedure to configure scheduling.

1. Select the option for **Report Scheduling**.

2. Select the option for Enable separate scheduling of device reporting rules from drugs and vaccines.

3. Select the operand to use for scheduling a report from **Report Scheduling Causality Operand**.

4. Click **Save** to save the changes made to this screen.

Configuring Security

The Security Configuration screen enables you to modify the options available for security. Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

> **Tip:** The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **Security** section, click the **Common Profile--> Security** folder in the left panel. The configurable fields associated with **Security** appear in the right panel.
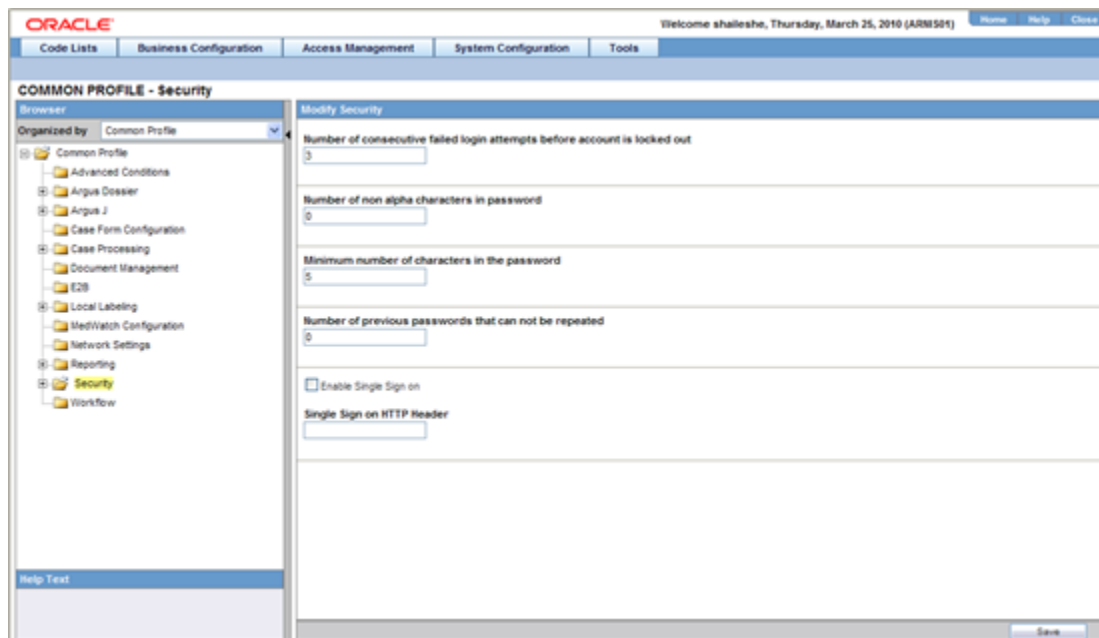
Field Descriptions

The following table lists the fields available under **Security:**

Field/Control Name	Description
Number of previous passwords that cannot be repeated	Enables you to configure the number of passwords that can be allowed.
	For example, if you enter 4 in this field, it configures the system to enable up to 4 previous passwords that cannot be used as passwords again.

Field/Control Name	Description
Number of non-alpha characters in password	Enables you to configure the number of non-alpha characters that should exist in a password. Non-alpha characters include characters such as @, $, etc. **Note:** To avoid bad configuration, we recommend that the value of this switch is kept as 0 or 1 only.
Minimum number of characters in the password	Enables you to configure the minimum number of characters that a password must have. For example, if you enter 8 in this field, it configures the system to ensure that every password contains at least 8 characters.
Number of consecutive failed login attempts before account is locked out	Enables you to configure the number of consecutive failed login attempts that can be allowed before an account is locked out. For example, if you enter 3, it means that up to 3 consecutive failed login attempts are allowed. If the fourth consecutive login attempt also fails, the account gets locked out.

Use the following procedure to configure security.

1. Enter the value for the number of unique previous passwords in **Number of previous passwords that cannot be repeated**.

2. Enter the value for the number of non-alpha characters in **Number of non-alpha characters in password**.

3. Enter the value for the minimum number of characters for a password in **Minimum number of characters in the password**.

4. Enter the value for the number of consecutive failed login attempts in Number of consecutive failed login attempts before account is locked out.

5. Click **Save** to save the configured values.

6. Click **LDAP** to configure the LDAP fields.

The configurable fields associated with **LDAP** appear in the right panel.

Field Descriptions

The following table lists and describes the fields available under **LDAP:**

Field/Control Name	Description
Enable LDAP at system level	The available options for this are : ■ Yes ■ No

Use the following procedure to configure security:

1. Select the option for Enable LDAP at system level.

2. Click **Yes** to enable the LDAP Search Domain Account. This displays the **LDAP Search Domain Account** dialog.
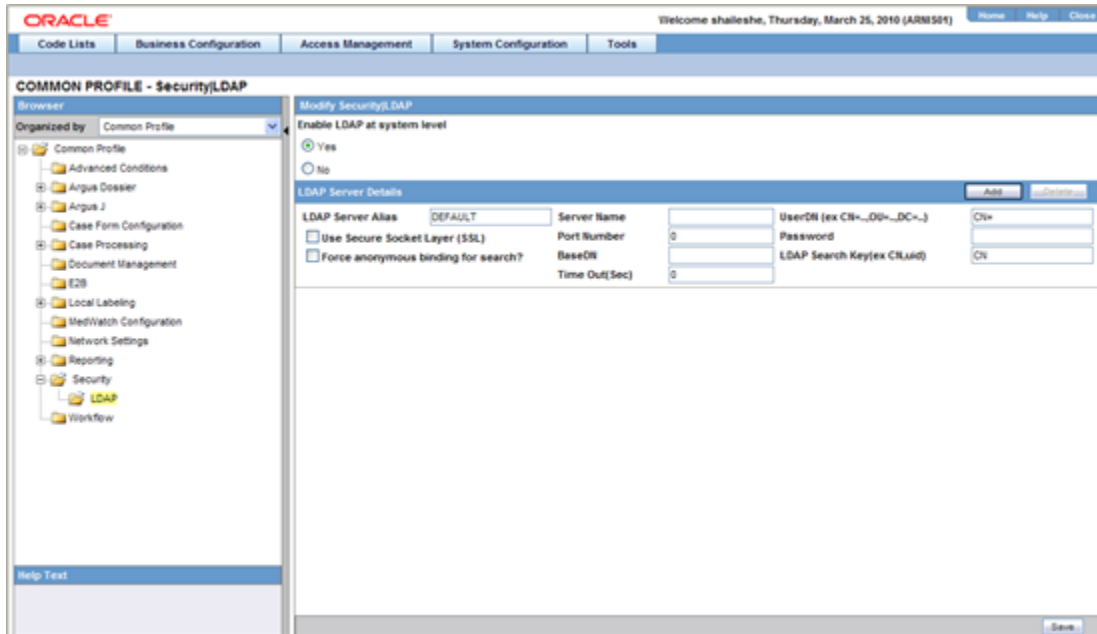
The following table describes the fields of the LDAP Search Domain Account dialog:

Field/Control Name	Description
Use Secure Socket Layer	If your LDAP Server is configured to use SSL for communication, please check this box. Use of SSL enables for a Secure communication between the client and the server using secure keys.
Force Anonymous Binding for Search	When setting up the LDAP Server, you have the option to force users to bind (authenticate) to the LDAP Server prior to being able to search the LDAP Tree. If this option has been setup in your LDAP server, this option must be checked.
UserDN	During the setup of the LDAP server, the distinguished name and tree structure is created for users to be configured under. Enter in the defined structure as defined in your LDAP server into this box. This is required only if the server is setup for Force Anonymous Binding for Search".
Password	Enter in the password for the User entered in the UserDN box for the bind to the server.
Server Name	Enter in the LDAP Server name or IP Address to which LDAP Authentication needs to occur on.
Port Number	Enter the port on which the LDAP Authentication Services are enabled on the LDAP Server (Default Value: 389).
BaseDN	Enter in the topmost distinguished name of your tree defined on the LDAP Server for which you would like to search for users under.
Time Out (Sec)	Enter a value in seconds, which will tell Argus how long to wait for a response from the LDAP Server during any authentication before timing out (Default Value: 10).
LDAP Search Key	Enter the key to authenticate the user name against in the LDAP Tree structure. For Example, when using Microsoft Active Directory, to authenticate using the Windows Username (Not Full Name), enter in sAMAccountName.

- If you select the **Use Secure Socket Layer (SSL)** checkbox, the **Port Number** is auto-populated with the value **636**.

- If this checkbox is not selected, the **Port Number** is auto-populated with the value **389**.

- A generic LDAP server can accept anonymous as well as non anonymous binding, based on the configuration.

- If the **Force anonymous binding for search?** checkbox is not selected, both **UserDN** and **Password** are enabled.

3. Enter the LDAP username and password in the **UserDN** and **Password** fields, respectively.

4. Enter the values for Server Name, Port Number, Base DN, Time Out and LDAP Search Key, as required.

   - The field length for **Port Number** and **Time Out** is 5 characters, while the **Server Name, BaseDN, LDAP Search Key, UserDN** and **Password** can be up to 255 characters.

5. Click **Save** to save the changes made to this screen.

Configuring Cryptography within Common Profile > Security

Common Profile > Security > Cryptography contains two key settings:

1. Configured hashtag algorithm to use - This setting determines the Hashtag algorithm that will be used in encrypting passwords.

2. *De-optimizer counter for hashtag routine* - This setting determines the strength of encryption (for example, the higher the value of this setting, the stronger will be the encryption, and vice-versa). The default/recommended value is 1000.

Configuring Single Sign-on

A common profile switch determines whether the system uses the single sign on function. The Enable Single Sign-on checkbox, enables you to configure the system to use the single sign-on feature.

Before enabling the single sign-on feature, be aware of the following:

- If the user enables the Single Sign on feature, the user must enter Single Sign on the HTTP Header element Argus application uses for authentication.

  - This field can contain a maximum of 40 characters

  - If the single sign on feature is enabled and the user does not enter the Single Sign On HTTP Header, the system displays the following error message:

- Please enter the Single Sign on HTTP Header or disable the Single Sign on feature.

The following table lists dialog boxes in the Argus Application that must require passwords. In such cases, the system single sign on feature redirects the password to Argus for validation. When single sign-on is enabled, the system locks the user account if the user enters and incorrect password three consecutive time. The Administrator must unlock the account to enable the user to log in to the application.

Function	Section	Procedure
Case Locking	Activities|Lock	Locking a case
Case Unlocking	Activities|Lock	Unlocking a case

Function	Section	Procedure
Case Closing	Activities | Close	Closing a case
Case Unclosing	Activities | Close	Unclosing a case.
Case Unblinding	General | Blinding Status	Breaking a blind
E2B Incoming Accept	Reports | Incoming E2B Reports	Accepting E2B Reports
E2B Incoming Reject	Reports | Incoming E2B Reports	Rejecting E2B Reports
E2B Incoming Follow-up Accept	Reports | Incoming E2B Reports	Accepting E2B Follow-up Reports
E2B Incoming Follow-up Reject	Reports | Incoming E2B Reports	Rejecting E2B Follow-up Reports
E2B Incoming Nullification Accept	E2B Incoming Nullification Accept	Accepting E2B Nullification Reports
E2B Incoming Nullification Reject	E2B Incoming Nullification Reject	Rejecting E2B Nullification Reports
LAM Incoming	Local Affiliate Incoming Review	Accepting an Affiliate Event
Workflow Routing	Workflow Routing on Password on Route	Workflow Routing on Password on Route

The following modules launched in the Argus Application, continue to use single sign on feature:

- Argus Insight
- Argus Affiliate
- Argus J

The following modules **do not use** the Single Sign on feature:

- End of Study Unblinding
- Argus Safety Services
- Argus Interchange Services (ESM)
- Argus Interchange Mapping (ESM Mapping Utility)

Error Messages

Once the user is configured, the system automatically logs the user into the Argus Application without requiring reauthentication on the Argus Login application. If there is an authentication error, the system displays the current login page so the user can log in manually.

Configuring SMTP

This screen enables you to configure SMTP.

Currently there are multiple issues such as, Outlook related problems with AG Service due to new security features introduced by Microsoft. Due to these security enhancements, a new method to submit emails from AG Service has been implemented using the SMTP Protocol.

Select **System Configuration --> SMTP Configuration** to view the SMTP configuration pop-up dialog. The pop-up dialog opens as shown.
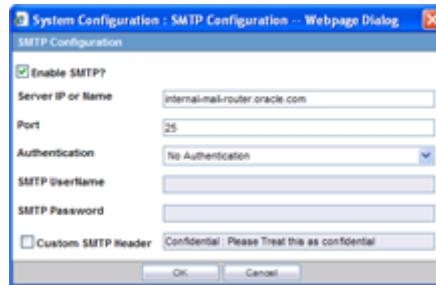
Field Descriptions The following table lists and describes the fields associated with this section.

Field/Control Name	Description
Server IP or Name	Enables the user enter the SMTP server name / IP address.
Port	Enables the user to enter the port number to use for SMTP server.
Authentication	Enables the user to select the Authentication mode for SMTP configuration
SMTP User Name	This is the username that the AG Service authenticates with for SMTP Emailing.
SMTP Password	This is the password that the AG Service authenticates with for SMTP Emailing.
	This field is required when Basic Authentication is selected in Authentication.
Enable SMTP	When this checkbox is checked, SMTP is used by AG Service to send emails.

Use the following procedure to modify SMTP.

1. Enter the SMTP **Server IP** or **Name**.

2. Enter the **Port** number to use for SMTP server.

3. Select the **Authentication** mode for the SMTP configuration, from the drop-down list.

4. Enter the **SMTP User Name**.

5. Enter the **SMTP Password**.

6. Select **Enable SMTP?** to ensure that the AG Service implements SMTP to send e-mails.

7. Click **OK** to save the changes made.

Configuring Workflow Items

The Workflow Items screen enables you to modify the options available for Workflow Items.

Select System Configuration **-->** System Management to view the Common Profile Configuration screen.

Tip: The Common Profile folder appears in a tree-view on the left panel. The components are categorized as folders. Each folder contains all the field labels associated with that section.

To configure the fields associated with the **User Interface** section, click the **Common Profile--> Workflow** folder in the left panel. The configurable fields associated with **Workflow** appear in the right panel.
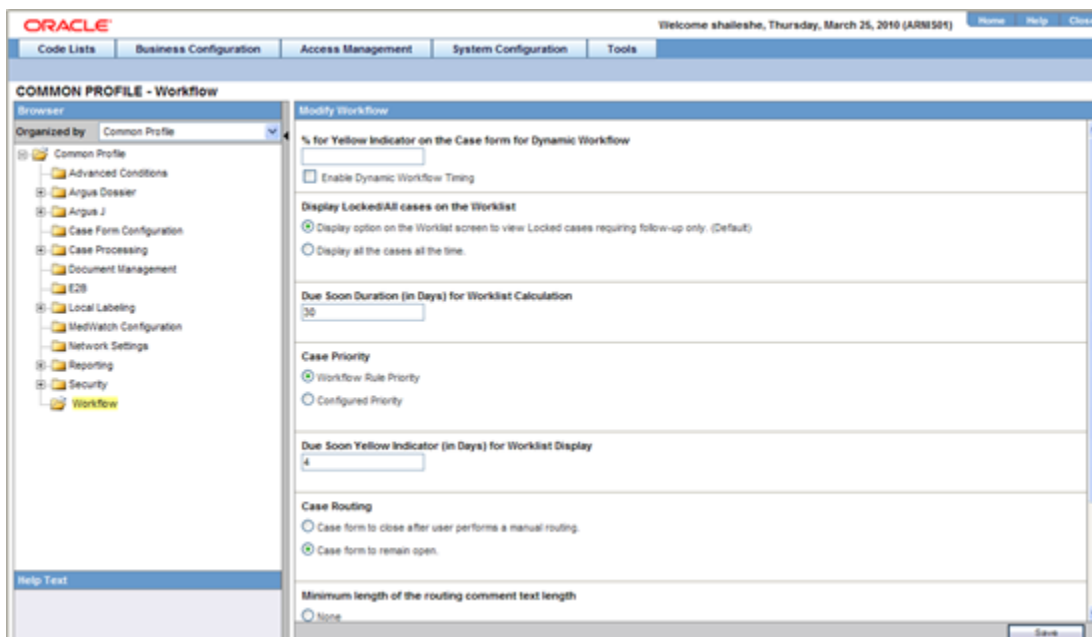
This section enables you to configure the total number of hours remaining for the present workflow state as well as the Total Number of the hours remaining for the case lock.

- The first element displays the number of hours remaining for the case to be processed with the current workflow state.

- The second element displays the number of hours remaining for the entire workflow for the case till Case Approval (Case Lock).

- If the time remaining is less than the specified value in **% for Yellow Indicator on the Case form for Dynamic Workflow**, the elements are highlighted in yellow.

- If the time remaining is more than the specified value in **% for Yellow Indicator on the Case form for Dynamic Workflow**, the elements are highlighted in green.

- If the time remaining has exceeded the allocated time for the case process, the value is displayed in red, with the time displayed in negative.

- The exceptions to this feature are those cases, which are archived and locked.

The **Worklist>New** and **Worklist>Open** also display a **!**" status beside **Priority**, denoting that the time remaining has exceeded the allocated time.

The total number of units is calculated by navigating across the possible routes the case can traverse. In case a case has to traverse through multiple possible routes, the preferred route is selected.

Field Descriptions The following table lists the fields available under **Workflow:**

Field/Control Name	Description
Case Routing	The available options are: ■ Case form to close after use performs a manual routing ■ Case form to remain open
Display Locked/All cases on the worklist	The available options are: ■ Display option on the Worklist screen to view Locked Cases requiring follow-up only. (Default) ■ Display all the cases at the time
Minimum length of the routing comment text length	The available options are: ■ None ■ Text field
Display date for cases in the worklist	The available options are: ■ Display Initial Receipt Date of the Case in the Worklist. (Default) ■ Display Follow-up Date of the Case in the Worklist. Follow-up date is the last entered follow-up date
Due Soon Duration (in Days) for Worklist Calculation	Enter the number of days in which the worklist calculation is due.
Due Soon Red Indicator (in Days) for Worklist Display	Enter the number of days in which the red indicator is to due to be displayed for the worklist.
% for Yellow Indicator on the Case form for Dynamic Workflow	Enter the percentage for the yellow indicator on the case form for dynamic workflow. This field cannot have a value more than 99.
Enable Dynamic Workflow Timing	Select this checkbox to view the dynamic workflow indicators on the case form.

Use the following procedure to configure workflow items.

1. Select the option for **Case Routing**.

2. Select the option for Display Locked/All cases on the worklist.

3. Enter the Minimum length of the routing comment text length in the text box.

4. Select the option for Display date for cases in the worklist.

5. Enter the number of days in which the worklist calculation is due in **Due Soon Duration (in Days) for Worklist Calculation**.

6. Enter the number of days in which the red indicator is to due to be displayed for the worklist in **Due Soon Red Indicator (in Days) for Worklist Display**.

7. Enter the percentage for the yellow indicator on the case form for dynamic workflow in **% for Yellow Indicator on the Case form for Dynamic Workflow**.

8. Select the **Enable Dynamic Workflow Timing** checkbox to view the dynamic workflow indicators on the case form.

9. Click **Save** to save the changes made to this screen.

Configuring Workflow

When a case is received by the company and initial details have been entered and saved into Argus Safety, its status in the system becomes 'New' or 'Data Entry'. Various actions may be required before a case makes the transition from one workflow state to another.

Example: The case may require review, letters may need to be issued, the case may need to be reported elsewhere in the company, or regulatory reports need to be submitted to regulatory authorities. The case can be closed after all outstanding actions have been carried out and it flows through its life cycle.

For each stage in case processing, Argus Safety enables responsibility for cases to be assigned to specific user or group of users. Click the following link for information about how worklist permissions have changed.

Worklist Updates

The Worklist is driven by the group permissions defined for each user.

- Granular permissions have replaced the current worklist options for the following worklist elements in group permissions:
    - Worklist - New
    - Worklist - Open
    - Worklist - Reports
    - Worklist - Action Items
    - Worklist - Coding Action Items
    - Worklist - Contacts
    - Worklist - Bulk Transmit
    - Worklist - Bulk Print
    - Worklist - Bulk E2B Transmit
    - Worklist - Local Labeling
    - Worklist - Coding Status
    - Worklist - Letters
    - Worklist - Intake (default is disabled)
- If the worklist is disabled during the upgrade, then all the sub-elements are disabled; otherwise, all are enabled.

- The default for **New Group Creation** is enabled.

- The **User Group Permissions Report** has been updated to reflect granular permissions.

Configuring Case Workflow

Configuring case workflow involves configuration of:

- Workflow States

- Workflow Rules

Configuring Workflow States This screen enables you to configure the workflow states. The following illustration shows the fields associated with this section.

Field Descriptions

The following table lists and describes the fields available under **Total Number of Rows**:

Field/Control Name	Description
State Name	Displays the name of a workflow state.
State Description	Displays a brief description about the workflow state.
Site	Displays the site associated with a workflow state.

> **Tip:** Click **Add New** to add a new workflow state to the list of existing workflow states.

Use the following to modify workflow states

1. Enter the name of the workflow state under **State Name**.

> **Tip:** This name is displayed as **Case Status** in the General Information section of the Case Form.

2. Enter the description of the workflow state under **Description**.

3. Select the site to be associated with the workflow state from the **Site** drop-down list.

4. The drop-down list is populated with the configured user sites.

5. Click **Save** to save the changes made.

Configuring Workflow Rules This screen enables you to configure workflow rules. The following illustration shows the fields associated with this section.

Field Descriptions

The following table lists the Field Descriptions for this section.

Field/Control Name	Description
From	Defines the original state for the transition.
To	Defines the destination state for the transition.
Group	Specifies the group which will own the case once it moves from the From state to the To state (via this transition).
	The drop-down list displays all the configured user groups of Argus.

Field/Control Name	Description
Normal Time (days) Max Time (days)	The workflow system monitors the time frames of each case in a state with respect to the Normal and Maximum parameters through AG Service. ■ The AG Service evaluates the status of each open case. ■ If a case has existed in its current state longer than the Normal time specified for the transition, the system raises the priority of the case by one level. This escalation occurs only once for a case within a given state. ■ The case priority is not reset to its assigned priority upon transition. ■ If a case has existed in its current state longer than the Maximum time specified for the transition, the system raises its priority to level one (the highest priority). ■ In addition, an email notification is sent to the group's supervisor, indicating that the case has exceeded its maximum time. ■ The email message identifies the Case ID, Current State, Current Owner, and the time it has spent in its current state.
Units	Enables the user to specify the number of units.
Product Group	Enables the user to associate a specific Product group as additional criteria for the workflow transition.
Restrict to Workflow Group	Enables the user belonging to the identified workflow rule group to have case access rights, based on the definitions of only the identified group.
Email	When checked, the system sends an email notification to the user group address specified in group information whenever a case makes this particular transition. By default, the checkbox is unchecked.
Require Password on Route	■ If the switch PASSWORD_ON_ROUTING" is disabled (0), the password option on the Workflow Dialog is not displayed and the Routing dialog does not ask the user for a password. ■ If the switch PASSWORD_ON_ROUTING" is enabled (1), the password option on the Workflow Dialog is displayed to users. If the Workflow Rule has the password option checked and the case being routed passes that workflow rule criteria, the password option is displayed on the routing dialog. ■ If the Workflow Rule that the case has passed does not have the Password option checked, no password option is displayed on the routing dial.
Lock Case on Route	Enables the user to lock the case on routing.
Reason for not being able to route	Enables the user to enter the description needed by the system to display while routing the case, when the case is ineligible to be routed to any of the configured To State".
Privileges to others	Specifies the access rights for groups other than To Group' of the transition have to the case when it follows that transition. The choices are: ■ No Access ■ Read-Only ■ Read/Write (default)
Preferred State	Enables the user to specify the preferred state for the rule.

Use the following procedure to modify workflow rules.

1. Select the appropriate **Filter Criteria.**

   ■ Execute the following steps to apply a filtering criteria to search for specific workflow rules.

   ■ Select the check boxes to enable the drop-down lists containing a filtering criteria.

   ■ Select the appropriate filtering criteria from the drop-down lists.

   ■ Click **Search** to remove the selected criteria or click **Apply Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

2. The entities in **Total Number of Rows** display the **From** and **To** states, the Advanced Condition, Group, Normal Time/Max Time and Number of User Defined Attributes in the Workflow.

3. Select the rule displayed under **Total Number of Rows** that needs to be modified.

4. The **ModifyWorkflow Rules** section is populated with information about the selected rule.

5. Select the original state of the workflow rule from the **From** drop-down list.

6. Select the destination state of the workflow rule from the **To** drop-down list.

7. Select the group from the **Groups** drop-down list.

8. Select the product from the **Product Group** drop-down list.

9. Select the **Email** checkbox, if required.

10. Select the **Lock Case on Route** checkbox, if required.

11. Select the **Require Password on Route** checkbox, if required.

12. Enter the number of days in the **Normal Time** (days) field.

13. Enter the number of days in the **Max. Time** (days) field.

14. Enter the number of units in the **Units** field.

15. Select the preferred state for the rule from **Preferred State**.

16. Select the relevant **Advanced Condition**, if any from the button.

    > **Tip:** Click here for details on Advanced Conditions

17. Enter the reason for not being able to route, if applicable, under **Reason for not being able to route**.

18. Specify the access levels available to others from the **Privilegesto others** drop-down list. The options available under this list are No Access, Read-Only and Read/Write.

    > **Tip:** Select the No Access option to disallow users outside the transition's group to open the case when it follows the transition.
    >
    > Select the Read-Only option to enable users outside the transition's group to view the case, but not to modify it.
    >
    > Select the Read/Write option to enable users outside the transition's group to modify the case when it follows the transition.

19. Specify the checklist of items to appear under **Checklist**.

> **Tip:** The Checklist row cannot be left blank. Click **Add** and **Delete** to add and delete checklist items.

20. Define custom attributes for a workflow rule under **User Defined Attribute**.

21. Click **Save** to save the changes made.

Worklist Intake

This section provides information about the Worklist Intake feature.

Pending Dialog The system enables the user to view a list of incoming attachments in Worklist View. In this view, the user can select an attachment for the case creation for Argus and Affiliate cases in the Pending dialog.

The following table lists and describes the fields available for the worklist

Field/Control Name	Description	Bookin Field	Property
Priority	Enables you to view the priority of a case	N/A	Non-scrollable field label
Initial Date	Enables you to view the Initial Receipt Date of the case.	Initial Receipt Date	Non-scrollable field label
Intake Date	Enables the user to view the date the system imported the attachment in the Intake Worklist	N/A	Non-scrollable field label
Product Name	Enables you to view the suspect product in questions.	Product Name	Scrollable field label
Generic Name	Enables you to view the generic name of the suspect product in question.	Generic Name	Scrollable field label
Event PT	Enables you to view the primary event and verbatim as reported	N/A	Scrollable field label

Field/Control Name	Description	Bookin Field	Property
Event Verbatim	The following format will be used: Primary Event (Verbatim as Reported)	N/A	Non-scrollable field label
Serious	Enables you to view the Case Level Assessments Serious (Y/N)	N/A	Non-scrollable field label
F, LT, or H	Fatal (F) or Life Threatening (LT) or Hospitalized (H) ■ If the case is Fatal, print F ■ If the case is Life Threatening, print LT ■ If the case is Hospitalized, print H ■ If any of the preceding are present together, Fatal takes precedence followed by LT, followed by H ■ If the case is neither, display No	Death for F Hospitalized for H Life Threatening for LT	Non-scrollable field label
Case Type	Enables you to view report type information.	Report Type	Non-scrollable field label
Study ID	Enables you to view the Study ID for the study cases This field is empty for cases where the Study ID is not available.	Study ID	Non-scrollable field label
Reporter Type	Enables you to view the reporter type for the primary reporter in the case. This field is empty if the reporter type is not available.	N/A	Non-scrollable field label
Country	Enables you to view the country of incidence	Country of Incidence	Scrollable field label
Central/Affiliate Site	Enables you to view the current Argus or Affiliate site of the case. You can view all the source documents from the site folder the user belongs to Workflow enterprise users can view all cases across all site	N/A	Scrollable field label
Attachment	Enables you to view the attachment associated with the case. If there are multiple files, they are separated by a comma.	N/A	Non-scrollable field label link
Classification	Enables you to view the attachment classifications associated with the attachment.	Classification	Scrollable field label

Field/Control Name	Description	Bookin Field	Property
Description	Enables you to view the attachment description associated with the case.	Description	Scrollable field label
View All	Enables the administrator and workflow manager/enterprise to see all items in the system across all sites.	N/A	Radio button
View Individual	Enables you to view all items assigned to this user site. ■ If there are no sites defined then **all** users have access to the case attachment. ■ This button is disabled if the user is not a workflow manager or enterprise user.	N/A	Radio button

Worklist Intake View The following table describes the Worklist Intake View:

Argus Site	Folder	Worklist Intake View
US	C:\USINTAKE	All users belonging to the US site can see the case and workflow enterprise users.
DE	C:\EUINTAKE	All users belonging to the DE, FR, CH site can see the case and workflow enterprise users.
CH	C:\EUINTAKE	All users belonging to the DE, FR, CH site can see the case and workflow enterprise users.
FR	C:\EUINTAKE	All users belonging to the DE, FR, CH site can see the case and workflow enterprise users.
JP	C:\JPINTAKE	All users belonging to the JP site can see the case and workflow enterprise users.

Worklist ■The system reads the XML that contains the preceding fields as tags and creates the Worklist based on the tags.

<Cases>

<Case>

<PRIORITY>: Single number from 1 - 8. All others to be ignored

<INITIAL_DATE>: Format of Date DD-MMM-YYYY

<PRODUCT_NAME>: Text Field up to 70 Characters

<GENERIC_NAME>: Text Field up to 70 Characters

<EVENT_PT>: Text Field up to 250 Characters

<EVENT_VERBATIM>: Text Field up to 250 Characters

<SERIOUS>: Yes / No. All others are ignored

<FLTH>: Format of F. All other after that are ignored

<LT>: Format of LT All other after that are ignored

<H>: Format of H. All other after that are ignored

<CASE_TYPE>: Text field of report type

<STUDY_ID>: Text field of Study ID

<REPORTER_TYPE>: Text field of Reporter Type

<COUNTRY_OF_INCIDENCE>: Text field of Country

<ASSIGNED_TO>: Text field of User

<GROUP>: Text field of Group

<SITE>: Text field of Site

<ATTACHMENTS>

<ATTACHMENT>:

<FILENAME>: Text field of Attachment File Name

<DOCID>: Document ID from Document Storage System

<CLASSIFICATION>: Text field of Attachment Classifications

<DESCRIPTION>: Text field of Attachment Classifications Descriptions

- The text on the worklist prints as specified in the XML and no lookup is performed.

- If any of the Tag elements are empty they will be empty in the Intake Worklist.

- If any fields are not available on the initial case entry, the system ignores them.

- If there are multiple tags for the same element, the system retrieves the first tag element.

- If the values do not match any elements in the Initial Case entry, the system ignores them.

- The minimum fields required for the Attachment to be visible in the Intake Worklist are

  - Filename

  - DocID

  - DocID is only required if a central document system is enabled. If DocID is blank then the physical file with the same name as specified in the tag <Filename> is also required in the same folder.

- If there is an error occurs while processing the Worklist, AG Service sends an e-mail to the General E-mail address.

- The system enables you to select only one case at a time when creating cases in the Initial Case entry dialog.

  - When you select an attachment row and click Create case, the system locks the file to prevent others users from booking in the same case.

  - The system displays the following message:

    The case attachment is being currently used by XXXX user.

    where:

    XXXX is the full name of the user who has locked the attachment row

- The system displays the standard Initial Case Entry where the system populates the fields within the XML Properties to the Initial Case entry dialog and display the PDF file for 40% of the screen (Similar to the New case from Image functionality)

- If multiple attachments are available, the system opens them. The end user system must be setup to open multiple documents in the same window in Internet Explorer.

- If the system is setup to use a central document storage system and the user clicks Create Case, the system retrieves the PDF from the central document system.

- The system adds the attachment to the Initial Case entry dialog and also includes the Classifications and Descriptions for the attachment.

- If the system is setup to use a central document storage system, Argus stores the document ID from the central document system. The file attachment will not be stored in Argus.

-

- The system fills all available fields in the Initial Case Entry dialog with data from the XML Messages.

- If you choose to open the cases after book-in, the system keeps the Attachment open in the split screen to enable the user to complete the case data entry.

- If you book in the case from the Worklist Intake and chooses not to open the case from the Initial Case Entry dialog after book in is complete, the system returns to the Worklist Intake dialog.

■ When you perform a Duplicate Search and select a Case from the list, you can attach an incoming file to an existing case.

- The system displays the Accept As Follow-up button and enables it when the user selects a case from the Duplicate search for the current Attachments to be added.

- When you click Accept as Follow-up, the system opens the selected case and continues to display the Source attachments.

- The system adds the attachments with the Classification and description (if provided) to the follow up case

- The system opens multiple attachments if they are available. The end user system must be setup to open multiple documents in the same window.

■ Once you accept the initial or Follow up case and successfully create the case in Argus / Affiliate, the system generates an Acknowledgement in the OUT folder at the same level. For example, if the incoming folder for Site US is C:\USSITE\Incoming, the system generates ACKS in the C:\USSITE\OUT folder.

- a. The Message format for the ACK is as follows::

  <CASES>

  <CASE>

  <CASE_NUMBER>: Argus Generated Case Number

  <PRODUCT_NAME>: Text Field up to 70 Characters for Primary Suspect Product of Case

<DATETIME>: The Date and time in the DD-MMM-YYYY hh:mm:ss format when the file was accepted / rejected by the system

<ATTACHMENTS>

<ATTACHMENT>:

<FILENAME>: Text field of Attachment File Name

<DOCID>: Document ID from Document Storage System

- If you click Copy to copy a case in Argus, the system generates an ACKS and puts it into the out folder for the site the original case belongs to. For example, Case A belongs to US Site and the user copies the case to Case B. The system creates an ACK in the US\Out Folder as configured in the US Site.

Rejected Cases In Argus Safety, the Workflow Manager or Enterprise User can click Reject Case to reject cases from the Intake Worklist.

- Affiliate Users can reject cases in the Intake Worklist.

  – When you try to reject a case, the system presents the Standard Justification dialog.

  – The Status row displays the following message:

    Case Rejected by XXXX on YYYY at MMM due to: ZZZZ

    where:

    XXX is the User Full Name,

    YYYY is the Date when the case was rejected in GMT

    MMM is the time in GMT

    ZZZ is the justification for rejecting the case as entered by the user.

  – Rejected Date: Date in GMT when the user rejected the case

  – Rejected By: User Full Name who rejected the case.

- The system displays the **Total number of Rows** in the Worklist header section.

- You can select the number of cases to display on the by selecting a value from page size drop-down list on the Worklist dialog.

- The page 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 updates the range automatically. For example. if you select 100 from the page size drop-down list, the system separates the displaying rows into groups of 100 cases.

- The system enables you to go directly to a range of cases from the **Displaying Rows** drop-down list.

- The system enables you to scroll through the Worklist page-by-page increments as defined by the **Page Size** drop-down list.

- The system enables you to sort on ALL the columns in the Worklist view by clicking the header column. The system displays a triangle to show which column is sorted currently.

  - The initial sorted column is Initial Date.

  - The default sort order is ascending

  - Clicking the column header again, toggles between ascending and descending order.

- The system maintains the worklist view with the sorting and filtering options defined by the user.

- The Intake Worklist enables you to filter on each element.

- The system enables you to filter on any element when you click the **Filter** button.

  - The system provides a Type Ahead feature to enables users to filter on any text/date element.

  - The system enables you to Close the filtering options by clicking the **X** icon on the filtering options.

  - If filtering criteria are specified, the **Filter** icon has the **paper clip** icon to indicate there are filtering elements.

  - The system permits a Like search (e.g. if you search for Cure, it returns all elements starting with Cure).

  - The system enables wild card searches . For example, if the user searches for %Cure, the system returns all elements containing Cure

  - Clicking the **Search** button enables you to filter for the reports in the list of reports.

  - These are filtering options are available from Worklist-specific views and when you drill down for cases or reports.

- The system saves all user preferences for future use.

- Clicking the Search button enables you to filter the elements on the dialog.

User Site Updates and Access Management You can configure the Path for the File Intakes per Site (Argus and LAM) in the Site configuration

- When you click the **Browse** button, the system enables you to browse to the Folder for the Site where the XMLS and the PDFs are stored

- The Path length is up to 255 characters

- The current Worklist options are replaced with granular permissions for Worklist elements in the Group Permissions as per the following:

- Worklist Intake (default is disabled)

- The Audit Log tracks the updates made to Site Configuration

- The User Site print out displays the File Intake Path.

Configuring System Numbering

This screen enables you to specify the case numbering preferences. Select **System Configuration --> System Numbering** to view the LAM System Numbering screen.

The screen appears as shown.

Field Descriptions

The following table lists and describes the fields for this section.

Field/Control Name	Description
Manually Number Cases	Enables the user to manually number the cases on booking or while copying the case, using the save as' option on the case form.
Automatically Number Cases	On selection, the system automatically numbers the cases as defined by the user in the numbering format.
Start at	Enables the user to initialize the counter of the sequence number.
Separate sequence for each site	Enables the user to separate the sequence numbering for cases on site by site basis. If there are cases being entered from two different sites then each site will have different sequencing of case numbers.
Separate sequence for each report type	Enables the user to separate the sequence numbering for cases by the report type of the case.
Separate sequence for each year	Enables the user to reset the sequence numbering for cases after each year based on the initial receipt date of the case.
Separate sequence for each month	Enables the user to reset the sequence numbering for cases after each month based on the initial receipt date of the case.
Separate sequence for each product abbreviation	Enables the user to reset the sequence numbering for cases for each different product abbreviation.
Numbering Format	Enables the user to select the numbering format by selecting the different placeholders.
	Define the numbering format by typing in custom keywords to print on every case number and selecting different placeholders.
	[YY][MM]-[###] is the default format.
Placeholder	Placeholders are used to pickup values from the database to be used in the Case numbering format.
	The possible values populated in this list are:
	# - Number: defines the digits to be used as the sequence number in the format. The field is used to display the sequence number on the case numbers.
	CC- Country Code: When selected, this uses the A2 code for the country of incidence for the case number.
	DD - Day: When selected, this uses the date of the Initial receipt date' field of the case.
	MM - month: When selected, this uses the month of the Initial receipt date' field of the case.
	P - When selected , this uses either of the two values:
	If report type is Spontaneous' or other' during booking: the system uses the value of the Product Abbreviation' field specified in the Product configuration for the selected Primary suspect product.
	If report type is of the type report from study' during booking: the system uses the Product Abbreviation' field specified in the study configuration.
	SSS - User Site: When selected this uses the Site abbreviation of the site belonging to the user who booked in the case.
	TTT - Report Type: When selected this uses the report type abbreviation of the report type selected during bookin of the case.
	YY- Year: When selected, this uses the year of the Initial receipt date' field of the case.

Use the following procedure to configure LAM system numbering.

1. Select the **Numbering** feature as required. This can be manual numbering or automatic numbering of cases.

2. Select the **Sequencing Options** as required.

   > **Tip:** For the complete explanation of the sequencing options refer to the Field Descriptions

3. Select the Numbering Format.

   > **Tip:** To customize the **Numbering Format**, use the **placeholder** values.

   > **Example**: To select Country Code, Month and Year (as values to be incorporated from the database) as the Case numbering format, execute the following steps.

   - Click on *Country Code.* This appears in the **Numbering Format** field.

   - Click on *Month*. This appears in the **Numbering Format** field next to the Country Code.

   - Click on *Year*. This appears in the **Numbering Format** field next to the Country Code and Month.

   > The final data listed in the **Numbering Format** field is the Case Numbering Format.

4. Click **Save** to save the changes made.

Configuring Field Labels

This section enables you to change field label names and hide or display fields in the Case Form.

Select **System Configuration --> Field Labels** to view the Case Form Field Configuration screen shown in the following illustration.

Tip:

The Case Form tabs appear in the left panel and are categorized as folders. Each folder contains all the field labels associated with that section.

Example : The General Tab in the Case Form contains sections such as Study, Follow-Up, Case Literature etc.

- To view the list of field names associated with the Study section , click **Study** in the left panel.

- The field names associated with Study appear in the right panel.

Field Descriptions

The following table describes the fields associated with this section.

Field/Control Name	Description
Field Name	Enables the user to view the field name. This is a read only field.
Field Form Label	Enables the user to enter the field label names for those fields that can be edited.
Help Text	Enables you to enter help text for fields that can be edited.
Selectable	When checked, enables you to???
Read Only	Enables you to make inrug, device, or vaccine field read- only.
Drug	Enables the user to make a field Read only in the Product tab, when the Argus user chooses Drug" option on the Product screen.

Field/Control Name	Description
Device	Enables the user to make a field Read only in the Product tab, when the Argus user chooses Device" option on Product screen.
Vaccine	Enables the user to make a field Read only in the Product tab, when the Argus user chooses Vaccine" option on Product screen.
Hidden	Enables the user to hide or unhide a field by selecting the radio button.
	Select **Yes** to hide the field on case form; select **No** to unhide the field on case form.
	Note: Some fields cannot be hidden. Hidden fields do not appear in the case form printout.
E2B Field	When checked, hows which fields are required for E2B.

Use the following to modify case form field names.

1. Select the folder (or section) in the left pane, for which the field names are to be modified.

2. The places the list of field labels associated in the right panel.

3. Click on the **Field Name** to be modified.

4. The system highlights the selected row is highlighted and puts the details about this field in the **Modify** section at the bottom of the screen.

5. Enter the new field name in **Field Form Label**.

> **Tip:** : This label will appear in the Case Form section.

6. Select the **Hidden** preference. Select **Yes** if you want to hide the field on the Case Form.

7. Click this checkbox to indicate which fields are required for E2B.

8. Select any or all of the following options **Drug**, **Device** or **Vaccine** as **Read Only** based on your requirement.

9. Click **Save** to save the changes made.

> **Note:** Label Changes will not be reflected in Argus Case Form unless IIS is reset.

Adding User Defined Fields

User defined fields of type Text, Date, and Number may be added to a Case Form. Follow the steps listed below to add a user defined field to a Case Form and/or confirm that the Case Form supports user-defined fields:

1. In Argus Console, navigate to System Configuration > Field Labels.

2. In the left-hand section, select a Case Form by clicking on its name.

3. In the right-hand section with a title bar matching the selected Case Form, scroll down till the words "User Defined.." are visible in the Field Name column.

4. Click on the desired Field Name.

5. In the lower, right-hand section, make the appropriate corrections and save any changes.

> **Note:** Oracle Argus Safety controls the total number of User Defined Fields on any given Case Form by only allowing a single occurrence of each sequence number. Therefore, if "User Defined Number 1" is used, "User Defined Text 1" and "User Defined Date 1" cannot be activated. If a Date and/or Text field is desired the user must select from the fields that have a higher sequence number such as User Defined Date 2, User Defined Date 3, etc., thus always ensuring that the sequence number is unique.

Configuring User Defined Fields

The Argus Safety administrator can customize a user-defined field as a drop-down list. These drop-down lists may contain customized lookup data which can be independent of Argus data.

Use the following procedure to create a user-defined field.

1. Identify the User Defined field in the CMN_FIELDS table.

2. Create a custom table containing lookup information.

3. Create a custom index and specify the required values for the table.

4. Update the record in the CMN_FIELDS table for the User Defined Field.

5. Create a Role and Synonym for the table.

6. Restart IIS.

7. Verify the update made in the application.

Consider the following example that show a sample set of scripts required to configure User Defined Fields as a drop-down list. Assume the requirement is for a **User Defined Field** (UDF) with the following features:

Requirement: A User Defined field "SOURCE_OF_INFORMATION" to be created, with its drop-down values as Fax, E2B, Letter, Email and Telephone under Case Form **->** General Tab **->** General Information.

Attribute	Value
Field Name	SOURCE_OF_INFORMATION
Drop-down Values	Fax, E2B, Letter, Email and Telephone
Field Location	Case Form **=>** General tab **=>** General Information

Use the following procedure to create a user-defined field:

1. Login to Argus **-->** Argus Console **-->** System Configuration **-->** Field Labels.

2. Enter the Field Form Label as Source of Information.

3. Select No against Hidden and click Save.

4. Query the following required field for an update, based on the field_label

   SELECT

   field_ID, field_label, table_name, column_name, tree_view, data_type, data_length

   FROM

   cmn_fields

WHERE

field_label LIKE '%SOURCE_OF_INFORMATION%';

5. Create a Custom Table

create table pf_SOURCE_OF_INFORMATION(

pf_SOURCE_OF_INFORMATION_code number,

pf_SOURCE_OF_INFORMATION_desc varchar2(100))

/

6. Create a Custom Index

create index idx_pf_SOURCE_OF_INFORMATION

on pf_SOURCE_OF_INFORMATION (pf_SOURCE_OF_INFORMATION_code)

/

7. Insert values

insert into pf_SOURCE_OF_INFORMATION values (1, MI Fax');

insert into pf_SOURCE_OF_INFORMATION values (2, MI E2B');

insert into pf_SOURCE_OF_INFORMATION values (3, MI Letter');

insert into pf_SOURCE_OF_INFORMATION values (4, MI Email');

insert into pf_SOURCE_OF_INFORMATION values (5, MI Telephone');

8. Update CMN_FIELDS table

update cmn_fields

set join_type = 1,

GUI_field_type = 6,

field_length = 100,

JOIN_FLD_ID = 50001,

select_table = 'pf_SOURCE_OF_INFORMATION',

join_field = 'PF_SOURCE_OF_INFORMATION_CODE',

select_column = 'PF_SOURCE_OF_INFORMATION_DESC'

where field_id = 2150032

/

commit;

/

9. Grant select to ARGUS_ROLE

grant select on pf_SOURCE_OF_INFORMATION to argus_role;

10. Create Public Synonym

create public synonym pf_SOURCE_OF_INFORMATION for argus_app.pf_
SOURCE_OF_INFORMATION;

11. Restart the Web Server

12. Go to the command prompt and enter the iisreset command for changes to take effect.

13. Verify the outcome from the front end

14. Login to Argus Safety and open a Case Form.

Go to General tab | General Information and check that the configured user-defined fields display the updated drop-down text.

5

Code List Configuration

Information about configuring the following code list items is included in this chapter.

- Autosignals
- Batch Reports
- Letters
- Justifications
- Electronic Transmission Recipient
- Event Groups
- Literary Citations
- Reporting Destination
- Routes of Administration
- Study Center
- Holiday Calendar
- Other Code List Items

Configuring Code Lists

Code List items appear at several locations in the Case Form. It is essential to configure relevant Code List items in order to ensure that case entry in Argus Safety is done according to your company's policies. Before configuring Code List items , the Administrator should consult the company's policies and the terminology used by the company.

To ensure that the Administrator does not have to enter excessive amounts of data during Code List configuration, Argus Safety is shipped with factory data for many of the Code List items.

> **Tip:** The following Code List Items have been described to familiarize you with the Code List configuration.
>
> - For the complete set of Code Lists refer to the **Argus Console->Code List** section.
> - The default help text associated with each code list item is displayed at the bottom of the left panel.

Code List Item	Description

Autosignals	This screen helps in capturing Auto Signal information. Users can define the criteria that triggers Autosignal within Argus
Batch Reports	This screen helps in capturing Batch Reports information.
Letters	The screen helps in configuring the system to create and schedule letters automatically, according to pre-defined business rules.
Justification	This screen helps in capturing justification information.
Electronic Transmission Recipient	This screen helps in capturing electronic transmission recipient information.
Literary Citation	This screen helps in capturing information about Literary Citations.
Reporting Destination	This screen helps in capturing Reporting Destination information.
Routes of Administration	This screen helps in capturing Route of Administration information.
Study Center	This screen helps in capturing Study Center information.

Configuring Autosignals

This screen enables you to capture the Auto Signal information.Using this screen, you can define the criteria that triggers Autosignal within Argus.

Example: If an event is reported within x number of days, an email is sent to the defined individual or workgroup. The system checks for patterns each time new data is entered, and sends e-mails to the appropriate individuals or departments on finding a matching pattern.

Select Code Lists **-->** Argus to view the Code List Maintenance screen.

> **Tip:** The code list items are displayed in the left-panel. Click on the required Code List folder to be configured. The details of this code list item appear in the right panel.

Field Descriptions

The following table describes the fields associated with this section.

Field/Control Name	Description
Name	Enables the user to enter the name of the Autosignal. This is a required field.
Number of Occurrences	Enables the user to enter the number of occurrences of the autosignal.
Occurrences of	Enables the user to enter the user to select or create an advanced condition for the autosignal through Select icon.
Number of days	Displays the number of days for the autosignal.
As cases are entered	Enables the user to perform autosignal as cases are entered.
Every N Days	Enables the user to enter the number of days, when autosignal should be executed.
Email	Enables the user to enter the email address of Argus users to whom the email about autosignal occurrence should be sent.

Use the following procedure to configure Autosignals.

1. Click on the **Autosignals** folder in the left panel. The associated autosignal data appears in the **Total Number of Rows** section in the right panel.
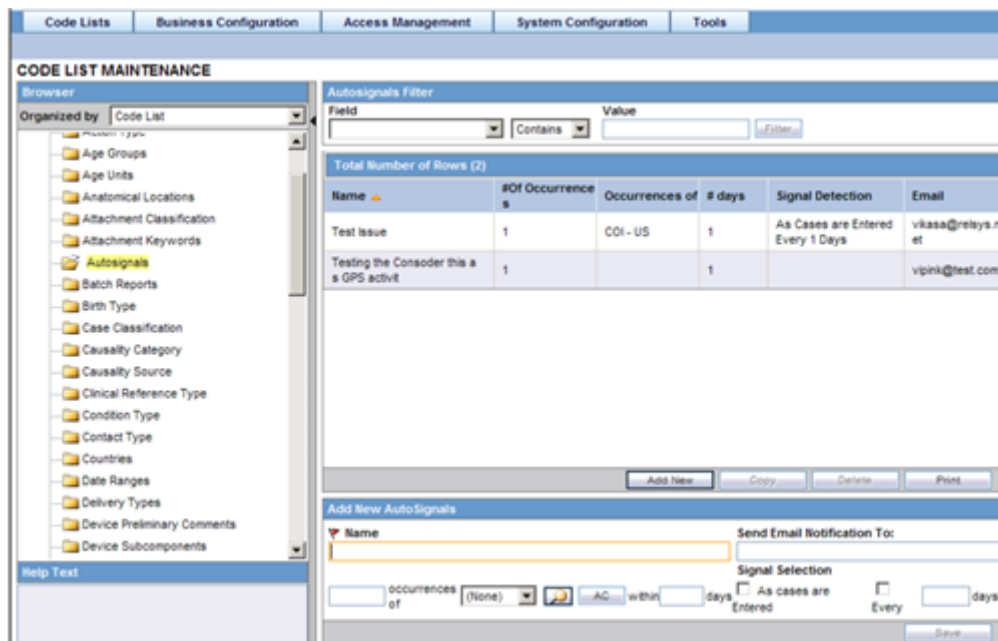
2. Click on the **Name** (or row), to view the details associated with the selected autosignal. The details appear in the **Modify Autosignal** section.

   You can use the **Autosignals Filter** to make your search specific to an autosignal. The filtering criterion is essential as it helps you to search for specific items.

3. Select the appropriate **Field** as the filtering criteria from the drop-down list.

4. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

5. Enter the search criteria in **Value**.

6. Click **Filter** to apply the selected criteria.

   This displays the search results under **Total Number of Rows**.

   > **Tip: You can alternatively click Add New to create a new auto signal.:** Click **Copy** to make an editable copy of an existing autosignal.

   Click **Delete** to delete a selected autosignal.

7. Enter the name of the autosignal in the **Name** field.

8. Enter the number of occurrences of the autosignal in the **Number of Occurrences** field.

9. Select or create an Advanced Condition, if any from the button in the **Occurrences of** field.

   > **Tip:** Click here for details on Advanced Conditions

10. Enter the number of days for the autosignal under the **Number of days** field.

11. Select the **As cases are Entered** checkbox to perform autosignal as cases are entered.

12. Enter the number of days when the autosignal should perform under the **Every N Days** field.

13. Enter the e-mail address that receives email about autosignal occurrence in the **Email** field.

14. Click **Save** to save the changes made to this screen.

Configuring Batch Reports

This screen enables you to configure Batch Reports information.

- Scheduled reports can be automatically generated and stored in the database by Argus Safety Service. This screen displays a list of all the existing Batch Reports.

- By default the Batch reports shown are memorized reports. The Argus user can see the list of scheduled reports for memorized reports, using the Memorized Reports option.

- Select Code Lists **-->** Argus to view the Code List page.

- Click on the **Batch Reports** folder in the left panel.

The associated report data appears in the **Total Number of Rows** section in the right panel.

> **Tip:** : The code list items are displayed in the left-panel. Click on the required Code List folder to be configured. The details of this code list item appear in the right panel.

Field Descriptions

The following table describes the fields associated with this section.

Field/Control Name	Description
Title Name	This is the unique name for the batch report name.
Report	Enables the user to select a report that has to be scheduled.
	Report Regeneration
	Memorized report
Product	Enables the user to select a product for which the report is generated.
Frequency: Every Days.	Enables the user to enter the number of days after which the report is to be generated. The value has to be **-->** 0.
Next Run Date	Enables the user to enter the next date from which the report has to be scheduled.
Advanced Condition	Enables the user to select the Advance Condition that satisfies the criteria which will trigger the Signal. You can either select an existing criteria or create a new one.
Report Type	Enables the user to select the type of the report.
Group	Enables the user to select the group to which the report must be assigned.

Use the following procedure to configure Batch Reports

1. Click on the **Report Title** (or row), to view the details associated with that report. The details appear in the **Modify Batch Report** section.

   You can use the **Batch Reports Filter** to make your search specific to a batch report. The filtering criterion is essential as it helps you to search for specific items.

2. Select the appropriate **Field** as the filtering criteria from the drop-down list.

3. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

4. Enter the search criteria in **Value**

5. Click **Filter** to apply the selected criteria.

6. This displays the search results under **Total Number of Rows**.

   Tip:

   You can alternatively click **Add New** to create a new report.

   - Use **Copy** to make an editable copy of an existing report.

   - Use **Delete** to delete an existing report.

7. Enter the **Title Name** for the batch report.

8. Select the **Report Type** from the drop-down list.

9. Select the **Group** to which the report must be assigned.

10. Select the report to be scheduled as **Memorized Reports** or **Reports Regeneration**.

11. Select the **Frequency** of generating the report after the specified number of days have elapsed.

12. Select the **Product** for which the report is to generated, from the drop-down list box.

13. Select the **Report** from the drop-down list.

14. Enter the **Next Run Date**. This is the next date from which the report has to be scheduled.

15. Select the **Advanced Condition** associated with the report configuration.

16. Click Select icon to launch the Advanced Conditions browser.

> **Tip:** : Click here for details on Advanced Conditions

17. Click **Save** to save the changes made to this section.

Configuring Letters

Argus Safety enables the customization of letter templates in order to correspond with reporters or health officials and keep them updated with case activity. Access to the **Letter Configuration** dialog can be granted to any user or user-group, as found appropriate by the Administrator.
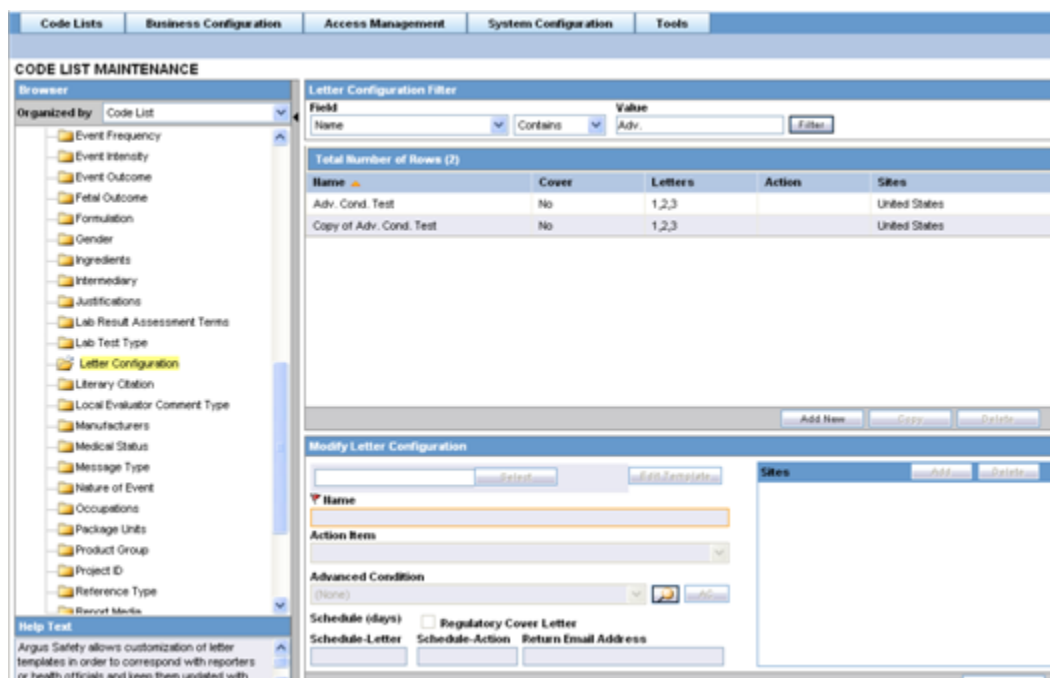
- To automatically generate a letter, the system reads a template that specifies the information that must appear in the letter.

- The template is a file in Rich Text Format (".rtf" format) that contains the letter text and some field identifiers (also called placeholders). The system substitutes information specific to the current case for the placeholders in the template. Thus, a letter containing case-specific information is automatically generated.

- The administrator can set up the system to create and schedule letters automatically, according to pre-defined business rules. This section discusses the creation, modification, and deletion of letter templates.

Select **Code Lists--> Argus** to view the Code List page.

> **Tip:** The code list items are displayed in the left-panel. Click on the required Code List folder to be configured.
>
> The details of this code list item appear in the right panel.

Configuring letter (RTF) templates

RTF Document can be created using the required placeholders such as:

[patient_last_name], [product_name]:[n], [rec_vacc_date]:[n]:[m], [event_prior_hist:primary_event], [reg_report_timeframe]

Most of the placeholders have one parameter or two and these are almost always linked to sort order.

Here are some examples of how these placeholders extract data:

For single value columns:

[age],[case_id],[comments],[case_status],[country_of_inc]

For multiple value columns:

[event_death:primary_event] picks data from case_primary_event table

[event_death]:[n] picks data from case_event/lam_event table based on Sort order

[case_notes]:[n], [concentration]:[n],[drug_code]:[n]

For multiple parameter columns:

[ingredient]:[n]:[m] - It lists nth case product and lists its mth ingredient

Field Descriptions

The following table describes the fields associated with this section.

Field/Control Name	Description
Name	Enables the user to specify the name of the letter as it will appear in the Letters menu.
Name (J)	Enables the user to specify the Japanese name of the letter as it will appear in the Letters menu.
Edit Template	Enables the user to open the letter in MS-Word (template) for editing.
Regulatory Cover Letter	Enables the user to indicate whether this letter template should appear in the Regulatory Rules dialog Cover letter drop-down list box.
Schedule - Letter	Enables the user to enter the number of days (from the receipt date) when the letter will be due.
Schedule - Action	The Action field enables the Administrator to specify the number of days (from the current date) after which the Action Item for following up on this letter will be due.
Sites	Argus Console provides the ability to configure letters to user sites. Enables users to select single or multiple sites for that letter. The system will only allow users to see letters that are configured to their site.
Action Items	The action items list is a drop-down list of action item codes from the Action Type List Maintenance.

Field/Control Name	Description
Return Email Address	Enables the user to enter a default email address where the mails will be sent. This address is displayed by default in the Activities tab of the Case Form.
Advanced Condition	Enables the user to configure Advanced Conditions. If the case matches with the Advanced Condition, the configured letter is scheduled for the case.

Use the following procedure to configure letters.

1. Click on the **Letter Configuration** folder in the left panel. The associated data appears in the **Total Number of Rows** section in the right panel.

2. Click on the **Name** (or row), to view the details associated with that letter. The details appear in the **Modify Letter Configuration** section.

3. You may use the **Letter Configuration Filter** to make your search specific to a letter. The filtering criterion is essential as it helps you to search for specific items.

4. Select the appropriate **Field** as the filtering criteria from the drop-down list.

5. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

6. Enter the search criteria in **Value**.

7. Click **Filter** to apply the selected criteria.

8. This displays the search results under **Total Number of Rows**.

   > **Tip:**   Tip : You can alternatively click **Add New** to create a new letter.
   >
   > - Use **Copy** to make an editable copy of an existing letter.
   >
   > - Use **Delete** to delete an existing letter.

9. Click **Select** to specify the path of the letter template to be used.

   > **Tip:**   Click **Edit Template** to save the existent template on to your local drive of the system.
   >
   > You can edit this template and repeat the step listed above, to ensure that the updated template is used for letters.

10. Enter the name of the letter, as it will appear, in the **Letters Menu** section in **Enter a new item**.

11. Click **Add** or **Delete** to configure letter to the user **Sites**.

12. Select the **Action Item** from the drop-down list box. The action items list is a drop-down list of action item codes, from the **Action Type List Maintenance**.

13. Configure the **Advanced Condition** for the case.

14. Enter the **Schedule (days)-Letter.** This is the number of days from the receipt date when the letter is due.

15. Enter the **Schedule (days)-Action.** This is the number of days from the current date, after which the Action Item for the follow up on this letter will be due.

16. Enable the **Regulatory Cover Letter** option to indicate whether this letter template should appear in the Regulatory Rules dialog.

17. Enter the default e-mail address in **Return Email Address**.

18. Click **Save** to save the changes made for this section.

Configuring Justifications

This screen enables you to capture justification information.
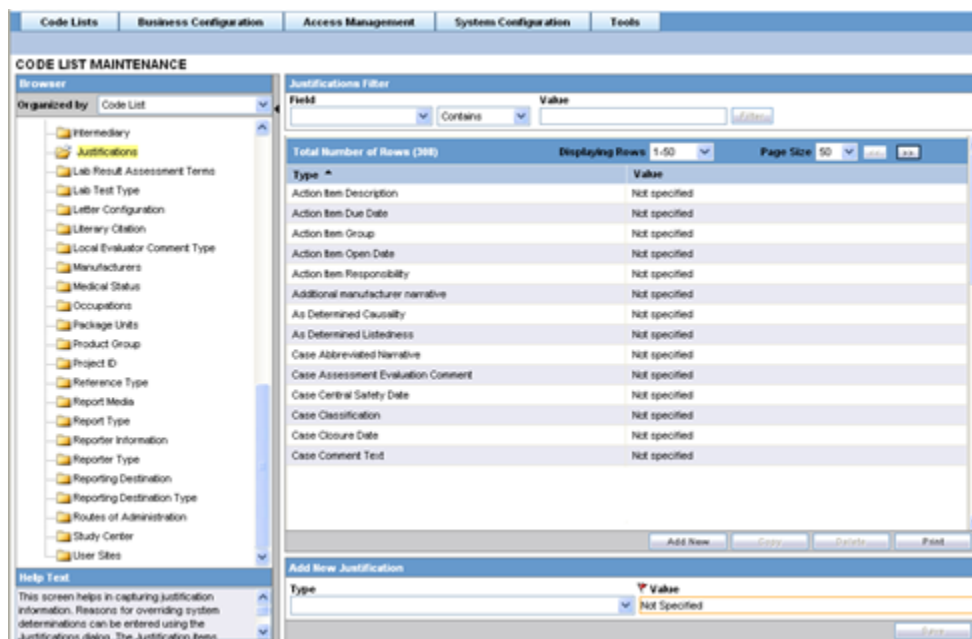
Argus Safety users can enter the reasons for overriding system determinations using the Justifications dialog. The Justification items appear on the Action Justification dialog on the screen.

Select **Code Lists--> Argus** to view the Code List page.

> **Tip:** The code list items are displayed in the left-panel. Click on the required Code List folder to be configured.

> The details of this code list item appear in the right panel.

Field Descriptions

The following table describes the fields associated with this section.

Field/Control Name	Description
Type	Enables the user to configure the type.
Value	Enables the user to configure the value.

Use the following procedure to configure justification.

1. Click on the **Justifications** folder in the left panel. The associated report data appears in the **Total Number of Rows** section in the right panel.

2. Click on the **Type** (or row), to view the details associated with that justification. The details appear in the **Modify Justification** section.

3. You may use the **Justifications Filter** to make your search specific to a justification. The filtering criterion is essential as it helps you to search for specific items.

4. Select the appropriate **Field** as the filtering criteria from the drop-down list.

5. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

6. Enter the search criteria in **Value**.

7. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

   Tip: You can alternatively click **Add New** to create a new justification.

   ■ **Use Copy** to make an editable copy of an existing justification.

   ■ Use **Delete** to delete an existing justification.

8. Select the **Type** from the drop-down list.

9. Enter the **Value** for the justification.

10. Click **Save** to save the changes made for this section.

Configuring Electronic Transmission

This screen enables you to configure electronic transmission recipient information.

■ Details of electronic transmission recipient such as name, title, address etc. are submitted here.

■ Select **Code Lists--> Argus** to view the Code List page.

> **Tip:** The code list items are displayed in the left-panel. Click on the required Code List folder to be configured. The details of this code list item appear in the right panel.

Field Descriptions

The following table lists and describes the fields associated with this section.

Field/Control Name	Description
Name	Enables the user to enter the name of Electronic Transmission Recipient.
Title	Enables the user to enter the title of Electronic Transmission Recipient.
Address	Enables the user to enter the address of Electronic Transmission Recipient.
City	Enables the user to enter the city of Electronic Transmission Recipient.
State/Province	Enables the user to enter the state/province of Electronic Transmission Recipient.
Country	Enables the user to select the country of the user.
Postal Code	Enables the user to enter the postal code of Electronic Transmission Recipient.
Phone	Enables the user to enter the phone number of Electronic Transmission Recipient.
Fax	Enables the user to enter the fax of Electronic Transmission Recipient.
Email	Enables the user to enter the email of Electronic Transmission Recipient.
Preferred Method	Enables the user to select the preferred method of transmission from the drop-down list. This can be by fax or by email.

Use the following procedure to configure the electronic transmission recipient.

1. Click on the **Electronic Transmission Recipient** folder in the left panel. The associated data appears in the **Total Number of Rows** section in the right panel.

2. Click on the **Name Title** (or row), to view the details associated with that electronic transmission. The details appear in the **Modify Electronic Transmission Recipient** section.

3. You may use the **Electronic Transmission RecipientFilter** to make your search specific to an electronic transmission recipient. The filtering criterion is essential as it helps you to search for specific items

4. Select the appropriate **Field** as the filtering criteria from the drop-down list.

5. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

6. Enter the search criteria in **Value**.

7. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

> **Tip:** **Tip** : You can alternatively click **Add New** to create a new electronic transmission recipient.
>
> ■ Use **Copy** to make an editable copy of an existing electronic transmission recipient.
>
> ■ Use **Delete** to delete an existing electronic transmission recipient.

8. Enter the **Name** of the electronic transmission recipient.

9. Enter the **Title** of the electronic transmission recipient.

10. Enter the **Address** of the electronic transmission recipient.

11. Enter the **City** of the electronic transmission recipient.

12. Enter the **State/Province** of the electronic transmission recipient.

13. Select the **Country** of the electronic transmission recipient, from the drop-down list.

14. Enter the **Postal Code** of the electronic transmission recipient.

15. Enter the **Phone** of the electronic transmission recipient.

16. Enter the **Fax** of the electronic transmission recipient.

17. Enter the **Email** of the electronic transmission recipient.

18. Select the **Preferred Method** of communication (by fax or email) for the electronic transmission recipient.

19. Click **Save** to save the changes made to this section.

Configuring Event Groups

This screen enables you to configure Event Groups information.

■ The list of terms which are used across labeledness determines are defined in a central location for users. These users can update these event groups (list of terms) when the product configuration updates are required or when MedDRA versions are upgraded when MSSO releases the new MedDRA updates.

■ The values entered here and marked as **Display** appear in the **Console > Business Configuration > Products and Licenses > Product Family > Datasheet > Add Event Groups** section.

Terms tab

The following table describes the fields associated with Event Groups > Terms tab.

Field Name	Description
Event Group Name	Allows the user to enter a new Event Group name.
Event Group Name (J)	Allows the user to enter a new Event Group name in Japanese. This screen and its print form will be visible to only the Japanese users.
Display	Allows the user to display the Event Group in Business Configuration > Products and Licenses > Product Family > Datasheet.
Terms	The Terms tab contains terms selected from the MedDRA browser. These terms are displayed in the following format for English users: MedDRA Term in English These terms are displayed in the following format for Japanese users: MedDRA Term in English (MedDRA Term in Japanese) The count of the total number of MedDRA terms present for the case is displayed on the header of the Terms tab.
Term Type	Displays the type of the MedDRA term. This field can contain the MedDRA term type values such as PT, HLT, HLGT or SOC.

Use the following procedure to configure Terms:

1. Click **Event Groups** on the left pane of the Code List.

   You can use the **Event Group Filter** on the right pane, to make your search specific to an event group. The filtering criterion is essential as it helps you to search for specific items.

2. Select the appropriate **Field** as the filtering criteria from the drop-down list.

3. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

4. Enter the search criteria in **Value**.

5. Click **Filter** to apply the selected criteria.

6. This displays the search results under **Total Number of Rows**.

   Tip:

   You can alternatively click **Add New** to create a new event group.

   ■ Use **Copy** to make an editable copy of an existing event group.

   ■ Use **Delete** to delete an existing event group.

7. Enter the name of the event group under **Event Group Name**.

8. If it is also required for a Japanese user, enter the Japanese name of the event group under **Event Group Name (J)**.

9. Check the **Display** checkbox to display the Event Group in **Business Configuration > Products and Licenses > Product Family > Datasheet**.

10. Click **Export** (or **Import**) to export (or import, respectively) a file in a valid file format from (or into) your local system. Valid file formats require that the file be in .xls, .xlsx, or .csv formats.

    Important: The format of the data in the csv, xls or xlsx file must be as follows:

    It must have only a single column of data. An import file can have ~ 16 K Terms.

    The first/header row must have text as "PT" or "HLT" or "HLGT" or "SOC" in upper or lower case.

    All the rows below the header row must contain corrsponding terms (text) such as PT text or HLT text or HLGT text or SOC text.

11. Click **Save** to save the changes made to this tab.

Event Groups tab

Click the **Event Groups** tab to configure event groups.

The following screen is displayed:
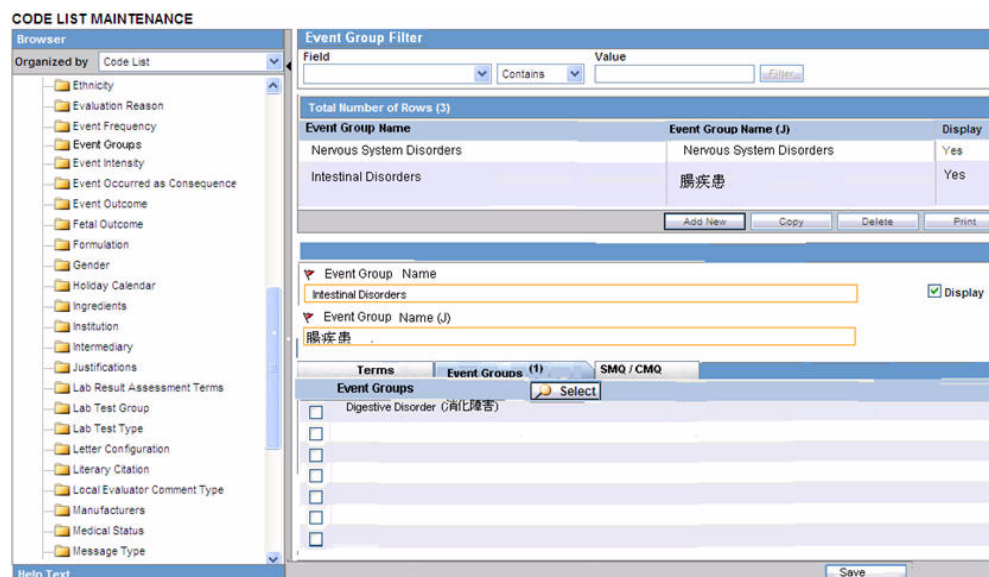
The following table describes the fields associated with Event Groups > Event Groups tab.

Field Name	Description
Event Groups	The Event Group, selected from the **Select** button > **Available Event Groups** dialog, is displayed as follows: Event Group Name in English The event group name is displayed in the following format for Japanese users: Event Group Name in English (Event Group Name in Japanese) The count of the total number of Event Group Names present for the case is displayed on the header of the Event Groups tab.
Select button	Click this button to select the relevant event groups from the **Available Event Groups** dialog. This dialog displays the event groups in a tree-format, with the child event groups being paired under the parent event groups.

SMQ tab

Click the **SMQ** tab to configure SMQ terms.

The following screen is displayed:
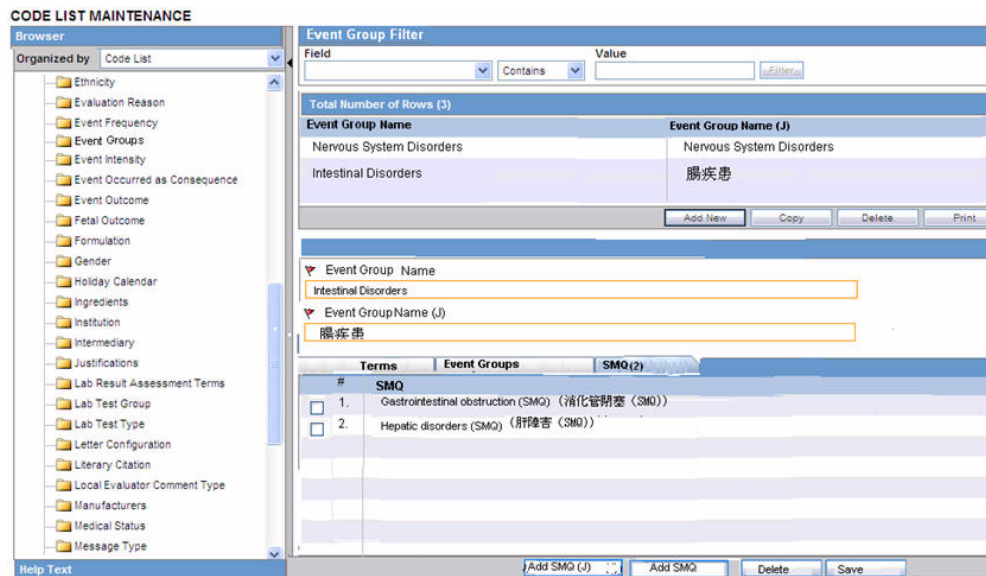
The following table describes the fields associated with Event Groups > SMQ tab.

Field Name	Description
SMQ	The SMQ term is selected from the **Add** button > **MedDRA Browser** dialog.

On clicking the **Add** button, the **MedDRA Browser** is displayed, as shown below:
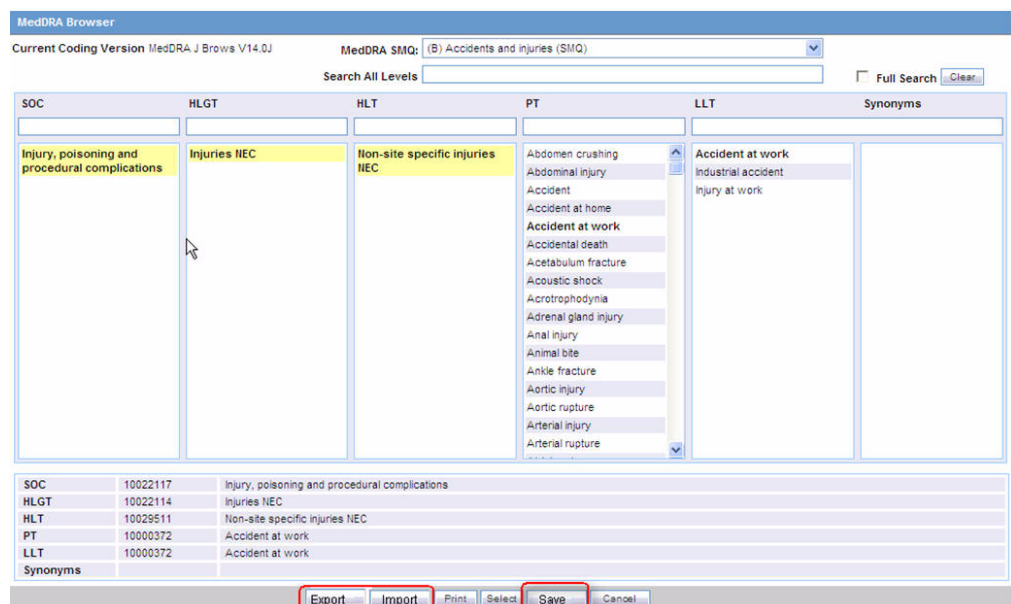
Export:

The Export button is enabled in two scenarios - when MedDRA is opened from:

i) Argus Console > Business Configuration > Products and Licenses > Product Family > Datasheet

or, from:

ii) Argus Console > Code Lists > Argus > Event Group

MedDRA terms are selected at any level of the MedDRA hierarchy.

On clicking this button, a dialog is displayed, that allows you to select the file type - .csv / .xls / .xlsx file.

On specifying the file type, the selected PT terms are then exported in the Export file. in the <PT terms> format.

Import:

This button is enabled in two scenarios - when MedDRA is opened from:

i) Argus Console > Business Configuration > Products and Licenses > Product Family > Datasheet

or, from:

ii) Argus Console > Code Lists > Argus > Event Group

MedDRA terms are selected at any level of the MedDRA hierarchy.

On clicking this button, a dialog is displayed, that allows you to browse and upload a .csv / .xls / .xlsx file from the desired location on your local machine.

The format of the data in the selected file should be as follows:

It should have only one column of data

The first header/row must display 'PT' or 'HLT' or 'HLGT' or 'SOC'.

All the rows under the header row should contain corresponding terms such as PT text, or HLT text, or HLGT text, or SOC text.

The MedDRA terms in the file should be matched against the MedDRA terms table at the level specified in the header row. Duplicate terms within the import file should be ignored.

If the user enters a search criteria at any levels of the MedDRA hierarchy and continues to search for terms, the results obtained from the Import will be lost. The user may need to import terms again, using the **Import** button.

Save:

The Save button is enabled only on selection of the PT term(s).

Configuring Literary Citations

This screen enables you to configure information about Literary Citations.

- The information configured in this form is displayed in the **Literature Info** section of the **Case Form**.

- Select Code Lists **-->** Argus to view the Code List Maintenance screen.
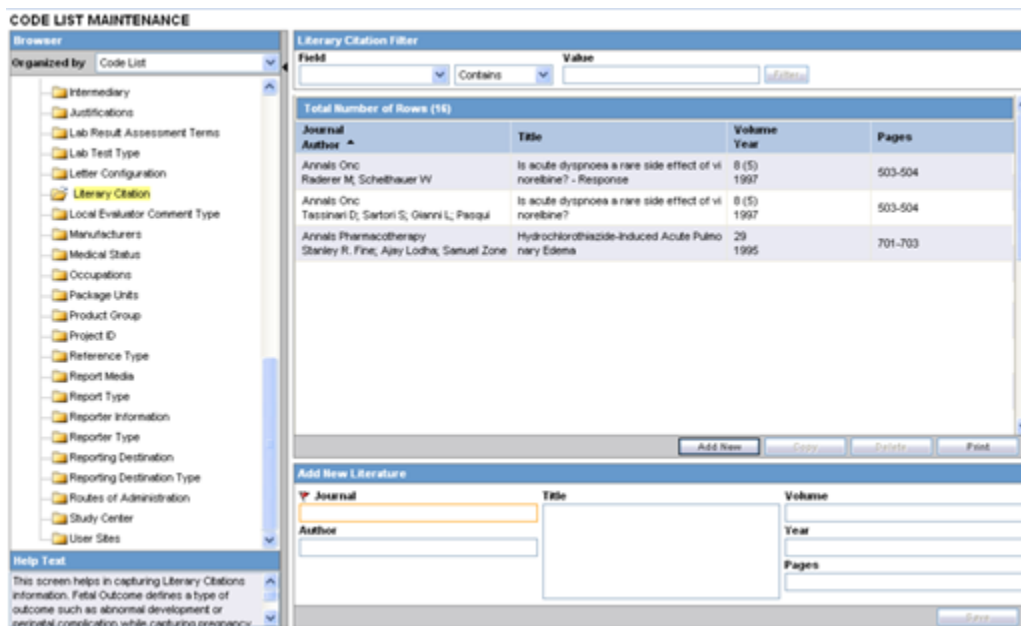
Tip: The code list items are displayed in the left-panel. Click on the required Code List folder to be configured. The details of this code list item appear in the right panel.

Field Descriptions

The following table lists and describes the fields associated with this section.

Field/Control Name	Description
Journal	Displays the name of the journal where the citation appears. This is a required field.
Author	Displays the name of the author.
Title	Displays the title of the citation.
Volume	Displays the volume number of the journal where the citation appears.
Year	Displays the publication year of the journal where the citation appears.
Pages	Displays the number of pages in the journal where the citation appears.

Use the following procedure to configure literary citations.

1. Click on the **Literary Citations** folder in the left panel. The associated data appears in the **Total Number of Rows** section in the right panel.

2. Click **Journal/Author** (or row) to view the details associated with the literary citation. The details appear in the **Modify Literature** section.

3. You may use the **Literary Citation Filter** to make your search specific to a citation. The filtering criterion is essential as it helps you to search for specific items.

4. Select the appropriate **Field** as the filtering criteria from the drop-down list.

5. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

6. Enter the search criteria in **Value.**

7. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

> **Tip:** You can alternatively click **Add New** to create a new citation.

- Click **Copy** to make an editable copy of an existing citation.

- Click **Delete** to delete a selected citation.

- Click **Print** to print the selected information as a PDF.

8. Enter the name of the journal in the **Journal** field.

9. Enter the name of the author of the citation in the **Author** field.

10. Enter the title of the citation in the **Title** field.

11. Enter the Volume Number in the **Volume** field.

12. Enter the year in the **Year** field.

13. Enter the number of pages in the **Pages** field.

14. Click **Save** to save the changes made.

Configuring Message Type

This screen enables you to configure information about message type.

- The message type specified in this section enables you to specify auto-submission of reports.

- Select Code Lists **-->** Argus to view the Code List Maintenance screen.

> **Tip:** The code list items are displayed in the left-panel. Click on the required Code List folder to be configured. The details of this code list item appear in the right panel.

Field Descriptions

The following table lists and describes the fields associated with this section.

Field/Control Name	Description
Message Type	Displays the message type for a report.
English ICSR	Displays if the message type belongs to English ICSR.
Expedited/Periodic	Displays if the message type is expedited or periodic. **Note:** By default, ICHICSR is considered as Expedited, while the other message types are considered as Periodic.
Description	Displays a description about the message type.
Auto Submit	Displays if the report has been auto submitted.
Japan ICSR	Displays if the report belongs to Japan ICSR.
Display	Displays if the report needs to be displayed or hidden.

Use the following procedure to configure message type.

1. Click on the **Message Type** folder in the left panel. The associated data appears in the **Total Number of Rows** section in the right panel.

2. Click **Message Type** (or row) to view the details associated with the message type. The details appear in the **Modify Message Type** section.

3. You may use the **Message Type Filter** to make your search specific to a message type. The filtering criterion is essential as it helps you to search for specific items.

4. Select the appropriate **Field** as the filtering criteria from the drop-down list.

5. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

6. Enter the search criteria in **Value.**

7. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

    Tip: You can alternatively click **Add New** to create a new message type.

    - Click **Copy** to make an editable copy of an existing message type.

    - Click **Delete** to delete a selected message type.

    - Click **Print** to print the selected information as a PDF.

8. Enter the type of message in the **Message Type** field.

9. Enter the description for the message type in the **Description** field.

10. Select the **English ICSR** or **Japan ICSR** radio button, as applicable.

11. Click the **Expedited** checkbox if the message type is for an expedited report.

12. Click the **Mark as Auto Submit** checkbox if you wish to mark for auto submission.

13. Click the **Display** checkbox if you wish to display the message type.

14. Click **Save** to save the changes made.

Configuring Reporting Destination

Regulatory reports are submitted to the Reporting Destination. Local company contact information is also provided on this screen.

The system enables the user to configure the XML Source Classification and the PDF Source Classifications used for classifications defined while the Source E2B File / PDF for Initial Intake or E2B Differences report is classified.

Be aware of the following

■ During upgrade the system automatically populates the Selection source classification as ”E2B Differences Report" from existing classifications and the XML Source Classifications are empty

■ The system tracks updates made in the Audit Log

■ The system prints the additional fields on the Printout as shown in the following illustration.

When a case is accepted as an initial or follow-up case, the system attaches the source XML and the Initial Selection PDF to the case on the Additional Info tab with the as follows.

Initial/Follow-up Source XML

Attachment Classification: As specified in the Reporting Destination for XML Source Classification.

Date: System Date when the user accepted the case for XML.

Description: Acceptance Notes the user entered for XML.

When you click the Source ICSR, the system you can view the ICSR opening the ICSR Viewer (E2B Viewer) as configured for the ICSR Viewer. The following is an illustration of the icon that identifies the XML Attachment.

Initial Selection PDF

Attachment Classification: As specified in the Reporting Destination for Selection Source Classification

Date: The system date the user accepted the Case for XML

Description: Acceptance Notes the user entered r for XML
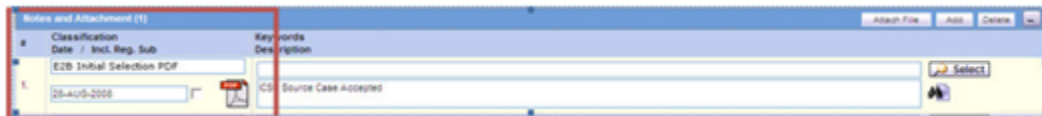
Follow-up Source XML

On clicking the Source ICSR PDF or the E2B Difference Report, the system enables the user to view the Initial Selection PDF or the E2B Difference Report in a different IE dialog.
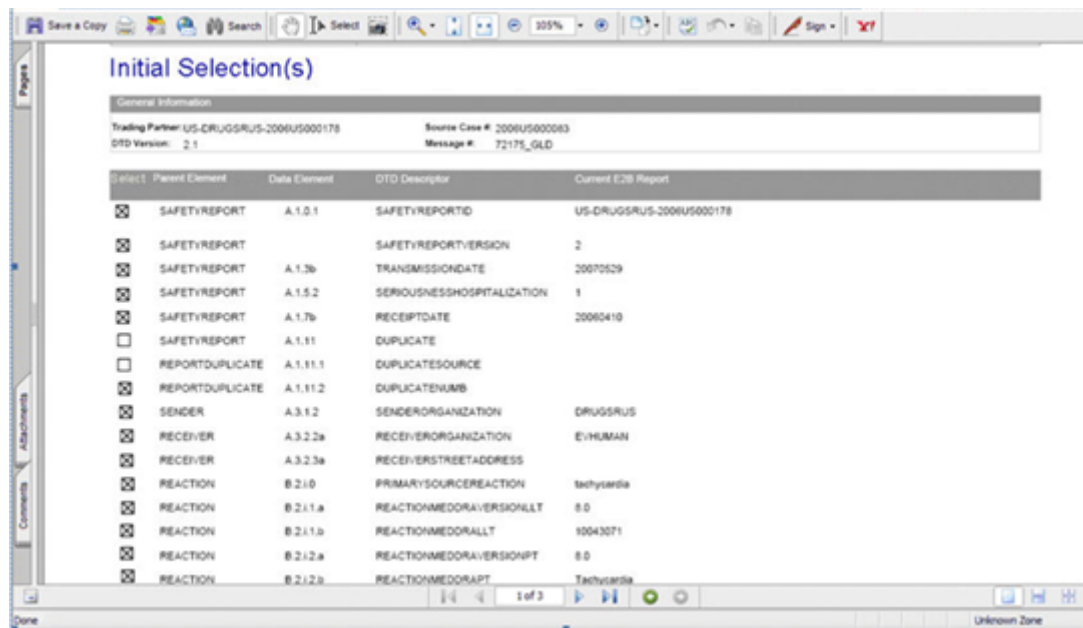
Be aware of the following:

■ Once the Case is accepted as an Initial or a Follow-up ICSR, the system prefixes the Business Level Acknowledgement Notes with the Case Number in the following format:

– Notes Imported Case #: XXXXX followed by the current Notes which are sent in the Business Level Acknowledgement

■ If the ICSR is received via the Physical Gateway (Configured at the reporting destination level) the system sends out a low level ACK in the following format to indicate that the file was received by the Interchange Services at Argus.

■ For the Auto Accepted ICSR's, the system does not attach the Source PDF within the case since the Source XML is attached as is with the case.

Name	Description
M.1 ICHICSRMESSAGE HEADER	Type: Entity
	Source Format: None
	E2B Element Format: None
	Notes: This is an entity name that appears as first line of each E2B acknowledgment.
M.1.1 MESSAGETYPE	Type: Data element
	Source Format: None
	E2B Element Format: Alphanumeric (16)
	Notes: The message type contains the value **ARGUSINTERACK**
M.1.2 MESSAGEFORMAT VERSION	Type: Data element
	Source Format: Character(5)
	E2B Element Format: Alphanumeric (3)
	Notes: The message format version is the DTD version of the acknowledgment and contains the value 1.1"

Name	Description
M.1.3 MESSAGEFORMAT RELEASE	Type: Data element
	Source Format: Character(5)
	E2B Element Format: Alphanumeric (3)
	Notes: The message format release is the release version of the acknowledgment DTD and contains the value 1.0"
M.1.4 MESSAGENUMBER	Type: Data element
	Source: Sequence from the table where the acknowledgment information stored that way this value will be always unique Source Format: Number
	E2B Element Format: Alphanumeric (100)
	Notes: The message number is a unique identifier for the acknowledgment message assigned by the sender of the acknowledgment. Each acknowledgment has a unique message number automatically created by ESM.
M.1.5 MESSAGESENDERIDENTIFIER	Type: Data element
	Source: Element M.1.6 of the ICH ICSR message header, i.e. receiver of the ICSR reports.
	Source Format: Alphanumeric (60)
	E2B Element Format: Alphanumeric (60)
	Notes: This field identifies the sender of the E2B acknowledgment. In other words, this field contains the receiver of the E2B message (ICSR report) i.e. value from M.1.6 of the E2B Message.
M.1.6 MESSAGERECEIVERIDENTIFIER	Type: Data element
	Source: Element M.1.5 of the ICH ICSR message header, i.e. sender of the ICSR reports.
	Source Format: Alphanumeric (60)
	E2B Element Format: Alphanumeric (60)
	Notes: This field identifies the receiver of the E2B acknowledgment. In other words, this field contains the sender of the E2B message (ICSR report) i.e. value from M.1.5 of the E2B Message.
M.1.7a MESSAGEDATEFORMAT	Type: Data element
	Source: Hard code to 204"
	Source Format: None
	E2B Element Format: Number (3)
	Notes: The value is hardcoded to 204" and 204 means format CCYYMMDDHHMMSS. Where C = Century, Y = Year, M= Month, D= Day, H= Hour and S= Second.
M.1.7b MESSAGEDATE	Type: Data element
	Source: sysdate (Database date)
	Source Format: Date
	E2B Element Format: Number (14)
	Notes: This data element contains the system date (database date in GMT) on the day the acknowledgment was initiated.

Name	Description
A.1 MESSAGEACKNOWLEDGMENT	Type: Entity
	Source Format: None
	E2B Element Format: None
	Notes: This is an entity name that appears as first line of each E2B acknowledgment.
A.1.1 ICSRMESSAGENUMB	Type: Data element
	Source: Element M.1.4 of the ICH ICSR message header, i.e. message tracking number of the ICSR message.
	Source Format: Alpha Numeric (100)
	E2B Element Format: Alpha Numeric (100)
	Notes: This field identifies the unique tracking number assign to a specific ICH ICSR message file. The sender of the E2B message assigns this number.
	Transmit: When system generates the acknowledgment for the received E2B message. The system assigns the value to this element from M.1.4 of the received E2B message.
	Receive: This element is used to find the E2B message in the system.
A.1.2 LOCALMESSAGENUMB	Type: Data element
	Source Format: None
	E2B Element Format: Alpha Numeric (100)
	Notes: This field identifies the unique number assign to a specific ICH ICSR message file by the receiving organization of the ICH ICSR message. Example if Pharma company transmitting an E2B message to regulatory authority. The regulatory authority assigns a unique message number to E2B message. This number is used for this element in building the acknowledgment.
A.1.3 ICSRMESSAGESENDERIDENTIFIER	Type: Data element
	Source: Element M.1.5 of the ICH ICSR message header, i.e. sender of the ICH ICSR message.
	Source Format: Alpha Numeric (60)
	E2B Element Format: Alpha Numeric (60)
	Notes: This field identifies the sender of the ICH ICSR message file.
A.1.4 ICSRMESSAGERECEIVERIDENTIFIER	Type: Data element
	Source: Element M.1.6 of the ICHICSR message header, i.e. receiver of the ICH ICSR message.
	Source Format: None
	E2B Element Format: Alpha Numeric (60)
	Notes: This field identifies the receiver of the ICH ICSR message file.
A.1.5a ICSRMESSAGEDATEFORMAT	Type: Data element
	Source: Hard code to 204"
	Source Format: None
	E2B Element Format: Number (3)
	Notes: The value is hardcode to 204" and 204 means format CCYYMMDDHHMMSS. Where C = Century, Y = Year, M= Month, D= Day, H= Hour and S= Second.

Name	Description
A.1.5b ICSRMESSAGEDATE	Type: Data element
	Source: sysdate (Database date) Element M.1.7b message date of the E2B message was initiated
	Source Format: Date
	E2B Element Format: Number (14)
	Notes: This data element contain the system date (database date) on the day the E2B message was initiated. The value can be assign from M.1.7b message date of the E2B message was initiated.
A.1.6 TRANSMISSIONACKNOWLEDGMENTCODE	Type: Data element
	Source Format: Number
	E2B Element Format: Number (2)
	Notes: This data element is used to inform the sender about the status of each report. The value of this element can be 01,02,03. If all reports successfully loaded without any error then value of this element is 01. If some reports are loaded and some has the errors then the value of this element is 02. If none report is loaded due to the SGML parsing error, then the value of this element is 03.
A.1.7 PARSINGERRORMESSAGE	Type: Data element
	Source Format: None
	E2B Element Format: Alphanumeric (250)
	Notes: If the above element A.1.6 (transmission acknowledgment code) has value 03 then only this element contains the value. The value of this element is the description of SGML parsing
	■ This file is placed in the Physical Out folders as configured for the reporting destination within the E2B Mapping configuration.
	■ For EDI received files, the system continues to let the EDI Gateway send the Low level ACK as current functionality.
	■ The Low Level ACK received in the Physical In folder for the destination does not process by the Interchange Service but enters any errors in the Log file as the file will always be rejected by the ESM Service.

Use the following procedure to configure reporting destination.

1. Select Code Lists **-->** Argus to view the Code List Maintenance screen.

>   **Tip:**   The code list items are displayed in the left-panel. Click on the required Code List folder to be configured. The details of this code list item appear in the right panel.

2. Select **Reporting Destination**. The screen appears as shown.

Agency Information

The **Agency Information** tab is displayed by default, on selecting **Reporting Destination**.

Field Descriptions

The fields under the **Agency Information** tab are described in the following table:

Field/Control Name	Description
Agency Name	Displays the name of the agency. This is a required field.
Agency Type	Enables the user to select the agency type.
Department	Enables the user to enter the name of the department.
Email Address	Enables the user to enter the email address of the agency.
Preferred Method	Enables the user to select the preferred method of agency information.
Registration #	Enables the user to enter the registration number.
FAX	Enables the user to enter the FAX Number.
FAX Cover	Enables the user to enter the FAX Cover.
Contact Type	■ Manufacturer - Enables the user to select manufacturer as the type of contact ■ Importer - Enables the user to select importer as the type of contact ■ Distributor - Enables the user to select distributor as the type of contact
Offline Recipient	Enables the user to configure the regulatory agency as an offline agency.
Title	Enables the user to enter the title of the regulatory contact.
First Name	Enables the user to enter the first name of the regulatory contact.

Field/Control Name	Description
Middle	Enables the user to enter the middle name of the regulatory contact.
Last	Enables the user to enter the last name of the regulatory contact.
Address	Enables the user to enter the address of the regulatory contact.
Phone	Enables the user to enter the phone number of the regulatory contact.
Ext	Enables the user to enter the extension number of the regulatory contact.
Country Code	Enables the user to enter the country code of the regulatory contact.
FAX	Enables the user to enter the fax number of the regulatory contact.
Ext	Enables the user to enter the extension number of the regulatory contact.
Country Code	Enables the user to enter the country code of the regulatory contact.
City	Enables the user to enter the city of the regulatory contact.
State/Province	Enables the user to enter the state/province of the regulatory contact.
Country	Enables the user to enter the country of the regulatory contact.
Postal Code	Enables the user to enter the postal code of the regulatory contact.
Report per Email	Enables the user to enter the number of reports to be received in each email.
Attachments	Enables the user to select the format of attachments.
Email Text Body	■ Select - Enables the user to select a .txt or .rtf file to be uploaded. **Note:** The file should be in .txt, or .rtf format. After the uploaded file is saved, the **Edit** button displays a clip button, denoting an attachment. ■ Edit - Enables the user to open the uploaded file / text in a word document from the server and edit the text inside it. If no file was uploaded earlier, a blank document is opened. **Note:** You can save the edited document on the local machine and click **Select** to save the file.
Report for Marketed	Enables the user to select whether reports are to be marketed always or only for the Spontaneous cases or no Investigational.
Allow WHO Drug reporting	Enables the user to schedule a report for WHO Drug Reporting.
Report for Investigational	Enables the user to select if the reports are to be investigational always or only for clinical case or no marketed license.

Use the following procedure to configure agency information.

1. Select the **Agency Name** (or row) of the reporting destination displayed under **Total Number of Rows** that needs to be modified. The **Modify** section displays the information about the selected code list.

2. You may use the **Reporting Destination Filter** to make your search specific to an agency. The filtering criterion is essential as it helps you to search for specific items.

3. Select the appropriate **Field** as the filtering criteria from the drop-down list.

4. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

5. Enter the search criteria in **Value**

6. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

> **Tip:** Tip: You can alternatively click **Add New** to create a new agency information.
>
> - Click **Copy** to make an editable copy of an existing agency information.
>
> - Click **Delete** to delete the selected agency information.
>
> - Click **Print** to print the selected information as a PDF.

7. Enter the name of the agency in the **Agency Name** field.

8. Select the type of agency in the **Agency Type** field.

9. Enter the department in the **Department** field.

10. Enter the email address in the **Email** field. Multiple e-mail addresses must be separated by a comma (,), and not by a semi-colon (;). If you separate the email addresses by a semi-colon, the transmission service will fail.

11. Select the preferred method from the **Preferred Method** drop-down list. The options available are **Fax** or **Email**.

12. Enter the registration number in the **Registration #** field.

13. Enter the Fax Number in the **FAX** field.

14. Enter the Fax Cover in the **FAX Cover** field.

15. Select the preferred contact type by clicking the checkboxes available under **Contact Type**.

    The options available are **Manufacturer, Importer** and **Distributor**.

16. Select the **Offline Recipient** checkbox to configure the regulatory agency as an offline agency.

17. Select the **Title** of the regulatory contact. The options available are **Mr., Miss** and **Mrs**.

18. Enter the first name of the regulatory contact under the **First Name** field.

19. Enter the middle name of the regulatory contact under the **Middle** field.

20. Enter the last name of the regulatory contact under the **Last** field.

21. Enter the postal contact address of the regulatory contact under the **Address** field.

22. Enter the phone number of the regulatory contact under the **Phone** field.

23. Enter the extension number of the regulatory contact under the **Ext** field.

24. Enter the country code to be dialed in calling up the regulatory contact under the **Country Code** field.

25. Enter the fax number of the regulatory contact under the **FAX** field.

26. Enter the fax extension number of the regulatory contact under the **Ext** field.

27. Enter the country code required in faxing up the regulatory contact under the **Country Code** field.

28. Enter the name of the city where the regulatory contact lives in the **City** field.

29. Enter the name of the state/province where the regulatory contact lives in the **State/Province** field.

30. Enter the name of the country where the regulatory contact lives in the **Country** field.

31. Enter the postal code of the place where the regulatory contact lives in the **Postal Code** field.

32. Enter the number of reports that need to be sent in every email to the regulatory contact in the **Report per Email** field.

33. Select the format of the attachments being sent with the emails through the **Attachments** drop-down list.

    The formats available to be sent as attachments are PDF or RTF formats.

34. Click **Text** or **RTF** to save and view a letter attachment in text or RTF format.

    This enables the user to select the email body in Text or RTF format.

35. Select how the report is to be marketed from the **Report to be marketed** drop-down list.

36. The options in this list are **Always** or **Spontaneous** or **No Investigational**.

37. Select the **Allow WHO Drug Reporting** checkbox to schedule the report for WHO Drug Reporting.

38. Select the type of reports as Investigational always or Only for clinical case or No marketed license from the Report for Investigational drop-down list.

39. Click **Save** to save the changes made.

Local Company Contact

This section lists the Field Descriptions and configuration steps for the **Local Company Contact** tab.

Field Descriptions

The fields the following table lists and describes the fields on the **Local Company Contact** tab.

Field/Control Name	Description
Company Name	Displays the name of the company. This is a required field
Sender Type	Enables the user to select the sender type
Department	Enables the user to enter the name of the department
Email Address	Enables the user to enter the email address of the agency
Lab Code	Enables the user to enter the lab code
Event Term on Expedited Reports	Enables the user to select the event term on expedited reports.
Title	Enables the user to enter the title of the local company contact
First Name	Enables the user to enter the first name of the contact
Middle	Enables the user to enter the middle name of the contact
Last	Enables the user to enter the last name of the contact
Address	Enables the user to enter the address of the contact

Field/Control Name	Description
Phone	Enables the user to enter the phone number of the contact
Ext	Enables the user to enter the extension number of the contact
Country Code	Enables the user to enter the country code of the contact
FAX	Enables the user to enter the fax number of the contact
Ext	Enables the user to enter the fax extension number of the contact
Country Code	Enables the user to enter the fax country code of the contact
City	Enables the user to enter the city of the contact
State/Province	Enables the user to enter the state/province of the contact
Country	Enables the user to enter the country of the contact
Postal Code	Enables the user to enter the postal code of the contact

Use the following procedure to configure the local company contact.

1. Select the **Agency Name** (or row) of the reporting destination displayed under **Total Number of Rows** that needs to be modified. The **Modify** section is populated with information about the selected code list.

2. You can use the **Reporting Destination Filter** to make your search specific to a company. The filtering criterion is essential as it helps you to search for specific items.

3. Select the appropriate **Field** as the filtering criteria from the drop-down list.

4. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

5. Enter the search criteria in **Value**

6. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

> **Tip:** You can alternatively click **Add New** to create a new company contact.

- Click **Copy** to make an editable copy of an existing company contact.

- Click **Delete** to delete a selected company contact.

- Click **Print** to print the selected information as a PDF.

7. Enter the name of the company in the **Company Name** field.

8. Select the type of sender in the **Sender Type** drop-down list.

9. Enter the name of the department under the **Department** field.

10. Enter the email address of the agency under the **Email Address** field.

11. Enter the lab code of the agency under the **Lab Code** field.

12. Select the type of event term on preferred reports from the **Event Term on Preferred Reports** drop-down list. The options available under this list are **Preferred** and **Lower Level**.

13. Select the **Title** of the regulatory contact. The options available are **Mr.**, **Miss** and **Mrs**.

14. Enter the first name of the regulatory contact under the **First Name** field.

15. Enter the middle name of the regulatory contact under the **Middle** field.

16. Enter the last name of the regulatory contact under the **Last** field.

17. Enter the postal contact address of the regulatory contact under the **Address** field.

18. Enter the phone number of the regulatory contact under the **Phone** field.

19. Enter the extension number of the regulatory contact under the **Ext** field.

20. Enter the country code to be dialed in calling up the regulatory contact under the **Country Code** field.

21. Enter the fax number of the regulatory contact under the **FAX** field.

22. Enter the fax extension number of the regulatory contact under the **Ext** field.

23. Enter the country code required in faxing up the regulatory contact under the **Country Code** field.

24. Enter the name of the city where the regulatory contact lives in the **City** field.

25. Enter the name of the state/province where the regulatory contact lives in the **State/Province** field.

26. Enter the name of the country where the regulatory contact lives in the **Country** field.

27. Enter the postal code of the place where the regulatory contact lives in the **Postal Code** field.

28. Click **Save** to save the changes made.

Configuring EDI

This section lists the field descriptions and configuration steps for the **EDI** tab.

Field Descriptions
The following table lists and describes the fields on the **EDI** tab.

Field/Control Name	Description
SGML/XML	Enables the user to select whether to send the report in SGML of XML format.
Mark as Auto Submit	Enables the user to mark the report for auto submission.
Imported Cases are assigned to	Enables the user to select the country, where the imported cases need to be assigned. **Note:** This list comprises the configured Argus sites. The default value is the site of the importing user.
Initial Workflow State	Enables the user to configure the initial workflow state of the case. **Note:** This list comprises Argus workflow states, with the default value being blank. If you select blank as the workflow state, it is treated as a new case being booked-in.
Agency Identifier	Enables the user to enter the routing ID configured in Cyclone for the sender community.
Identification Code	Enables the user to enter the agency Duns code, a unique identification code that identifies the trading partner.
Code Qualifier	Enables the user to enter the code qualifier here. The code qualifier is used to interpret the identification code.
Message Profile	Enables the user to select a message profile.
ACK Profile	Enables the user to select the acknowledgement profile.
Identification Code	Enables the user to enter the company Duns code, a unique identification code that identifies the trading partner.
Company Identifier	Enables the user to enter the company identifier
Code Qualifier	Enables the user to enter the code qualifier here. The code qualifier is used to interpret the identification code.
File Name	Enables the user to enter the file name
SGML Declaration File	Enables the user to enter the SGML Declaration File.
Maximum # of reports to include in the msg	Enables the user to enter the maximum number of reports that will be transmitted in one message.
Method	Enables the user to select a method here. This field contains **E2B ESTRI Gateway** and **E2b Media** values.
EDI Header	Enables the user to generate the EDI Header
XML Version	Enables the user to enter the XML Version.
URL of Message DTD	Enables the user to enter the path where the message DTD resides on the internet or enter full path if it is located on the disk.
Encoding	Enables the user to select the character set encoding used in XML
URL of ACK DTD	Enables the user to enter the path where the ACK DTD resides on the internet or enter the full path if it is located on the disk.
Auto Accept ICSR's	Click this checkbox to auto accept ICSR's. This checkbox is visible only when case numbering is set to **Automatic**.
Transmit E2B Attachments	Click this checkbox to transmit E2B attachments.

Use the following procedure to configure EDI.

1. Select the **Agency Name** (or row) of the reporting destination displayed under **Total Number of Rows** that needs to be modified. The **Modify** section is populated with information about the selected code list.

2. You may use the **Reporting Destination Filter** to make your search specific to an EDI. The filtering criterion is essential as it helps you to search for specific items.

3. Select the appropriate **Field** as the filtering criteria from the drop-down list.

4. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

5. Enter the search criteria in **Value**

6. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

    > **Tip:**   You can alternatively click **Add New** to create a new EDI.

    -   Click **Copy** to make an editable copy of an existing EDI.

    -   Click **Delete** to delete a selected EDI.

    -   Click **Print** to print the selected information as a PDF.

7. Select the format in which the report is to be sent by selecting the **SGML** and **XML** radio buttons.

8. Click the **Mark as Auto Submit** checkbox if you wish to mark the report for auto-submission.

9. Select the country where the imported cases need to be assigned.

10. Select the initial workflow state of the case.

11. Enter the routing ID configured in Cyclone for the sender community under the **Agency Identifier** field.

12. Enter the Agency Duns code under the **Identification Code** field.

13. Enter the Code Qualifier under the **Code Qualifier** field.

14. Select the message profile from the **Message Profile** drop-down list.

15. Select the acknowledgement profile from the **ACK Profile** drop-down list.

16. Enter the Agency Duns Code in the **Identification Code** field.

17. Enter the Company Identifier in the **Company Identifier** field.

18. Enter the Code Qualifier in the **Code Qualifier** field.

19. Enter the name of the file in the **File Name** field.

20. Select the SGML file in the **SGML Declaration File** drop-down list.

21. Enter the maximum number of reports that need to be included in the message under the **Maximum # of reports to include in the msg** field.

22. Select the method from the **Method** drop-down list. This list contains options like **E2B - Gateway**, **Physical Media** and **XML Transmission**.

23. Click the **EDI Header** checkbox to generate an EDI Header.

24. Enter the version of XML in which it is coded in the **XML Version** field.

25. Enter the path where the message DTD resides on the internet or enter full path if it is located on the disk under the **URL of Message DTD** field.

26. Select the character set encoding used in XML in the **Encoding** drop-down list.

27. Enter the path where the ACK DTD resides on the internet or enter the full path if it is located on the disk in the **URL of ACK DTD**.

28. Click **Auto Accept ICSR's** to auto accept ICSR's.

29. Click **Transmit E2B Attachments** to transmit E2B attachments.

30. Click **Save** to save the changes made.

SMTP

This section lists the Field Descriptions and configuration steps for the **SMTP** tab.

Field Descriptions

The following tables lists and describes the fields on the **SMTP** tab.

Field/Control Name	Description
From	Enables the user to enter the email address of the sender.
CC	Enables the user to enter the email addresses to send email as CC.
BCC	Enables the user to enter the email addresses to send email as BCC.
Delivery Receipt	Enables the user to check this box to receive a delivery receipt.
Read Receipt	Enables the user to check this box to receive a read receipt.

Use the following procedure to configure SMTP.

1. Select the **Agency Name** (or row) of the reporting destination displayed under **Total Number of Rows** that needs to be modified. The **Modify** section is populated with information about the selected code list.

2. You may use the **Reporting Destination Filter** to make your search specific to an SMTP. The filtering criterion is essential as it helps you to search for specific items.

3. Select the appropriate **Field** as the filtering criteria from the drop-down list.

4. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

5. Enter the search criteria in **Value**

6. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

> **Tip:** You can alternatively click **Add New** to create a new SMTP.
>
> - Click **Copy** to make an editable copy of an existing SMTP.
>
> - Click **Delete** to delete a selected SMTP.
>
> - Click **Print** to print the selected information as a PDF.

7. Enter the email address of the sender under the **From** field.

8. Enter the email addresses to send email as CC under the **To** field. Multiple e-mail addresses must be separated by a comma (,), and not by a semi-colon (;). If you separate the email addresses by a semi-colon, the transmission service will fail.

9. Enter the email addresses to send email as BCC under the **BCC** field. Multiple e-mail addresses must be separated by a comma (,), and not by a semi-colon (;). If you separate the email addresses by a semi-colon, the transmission service will fail.

10. Click the **Delivery Receipt** checkbox to receive a delivery receipt.

11. Click the **Read Receipt** checkbox to receive a read receipt.

12. Click **Save** to save the changes made.

13. Click **Save** to save the changes made.

Configuring Routes of Administration

This screen enables you to configure the Route of Administration information. This describes the route of drug administered to the patient. This data is reflected in Expedited and Periodic regulatory reports.

- The values entered here and marked under **Display** appear in the in the **Route of Administration** list on the **Products** tab.

- Select Code Lists **-->** Argus to view the Code List Maintenance screen.
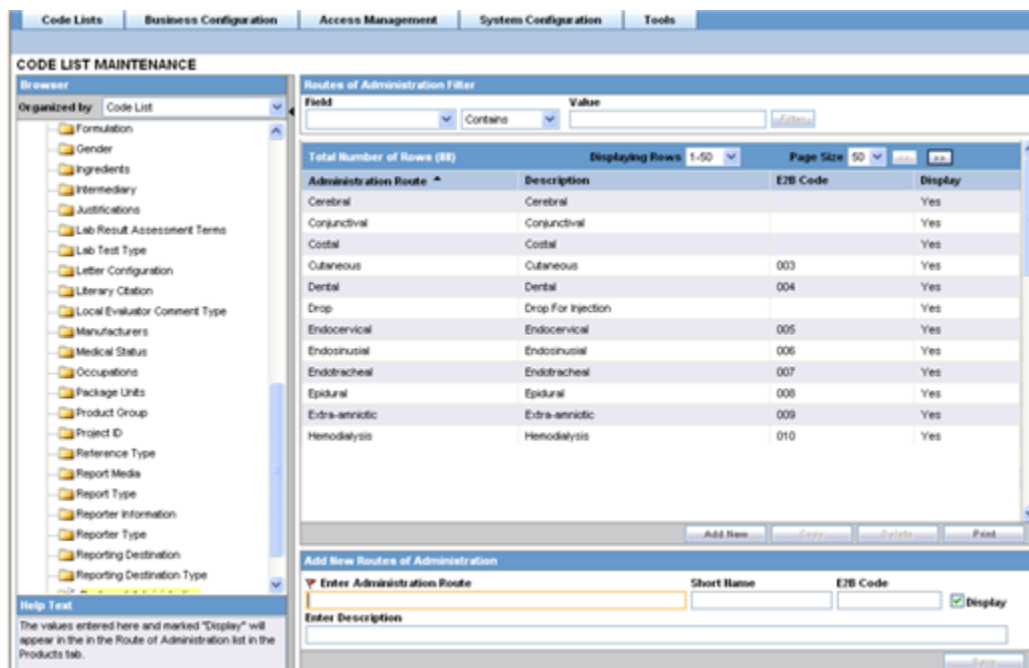
> **Tip:** The code list items are displayed in the left-panel. Click on the required Code List folder to be configured. The details of this code list item appear in the right panel.

Click on the **Routes of Administration** folder in the left panel. The associated data appears in the **Total Number of Rows** section in the right panel.

Field Descriptions

The following table describes the fields associated with this section.

Field/Control Name	Description
Administration Route	Displays the administration route information. This is a required field.
Short Name	Displays the short name of the administrator route.
Description	Displays a description of the administrator route.
E2B Code	Displays the E2B Code of the administrator route.
Display	Enables the user to display the record in the Administrator Route in the Products screen.

Use the following procedure to configure routes of administration.

1. Click the **Administration Route** (or row) to view the details associated with the administration route. The details appear in the **Modify Administration Route** section.

2. You may use the **Routes of Administration Filter** to make your search specific to a route. The filtering criterion is essential as it helps you to search for specific items.

3. Select the appropriate **Field** as the filtering criteria from the drop-down list.

4. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

5. Enter the search criteria in **Value**

6. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

> **Tip:** Tip: You can alternatively click **Add New** to create a new route.

- Click **Copy** to make an editable copy of an existing route.

- Click **Delete** to delete a selected route.

- Click **Print** to print the selected information as a PDF.

7. Enter information about the administrator route in the **Enter Administrator Route** field.

8. Enter a short name about the administrator route in the **Short Name** field.

9. Enter the E2B Code of the administrator route in the **E2B** field.

10. Select the **Display** checkbox to display the record in the Administrator Route in the Products screen.

11. Enter the description about the administrator route in the **Enter Description** field.

12. Click **Save** to save the changes made.

Configuring Study Center

This screen enables you to configure the Study Center information. This screen is used to enter information regarding each Study Center. The Study Centers defined in this dialog appear on a drop-down list in the **Clinical Studies Information** dialog under the **Centers** tab in **List Maintenance**. You can create a Study Center with the same Center ID but with a different name and address. When you select the studies in the Study Look and Center Lookup in the Console, the system concatenates the Center Name (Center ID) in the look-up dialog.

- Investigators for each Center can also be added via this dialog.

- Select Code Lists **-->** Argus to view the Code List Maintenance screen.

- Click on the **Study Center** folder in the left panel. The associated data appears in the **Total Number of Rows** section in the right panel.
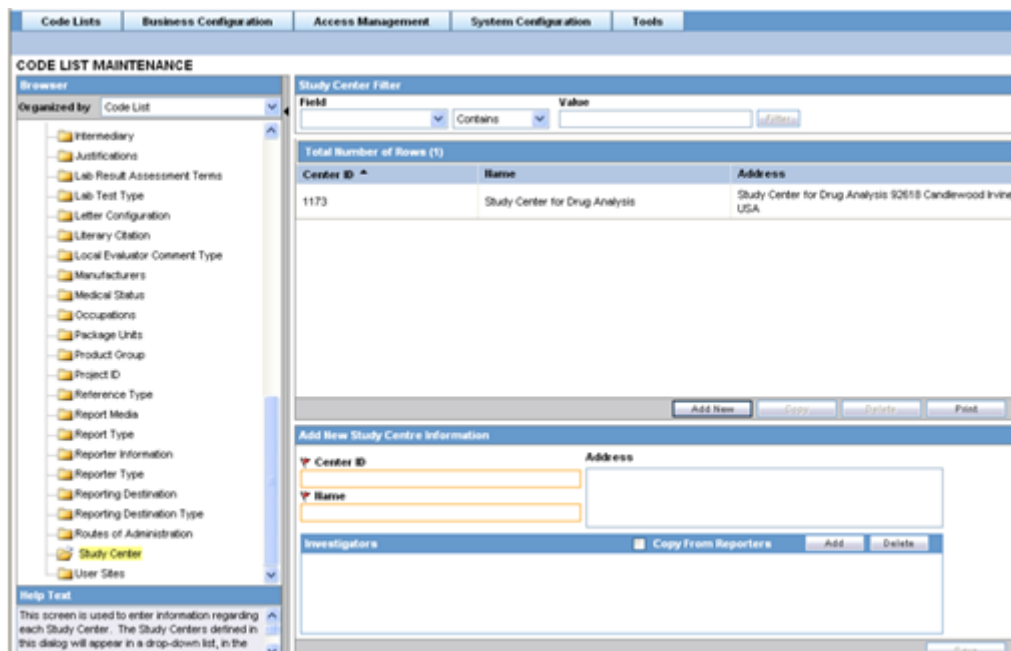
Tip: The code list items are displayed in the left-panel. Click on the required Code List folder to be configured. The details of this code list item appear in the right panel.

Field Descriptions

The following table lists and describes the fields associated with this section.

Field/Control Name	Description
Center ID	Enables the user to enter the Center ID.
Name	Enables the user to enter the name of the center.
Address	Enables the user to enter the address of the center.
Copy from Reporters	Enables the user to copy the information from Reporters.
#	Displays the row count of the number of investigators.
Investigator	Enables the user to enter the name of the investigator.
Phone	Enables the user to enter the phone number of the investigator.
Fax	Enables the user to enter the fax number of the investigator.
Notes	Enables the user to enter comments or remarks.

Use the following procedure to configure study center.

1. Click the **Center ID** (or row) to view the details associated with the administration route. The details appear in the **Modify StudyCenter** section.

2. You may use the **Study Center Filter** to make your search specific to a center. The filtering criterion is essential as it helps you to search for specific items.

3. Select the appropriate **Field** as the filtering criteria from the drop-down list.

4. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

5. Enter the search criteria in **Value**

6. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

> **Tip:** You can alternatively click **Add New** to create a new center.

- Click **Copy** to make an editable copy of an existing center.
- Click **Delete** to delete a selected center.
- Click **Print** to print the selected information as a PDF.

7. Enter the ID of the center in the **Center ID** field.

8. Enter the name of the center in the **Name** field.

9. Enter the address of the center in the **Address** field.

10. Select the **Copy from Reporters** checkbox to copy the information from Reporters.

11. Enter the name of the investigator in the **Investigators** field.

> **Tip:** **Tip:** Click **Add** to add a new investigator. Click **Delete** to delete a selected investigator record.

12. Enter the phone number of the investigator in the **Phone** field.

13. Enter the fax number of the investigator in the **Fax** field.

14. Enter comments, if any, under the **Notes** field.

15. Click **Save**.

Configuring Holiday Calendar

This screen enables you to configure the Holiday Calendar information. The Code List allows the user to define holidays at country level.

The Country of Reporting Destination will be matched with the Country in the Holiday Calendar to identify the holidays to be adjusted for the Reporting Destination.

Go to Code Lists > Argus to view the Code Lists page and click the Holiday Calendar folder in the left panel.

The associated report appears in the Total Number of Rows section in the right panel.

> **Tip:** The code list items are displayed in the left-panel. Click on the required Code List folder to be configured. The details of this code list item appear in the right panel.

Field Descriptions

The following table describes the fields associated with this section.

Field/Control Name	Description
Holiday Name	This field displays the unique name for the holiday name.
Date	This field displays the date on which the holiday has been scheduled.
Description	This field displays a description of the holiday.
Country	This field displays the name of the country (or countries) with which the holiday is associated.

Use the following procedure to configure study center.

1. Click the **Holiday Name** (or row) to view the details associated with that Holiday Calendar. The details appear in the **Modify Holiday Calendar** section.

2. You may use the **Holiday Calendar Filter** to make your search specific to a Holiday Calendar record. The filtering criterion is essential as it helps you to search for specific items.

3. Select the appropriate **Field** as the filtering criteria from the drop-down list.

4. Once you have selected the **Field,** you can specify whether your search should **contain** or **start with** specific alphabets.

5. Enter the search criteria in **Value**.

6. Click **Filter** to apply the selected criteria. This displays the search results under **Total Number of Rows**.

> **Tip:** You can alternatively click **Add New** to create a new Holiday Calendar record.
>
> - Click **Copy** to make an editable copy of an existing Holiday Calendar record.
>
> - Click **Delete** to delete an existing Holiday Calendar record.

7. Enter the Holiday Name for the Holiday Calendar.

8. Enter the Date for the record.

9. Enter the Country (or countries) with which the holiday must be associated.

10. Enter the Description for the Holiday Calendar record.

11. Click **Save**.

Other Code List Items

The following table lists and describes addition code list items that you should be aware of.

Code List Item	Description
Accidental Exposure	Enables you to capture Accidental Exposure information. Accidental Exposure is in the Dosage regimen section of the Products tab as a drop-down.
Action Taken	Enables you to capture Action Taken information. Action Taken information is required when capture information about steps taken when a an adversee drug eevent occurs. The values you enter in this field are read-only and appear in the Dosage Regimen section on the Action Take drop-down on the Case Form Product tab.
Action Type	Enables you to capture Action Type information that describes the action type required for the case. Values entered in this field are read-only and appear in the Code/Description list of the Activities tab. Select Code List Maintenance-->Cde List-Argus and click Action Type in the browser tree.
Age Group	Enables you to capture Age Group information. An Age Group is the range of lower and upper age limits. Patients are categorized in diferent age groups. This data appears in Expedited and Periodic regulatory rpoerts. The values you enter in this field appear on the Patient Information Screen, Age Group drop-down list.
Age Unit	Enables you to capre Age Unit information. An Age Unit isexpresses time in periods su as year, month, day, hours, and so forth. This dta appears in the Expedited and Periodic regulatory reports and in the Age Unit drop-down list on the Patient Information screen.

Code List Item	Description
Anatomical Location	Enables you to capture information about the location where vaccination aregiven. This data appears in the epedited and periodic regulatory reports. The values you enter in these fields appear on the Anatomical Location drop-down list on the Vaccine screen.
Attachment Classifications	Enables you to capture attachment classification used to describe attachment types. The values you enter in these fields appear in the Attahment Classification section on the Additional Information screen.
Attachment Keywords	Enables you to capture information about the attachment keywords used to define an attachment type. The values appear in the Attachment Keywords section on the Additional Informtion screen.
Birth Type	Enables you to capture birth type information when capturing pregnancy information. This data appears in multiple regulatory reports and appear in the Birth Type drop-down list on the Pregnancy information screen.
Case Classifications	Enables you to capture Case Classification to help categorizee cases. This information does not impact any report or screen but is used during case searches to narrow the results set. These values appear on the
Causality Category	Enables you to capture information about the causality type. This data appears in expedited and periodic regulatory reports amd on the Event Causality drop-down list in the Eve Assessment section on the Event screen.
Clinical Reference Type	Enables you to capture information about the clinical refernce type. The Clinical Reference Type appears as a drop-down list in the Study configuration
Condition Type	Enables you to capture information about the condition of the patient. Categories for condition types are Medical history relevant to AE, historical condition, and current condition. This data appears in expedited and periodic regulatory reports and in the Condition Type drop-down list on the Other Relevant History screen.
Contact Type	Enables you to capture information about the type of contact (e.g., Follow-up, Investigator). The values appear in the Contact Type drop-down list in the Contact Log section of the Activity Tab.

Code List Item	Description
Countries	Enables you to capture information about the country where the adverse event occurred. If you enter A2, A3, or the numeric country code, the system automatically populates the Country field with the name of the country. You can also check a checkbox called 'Group 2 Country' (unchecked by default) to enable administrators to add a Group 2 Country. This is required when the Due Date for expedited reports differ from country to country as per their regulations. For Group 1 countries, the Due Date is based on the Aware date received globally for the case. For Group 2 countries, the Due Date is based on the aware date when the affiliate or a company representative of that country received information about the case. Obtain the country name and country codes from the ISO 3166 country code specification.
	You may receive the following error messages:
	■ "A duplicate country name already exists! " -- The country name you entered already exists in the system.
	■ "A duplicate A2 code already exists!" -- The A2 code you entered already exists in the system.
	■ "A duplicate A3 code already exists!" -- The A3 code you entered already exists in the system.
	■ "A duplicate country number exists!" -- The country number you entered already exists in the system.
	■ "Please enter a valid code (A2)." -- The two-character code is not specified.
	■ "Please enter a valid code (A3)." -- The three-character code is not specified..
Date Ranges	Enables you to capture date range information as follows:
	■ Description -- Enables you to enter a description of the date range.
	■ Duration -- When selected, enables you to specific a specific length of time as opposed to a range of dates. Must be used in conjunction with Amount and Units. When you select "Duration," the system disables the "Range" radio button.
	■ Amount -- The numeric value that specifies the length of the time period when combined with a value selected from the Units drop-down list (e.g., days, weeks, months, years, etc.)
	■ Units -- The unit of the duration (e.g., days, months, years, etc.
	■ Range -- Enables you to select a specific range of dates. Must be used in conjunction with the Start and End fields. When you select "Range," the system disables the "Duration" radio button.
	■ Start -- The beginning date of the date range.
	■ End -- The ending date of the date range.
Delivery Types	Enables you to capture information about the type of delivery that occurred during pregnancy. This data appears in expedited and periodic regulatory reports and on the Delivery Types drop-down list on the Pregnancy Information screen.
Device Preliminary Comments	Enables you to capture comments about medical devices. Device Preliminary Comments appear on the Product screen when the user selects the Device option.
Device Subcomponents	Enables you to capture information about subcomponents that are part of a medical device. This information appears on the Product screen when the user selects the Device option.

Code List Item	Description
Causality Source	Enables you to capture Causality Source information. It appears on the Case Form Event Assesment tab.The E2B report uses this information to determine the drug assessment method.
Device Type	Enables you to capture information about patient device types. This data appears in expedited and periodic regulatory reports.
Dosage Frequency	Enables you to capture information about how often medication is given (e.g., daily, bid, weekly, etc.) This information appears on the frequency drop-down list on the Products screen. ■ Frequency -- how often the dose is given ■ Number of doses per day -- The number of doses administered each day. ■ Number of separate dosage -- Enables the use to define the dosage verbatim. ■ Number of units in the interval -- Enables the user to define the dosage verbatim. ■ Definition of Interval -- The length of time between doses (i.e., year, month, day week (default), hour, minute).
Dosage Unit	Enables you to capture dosage units information. This information is required when captureing the quantity of drug on sale and also appears in expedited and periodic reports. ■ Unit Name -- The name of the dosage unit. ■ E2B Code -- The E2B code associated with the Dosage Unit. ■ Dosage Unit -- When checked, indicates that the current item is the dosage unit. ■ Lab Test Unit -- When checked, indicates that this is a lab test unit. ■ Display -- When checked, indicates that the Unit Name displays in the application.
Ethnicity	Enables you to capture information about the ethnic groups patients belong to. This information appears in periodic regulartory reports and on the Ethnicity drop-down list on the Patient Information screen.
Evaluation Reason	Enables you to capture information about the reason the product is being evaluation. This information appears in the Evaluation Reason list on the case form Product tab.
Event Frequency	Enables you capture information about the frequency of the event. It includes categories such as intermittent, continuous, and single episodel The values enter in this field appear in the Event Frequency drop-down list on the Event Information screen.
Event Intensity	Enables you to capture information about the intensity of the adverse event and includes categories such as mild, moderate, and severe. The values you enter on this screen appear on the Event Intensity drop-down list on the Event Information screen
Event Outcome	Enables you to capture event outcome informatioin such as Fatal, Abortion due to AE/Infection, and Recovered. This data appears in expedited and periodic regulatory reports and on the Event Outcome drop-down list on the Event Informationi screen.
Fetal Outcome	Enables you to capture information about fetal outcome and includes informtion such as abnormal development or perinatal complications. This data appears in expedited and periodic regulatory reports and values entered here appear on the Fetal Outcomes drop-down list on the Pregnancy Information screen.

Code List Item	Description
Formulation	Enables you to capture information about the formulations (cream, drop, capsule, etc) available for a product. The values you enter appear on the Formulation drop-down list on the Product screen.
Gender	Enables you to capture gender information. This information appears in expedited and periodic regulatory reports.
Ingredients	Enables you to capture information about the ingredients in the product. This includes the ingredient and the concentration and units of ingredients used to make the product. This information appears in expedited and periodic regulatory reports.
Intermediary	Enables you to capure information about intermediaries such as sales rep, licensee, regulatory authority or local affiliate. The values you enter appear on the Intermiediary drop-down list on the Reporters screen.
Justifications	Enables you to capture justification information. You can enter reasons for overriding system determinations in the Justifications dialog box. The values you enter appear in the Action Justification dialog.
Lab Assessment Terms	Enables you to capture the lab reuslt assessment terms that define the terms that describe the patient's results on various lab tests (e.g., elevated and depressed, etc.). This data is reflected in expedited and periodic regulatory reports. The values you enter appear on the Lab Result Assessment Terms drop-down list on the Laboratory Data screen.
Lab Test Type	Enables you to capture the lab test type. This defines test type and its normal, high, and low values and can be coded as defined in the MedDRA dictionary. The values you enter appear on the Lab Test drop-down on thePatient screen.
Literary Citations	Enables you to literary citations information.
Local Evaluation Comment Type	Enables you to capture the category of a local comment such as French, German, English, etc. The values you enter appear in the Analysis, Local Comment type.
Manufacturer	Enables you to capture information about the product manufacturer. Manufacturer is required while captureing, adding, or modifying information on manufacturer sites. This data appears in expedited and periodic regulatory reports and on the Manufacturer drop-down list on the Product Configuration screen.
Medical Status	Enables you to capture medical information about patient status. This data appears in both the expedited and periodic regulatory reports. The values you enter here appear on the Medical Status drop-down list,
Message Type	Enables you to enter information about each E2B message type. The system uses the defined message types when it creates an E2B file.
Nature of Event	Enables you to capture information about the type of adverse event that occurred.
Occupations	Enables you to capture information about patient and reporter occupations such as physician, regulatory agent, and journalist. This data appears in both expedited and periodic regulatory reports. The values you enter are marked as ICH Occupation appear in the Reporter's Occupation drop-down list on the General Screen.
Package Units	Enables you to capture information about product packaging. The package units defines the number of units in a package.

Code List Item	Description
Product Group	Enables you to capture information about a specific Product Group. Users can use the Product group field to categorize Product Families based on therapeutic area. The values you enter here appear in the drop-down list associated with the Project Group field of the Product Family.
Project ID	Enables you to capture project ID information used to group similar studies under a single project. The values you enter in this field appear on the Project ID field drop-down on the Study Configuration.
Reference Types	Enables you to capture reference type information and defines a list a reference types such as Parent-Child Link, Patient ID, etc. The values you enter appear in the Type drop-down in the References section on the Additional Info tab.
Report Media	Enables you to capter Report Media information. The values you enter appear on a drop-down field in the Reporter Information section.
Report Types	Enables you to capture information about report types. The report type describes the type of report and the abbreviation associated with the specific type. This data appears in expedited and periodic regulatory reports. The values you enter here appear on the Report Type drop-down list on the General Screen.
Reporter Type	Enables you to capture information about the person reporting the adverse event and includes categories such as lawyer, nurse, doctor, etc. The values you enter here appear on the Treporter Type drop-down list on the Product screen.
Reporting Destination Type	Enables you to capture information about the reporting destination. The values you enter here appear on the Reporting Destination configuration.
Routes of Administration	Enables you to capture information about how a drug is administered to a partient such as shot, by mouth, etc..
Study Center	Enables you to capture information about the study centers. Values entered here appear on a drop-down in the Clinical Studies Information dialog and on the Centers tab in List Maintenances. Yu can also add investigators for each center.
	You can carete a study center with the same center ID but with a different name and address.

Formulation Factory Data

The following table provides information about the Formulation Factory Data.

Formulation ID	Formulation	Formulation Name	Formulation Symbol
38	Aerosol (Spray and Inhalation)	Aerosols	AER
13	Alternative Form		
23	Cachet (including wafer)	Cachet	CTS
2	Capsule	Capsules	CAP
24	Chewable Tablet	Chewing Tablest	CTB

Formulation ID	Formulation	Formulation Name	Formulation Symbol
25	Drop	Drops	DRO
32	Dusting Powder	Dusting Powders	DPO
39	Ear Drops	Ear Drops	EDR
8	Effervescent Tablet		
47	Enema	Enemas	ENM
21	Enteric Table	Enteric-coated dosage forms	ENT
49	External Use		
12	Extra Formulation	External Preparations of Uncertain Dosage Form	EXT
40	Eye Drops	Eye Drops	EED
41	Eye Ointment	Eye Ointments	EOI
20	Grain	Granules	GRA
18	Granule	Fine Granules	FGR
46	Implantation	Inserting Preparations	IMP
43	Inhalation Gas	Gas Inhalant	INS
6	Infusion	Infusing Preparations	INF
9	Inhaler	Inhalants	INH
5	Injection	Injections	INJ
48	Jelly	Jellies	JEL
11	Liquid	External Liquids	LIQ
33	Lotion (except lotion for eye)	Lotions	LOT
28	Lozenge (troche and candy too)	Lozenges	LOZ
45	Mouthwash	Throat Washings	MWH
17	N/A		
42	Nasal Drops/Spray	Nose Drops	NDF
34	Ointment/Cream	Ointments/Creams	OIT
31	Oral Drug Unspecified Form	Oral Preparations of Uncertain Dosage Form	POR
4	Patch		
26	Pill (except tablest)	Pills	PIL
19	Powder (except DPO)	Powders	POW
35	Shampoo	Shampoos	SHP
22	Slow Release Capsules	Slow-release Capsules	SRC
30	Slo Release Granule	Slow-release Granules	SRG
29	Slow Release Tablet	Slow-release Tablets	SRT
27	Solution (except Syrup)	Solutions for Oral Use	SOL
44	Spin Cap	Spin Cap	SPC

Formulation ID	Formulation	Formulation Name	Formulation Symbol
36	Spray (except Inhalation)	Sprays	SPR
3	Suppository	Rectal Suppositories	SUP
7	Syrup	Syrups	SYR
1	Tablet	Tablets	TAB
37	Tape (including Poultice)	Tapes	TAP
16	Unknown	Uncertain	XXX

6

Accessing Tools

Accessing Tools

This section explains the report (features and purpose) generated when **Tools->E2B Length Check** is accessed.
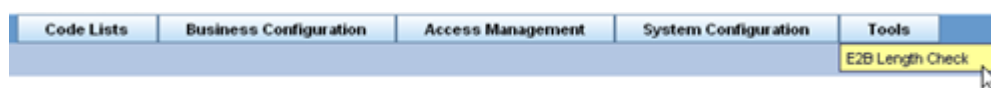
When Argus Code List item length is greater than the E2B field length, the data is truncated when maximum length is entered and an E2b report is generated.

Report Features

Each profile is printed on a new page of the same report. The report prints the Code-List items length check and the error messages warnings. The report prints all terms that are not encoded.

The report contains the following fields as illustrated:

Viewing the E2B Length Check Report

This section enables you to view the E2B Length Check Report.

Use the following procedure to view the E2B length report.

1. Select Tools->E2B Length Check.
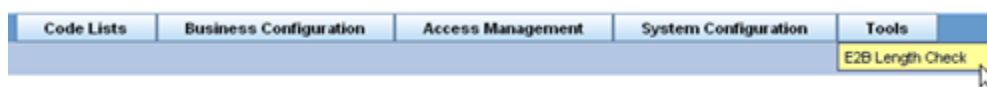
2. The **E2B Length Check** PDF report opens in a separate window.

E2b Report Data Check errors & Warnings
As of 09 October 2006

	List Maintenance
1.	ICH-ICSR V2.1 MESSAGE TEMPLATE
2.	ICH-ICSR V2.1 MESSAGE TEMPLATE - EMEA
3.	ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA

Validation Type	Data Element	DTD Element	Case Form Field	Actual Error Message	Profiles	LM Data
Length Check Validation	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (2000) DTD Length = (100), Data Truncated = (1900)	1, 2, 3	amoxilin study
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (150) DTD Length = (100), Data Truncated = (50)	1, 2, 3	clinical study
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (256) DTD Length = (100), Data Truncated = (156)	1, 2, 3	Gentile X
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (234) DTD Length = (100), Data Truncated = (134)	1, 2, 3	oProduct Study
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (234) DTD Length = (100), Data Truncated = (134)	1, 2, 3	tonsillitis PT
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (2000) DTD Length = (100), Data Truncated = (1900)	1, 2, 3	Study Ammoxilian project
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (2001) DTD Length = (100), Data Truncated = (1901)	1, 2, 3	AM study
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (234) DTD Length = (100), Data Truncated = (134)	1, 2, 3	Copy Ammox
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (2001) DTD Length = (100), Data Truncated = (1901)	1, 2, 3	Smq Study
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (2000) DTD Length = (100), Data Truncated = (1900)	1, 2, 3	Study-Product
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (235) DTD Length = (100), Data Truncated = (135)	1, 2, 3	Study Relsys
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (235) DTD Length = (100), Data Truncated = (135)	1, 2, 3	Copy Of Relsys Study
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (234) DTD Length = (100), Data Truncated = (134)	1, 2, 3	Copy Of Copy Of Relsys Study
	A.2.3.1	STUDYNAME	List Maintenance - Clinical Studies - Description	Actual Data Entered = (235) DTD Length = (100), Data Truncated = (135)	1, 2, 3	Relsys Study

Tip: This report compares the lengths of the code list elements with the maximum E2B length allowed for each of the DTD profiles (ICH, FDA, EMA).

It also displays the elements where the length of the code-list element is greater than the allowed E2B length.

7

Using Advanced Conditions

Using Advanced Conditions

This section discusses how to create and use Advanced Conditions. If you **not** have access to the advanced conditions on certain screens, the system displays only the **Advanced Condition Names** you can access (instead of displaying a blank) and **does not** permit you to modify or view the advanced condition details. The system displays a warning message stating that you **do not** have permissions to update the advanced conditions. The following screens are affected by this change:

- Expedited Reporting Rules

- Auto Signals

- Batch Reports

- Letters

- Studies

- Case Priority

- Field Validation

- Narrative Templates

- Profile Switches | Auto Archiving

This option is available from the Advanced Conditions icon.

Argus Safety provides a powerful search tool that enables complex queries to be built in order to retrieve data from the system. Detailed knowledge of the database schema is not required.

Complex or non-standard queries are constructed by means of the Advanced Conditions dialog, that enable users to define field level search criteria.

Sets of search criteria (advanced conditions) can be saved and retrieved from the Advanced Conditions dialog. These conditions may then be added, edited, or deleted.

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.

Features within Advanced Conditions

By default, the Advanced Conditions drop-down list enables you to view only the **New**, **None** and already selected Advanced Conditions.

1. Select **New** or **None** from the drop-down list and click the AC button to create a new advanced condition.

2. Click the lookup icon to filter for existing advanced conditions.

3. Execute the steps below to filter for existing Advanced Conditions:

4. Click Lookup in the **Case Search Criteria** section. The **Advanced Conditions Lookup** dialog is displayed.
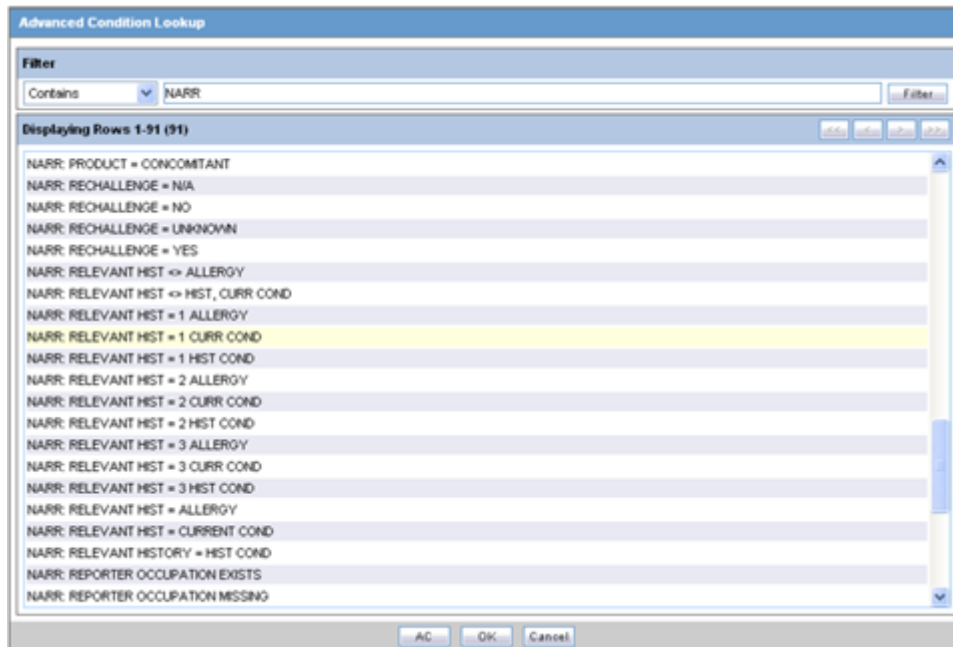
5. Select one of the following options from the drop-down list under **Filter**.

   ■ **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.

6. Enter the search criteria for the advanced conditions in the text box, as applicable.

7. Click **Filter**.

   The advanced conditions matching the specified filtering criteria are displayed.

8. Select an advanced condition from the list, as per your search requirements.

9. Execute any of the actions below, as applicable:

   ■ Click **OK**. The selected advanced condition is listed in the **Advanced Condition** drop-down list.

   ■ Click **AC**. The details of the selected advanced condition are displayed in the **Advanced Conditions** dialog.

- Click **Cancel**. The **Advanced Condition Lookup** dialog is closed without saving any changes.

- Select a previously selected advanced condition from the drop-down list to apply the search criteria for that condition.

Using Advanced Conditions

Use the following procedure when using advanced conditions.

1. Click Select lookup to view/edit/create the Advanced Condition in the Advanced Condition dialog.

2. To use advanced conditions, the following options are available, depending on how the set of criteria is to be used:

- To use a set of previously saved criteria, select the appropriate set of criteria from the **Advanced Condition** list

- To add a new condition to a set of criteria, select the set of criteria from the **Advanced** list and click the adjoining Advanced Condition icon.

- To enable the creation of new advanced conditions by associating logical operators (like AND, OR) with items from the Case Form, refer to **Creating Advanced Conditions**.

- To create an advanced condition query set from existing advanced condition search criteria, refer to Creating a Query Set of Advanced Conditions.

Creating Advanced Conditions

Use the following procedure to create advanced conditions.

1. Select **New** from the **Advanced Conditions** drop-down list or click the **Advanced Conditions** icon

2. This displays a confirmation dialog.

3. Select whether you wish to create a query set by using previous advanced condition query sets or by creating one through logical operators.

- Click **Yes** to create a new advanced condition query set.

- Click **No** to create a new advanced condition by associating logical operators (like AND, OR) with items from the Case Form.

4. If you select **No**, an **Advanced Condition Set** dialog is displayed.
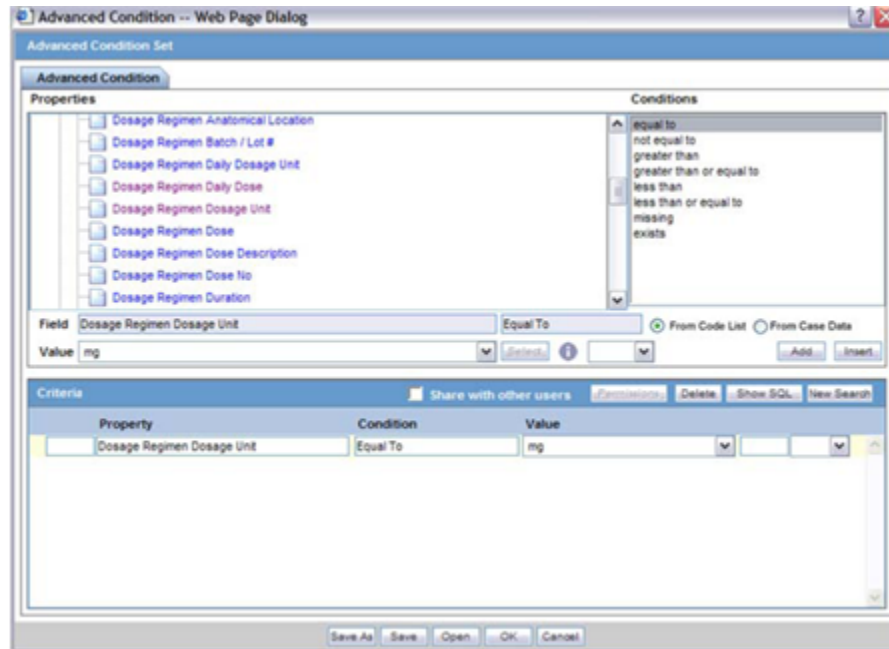
> **Note:** The **Advanced Condition Set** dialog enables you to search for those entities under the **Properties** tree-list, which are from either the case data or from the code list. For this, the dialog provides two radio buttons - **From Code List** and **From Case Data**.
>
> - Select the relevant entity and one of the radio buttons, as applicable.
>
> - This searches the entity based from the code list or case data, as specified.
>
> - The radio buttons are displayed only if the selected entity belongs to a code list.
>
> - If the selected entity is part of the code list, and the user selects:
>
>   - **From Code List** - If this option is selected, the **Value** drop-down list displays the list of all values configured in the Code List.
>
>   - **From Case Data** - If this option is selected, the **Value** drop-down list displays the list of only those values, which are actually present in the cases.

5. Select a property type from the **Properties** tree list.

   The items available under the folders in the Properties list represent those fields on the Case Form that can be used to perform the search in the advanced conditions.

> **Note:** When a Property for which terms can be encoded is selected, the **Select** button is enabled. You can use the MedDRA Browser to select (possibly) multiple terms for the property.
>
> An SMQ icon is enabled when the SMQ-related properties are selected from the Properties tree-list. Click this icon to view the SMQ Info dialog. The SMQ Info dialog contains details about the selected SMQ.

6. In the **Conditions** list, select a condition that must apply to the item selected above.

   The available conditions are "equal to", "contains", "less than", "greater than", "not equal to", "missing", "greater than or equal to", "less than or equal to", "exists", "does not contain" or "begins with".

7. Under **Value**, enter the value which will apply to the property, or select an appropriate value from the list, as applicable.

8. If the condition created in steps 4 through 6 above is to be linked with another condition, select the appropriate logical operator in the list adjoining **Value**.

   > **Tip:** The logical operators that can be used to link the existing condition to a new condition are *AND/OR.*

9. Click **Add** to add the newly created condition to the advanced condition.

10. Repeat steps 3 through 7 to add more conditions to the advanced condition.

11. When each of the required conditions for the advanced condition is entered, click **Save**.

12. Enter a name for the advanced condition and click **OK**.

   > **Note:** To enable other users to use the advanced condition, the **Share with other users** check box should be selected. More about sharing advanced conditions
   >
   > - If an Advanced Condition is not shared with other users, it does not appear in the Advanced Condition list for any user except the Administrator and the user that created it.
   >
   > - If the Advanced Condition is shared, all users can view the advanced condition, but they cannot modify it.
   >
   >   - Not allowed if the Advanced Condition is in use in the system.
   >
   >   - The console manages access to the **Advanced Condition Library** screen.
   >
   >   - The **Advanced Condition Library** option has been added to enable or disable (default) access to the following screen:
   >
   > Access Management **-->** Argus **-->** Groups> Menus> Utilities (subarea) section

> **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**.

Creating a Query Set of Advanced Conditions

The user can configure the Action Items type to be scheduled based on the Advanced Conditions rules as shown in the following.

New Action Type Fields and Field Description

Field/Control Name	Description	Property
Query Action	Defines the Action Item as a Query Action used to generate the letter and used as a placeholder.	Checkbox
Advanced Conditions	Enables the user to configure an Advanced Conditions Rule for creating the Query Type Action Item in the case.	User Selectable
User Group	Enables the user to define a User group (undeleted user groups in Access Management) for the Action Item created in the case.	Type Ahead
Letter Placeholder Content	Enables the user to enter Letter Text that prints in the letter using the Open Query placeholder.	Text (1000 characters)
Due In (days)	When the action item is created on the Case form, this option enables the user to define the number of days until the Action Item is due..	-

Be aware of the following:

- The Advanced Conditions, User Group, Letter Placeholder Content, and Due In fields are enabled only if Query Action is checked.

- The system tracks any changes made to the profile switch in the audit log.

- The **Action Type** report prints any additional fields.

- The system has a profile switch to enable the user to generate open queries when he/she saves the case.

    - **No (Default)** - When the user clicks **No**, the system **does not** generate open queries in the case when the user saves the case.

    - **Yes** - When the user clicks **Yes**, the system generates **all** action items with a query action type based on the advanced conditions defined for the Action Taken due in *xxx* days for User group *yyy*

      where:

      xxx is the number of action items defined + the System Date for the defined user group

      yyy is the user group

    - The system tracks changes made to the **Profile Switch** in the audit log.

Use the following procedure 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 opens.

   In this dialog, previously-created advanced conditions can be linked together using set operators like UNION, MINUS, and INTERSECT.
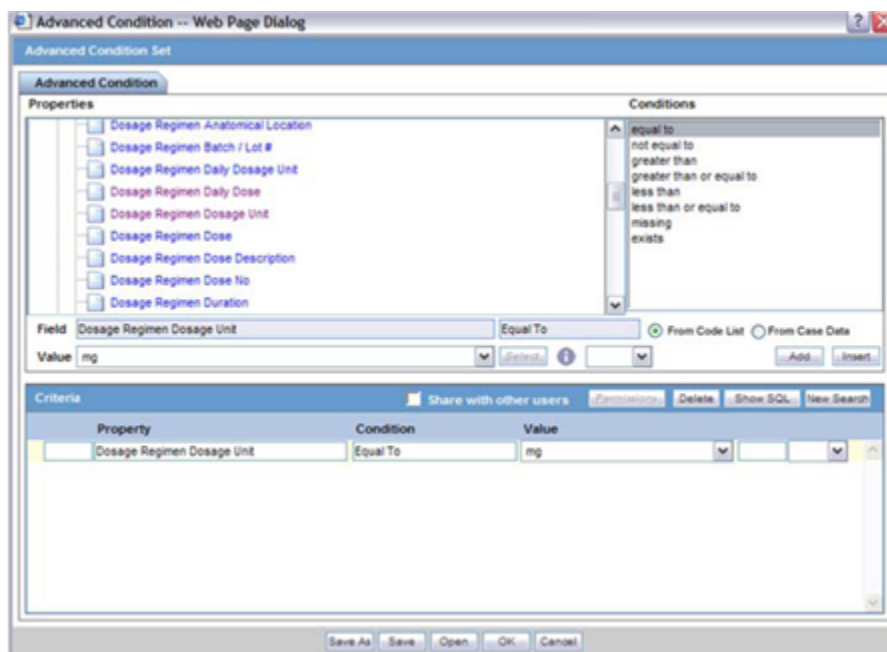
5. Click **Add** to add an advanced condition to the query set. A new row opens in the advanced condition selection area. In this row, select an appropriate advanced condition from the **Advanced Condition** list.

   > **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.

Tip: 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.

9. When each of the advanced conditions for the query set is entered, click **Save**.

10. Enter a name for the advanced condition and click **OK**.

Tip: **Tip:** 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.

The Hit List Tab

The **Hit List** tab in the Advanced Condition Set dialog can be used to search for cases that match the query set criteria.
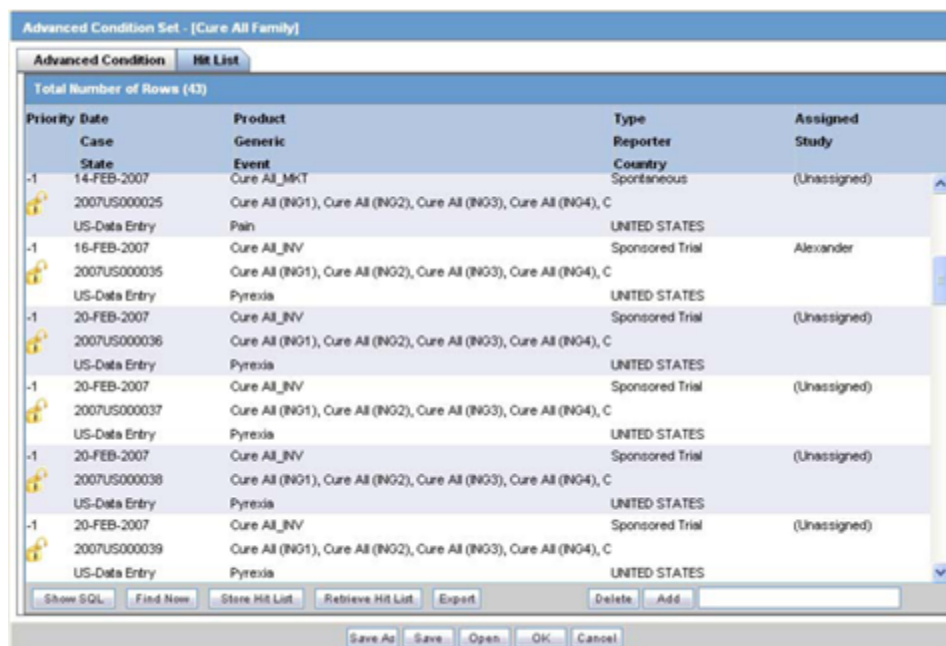
1. Click **Find Now** in the **Hit List** tab of the Advance Conditions dialog.

This 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.

2. Perform these operations to do the following:

To...	Click...
Manually add an existing case to the hit list	**Add** and enter the **Case ID**
Remove a case from the hit list	Remove
Save the hit list result for future use	Store Hit List

To...	Click...
Retrieve results of the saved hit list	Retrieve Hit List
Save the hit list as a text file	Export
View SQL for Query	Show SQL
Run a Query	Find Now

8

Multi-Tenancy Best Practices

This chapter provides the administrator of a multi-tenant environment best practice information.

Best Practices in a Multi-Tenant Environment

This section lists the the best practices to follow in a multi-tenant environment.

Single Sign On

Single Sign On needs to be enabled to have the capability to switch client context and to open the Argus Safety application from the Global Worklists/Application Access Portlet. If SSO is enabled, then it becomes mandatory for a user to be configured as an LDAP user in all the enterprises where the data displays on the screen/portlet.

Accessing Argus Safety Directly via URL

It is expected that the you will pass the internal Enterprise ID as a URL parameter for the Argus Safety application to open with the appropriate Enterprise context. If Enterprise ID is not passed, the user is validated against the default enterprise.

For ESM Mapping Utility and EOSU Tool which are client-server applications and do not have a mechanism to specify the Enterprise ID, will always validate users against the default enterprise. Hence, users that are expected to login into these applications are configured with appropriate access/roles within default enterprise. For this reason, "Active" checkbox for the default enterprise is always marked checked and disabled in Global Enterprise Management screen.

Global Homepage and Portlets

Set up appropriate Portal user and user group privileges to restrict access to Portlets and the Global Homepage. It is recommended that you configure the out-of-the-box Portlets so these (specified below) are accessible to all multi-tenant users who need to access data across multiple enterprises, except the ones specifically recommended for administrators.

- Global Worklist - New

- Global Worklist - Open

- Global Worklist - Action Items

- Global Worklist - Contacts

- Global Enterprise Management: Recommended for Administrators

- Global User Management: Recommended for Administrators
- Application Access Portlet

Global Worklists Columns

The system allows flexibility to hide some of the fields/columns in the Global Worklist Portlets through the Global Worklist grid/menu XML(s) which resides on the Web Server(s). It is advisable to hide only those fields/columns which are not updated nor referred by any Worklist context menu actions.

Global User Management

In order to apply updates to the "Synchronizable" fields to all the enterprises in the system, you should maintain some administrative users with the Console'Access Management 'Groups' Menus 'Console: Access Management: User menu access enabled for all enterprises in the system.

User-Enterprise Association

When a user is copied from one enterprise to another, it is expected that you have set up the appropriate site and the usergroups in the target enterprise. Otherwise the user-association with fail with the appropriate error message.

New User Creation/Association

Argus Console allows same UserID to be used to create different users across multiple enterprises. It is recommended that this feature is only be used if users are not expected to be shared across enterprises. Otherwise, if users are expected to be shared across multiple enterprises, then same UserID will not be used to create different users across different enterprises. Instead of that, a user created in one enterprise is associated to other enterprises through Global User Management.

Inactivating an Enterprise

It is recommended that you first archive all the cases belonging to the Enterprise before inactivating the Enterprise.

New Enterprise Setup

It is expected that you create and choose the appropriate Enterprises with generic configuration data which can be used as source for copying the configuration data for creation of a new enterprises. Following is a list of items that the you are recommended to ensure that the values being copied from the source enterprise are appropriate for the newly created enterprise:

- Advanced Conditions used within any configuration item
- Reporting Destination Code List ' Company identifier field values
- System Numbering and LAM System Numbering Formats
- ESM Mapping Utility ' Setup INI File Setup ' Service DB Setup ' Outgoing and Incoming folders for each Agency.

Common Profile Switches

- MedWatch Configuration
- Documentum configuration
- Lot Number Web Service Configuration

Segregated by Enterprise

Following is the list of items that are segregated by enterprises. It is recommended that you configure distinct values across enterprises to ensure proper data segregation across enterprises

- Literature Intake folder: Argus Console ' Common Profile Switches ' Argus J ' Shared Path for the Literature Intake

- Case Intake folder: Argus Console ' Code List ' User Sites ' Intake File Path

- Path for New Case from Image: Argus Console ' Common Profile Switches ' Case Processing ' Default Network directory for scanned images

- E2B Incoming Folder: ESM Mapping Utility ' Setup INI File Setup ' Service DB Setup ' Incoming Folder

- Site Printers: Argus Console ' Code List ' User Sites ' Site Printers ' Path

Maintaining Consistency Across Enterprises

The following is the list of items that are segregated by enterprises but the CRO is recommended to maintain consistent across all enterprises:

- Common Profile Switches ' Argus Insight URL

- Common Profile Switches ' Argus Safety Load Balancer Server

- System Configuration ' Enabled Modules

Shared Across Enterprises

Following is the list of items that are common for all enterprises

- MedDRA and WHO Web Services

- Common Profile Switches ' Security ' LDAP ' Enable/disable LDAP

- Common Profile Switches ' Security ' LDAP ' LDAP Server configuration

- Common Profile Switches ' Security ' Enable/disable SSO

- Common Profile Switches ' Security ' SSO Header Configuration

- Common Profile Switches ' Case Processing ' Where to store temporary case information during data entry

- Common Profile Switches ' Case Processing 'Auto Archiving ' The database job and its frequency - "Execution Period (in Days)"

- Default Enterprise

The common profile switches (related to SSO, LDAP, Auto Archiving job & frequencyand Temporary Case Data Storage) which are common for all enterprises will only be displayed, updated and audit logged in DEFAULT enterprise. This is because any update to global level profile switches impacts all enterprises and is controlled. Also, such an update will also require propagation of the audit log to all other enterprises where the current user may not even exist or may not have proper access.

Pre-upgrade Considerations for Existing Databases

Make sure that all the AG Service users (login user id) in all the databases that are to be merged into single database are in sync with the DEFAULT ENTERPRISE. If there are AG Service users in other enterprises which do not exist in the DEFAULT

ENTERPRISE, then you can either rename their login user IDs to map them to existing AG Service users in the DEFAULT ENTERPRISE or delete them. If extra users are found in other enterprises during multi-tenant database migration, then they will be marked disabled and you will not be enable them later.

Make sure that all the event & indication and who-drug encoding dictionaries used in Argus Console ' System Configuration 'Common Profile Switches 'Case Form Configuration 'Auto Encoding, Dictionary and Central Encoding section and Argus Console ' Business Configuration 'Studies 'Enable Study Specific Encoding 'Auto Encoding dialog, in all databases that are to be merged into single database are already loaded in the target database with the same name. This is required to enable the automatic linking of dictionaries configured in the separate databases to the already existing dictionaries present in the target database during the database merge script/process.

Post-upgrade Considerations for Existing Databases

E2B Outgoing and Incoming folders is configured again in ESM Mapping Utility because various folders for different transmission methods are now merged as one pair of folders for all transmission methods. Now these are saved into database rather than the ESM Service INI file.

Document Type field value from ESM Service configuration and AG Service configuration tool is now be configured again into Argus Console ' Common Profile Switches ' Documentum configuration as these fields are now moved to Argus Console.

Make sure that all the event & indication and who-drug encoding dictionaries used in Argus Console ' System Configuration 'Common Profile Switches 'Case Form Configuration 'Auto Encoding, Dictionary and Central Encoding section and Argus Console ' Business Configuration 'Studies 'Enable Study Specific Encoding 'Auto Encoding dialog, in the newly migrated enterprises are linked properly to the global dictionaries already present in the target database. This is required to correct any dictionary configuration linking that could not be done automatically by the database merge script due to mismatch in dictionary names in the source and target databases.

Documentum Migration

Existing single-tenant as well as multi-tenant Documentum users upgrading to AS 7.0 release, and are migrating/keeping all the documents in the Documentum server, is also add additional attributes- "enterprise_id" and "enterprise_short_name" and populate these appropriately for all their documents that are to be accessed by Argus Safety in Documentum server.

Existing single-tenant as well as multi-tenant users which are upgrading to AS 7.0 release, and have configured "Use Logged in User's Username/Password" for Argus Console ' System Configuration ' Common Profile Switches ' Document Management for Case Attachments will switch to Common Username/Password for Documentum login if not already configured for E2B, Expedited and Periodic Reports.

MedDRA and WHO Webservices: As MedDRA and WHO webservice is common for each enterprise, it will use only single version for encoding events and drugs. However, as these web services use the dictionaries configured in Argus Console ' System Configuration 'Common Profile Switches 'Case Form Configuration 'Auto Encoding, Dictionary and Central Encoding section for the respective enterprises for populating dictionary id and dictionary version information for the encoded items, configure these dictionaries as same across all enterprises.