

Oracle Argus Safety Administration Guide



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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)

Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

Related resources

For information about Oracle Argus patches, see [My Oracle Support](#).

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Access to Oracle Support

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1

Introduction

Oracle 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.



Note:

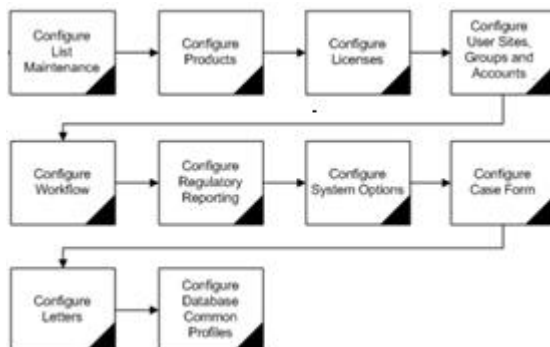
An * has been placed before fields that have been introduced in a previous release but are currently non-operational.

For more information, see:

- [Oracle Argus Safety Configuration Process Overview](#)
- [Getting Started](#)
- [Argus Console Architecture](#)
- [Administrator Login](#)

Oracle Argus Safety Configuration Process Overview

To configure Oracle 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 Oracle 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.

Task	Purpose
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.
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 Oracle Argus Safety application.

Getting Started

This section introduces the basic tasks for configuring Oracle Argus Safety. To get started with the configuration process, the person responsible for configuring Oracle 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

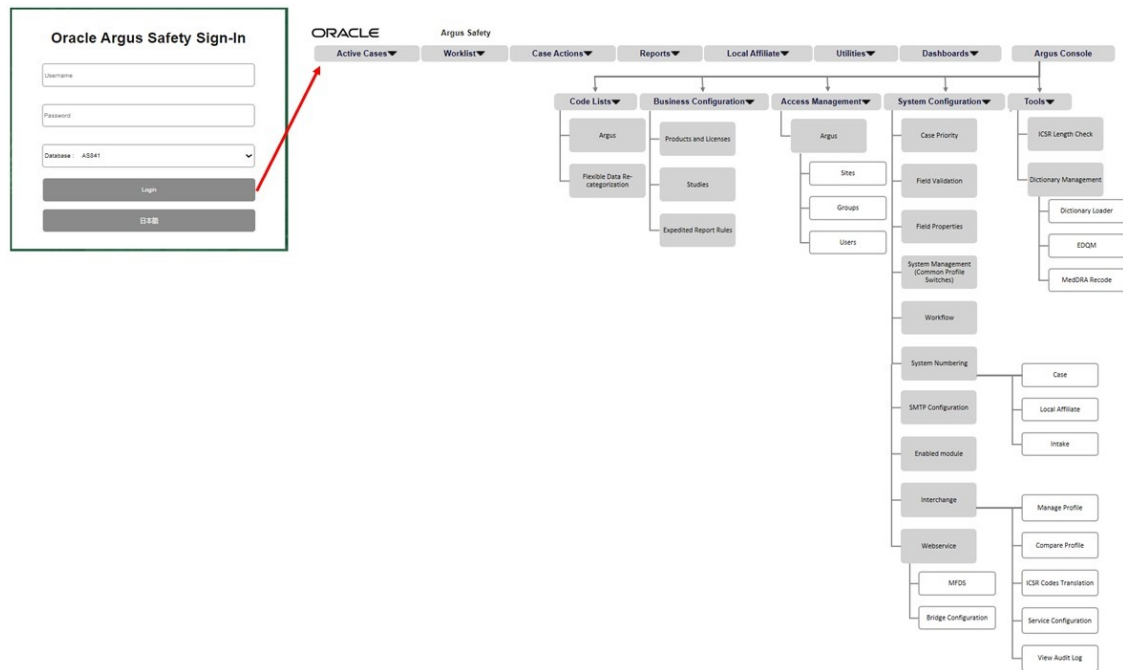
The Oracle Argus Web Administration Console has been designed to enhance ease of navigation for the Oracle Argus Safety end-users.

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.



For more information, see:

- [Required Fields](#)
- [Standard Buttons](#)
- [Standard Icons](#)

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



Note:

The Administrator or System password can be reset from new Argus Key Management Tool > Reset Password for the default Administrator and System Account.

For more information, see:

- [Logging In as an Administrator](#)
- [Changing the Administrator's Password](#)
- [Logging out](#)
- [Accessing the Home Page](#)
- [Launching Online Help](#)
- [View the Error Log](#)
- [Understanding Argus Console GUI](#)

Logging In as an Administrator

1. Enter the **Argus URL** in your web browser, to launch Oracle Argus Safety.

 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 Oracle 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 browser's pop-up blocker is disabled.

 Note:

If you receive a message as **System is currently down for maintenance. Please contact your system administrator for more information.**, it implies that the system is being updated for necessary updates to streamline operations and improve performance. During this period, DB Jobs, ESM or AG Services, or Other Windows Services will not be able to perform their functions

You will be able to login only when you have Global Admin user access rights, and perform the following actions:

- Access the Argus Console.
- Open Case Forms and work on them.
- Book In new cases via case form.
- Initiate Meddra Recoding from self service.

6. Click **Argus Console** to launch the Argus Console Administrator screen.

 Note:

If the window does not appear, verify that your browser's pop-up blocker is disabled.

Changing the Administrator's Password

1. Select **Utilities > Change Password** in Oracle Argus Safety and the Change Password dialog opens.
2. 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.

3. 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 Oracle 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 the Online Help, click **Help**.

View the Error Log

To view the error log for information about errors that occurred during case processing:

1. From the **Utilities** drop-down menu, go to **Logs > View Error Log**.
2. To search for error logs based on pre-defined or custom date ranges, in the Search Conditions section, enter a value, and click **Search**.

The search results appears in the Total Number of Rows section.

3. Locate the error log you want to view, and click to view the error message text.
4. Click the **Zoom** icon to view the complete text.

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.

Section	Sub-Section	Description
Business Configuration	Groups	This section enables the administrator to enter and configure new user groups.
	Users	This section enables the administrator to configure user accounts.
	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.
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.
	Interchange Mapping	This section enables the user to access the Interchange Mapping client utility from the Argus application to set up and configure the Service INI File.
	Code Lists	This section helps in capturing Code List information. Code lists appear as drop-downs in the Argus application.
Tools	ICSR Length Check	This screen enables the user to view the ICSR Length Check report in PDF format.

Section	Sub-Section	Description
	Dictionary Loader	The Dictionary Loader option is used to load new MedDRA, MedDRA J, WHODrug, WHODrug Global and Chinese, and J Drug dictionary files, as well as to overwrite them.
	EDQM	The EDQM Term List Loader utility can be used to load the EDQM Standard Terms database in Argus, to maintain a local repository for the EDQM Standard Terms database, and to synchronize the Argus code list for Routes of Administration and Dose Forms.
	MedDRA Recode	The MedDRA Recode window is used to recode the already coded MedDRA terms to the MedDRA dictionary version configured in System Configuration. It supports recoding in multi-tenant environments.

2

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.

For more information, see:

- [Configuring User Sites](#)
- [Configuring Groups](#)
- [Configuring Users](#)
- [User Configuration - Roles](#)

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.

For more information, see:

- [Field Descriptions](#)
- [Adding User Sites](#)

Field Descriptions

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

Field or Control Name	Description
Description	Enter a description of the site, like United States.

Field or Control Name	Description
Abbreviation	Enter an abbreviation of the site name. A one to four character abbreviation is required for each site. Ex: US.
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 Oracle 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.
13. In the Path text box, enter the full path of the printer on the network. This path name can have up to 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.

Description	Abbreviation	Site Type	Intake File Path
		LAM	
		LAM	

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

Configuring Groups

Each user of Oracle 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.

The system enables users to configure access permissions for the Argus Console from the Argus Console menu options.

For more information, see:

- [Field Descriptions](#)
- [Adding User Groups](#)
- [Printing a User Group](#)
- [About Filtering Criterion](#)

Field Descriptions

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

The screenshot shows the Oracle ARSP00823 'GROUPS AND USERS' configuration window. The window is titled 'GROUPS AND USERS' and has a 'Modify Group Information' form. The form includes fields for 'Group Name' (Administrator Group), 'Email', and 'Supervisor Email'. There are sections for 'Menus', 'Case Form', 'Advanced Condition', 'Listedness Determination', and 'Restrictions'. The 'Restrictions' section has checkboxes for 'Products' and 'Studies'. The bottom of the window has buttons for 'Save', 'Add Group', 'Copy', 'Delete', and 'Print'.

Field or Control Name	Description
-----------------------	-------------

Group Name	Enter a unique name for the group.
E-mail	Add the group e-mail, used for case priority notification and workflow routing notification.
Supervisor E-mail	Add the Group's Supervisor E-mail 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.
Advanced Condition	• If No Access to Create Advanced Conditions is selected, the Advance Condition will not appear as an option for any user belonging to the group. • If No Access to Share Advanced Conditions is selected, any user belonging to the group cannot share the Advance Conditions with others. • If No Access to View and Edit SQL is selected, the SQL option will not appear for the user belonging to the group.
Advanced Condition	Allows you to configure advanced condition settings, as applicable. The options are: No Access to Create Advanced Conditions, No Access to Share Advanced Conditions, No Access to View and Edit SQL.
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	When you enable this option and select the products, the users associated with this product-restricted group can only view the cases that have the assigned products. The cases that have other products than those selected in the user group are not accessible.

Field or Control Name	Description
Restrictions - Studies	When you enable this option and select the study, the users associated with this study-restricted group can only view the cases that have the assigned study. The cases that have another study than the one selected in the user group are not accessible.
 Note: When you select both the product and the study restrictions for a user group, the users associated with this group can only view the cases that contain the study and the products assigned to that group.	
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 Oracle Argus Safety 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 Oracle Argus Safety.

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.

The following user group accesses have been renamed:

- *Case Patient – Personal Patient Information* has been renamed as *Case Patient - Patient Information*.
- *Case Patient – Patient Information* has been renamed as *Case Patient – Patient Details*.

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

 Tip:

Refer to the *Oracle Argus Safety User's Guide* for information about the functions of the Case Form sections and the menu items in the Oracle 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**.

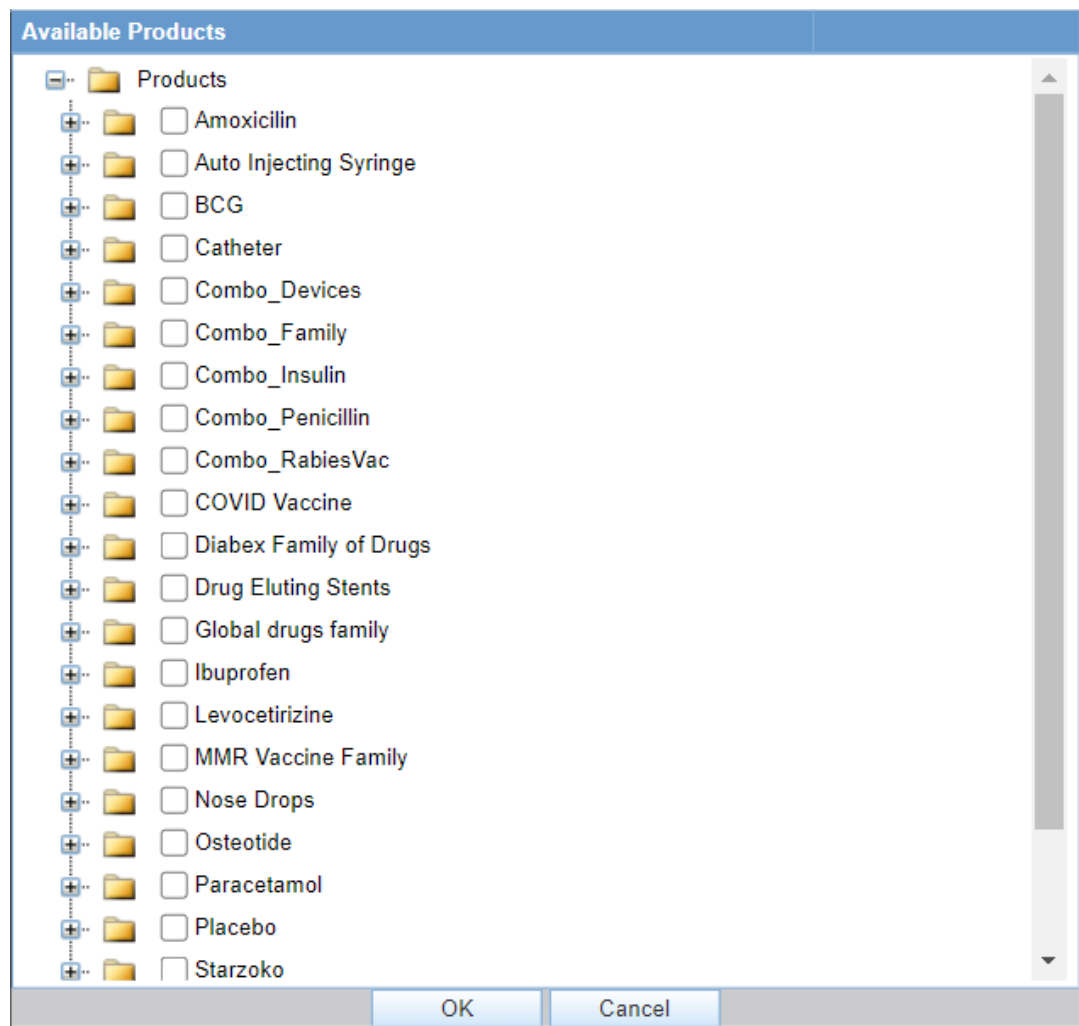
 Note:

Only trusted users should be given access to Advanced Conditions. This is because users who have this access will have complete access to the information in the Argus Schema.

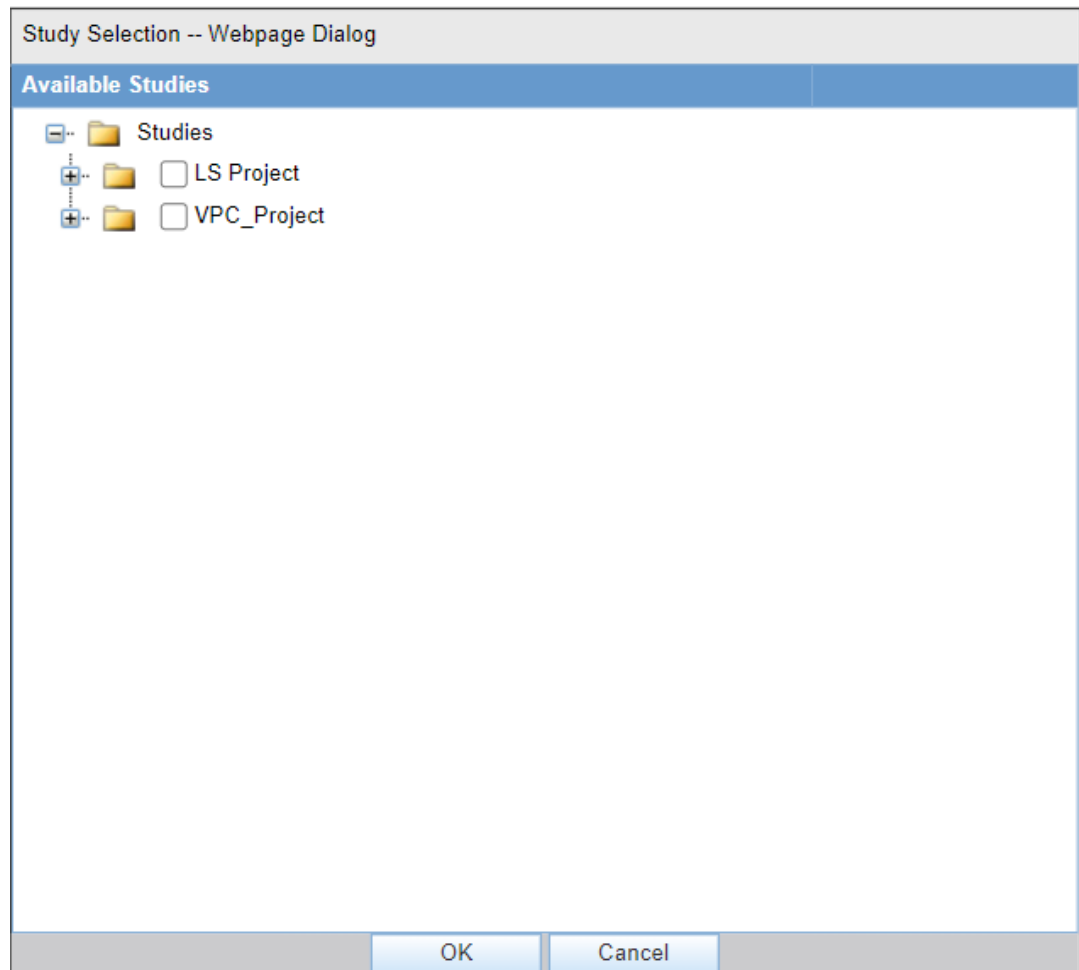
 Tip:

- 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.

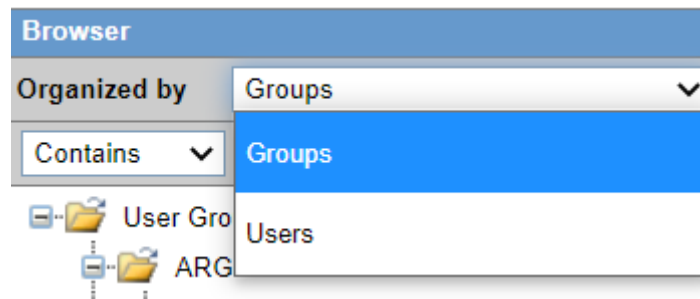
Group	Description
Administrator	This group has access rights to all areas and all the functionality of Oracle Argus Safety.
Investigator	Receives an e-mail alert that can be set up during Clinical Study Configuration.

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

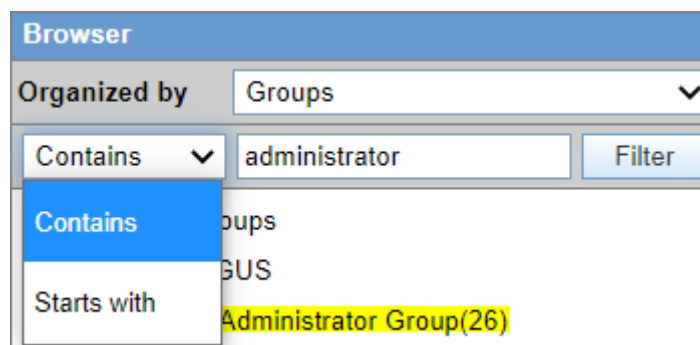
The system displays the filtering browser in the top-left corner of the left panel. You can filter based on either of the two combination shown in the following illustration.



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.

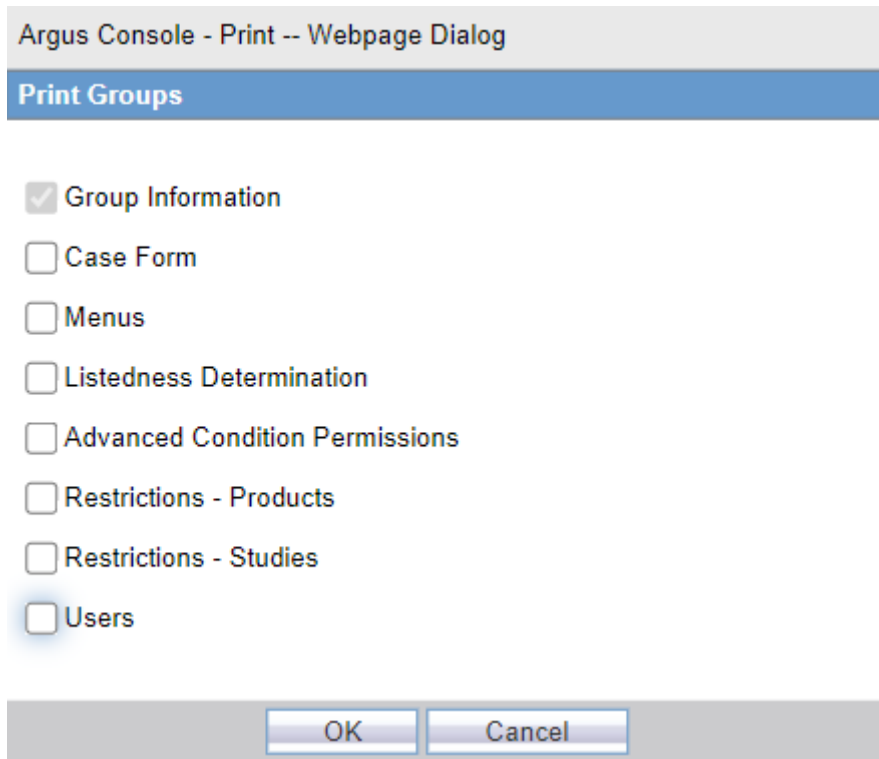
Using **contains** or **starts with** enables you to specify whether your search should contain or start with specific alphabetic characters. For example, filtering criterion shown in the following illustration enables the system to for all Groups that contain the word "administrator."



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 you 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**.



Argus Console - Print -- Webpage Dialog

Print Groups

☒ Group Information

☐ Case Form

☐ Menus

☐ Listedness Determination

☐ Advanced Condition Permissions

☐ Restrictions - Products

☐ Restrictions - Studies

☐ Users

OK Cancel

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

Users		
Full Name	User ID	Site
aditi	aditi	us
Administrator	admin	
alexandra	alexandra	us
Beena Wood	beenawood	us
Beena Wood UK only	beenawoodUK	UK
binchu	binchu	us
cristian	cristian	us

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 check box 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.

The screenshot shows the 'addita' user configuration form. The form is divided into several sections:

- User Information:** User Name (aditia), UserID (aditia), Email Address.
- Service User:** ☐ Service User.
- Enable LDAP Login:** ☐ Enable LDAP Login.
- Application Access:** ☒ Argus, ☒ Insight, ☒ Console.
- LDAP Server Alias:** Default Application (Argus).
- Access:**
 - ☐ Account Disabled
 - ☐ Security Disabled Account
 - ☐ Force Password Change At Login
 - ☐ Force Password To Expire Every Days
 - ☐ Reset Password
- Site:** Auto_United States.
- User Type:** ARGUS USER.
- User Group:** Administrator Group.
- User Roles:** AC Library Admin.
- Case Form:**
 - ☒ Allow Unblinding Of Cases
 - ☐ Protect From Unblinded Information
 - ☐ Protect From Printing Unblinded Information
 - ☒ Allow Locking Of Cases
 - ☒ Allow Local Locking
 - ☐ Allow Forced Unlock On Pending Reports
 - ☒ Allow Global Unlock On Pending Local Lock
 - ☒ Allow Closing Of Cases

For more information, see:

- [Field Descriptions](#)
- [Printing Users](#)

Field Descriptions

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

Field or 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.
E-mail Address	Enter the user's e-mail address.
Service User	Indicates whether the user is allowed to run background services. If the User Type was previously set to AG Service, this option is now selected instead.
User Type	Select the type of user account as: - Argus User (default) - Affiliate User If the User Type was previously set to AG Service, the Service User option is now selected instead.
Service User	Mark this check box to specify that user is a Service user that is used in background processing.
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 Oracle Argus Safety users. Such a user role should be assigned to users who need access to the Oracle Argus Safety Global application. Similarly, you can also select from other roles present within User Roles.
Application Access	Configure user access settings for Argus Console and Oracle 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 Oracle Argus. Displays personal Oracle Argus status on login. - Action Items - Opens Worklist - Action Items screen for the user on login into Oracle Argus Safety. - New - Opens Worklist - New screen for the user on login into Oracle Argus Safety. - Open - Opens Worklist - Open screen for the user on login to Oracle Argus Safety. - Reports - Opens Worklist - Reports screen for the user on login into Oracle Argus Safety.
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.

Field or Control Name	Description
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.
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 a certain number, the log in procedure will fail the password validation to lock the user out. This number is configurable from Argus Console > System Configuration > System Management (Common Profile Switches) > Security > Number of consecutive failed login attempts before account is locked 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 check box 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.
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 local locking	Enables the user, to locally lock/unlock a case for which local Japan data entry/assessment is complete, triggering the scheduling and/or generation of the applicable local reports.
Allow Global Unlock on Pending Local Lock	Allows users to be set up with the privilege to forcibly unlock a case that is still pending a local lock. This option is enabled only if the Allow locking of cases check box (above) is checked.
Allow closing of cases	Allows 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 check box is selected. If this check box 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. Select an option and click **OK** to display a list of Print User options.
5. Select the appropriate option(s) and click **OK**.

User Configuration - Roles

User Role	Description
Enterprise User	This privilege allows administrators to configure a workflow manager user as an Enterprise user. If Enterprise role is assigned, the user can view cases of any site outside its site.
ESM Admin	This privilege allows the user to access the Interchange Mapping utility in the Argus Console.
Copy Configuration	This privilege lets you copy all the configuration data from the enterprise where they have this role to any new enterprise that they create through the Global Enterprise Management portlet. The factory data Administrator user has this role enabled by default.
Global Admin	This privilege lets the administrator allow users to be designated as Global Users for selected enterprises and not necessarily all enterprises. The user associated with Global Admin role can perform the following: • In a multi-tenant setup, access multiple enterprises through Global Home Page. • Change the system maintenance mode to System Live after the maintenance process is complete. • Manage EDQM term loading.
AC Library Admin	This privilege lets the administrator allow users to perform specific operation on ACs such as re-assigning the ownership, grant access to various user groups using Permission, Modification, and Deletion.
Workflow Manager	This privilege allows the users to perform specific workflow operations such as routing cases to any workflow state, routing cases to user, viewing all open cases and all action items present in the system, changing the priority of a case and changing the assignee of an action item or a case.

3

Business Configuration

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

Sub-Section	Description
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.

For more information, see:

- [Editable and Non-editable Business Configuration Sections](#)
- [Configuring Product Family](#)
- [Configuring Products](#)
- [Configuring Licenses](#)
- [Configuring Clinical Studies](#)
- [Configuring Expedited Report Rules](#)
- [Configure Regulatory Reporting Rules](#)

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

For more information, see:

- [Type Ahead Fields](#)

- [Additional Comments Fields](#)

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 screenshot shows a web interface titled 'Key Ingredients'. Below the title is a table with a header row containing 'Ingredient Name', 'Add', and 'Delete'. The 'Ingredient Name' column is active, showing a dropdown menu with suggestions. The text 'Doxy' is entered in the input field, and the suggestions list includes: DOXYCYCLINE, DOXYCYCLINE CALCIUM, Doxycycline carragenate, Doxycycline fosfatex, DOXYCYCLINE GUAIACOLSULFONATE, DOXYCYCLINE HYCLATE, DOXYCYCLINE HYDROCHLORIDE, DOXYCYCLINE MONOHYDRATE, DOXYCYCLINE PHOSPHATE, Doxycycline sodium polyphosphate, DOXYLAMINE, and DOXYLAMINE SUCCINATE.

The following fields have the type-ahead feature:

- Clinical Reference Type (Under Clinical Studies 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 Oracle 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 Oracle 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 in the `Business Configuration >Products and Licenses` section.

For more information, see:

- [Field Descriptions](#)
- [Adding Product Families](#)
- [Creating Data Sheets](#)

Field Descriptions

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

Field	Description
Product Family Name	Enables you to enter a new product family name.
Product Family Name (J)	Enables you to enter a new product family name in Japanese.
Product Group	Enables you to select a product group name.
Search Equation Number	Enables you to enter a search equation number for <code>Literature Import > Bookin</code> .
Ingredient Name	Enables you to select the multiple key ingredients for the product family • You 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 Ingredients drop-down list enables you to enter up to 20 active ingredients for a product family.
Ingredient Name (J)	Enables you to select the multiple key ingredients for the product family • Sorting is not supported. • A maximum of 25 items are displayed as the search results in the drop-down list. • This field is optional, non-editable, and auto-populated based on the value in the English • The Key Ingredients drop-down list enables you 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 Oracle 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.

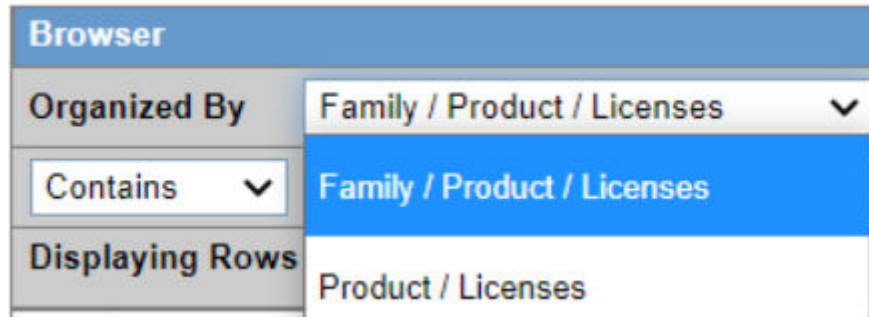
About Filtering Criterion

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

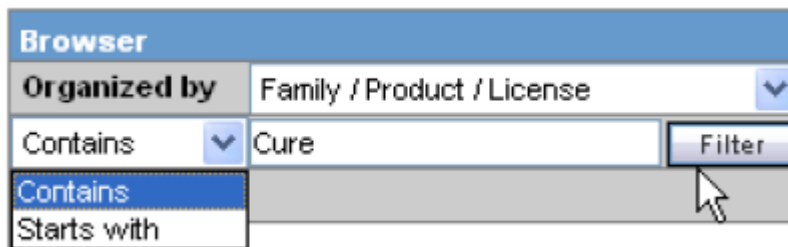
The filtering browser is displayed in the top-left corner of the left panel. The Products and Licenses section can be filtered based on any of the three combinations shown in the following illustration. Consider the following:

- 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 Configuration > Products Family` section.

- [Field Descriptions](#)

Field Descriptions

The following table lists the Field Descriptions for this section.

Field or Control Name	Description
Rename	Enables you to rename the datasheet.
Revision #	For an existing datasheet with revisions, this field displays the latest number of the datasheet revision. This is a non-editable field, value for which is incremented upon activation of the datasheet.
Revision Name	Enables you to enter revision name that can be viewed in the case form. For the existing datasheet that has revisions, this field is left blank. Revision name must be unique for each datasheet.
Revision Name (J)	This field is enabled for the Oracle Argus Safety Japan users and enables you to provide revision name in Japanese. Revision name must be unique for each datasheet.
Activate Datasheet	Enables you 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 Datasheet. • 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.
Core Sheet	The Core Sheet checkbox enables you 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 you 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.
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.
Preferred Term	This field displays the listed terms (Preferred Term) for the datasheet.
Revisions	Enables users to view a list of term that were added or removed with the added date.
Rename	Enables you to rename the datasheet.

**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.

Create a datasheet revision without adding any terms or event groups

1. To create the first revision without adding any term or event group, enter a **Revision Name** and click **Save**.

The revision # is updated as 1, and **Activate Datasheet** checkbox is enabled.

2. To activate the datasheet, check the **Activate Datasheet** checkbox, select the **Current Date** button, or **Other Date** radio button and enter the date.

When a datasheet is activated, the Current Date and Other Date options are disabled. Besides, Revision Name remains enabled and retains the name entered before.

If you change the **Revision Name** and click **Save**, the **Revision #** is incremented by 1, and Activate Datasheet checkbox remains enabled.

Create a datasheet revision with terms

1. To create the first revision, you must add terms or event groups, and click **Save**.

You can skip updating the Revision Name.

The revision # is updated as 1, and **Activate Datasheet** checkbox is enabled.

2. To activate the datasheet, check the **Activate Datasheet** checkbox, select the **Current Date** button, or **Other Date** radio button and enter the date.

When a datasheet is activated, the current date option is disabled. Besides, Revision Name remains enabled and retains the name entered before.

3. Click **Save**.

While saving, the application verifies the uniqueness of revision name within the context of current datasheet and displays error message, if any.

If you add or remove terms after the datasheet is activated and perform save, the Revision # is incremented by 1. However, subsequent changes made to the terms will not increment datasheet revision until the next datasheet activation happens.

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 Oracle 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 **Business Configuration > Products and Licenses**.

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.

The screenshot displays the Oracle Business Configuration interface. On the left, a 'Browser' pane shows a tree view of product families under 'Organized By: Family / Product / Licenses'. The main area on the right is titled 'test1' and contains several sections: 'Product Family Name' (test1), 'Product Group' (dropdown), 'Key Ingredients' (PARACETAMOL), and a 'Datasheet' section. The 'Datasheet' section has tabs for 'Preferred Terms (4)' and 'Event Groups'. The 'Preferred Terms' tab is active, showing a table with 4 terms: Pyrexia (发热), Nasopharyngitis (鼻咽炎), Rash (皮疹), and Headache (头痛). Each term has a 'Notes' link and a green checkmark icon. The bottom of the interface has buttons for 'Save', 'Add Family', 'Copy', 'Copy with Datasheets', 'Delete', and 'Print'.

For more information, see:

- [Field Descriptions](#)

- [Adding Products](#)

Field Descriptions

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

Field Name	Description
Product Family Name	Enables you 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. You 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.
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 .
Product Name (J)	Contains a unique Japanesse name for the product.
Generic Name (J)	Displays the generic name of the product. Click the Copy from Ingredient button, to generate the generic name.
J Drug Code -- Select	Provides the J Drug Code from the Drug Coding dialog box.
PSUR Group Name	This value is used to filter period reports in Oracle Argus Safety.
Comments	Enables you to enter the reason for configuring the elements.

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. Enter the Manufacturer's name.
14. Enter the Authorized Representative's name.
15. Click **Select** icon to select the **WHO Drug Code** associated with the product. Based on the WHO Drug Code selection, the **WHO Medicinal Product ID** is also populated as configured in the backend.

 Note:

The WHO Medicinal Product ID is populated only when the C3 format dictionary is configured. It does not populate for B3 format dictionary.

16. WHO Medicinal Product ID

17. Enter the `Company Code` allotted for the product.
18. 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.

19. 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 by Family/Product/License, the generated output is visible in a tree-format, in the left panel.
- If you enable Organized by Product/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 Oracle Argus Safety.

Configure licenses in the Business Configuration > Products and Licenses section.

The following illustration shows the fields associated with this section.

For more information, see:

- [Field Descriptions](#)
- [Adding Product Licenses](#)
- [Using the Product Browser](#)

Field Descriptions

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

Field/Control Name	Description
Trade Name	Enables you to enter the Trade Name under which this product(s) is (are) authorized by this license.
Trade Name J	Enables you to enter the Japanese trade name under which. the product is authorized by this license.
Award Date	Enables you to enter the license award date for this license.
Withdrawn Date	Enables you to enter the license withdrawal date for this license. The withdrawn date cannot be less than the award date.
Market Authorization Holder	Enables you to select a manufacturer or co-marketing partner for this license of the product.
PMDA Re-examination Date	The date of the next PMDA examination.
Biologic / Vaccine	Whether the license is for a Biologic/Vaccine (this can impact the MedWatch report output). 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.

Field/Control Name	Description
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 you to specify if the Product has been bought as an Over-the-Counter Product.
Pre-1938	For non-company products, enter the data. For company products, this field is updated based on the data available in the license configuration and is ready-only. For study products, this field is fetched based on the primary license number selected in the <code>Console > Studies Configuration</code>. When unblinded at case level, data is enabled irrespective of the product selected in the Study Drug drop-down.

**Note:**

The **Pre-1938** field available under the `Case Form > Analysis > MedWatch tab` will not be used in eMDR.

Biosimilar	For non-company products, enter the data. For company products, this field is updated based on the data available in the license configuration and is ready-only. For study products, this field is fetched based on the primary license number selected in the <code>Console > Studies Configuration</code>. When unblinded at case level, data is enabled irrespective of the product selected in the Study Drug drop-down.
Datasheet URL	User can enter a hyperlink to a site giving information about the datasheet of the product.
Authorization Country	This enables you 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	you 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 you 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.

Field/Control Name	Description
Product Identifier Type	This field is auto-populated based on the license selected on the Drug/ Device/ Vaccine tab of Argus Case Form > Products. This field is not mandatory.
Product Identifier	This field is auto-populated based on the license selected on the Drug/ Device/ Vaccine tab of Argus Case Form > Products. If Product Identifier Type is set, then this field becomes mandatory.
WHO Medicinal Product ID	Enables you to select the WHO medicinal product ID from the Drug Coding pop-up at license level.

**Note:**

If the B3 dictionary is configured, then this field is not populated as the B3 dictionary does not contain WHO Medicinal Product ID.

Application Type	Enables you to enter the license application type such as IND, NDA, STN etc.
License #	Enables you to enter the License Number of the Trade name.
Company Item Number	Enables you to enter the Company Item number corresponding to the license.
Trade Name J	Enables you to enter the Japanese trade name.
Clinical Compound Number	The number that identifies the specific chemical compound. - You can edit this field when the Authorization Country is Japan and the license type is either Investigational Drug or Investigational Vaccine. - The Clinical Compound field is only available to users to Oracle Argus Safety Japan.
Product Name (J)	The Product List box displays the list of products (product name, dosage form and strength) that this associated license covers for regulatory reporting purposes.
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.
Countries List	Enables you to select all the countries in which the same license was issued. The system adds the authorization country to the Countries List and updates the list when you updates the authorization country.
TIKEN	Selecting the TIKEN checkbox indicates that the customer will not send the investigational report for the other license.
Status Category of New Drugs	The Status Category of New Drugs field captures the Status category of new drugs. This information is transmitted in the J.2.4k element of PMDA E2B R3.
Risk Category of OTC Dugs	The Risk Category of OTC Dugs field captures the risk category of OTC drugs. This information is transmitted to the J.2.5k element of PMDA E2B R3.
Medical Device Terminology	This drop-down field was introduced under the new section header Device Information with the following options: EMDN, GIVD/EDMS, GMDN, Other, UMDNS(ECRI).
Medical Device Terminology-Other	This field becomes enabled only if the Device Terminology field has the Other value selected.
Conformity/ Market Availability	This field contains the details of the Conformity of the device product or Market availability of the device product: First declaration of conformity, Device first CE marked, First placed on the market, First put into service, Software, First Available.

Field/Control Name	Description
Date of Conformity/ Market Availability	This field provides the Date of Conformity or Market Availability of the Device product.
PMA/510(k)#	This field is associated with medical device information and prints in expedited reports.
Basic UDI-DI	This field contains Basic UDI-DI of the device product.
Nomenclature Code	This field is associated with medical device information and prints in expedited reports.
Nomenclature text	This field contains the Nomenclature text or the Device description of the Device Product.
Medical Device Information	This field contains the details of Medical Device Information based on the Risk Class of the Device.
CE Marked	CE marking is a mandatory conformity marking for certain products sold within the European Economic Area (EEA). For a Marketed or Investigational Device, this field can be set to Yes or No. For all other license types, this field is disabled.
CTPR Group Name	This value is used in Argus Safety when filter periodic report data.
Comments	Enables you to enter information about the element configuration.
Device Company Identification#	Enables you to capture information about the Device Company Identification number.
Device Identification#	Enables you to capture information about the Device Identification number.
Risk Class Type	This field contains the Risk Class Type of the Device Product based on the Medical Device Information.
Notified Body ID number (1)	This field captures the Notified Body ID number associated with the conformity of the Device product.
Notified Body ID number (2)	This field captures the Notified Body ID number associated with the conformity of the Device product.
Certificate Number of the Notified Body (1)	This field captures the Certificate Number of the Notified Body associated with the conformity of the Device product.
Certificate Number of the Notified Body (2)	This field captures the Certificate Number of the Notified Body associated with the conformity of the Device product.

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:

- Enter the Trade Name of the license.
- In the Manufacturer list, select the manufacturer of the product.
- Select the **Authorization Country** in which the license was issued.
- Select the **License Type**. This is the type of license.
- To select the **WHO Medicinal Product ID**, click **Select** adjacent to this field. From the Drug Coding pop-up, select a drug to populate the WHO Medicinal Product ID.
- Enter the license number in License#.
- If this license is to be reported is 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.
- Specify if the drug is **Labeled for Single Use** or not.
- Specify if the drug has been bought as an Over-the-Counter (OTC) Product.

Note:

If the **OTC Product** checkbox is checked in Business Configuration > Products and Licenses for a product whose Authorization Country is US and Withdrawn Date is blank, then the **OTC Product** checkbox in the Case Form > Analysis > Medwatch tab will be checked automatically on selecting the product license if the Initial Receipt Date is equal to or greater than the Award Date of the license.

- Specify if the drug is **Biosimilar** or not.
- Specify if the drug is **Pre-1938** or not.
- Under Award Date, enter the date the license was granted to the manufacturer.
- Enter the Withdrawn date, if applicable.
- Enter the Company item number in Company item number.
- Enter a URL reference for the license under Data Sheet URL (A URL reference might be a link to product label or product information).

- p. A world wide web address or an appropriate network path (For example: http://anydomainname/anypath or \\FILESERVER\LOCATION) can be entered in this field.
- q. Select **Not in Tradename lookup/Not Auto-Scheduled** if this license is not to be involved in reporting.
- r. In the **Countries List**, select the countries that define whether the case will be classified as domestic or foreign for regulatory report scheduling algorithm. The list of countries field in the product license screen used to display the ISO A3 codes assigned to each country. But since the new countries do not have ISO A3 codes, this field now displays the full country names with the semicolon as delimiter.

 Tip:

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

- s. Select the **Data Sheet Name** associated with the license, from the drop-down list.
- t. If you have a company product selected on the Drug/Device/Vaccine tab in Argus Case Form > Products, then the **Product Identifier Type** and **Product Identifier** fields are auto-populated based on the selected license. If the selected license does not have a Product Identifier Type and Product Identifier defined in Argus Console, then do not set the Product Identifier Type and Product Identifier fields.
- u. 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.

The Product Browser dialog opens.

- 6. Enter the name (partial or full) of the product and select **Full Search**.
- 7. Select the appropriate product in the search results, and click **Select**. Enter all the required products in this manner.

Using the Product Browser

- 1. Click **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 Configuration > Studies section.

When configuring clinical studies, be aware of the following:

- The CDER-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)

When configuring clinical studies, be aware of the following:

- The Study screen has a **J Data Entry** button that is available only to J users.
- When you click the **J Data Entry** button, the system presents a message telling you to enter data in the required fields (Study ID, Project ID, and at least one (1) Product) before opening the Japanese translation window.
The Study Type value displays in Japanese and can be one of the following:
 - Single Blinded
 - Double Blinded
 - Not Blinded
- The License Type value displays in Japanese and can be one of the following:
 - Investigational Drug
 - Investigational Device
 - Investigational Vaccine
 - Marketed Drug
 - Marketed Device
 - Marketed Vaccine
- When you click **Add J Drug**, the system opens the J WHO Drug Lookup Window to enable the user to add a J Drug. The system adds the drug to the product section of the pop-up.
- The WHO Encoded column has an **Encode** button. Click this button to open the WHO Drug browser. This enables you to associate the corresponding WHO drug with the J Drug if it is available. The associated WHO drug appears in the product section of the English screen.
- Before closing the J pop-up, the system reminds the user to associate corresponding WHO drugs with the J drugs.
- All error messages are in English.
- After saving the data in the pop-up window, the system makes the same changes on the English screen.
- In browser view, the system displays the English product name by default. If the English product name is not available, the system displays the Japanese product name.
- Clicking **Save** closes the window and saves the data, if all J drugs are WHO encoded. If they are not WHO encoded, the system presents the following message: Some J drugs are missing WHO drug association. Do you still want to close the J Data Entry dialog?
- Spell check is not available in the Study description dialog.
- When you click **Auto Encoding** on the J-popup, the system opens the Auto Encoding dialog.
The following fields appear in the dialog box:
 - Drugs
 - Events & Indications
 - Prevent manual encoding for event
 - Require Events & Indications encoding before case closure
- When you click the **Centers - Modify** button, the system opens the Modify Study Center dialog box.
This dialog box contains the following fields/controls

- Center
- Selected Center
- Add
- Add All
- Delete All
- Delete
- OK
- Cancel
- When you copy data, the system does not copy the equivalent Japanese data.
- When you copy data, the application puts `Copy of` at the beginning of the data in the Name field.
- You can save a duplicate last name if the English ID is unique. If the ID is not unique, the system presents the following message: `A duplicate Study ID already exists!`
- If the Japanese name is not unique, the system presents the following message: `A duplicate ID already exists!`
- When navigating from the English screen to the J pop-up for an existing study:
 - When you click the **J Data Entry** button, the system prompts you to save the data on the English screen before opening the J screen: `Do you want to save the changes before opening the Japanese screen?`
 - If you choose to save the data, the system saves the data and the changes appear on the J screen.
 - If you choose not to save the data, then changes made on the English screen will not appear on the J screen.
- When entering a new study:
 - When you click the **J Data Entry** button, the system asks you to save the data on the English screen before opening the J screen. The message is: `Data must be saved before opening the Japanese screen. Do you want to save?`
 - If you choose to save the data, the system saves the data and the equivalent data appears on the Japanese screen.
 - If you choose not to save the data, the system will not open the J screen.

The following illustration shows the fields associated with this section.

The screenshot displays the Oracle Clinical Studies configuration interface. It features several sections for data entry:

- Study Identification:** Includes fields for Study ID, Project ID, and Other ID. It also has a dropdown for Observe Study Type (E2B) and a checkbox for Template only.
- Arms:** Contains fields for Study Name, Study Type (with a dropdown), and Primary License. It includes Copy and Delete buttons.
- Products:** A table with columns: #, Product Name (Dosage Form / Strength / Units), License, Blinded, and Product Type. It has Add WHO Drug, Add Product, and Delete buttons.
- Clinical References:** A section with an Add and Delete button.
- Countries:** A table with columns: End Date and Selected Countries. It has Add and Delete buttons.
- Product Abbreviation:** A text field.
- Study Centers:** A text field with a Modify button.
- Study Description:** A text field with a dropdown arrow.
- Investigator Alert:** A dropdown menu with a search icon and an AC button.

For more information, see:

- [Field Descriptions](#)
- [Adding Clinical Study Configurations](#)
- [Adding WHO Drug Details](#)
- [Adding Product Details](#)
- [Configuring Auto Encoding](#)
- [Configuring Study Reporting](#)

Field Descriptions

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

Field or 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.

Field or Control Name	Description
Observe Study Type (E2B)	This enables you to select the study type from a drop-down list. - This element is populated from the Case Form Clinical Study section of the application. - The value selected in Study Configuration, Observe Study Type (E2B) is populated in the Case Form Study section when you select 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.
* Non-Interventional Study	Enables you to identify a study as a non-interventional study. The available options are Yes and No. The default value is set to No. This field is not used in the application (Case Form, Reports) for this release.

The following table lists and describes the arms available in this section.

Arms Field or Control Name	Description
Study Name	Enter the name of the study. This is a mandatory field. You can add up to 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.

Primary License	Select the applicable primary 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. When you schedule a report that meets the reporting criteria for a blinded product other than the default blinded product, then the report is scheduled against the Primary License product. If there is no Primary License product configured in Study Configuration, then the report is scheduled against the selected License for default blinded product configured in <i>Study Configuration > Products</i> list. If there is no license configured for default blinded products, then the report is scheduled against the first valid license for default blinded product.
Copy	Click this button to copy a selected Arm.
Delete	Click this button to delete a selected Arm.

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

Products Field or Control Name	Description
Product Name (Dosage Form /Strength/Units)	Provides information about the Product Name along with the (Product formulation/Product Concentration/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). The **Study is eligible for Unblinding** checkbox should be unchecked in study configuration. If this checkbox is checked, you will be able to see the complete case data even if he has protection enabled.

Product Type	Allows you to select a Product Type from the drop-down list. The possible values are: • Investigational Product - This value indicates that the study product is an experimental drug being studied in the clinical trial. • Comparator - This value indicates that the study product is an approved drug, and it is used in the clinical trials for comparing results with the investigational product. • Placebo - This value indicates that the study product is a dummy drug. This drug is used in the studies to eliminate bias that might occur due to knowledge of who receives which treatment. • No Study Drug Given - This value lets you classify an event into the No Study Drug Given category if a serious adverse event occurs even before a patient has started taking any study drug. • Additional Study Drug - These are additional or background drugs that are given as part of a combinational therapy. These drugs are generally given with both investigational products, and comparators. The additional study drug does not impact the case categorization, but it is an attribute for this configuration in the product temp table. In PBRER and DSUR reports, count of events are stratified against the product type values: Investigational Product, Comparator, and Placebo.
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.

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

Clinical References Field or Control Name	Description
Reference Type	Shows the various reference types that can be setup for this study.
Country	Enables you 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 you to add another clinical reference.

Clinical References Field or Control Name	Description
Delete	Enables you to delete the selected clinical reference.
Countries	Enables you to select a country for the clinical reference type.
License	This is the license of the primary (company) product participating in the study.
Product Abbreviation	This enables you 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 you 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 you to choose the language from the list. The global language icon is displayed if the study description data is entered in a language different than English or Japanese.
Investigator Alert	Enables you 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.
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 check box 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 you selects from the list.

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

Study Reporting Field or Control Name	Description
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.

Study Reporting Field or Control Name	Description
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 check box 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 check box 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 you have 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.
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.
Select datasheet for onset assessment	If the companies have a need to associate a specific datasheet revision for the investigational products at study level, then the configuration of datasheet revisions can be made using this option. When you click this button, a dialog box appears to select a trade name pertaining to the product. You can add trade names that are associated with the product selected along with MAH country and License # with the following exceptions: • Trade name that are not associated with data sheet are not listed. • Trade names that are associated with the data sheet that does not have at least one active revision. • Trade name that has withdrawn date are listed. • Trade name that has Not in Tradename Lookup / Not Auto-Scheduled marked are listed as usual. • Trade name that was selected for the study product in the Select Datasheet Revisions dialog are not listed.

Oracle Argus Safety Japan specific fields

Field or Control Name	Description
Clinical Compound Number	Enables you to enter clinical compound information.
Target Disease Indication	Enables you to enter disease information.
Study Development Phase	Displays a list of all valid study development phases configured in the study development code lists.
Are any subjects given this investigational drug?	Select from the available options, or enter as desired.
Comments	Enables you to enter relevant comments regarding the study.
J Data Entry	This button appears only to Argus J users. When you click J Data Entry the application opens the Study Configuration dialog box with Japanese localization.
Test Drug Type	This drop-down list appears only to Argus J users and it is not used in the out-of-the-box Argus functionality. It is available for usage in advanced conditions. This drop-down list displays the types of test drugs. The supported values are Blank, Main Test Drug, Test Drug and Other than Test Drug. The default value is Blank.

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.

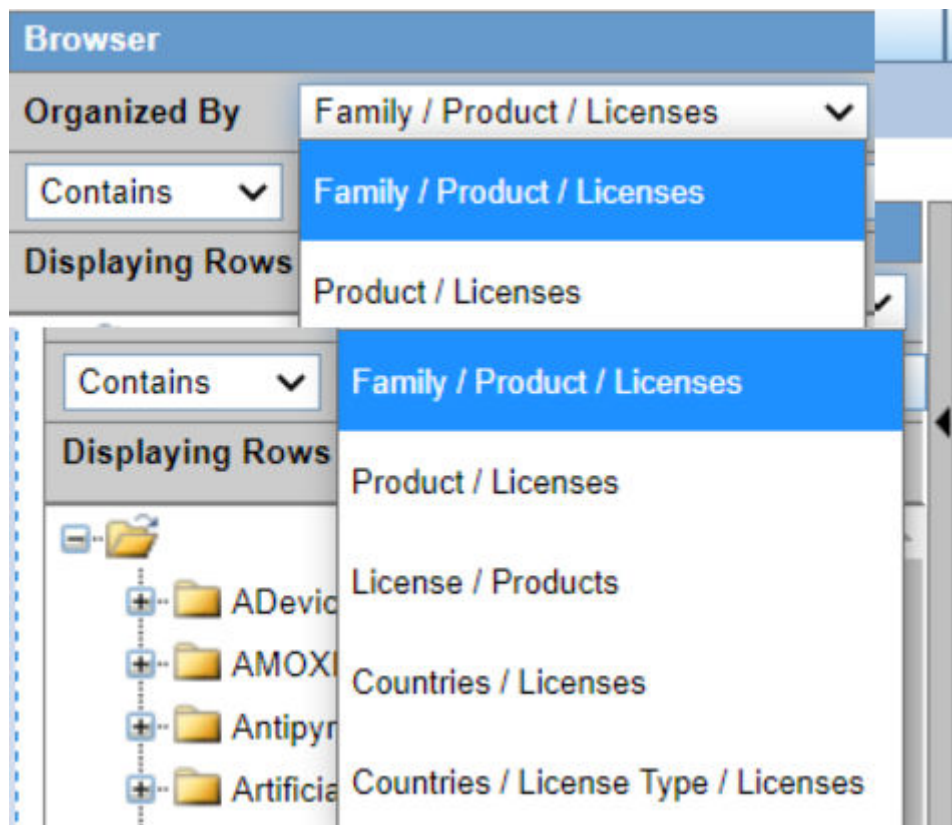
5. Enter the `Study ID` and `Study Name` associated with the Study.
6. Select the **Project ID** for the Study, from the drop-down list.
7. Select the **Study Type** associated with the Study, from the drop-down list.
8. Enter the `Other ID`. This will be an alternative id for the Study.
9. Select **Template** 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

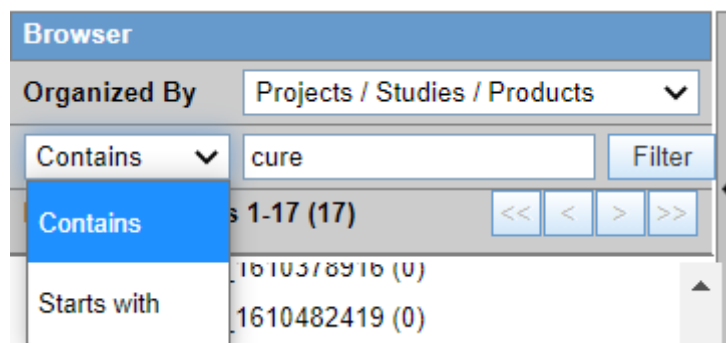
The filtering browser displays in the top-left corner of the left panel. The studies section can be filtered based on of any of the three combinations shown in the following illustration. The generated output is visible in a tree-format, in the left panel, based on the entire categorization of Projects, 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 **WHO Drug** to add WHO drug details (using the WHO Drug browser window) associated with the Study. The system opens the WHO Drug browser window.
3. 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.
4. Click **Search** to execute the search. The data is displayed as follows.
5. Select the required component/row (this can be the key Trade Name or Ingredient).
6. The row now appears highlighted and the Drug Details section displays the associated information.
7. Click **Select** to add this drug information in the Product Name section of the Studies Configuration window.
8. 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 Product** 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.

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

9. Select the **Country** associated with this Study, from the drop-down list.
10. 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.

11. The Countries field is a display only field. You can Add or Delete this list based on your requirements.
12. Select the **Product License** from the drop down list. This is the license of the primary (company) product participating in the study.
13. Enter the Product Abbreviation.
14. The Centers are displayed as per the centers you choose to associate with the Study. To modify this list, click **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.

15. Enter the `Study Description` associated with the Study.
16. Click **Select** placed next to Investigator Alert to select or create an Advanced Condition for this Study.
17. Select **Study is eligible for Unblinding** to enable the study to be unblinded.
18. 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.

CODE LIST MAINTENANCE

Organized by: Code List

Autosignals Filter

Name	# of Occurrences	Occurrences of	# days	Signal Detection	Email
Test Issue	1	CDI - US	1	As Cases are Entered Every 1 Days	vikasa@relays.net
Testing the Consider this a GPS activit	1		1		vpink@test.com

Add New Auto-Signals

Name:

Send Email Notification To:

Signal Selection

occurrences of AC within days

☐ As cases are Entered Every days

Save

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 Oracle Argus Safety Case Form, for study cases.

STUDIES CONFIGURATION

Organized By: Projects / Studies / Products

Contains: Filter:

Displaying Rows 1-2 (2)

V-Osteo Study

#	Product Name (Dosage Form / Strength / Units)	License	Blinded	Product Type
1.	Osteo d (/ /)		☒	
2.	Osteo d (/ /)		☒	
3.	Narafen (Injection / /)		☒	

Clinical References (0)

Reference Type: Country: Reference Number:

Study Encoding - Webpage Dialog

Auto Encoding, Dictionary & Central Encoding

☒ Drugs

☐ Events & Indications

☐ Prevent Manual Encoding for event terms

☐ Require event term encoding before case closure

OK Cancel

Study Reporting (0)

Inherit reporting rules from template:

Always report: Country: License Type: Reporting Destination: Time Frame: Possible Report Forms:

Comments:

Save Add Study Copy Copy with Products Delete Print

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

Study reporting is available for both Who Drugs and J Drugs. When you are a Japanese user and you click the **Add** button in either the English or the Japanese Study Reporting section, the following scenarios may occur:

- If the reporting destination contains WHO Drug or J Drug reporting, then you can add a record.
- If the reporting destination does not contain WHO drug or a J drug reporting, the following error message is displayed: There are no Reporting Destinations for which WHO Drug reporting or J Drug reporting is configured. The Japanese error message reads: WHO Drug 報告または J Drug 報告が構成されている報告先がありません

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 the application 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.
 - 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 Configuration > Expedited Report Rules` section.

The screenshot displays the Oracle Expedited Report Rules configuration page. The top navigation bar includes links for Code Lists, Business Configuration, Access Management, System Configuration, and Tools. The left-hand pane shows a tree view of countries and regions, with 'AUSTRIA (2)', 'EUROPEAN UNION (3)', 'JAPAN (3)', and 'UNITED STATES (8)' listed. The main form area is titled 'EXPEDITED REPORT RULES' and contains several sections: 'Report Name' with checkboxes for 'Active', 'Auto Distribute Reports', and 'Blind Study Products'; 'Report Destination' with checkboxes for 'Protect Reporter and Patient Confidentiality', 'Report on Drug Not Administered', 'Active Mole', 'HCP Case', and 'No Follow-up or Downgrade'; 'Origin of events to include' with checkboxes for 'Domestic' and 'Foreign'; 'Adjust due date for Group 2 Countries by' with a text input for 'days' and a checkbox for 'Force Distribute'; 'Form' with dropdowns for 'Local Comment Type', 'Clinical Reference Type', 'Language', and 'Message Type'; 'Product Specific' with dropdowns for 'Product Group', 'Family Name', and 'Study Reference Type'; 'Causality' with checkboxes for 'Most Conservative' and 'Include Non-Clinical Trial Cases'; 'Advanced Condition' with dropdowns for 'As Reported (Event)', 'As Determined (Event)', 'As Reported (Case)', and 'As Determined (Case)'; 'Reporting Category' with dropdowns for 'Reporting Category', 'License Category', 'Device Reporting Category', and 'Responsible Group'; and a 'Comments' text area. At the bottom, there are buttons for 'Save', 'Copy Rule', 'Add Rule', 'Delete', and 'Print'.

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
- Report scheduling takes into account listedness of additional datasheet and licenses added for blinded company case products, along with the default blinded product to determine SUSAR / Unlisted to schedule reports.
- When you schedule a report that meets the reporting criteria for a blinded product other than the default blinded product, then the report is scheduled against the primary license product.
- If there is no primary license product configured in Study Configuration, then the report is scheduled against the selected License for default blinded product configured in *Study Configuration > Products* list.
- If there is no license configured for default blinded products, then the report is scheduled against the first valid license for default blinded product.
- 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** field.

- If two or more duplicate reports have different due dates (regardless of license type), the system schedules the report with the earliest due date.
- 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.
- When a user configures a Reporting Rule for MIR Report from Console > Business Configuration > Expedited Reporting Rule, and the user selects MIR Report in the Form drop-down, the system will show the Message Type drop-down with Blank as a default value, and it will be disabled.
- When a user configures a reporting rule report and selects **PMDA Device Report** in the Form drop-down menu, then the application populates the Message Type drop-down menu with **ichicsr** and disables the field.

Expedited Report Rules
As of 05 January 2012

Expedited Report Rule Information	
Country	UNITED STATES
License Type	Marketed Drug
Report Name	US1997000003 & 6
Reporting Destination	CDER
Origin of Events to Include	☒ Domestic ☐ Foreign
Timeframe	3 days
Adjust Due date for Group 2 Countries by	3 days
Advanced Condition	Adv Condn for investigator alert
Responsible Group	US Distribution
Cover Letter	
☒ Active Rule	☐ Auto Distribute Reports
☐ Active Moiety	☐ Blind Study Products
☐ Force Distribute days before due	☐ HCP Case ☐ No Follow-up or Downgrade
☐ Protect Reporter & Patient Confidentiality	☒ Report on Study Drug not Administered
Reporting Category	
License Category	
☐ Super Rule - Cease evaluation of normal rules upon match	

For more information, see:

- [Field Descriptions](#)
- [Expedited Reporting Rules Algorithm](#)
- [Adding Expedited Report Rules](#)

Field Descriptions

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

Field or Control Name	Description
Report Name	Enables you to view or enter the name of the Report.
Report Destination	Enables you to select the name of the agency to which the report will be scheduled.
Active	Enables you 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 or Control Name	Description
Protect Reporter and Patient Confidentiality	Enables you 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 Drug Not Administered	If this checkbox is checked, system schedules report for the suspect products (study or non-study products) that are marked as 'Drug not administered' along with the other suspect products in the case. If this checkbox is unchecked, system ignores suspect products (study or non-study products) that are marked as 'Drug not administered' and Reports are scheduled for other suspect products in the case for which 'Drug not administered' is not marked.
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 you 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 you 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 <i>does not</i> 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.
Adjust due date for Group 2 countries by xxx days	This field allows you 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.

Field or Control Name	Description
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 enables you to select the appropriate clinical reference when printing the report. The following three FDA specific clinical reference values are also displayed in the drop-down list: • Pre-ANDA • CBER-IND • Cross reported IND This field is enabled for CIOMS-I and other forms.
Language	Enables you 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.



Note:

This field is displayed when an E2B or eVAERS report is selected as the Report Form. If the Report Form is selected as eVAERS, then the Message type is set to ICHICSR and is disabled.

Listedness	Enables you to check if the license being evaluated for reporting is listed. The possible values are: • Listed • Unlisted • Ignore (default)
Seriousness - Fatal/Life Threatening	Enables you to check if case level seriousness assessment is 'Death or Life Threatening'. The possible values are: • Yes • No • Ignore (default)
Seriousness - Serious (Case)	Enables you to check if case level seriousness assessment is 'Serious'. The possible values are: • Yes • No • Ignore (default)
Seriousness - Serious (Event)	Enables you to check if the event level seriousness assessment (for any event) is 'Serious'. The possible values are: • Yes • No • Ignore (default)
Seriousness - Severity	Enables you to select a term descriptive of the severity of the event. E.g. Mild, Moderate, severe, unknown.
Product Specific - Family Name	Enables you to configure product specific reporting rules.

Field or Control Name	Description
Product Specific - Product Group	Enables you to configure product specific reporting rules. Product Group drop-down always lists the configured Product Groups.
Product Specific - Study Reference Type	The Study Reference Type drop-down displays all clinical reference types as per the codelist. You can use these reference types as a filter criteria to schedule the reports.
Study Specific - Study Reference Type	The Study Reference Type drop-down displays all clinical reference types as per the codelist. You can use these reference types as a filter criteria to schedule the reports.
 Note: The Study Specific section is enabled only for Investigational drugs/devices/vaccines.	
Causality - Most Conservative	If this check box 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. <i>Ignored for non-study cases. Only applies to Study cases.</i> 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. <i>Ignored for spontaneous, literature and regulatory authority cases.</i> 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)

Field or Control Name	Description
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.
Advanced Conditions - Select	Enables you 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 you to select a group to whom reports scheduled by this rule will be assigned.
Super Rule - Cease evaluation of normal rules upon match	Enables you to provide a super rule.
Reporting Category	Enables you to configure the relevant reporting category.
Device Reporting Category	Enables you to configure the relevant device reporting category.
License Category	Enables you to configure the relevant license category.
Cover Letter	Enables you to use letters that have been configured for reporting template use.
Comments	Enables you to enter reporting rule comments, up to 2000 characters.

Expedited Reporting Rules Algorithm

The expedited reporting rules algorithm affects the following:

- Suppression of Duplicate Reports
- Blinded/Forced Distribution
- Letter Placeholder for the IND Cover Letter

Suppression of Duplicate Reports

You can suppress duplicate expedited reports to be scheduled at the reporting destination level by using the **Suppress Duplicate Reports** option.

This option:

- Determines the system to use the following attributes to determine whether the reports are duplicates of other reports:
 - Report Form
 - Reporting Destination
 - Aware Date
- Only applies to drug reports. It **does not** apply to device reports.

- **Does not** reduce the number of reporting rules the system evaluates. However, it **does** prevent the system from scheduling and generating expedited reports that match the duplication criteria.

Blinded/Forced Distribution

You can configure the **Blinded Study** option for products in a study to blind the products for the report being sent to the reporting destination. The functionality is similar to the corresponding option from the Bulk Reporting dialog box.

- If you select either of the **Blinded Study** product options (**Reporting Rules** or **Bulk Reporting**), the system blinds the study product information on the report form.
- The system blinds only active blinded studies. It does not blind the following case reports even if the Blind Study product is selected.
 - Open Label Studies.
 - Study is eligible for unblinding - If the Study is Unblinding checkbox is not kept as unchecked in study configuration, the user will be able to see the complete case data even if he/she has protection enabled.
- In cases where expedited reports are due, the system permits the user to force-distribute the reports based on user-defined reporting rules, even if case processing is incomplete.
- When you select the **Force Distribution** rule, the following occurs:
 - If a case encounters a rule where a report is due is locked, the system schedules the report based on the rule and does the following:
 - * Generates the report on the due date.
 - * Dynamically replaces the current case comment with the force distribution case comment.
 - * Transmits the report based on the preferences defined by the reporting destinations.
 - * Displays the status in the Worklist Bulk Transmit/Transmit ICSR dialog boxes.
 - The AG Service Force Reporting process for expedited reports completes the process by:
 - * Checking the reports required for force distribution.
 - * Locks the case (if it's not already locked).
 - * Generates the reports and makes sure it is ready for transmission.
 - The notes for the **Case Locking/Unlocking** are the same as those defined as the common profile value for the **Forces Distribution** option; SYSTEM is the user.

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 Drug not Administered**. This option ensures that all 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 select the appropriate clinical reference when printing the report.

 Note:

For FDA-specific clinical reference values, you can choose from the following three values displayed in the drop-down list:

- Pre-ANDA
- CBER-IND
- Cross reported IND



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:

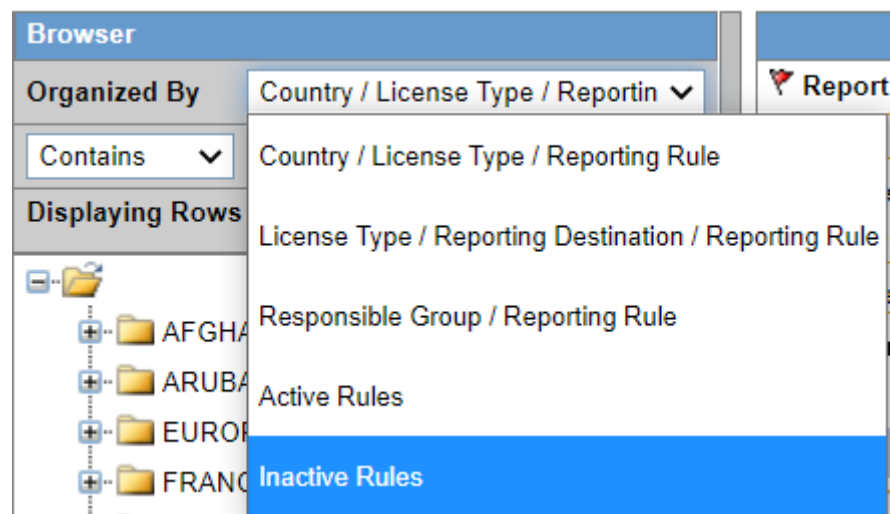
If you have added a new Reporting Rule, click **Add Rule** to save the new Expedited Reporting Rule.

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:

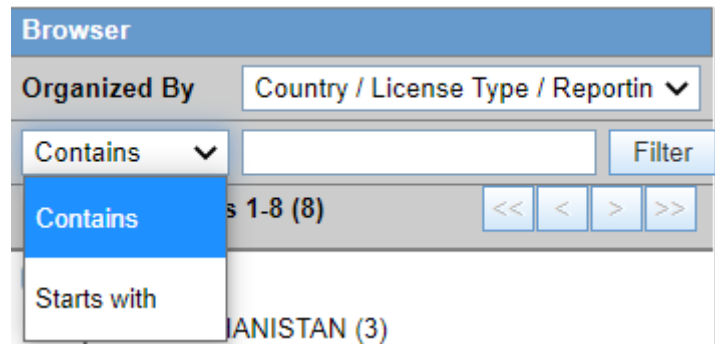
- If you enable Organized by Country/License Type/Reporting Rule, then the output generated will be visible in a tree-format, in the left panel, based on the entire categorization of Country, License Type and Reporting Rule.
- If you enable the Organized by Responsible Group/Reporting Rule, then only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



Sorting of Expedited Report Rules

The Reporting Rules are sorted in an alphanumeric order. The logic of ordering of Reporting rules based on Organized by is as follows:

1. Country/License Type/Reporting Rule

For each country, there will be a folder for license type. Within each folder, the active and inactive reporting rules will be presented together in alphanumeric order.

2. License Type/Reporting Rule

For each license type, there will be a folder for each reporting destination. For each destination, the active and inactive reporting rules will be presented together in alphanumeric order.

3. Responsible Group / Reporting Rule

There will be a folder for each reporting group. Within each folder, the active and inactive reporting rules will be presented together in alphanumeric order.

4. Active Rules

Only active rules will be presented. For each country, there will be a folder for license type. Within each folder, active rules will be presented in alphanumeric order.

5. Inactive Rules

Only inactive rules will be presented.

For each country, there will be a folder for license type. Within each folder, inactive rules will be presented in alphanumeric order.

Configure Regulatory Reporting Rules

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

This granularity allows individual license holders to override the normal listedness and causality assessment to control the need for submissions to their local regulatory authority.

Each affiliate could either suppress the need for a report by demoting the criteria, or add the requirement for a report by promoting the listedness or causality.

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

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

4

Dictionaries Management

You can manage your dictionaries in the following ways:

- Use the Dictionary Loader and the MedDRA Recode options from Argus Console, under Tools.
- Use the Dictionary Management Tool from the Application server.



Note:

It is recommended to use only one method at a time.

For more information, see:

- [Dictionaries management using the Console self-service options](#)
The Dictionary Loader and the MedDRA Recode options under Dictionary Management can be used as an alternative to the Dictionary Management Client/Server tool. The Dictionary Loader self-service option provides one screen to load all the dictionaries.
- [Dictionaries management using the Dictionary Management Tool](#)
The Dictionary Management Tool is used to load and update the dictionaries in Argus.
- [About the MedDRA Recoding tool](#)
- [About J Drug dictionaries](#)
J Drug dictionaries contain the drugs details approved in Japan.
- [Frequently asked questions](#)

Dictionaries management using the Console self-service options

The Dictionary Loader and the MedDRA Recode options under Dictionary Management can be used as an alternative to the Dictionary Management Client/Server tool. The Dictionary Loader self-service option provides one screen to load all the dictionaries.

The Dictionary Loader option is used to load and overwrite MedDRA, MedDRA J, WHODrug Global and Chinese, and J Drug dictionaries from Argus Console.

A new user and schema are automatically created for every dictionary load version in this self-service mode. When overwriting, a new schema user is not created.

The MedDRA Recode option is used to recode the cases that were already coded with a prior MedDRA version to the latest MedDRA version configured in the System Configuration.

The Dictionary Loader and the MedDRA Recode menu options are available for users logged in only through the default enterprise and who belong to a user group that has the **Dictionary Loader** and the **MedDRA Recode** options enabled under Access Management, in the Groups window, in the Menu section.

The Dictionary Loader and the MedDRA Recode pages are asynchronous, once the loading is initiated, you can move to other windows.

The logs are available for download from the self-service page.



Note:

The dictionary load is done using the Relsys Windows service. So, the Dictionary Loading requires that the RelsysWindowsService.exe.config is updated with the database details as in the *Oracle Argus Safety and Oracle Insight Installation Guide*.

For more information, see:

- [MedDRA dictionaries using the Console self-service options](#)
MedDRA and MedDRA J dictionaries can be loaded, overwritten and recoded using the Dictionary Loader and the MedDRA Recode self-service options from Argus Console.
- [WHODrug dictionaries using the Console self-service options](#)
WHODrug (Global) and WHODrug (Chinese) dictionaries can be loaded and overwritten using the Dictionary Loader self-service option from Argus Console.
- [J Drug dictionaries using the Console self-service options](#)
J Drug dictionaries can be loaded and overwritten using the Dictionary Loader self-service option from Argus Console.

MedDRA dictionaries using the Console self-service options

MedDRA and MedDRA J dictionaries can be loaded, overwritten and recoded using the Dictionary Loader and the MedDRA Recode self-service options from Argus Console.

For more information, see:

- [Prerequisites](#)
- [Load a MedDRA or MedDRA J dictionary](#)
- [Overwrite an existing MedDRA or MedDRA J dictionary](#)
- [Recode a MedDRA or MedDRA J dictionary](#)

Prerequisites

The Dictionary files (only MedAscii files) should be zipped and available in the user's local directory. The ZIP file should not contain embedded ZIP files or folders and should not be password protected.



Note:

In the Dictionary Loader self-service option, the new schema and user are automatically created for every dictionary load.

The latest MDB/Configuration File for MedDRA should be available for upload in the user's local directory.



Note:

The MDB file is shipped with Argus and it is available in <Installation path>\Oracle\Argus\DBInstaller Directory. The file can also be obtained by creating a request ticket on the HSGBU Customer Support Portal.

To recode the MedDRA dictionaries in Update Mode, set **Maintenance Mode** to **System down for Maintenance**. For more information, see [Configuring System Maintenance](#).

Load a MedDRA or MedDRA J dictionary

To load a MedDRA or a MedDRA J dictionary:

1. From Argus Console, go to **Tools**, click **Dictionary Management** and select **Dictionary Loader**.
2. Select **Load New**.
3. In the **Dictionary File (.zip file containing dictionary data)** field, select the local path to the dictionary ZIP file.
The dictionary type and version are automatically populated based on the selected ZIP file.
4. In the **Configuration File** section, upload the MDB file by browsing the local folders.
Once the MDB is loaded, the file is automatically used for the future loading of the same dictionary type. Any new version of the MDB upload overwrites the existing MDB files.
5. In the **Notification Email Address** field, set the email address to receive an update on the status of the load operation after completion. This field is autopopulated with the email address of the logged-in user from the user setup in Access Management.
6. Click **Load**.



Note:

You can provide multiple email addresses separated by semicolon (;).

The Status section will display the progress of the load. Once the load is complete, the log file is available for download.

For more information about the Dictionary Loader window, see [Dictionary Loader field descriptions](#).

Overwrite an existing MedDRA or MedDRA J dictionary

The Overwrite option allows the users to overwrite an existing dictionary version in the database. This option works only for dictionaries that are already successfully loaded from self-service.

The schema and dictionary name are reused from the initial load.

To overwrite a MedDRA or MedDRA J dictionary:

1. From Argus Console, go to **Tools**, click **Dictionary Management** and select **Dictionary Loader**.
2. Select **Overwrite**.
3. In the **Dictionary File (.zip file containing dictionary data)** field, select the local path to the Dictionary ZIP file.

The Dictionary Type field, the Configuration File and the dictionary version are automatically populated.

4. In the **Notification Email Address** field, set the email address you want to use for the status message.
5. Click **Overwrite**. The Status section will display the progress of the overwrite process.
6. When the load is complete, download the log.

For more information about the Dictionary Loader window, see [Dictionary Loader field descriptions](#).

Recode a MedDRA or MedDRA J dictionary

To recode the MedDRA terms:

1. From Argus Console, go to **Tools**, click **Dictionary Management** and select **MedDRA Recode**.
2. Select the enterprise. Multiple enterprises can be selected using the **CTRL + click** options.
3. In the **Select the Source MedDRA Version that was used for coding** field, select the version that is to be recoded.
4. Select:
 - **Update** to recode the Argus events encoded in the selected MedDRA version to the MedDRA version selected in the system configuration in the Common Profile Switch.
 - **View Only** to generate logs that can be used to evaluate the cases and fields that are affected by the recode. When this option is selected, the **Select the target MedDRA version that will be used to recode in View Only Mode** is displayed to allow you to select the target version for which you want to see the logs.
5. Select to code either the current or non-current terms in the **Coding Data Update/View Options (Currency determined at LLT level only)** section.
6. Click **Execute**.



Note:

The logs can be generated only for the last run of the recode.

The screenshot shows the Oracle Dictionary Management console. The top navigation bar includes 'Code Lists', 'Business Configuration', 'Access Management', 'System Configuration', and 'Tools'. The main header is 'DICTIONARY MANAGEMENT'. On the left, a 'Browser' pane shows a tree structure with 'Dictionary Management' expanded, containing 'Dictionary Loader', 'EDQM', and 'MedDRA Recode'. The 'MedDRA Recode' window is open on the right. It features a 'MedDRA Recode' title bar and a 'Enterprises' section with a list box containing 'DEFAULT'. To the right of the list box are two dropdown menus: 'Select the Source MedDRA Version that was used for coding' and 'Select the target MedDRA version that will be used to recode in View Only Mode'. Below these are radio buttons for 'Update' and 'View Only' (selected). Further down is a section for 'Coding Data Update/View Options (Currency determined at LLT level only)' with three checkboxes: 'Process Current Terms (Using Primary SOC Path)', 'Process Non-Current Terms (Using Primary SOC Path)', and 'Update dictionary version for coded terms where existing hierarchy is still current'. A note states: 'Note - Cases using Study Specific Dictionaries will NOT be included in the Re-Code logic.' Below this is the 'Output Log File Options' section with radio buttons for 'Delimited Text' (selected) and 'Excel File', and a 'Common Delimiter' dropdown set to ','. At the bottom of this section are buttons for 'Generate Log Files For Last Execution' and 'Execute'. A 'Status' section at the bottom displays a log of execution steps: '8/17/2022 11:09:11 PM: MedDRA Re-Code execution started', '8/17/2022 11:09:11 PM: Processing enterprise - DEFAULT', '8/17/2022 11:09:11 PM: Checking MedDRA Version...', '8/17/2022 11:09:27 PM: Processing complete for enterprise - DEFAULT', and '8/17/2022 11:09:27 PM: MedDRA Re-Code Execution completed'.

For more information about the MedDRA Recode window, see [MedDRA Recode field descriptions](#).

See also:

- [About the log file generation](#)

About the log file generation

The logs for the last recode are available for download by clicking the **Generate Log Files For Last Execution** button.

You can download the logs as:

- Delimited text: this option creates TXT files with the selected delimiter and zip them during the download.
- Excel File: this option generates the log files in XLSX format and zip them during the download. The ZIP file is named as ZIP_MEDDRA_RECODE_<Date>.

Note:

The logs are not automatically saved after running the recode.

The logs are available for both View only and Update options.

The log files are downloaded to the browser default download path that is locally configured. The logs are loaded in a temporary table and only the latest recode log is available for download.

In case of single tenant, the parameters selected for the last run and the details of the affected cases/LM are available in the log.

For more information on multi-tenant, see [About the MedDRA recode logs](#).

After clicking **Generate Log Files For Last Execution**, a zipped file containing all 8 log files is downloaded. For more information, see [About the MedDRA recode logs](#).

WHODrug dictionaries using the Console self-service options

WHODrug (Global) and WHODrug (Chinese) dictionaries can be loaded and overwritten using the Dictionary Loader self-service option from Argus Console.

For more information, see:

- [Prerequisites](#)
- [Load a WHODrug dictionary](#)
- [Overwrite an existing WHODrug dictionary](#)

Prerequisites

The Dictionary files (WHODrug Files [TXT for Global and CSV for Chinese dictionary]) should be zipped and available in the user's local directory. The ZIP file should not contain embedded ZIP files or folders and should not be password protected.

The latest MDB/Configuration File for WHODrug should be available for upload in the user's local directory.



Note:

The MDB file is shipped with Argus and it is available in <Installation path>\Oracle\Argus\DBInstaller Directory. The file can also be obtained by creating a request ticket on the HSGBU Customer Support Portal.

Load a WHODrug dictionary

To load a WHODrug (Global) or WHODrug (Chinese) dictionary:

1. From Argus Console, go to **Tools**, click **Dictionary Management** and select **Dictionary Loader**.
2. Select **Load New**.
3. In the **Dictionary File (.zip file containing dictionary data)** field, select the local path to the Dictionary ZIP file.

 Note:

Choose the TXT format files for Global and CSV format for Chinese.

4. Select the dictionary type.
5. In the **Configuration File** section, upload the WHODrug MDB file by browsing the local folders.

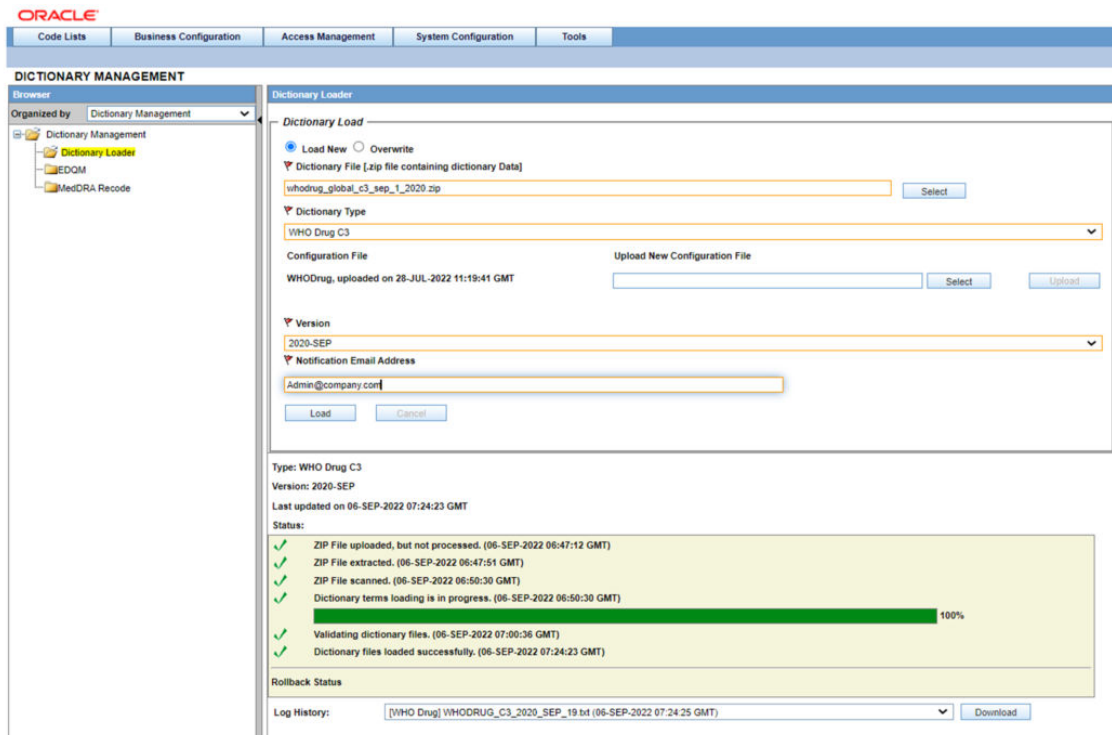
Once the MDB is loaded, the file is automatically used for the future loading of the same dictionary type.
6. Select the dictionary version from the list. The list is populated based on the used MDB configuration file.
7. In the **Notification Email Address** field, set the email address to receive an update on the status of the load operation after completion. This field is autopopulated with the email address of the logged-in user from the user setup in Access Management.

 Note:

You can provide multiple email addresses separated by semicolon (;).

8. Click **Load**.

The Status section will display the progress of the load.
9. When the load is complete, download the log.



ORACLE

Code Lists Business Configuration Access Management System Configuration Tools

DICTIONARY MANAGEMENT

Organized by Dictionary Management

Dictionary Management
Dictionary Loader
EDOM
MedDRA Recode

Dictionary Loader

Dictionary Load

Load New Overwrite

Dictionary File [zip file containing dictionary Data]
whodrug_global_c3_sep_1_2020.zip Select

Dictionary Type
WHO Drug C3

Configuration File
WHODrug, uploaded on 28-JUL-2022 11:19:41 GMT Upload New Configuration File Select Upload

Version
2020-SEP

Notification Email Address
Admin@company.com Load Cancel

Type: WHO Drug C3
Version: 2020-SEP
Last updated on 06-SEP-2022 07:24:23 GMT

Status:

- ✓ ZIP File uploaded, but not processed. (06-SEP-2022 06:47:12 GMT)
- ✓ ZIP File extracted. (06-SEP-2022 06:47:51 GMT)
- ✓ ZIP File scanned. (06-SEP-2022 06:50:30 GMT)
- ✓ Dictionary terms loading is in progress. (06-SEP-2022 06:50:30 GMT)
- ✓ Validating dictionary files. (06-SEP-2022 07:00:36 GMT)
- ✓ Dictionary files loaded successfully. (06-SEP-2022 07:24:23 GMT)

Rollback Status

Log History: [WHO Drug] WHODRUG_C3_2020_SEP_19.txt (06-SEP-2022 07:24:25 GMT) Download

For more information about the Dictionary Loader window, see [Dictionary Loader field descriptions](#).

Overwrite an existing WHODrug dictionary

To overwrite a WHODrug (Global) or WHODrug (Chinese) dictionary:

1. From Argus Console, go to **Tools**, click **Dictionary Management** and select **Dictionary Loader**.
2. Select **Overwrite**.
3. In the **Dictionary File (.zip file containing dictionary data)** field, select the local path to the Dictionary ZIP file.
4. Select the dictionary type.
5. In the **Configuration File** section, upload the WHODrug MDB file by browsing the local folders.

Once the MDB is loaded, the file is automatically used for the future loading of the same dictionary type.
6. Select the dictionary version from the list. The list is populated based on the existing dictionary versions that are already loaded via self-service.
7. In the **Notification Email Address** field, set the email address to receive an update on the status of the load operation after completion. This field is autopopulated with the email address of the logged-in user from the user setup in Access Management.
8. Click **Overwrite**. The Status section will display the progress of the overwrite process.
9. When the overwrite is complete, download the log.

For more information about the Dictionary Loader window, see [Dictionary Loader field descriptions](#).

J Drug dictionaries using the Console self-service options

J Drug dictionaries can be loaded and overwritten using the Dictionary Loader self-service option from Argus Console.

For more information, see:

- [Prerequisites](#)
- [Load a J Drug dictionary](#)
- [Overwrite an existing J Drug dictionary](#)

Prerequisites

The ZIP file should contain the dictionary files and should not have embedded ZIP files or folders.

The latest JDrug MDB/Configuration File should be available for upload in the user's local directory. The MDB file is shipped with Argus and it is available in <Installation path>\Oracle\Argus\DBInstaller Directory. The file can also be obtained by creating a request ticket on the HSGBU Customer Support Portal.

For more information on creating and modifying the required files, see [Create and Modify Required File](#).



Note:

In the self-service mode, formulationcode.txt is not required.

Load a J Drug dictionary

To load a J Drug dictionary:

1. From Argus Console, go to **Tools**, click **Dictionary Management** and select **Dictionary Loader**.
2. Select **Load New**.
3. In the **Dictionary File (.zip file containing dictionary data)** field, select the local path to the Dictionary ZIP file. For more information, see [Create and Modify Required File](#).
4. Select the dictionary type. The list is populated based on the Dictionary Type factory codelist.
5. In the **Configuration File** section, upload the JDrug MDB file by browsing the local folders. For more information, see [Modify the.mdb file](#).

Once the MDB is loaded, the file is automatically used for the future dictionary type loading.

6. Select the dictionary version from the list. The list is populated based on the used MDB configuration file.
7. In the **Notification Email Address** field, set the email address you want to receive an update on the load operation status after completion.
8. Click **Load**.
9. When the load is complete, download the log.

For more information about the Dictionary Loader window, see [Dictionary Loader field descriptions](#).

Overwrite an existing J Drug dictionary

To overwrite a J Drug dictionary:

1. From Argus Console, go to **Tools**, click **Dictionary Management** and select **Dictionary Loader**.
2. Select **Overwrite**.
3. In the **Dictionary File (.zip file containing dictionary data)** field, select the local path to the Dictionary ZIP file.
4. Select the dictionary type. The list is populated based on the Dictionary Type factory codelist.
5. In the **Configuration File** section, upload the JDrug MDB file by browsing the local folders. The MDB file can be uploaded from the local directory.

Once the MDB is loaded, the file is automatically used for the future dictionary type loading.

6. Select the dictionary version from the list. The list is populated based on the existing versions that are already loaded from the self-service.
7. In the **Notification Email Address** field, set the email address you want to receive an update on the load operation status after completion.
8. Click **Overwrite**. The Status section will display the progress of the overwrite process.
9. When the load is complete, download the log.

For more information about the Dictionary Loader window, see [Dictionary Loader field descriptions](#).

Dictionaries management using the Dictionary Management Tool

The Dictionary Management Tool is used to load and update the dictionaries in Argus.

For each dictionary, you need to create a schema with the **Dictionary Management Tool** and then load the dictionary.

Schema Name	Action
MedDRA Schema	To enable MedDRA, create this schema by using the MedDRA Loader option when MedDRA is loaded to the new database tables.
WHO Schema	To enable WHO, create this schema by using the WHO Drug Loader option when WHO is loaded to the new database tables.
J Drug Schema	To enable J Drug, create this schema by using the J Drug Loader option when J Drug is loaded to the new database tables.

For more details, refer to the *Oracle Argus Safety and Oracle Argus Insight Installation Guide > Create Argus Safety Database Schema*.

In this section:

- [MedDRA dictionaries using the Dictionary Management tool](#)
- [WHO Drug dictionaries using the Dictionary Management tool](#)

- [J Drug dictionaries using the Dictionary Management tool](#)

MedDRA dictionaries using the Dictionary Management tool

In this section:

- [Prerequisites](#)
- [Load MedDRA or MedDRA J Dictionary](#)
- [Overwrite an Existing MedDRA or MedDRA J Dictionary](#)
- [Run the Dictionary Management Tool to Recode Events](#)

Prerequisites

- The system where these dictionaries will be installed has a minimum of 50 MB space.
- In order to perform MedDRA recode, an enterprise must have at least one case. An enterprise is eligible for selection only if it has associated cases.
- The system has Oracle client installed, including the following:

```
SQLPLUS (Exe=sqlplus)  
SQL*Loader (Exe=sqlldr)
```

- There is an updated TNSNAMES file and Oracle client to connect to the Oracle Argus Safety database.
- The Dictionary Management Tool is installed.
- An Oracle database instance is available.
- A SYSTEM or DBA user account is created.

Note:

The `smq_list.asc` and `smq_content.asc` files containing SMQ data must be placed in the same folder as the other dictionary files.

Load MedDRA or MedDRA J Dictionary

Use these instructions to load a new MedDRA or MedDRA-J dictionary while not overwriting any MedDRA dictionary versions you may already have loaded.

1. Open the Dictionary Management Tool and click **MedDRA Loader**. The Oracle Database Connect dialog box appears.
2. Enter the SYSTEM or DBA username and password, the database name, and click **OK**. The MedDRA Dictionary Loader dialog box appears.
3. Do the following:
 - To load MedDRA dictionary for the first time, select **Load to New Tables**.
 - To load a MedDRA J dictionary, check **MedDRA J** checkbox.
 - To create a new MedDRA user, click **Create User**, enter the parameters, and click **OK**.
4. In the Dictionary to Load section, do the following:

- a. From the drop-down, select the **MedDRA Version**.
 - b. Click **Browse** and select the dictionary files.
 - c. Select the **MedDRA Browser** checkbox.
 - d. In the Tablespace Information section, select a **table** and an **index** from the drop-downs.
 - e. Click **Load**.
- The system loads the dictionary and a confirmation message appears.
5. Click **OK**.

Overwrite an Existing MedDRA or MedDRA J Dictionary

1. Open the Dictionary Management Tool and click **MedDRA Loader**. The Oracle Database Connect dialog box appears.
2. Enter the SYSTEM user password, the Database name and click **OK**. The MedDRA Dictionary Loader dialog box appears.
3. Do the following:
 - a. Select **Overwrite**.
 - b. To load a MedDRA J dictionary, check the **MedDRA J** checkbox.
 - c. From the **User** drop-down, select a user.
 - d. Enter the user password in the Password field; re-enter it in the Verify Password field.
 - e. From the **Current Version to Overwrite** drop-down, select the version to overwrite.
 - f. From the **MedDRA Version** drop-down, select the MedDRA version to load.
 - g. Click **Browse** and select the dictionary files.
 - h. Check the **MedDRA Browser** checkbox.
 - i. In the Tablespace Information section, select a **table** and an **index** from the drop-downs.
 - j. Click **Load**. The Oracle Database Connect dialog box appears.
4. Click **OK**.

Run the Dictionary Management Tool to Recode Events

1. Open the Dictionary Management Tool, click **MedDRA Loader**.
2. Enter the SYSTEM or DBA user password, the database name, and click **OK**.
3. In the MedDRA Dictionary Loader dialog box, click **Re-Code**.
4. In the Event Re-Coding dialog box, do the following:
 - a. In the Enterprises field, select an enterprise to recode. In order to perform MEDRA recode, an enterprise must have at least one case. An enterprise is eligible for selection only if it has associated cases.

 Note:

If Oracle Argus Safety is setup in Single Tenant Mode, you will only have one option here. If you are setup as a Multi-Tenant Database, you can choose which Enterprises to recode. Multiple enterprises can be selected.

- b. In the **Select the Source MedDRA Version that was used for coding** field, select the existing version of MedDRA that needs to be re-coded.
 - Select a specific version to only recode data coded with that version.
 - Select **All** to recode all existing coded data regardless of the version it is coded with.
- c. Select one of the following options:
 - **Update Data** to recode the Argus events encoded in the selected MedDRA version to the MedDRA version selected in the system configuration in the Common Profile Switch.
 - **View Only** to generate logs that can be used to evaluate the cases and fields that are affected by the recode. When this check box is selected, the **Select the target MedDRA version that will be used to recode in View Only Mode** field is available to allow you to select the target version for which you want to see the logs.
- d. In the Coding Data Update/View Options [Currency determined at LLT Level Only] field, Check one or all of the Process Current Terms, Process Non-Current Terms and/or Update dictionary version check boxes.
- e. In the Output Log File Options, select an output log file option and directory path for the log files.
 - Delimited Text
 - Excel Sheet output
- f. Click the **Execute** button to start the recoding process.
- g. When the system displays the Connect to Database dialog box, enter the Schema Owner name, password, and database. Click **OK**.
 - Enter the schema owner name in the Argus Schema Owner field.
 - Enter the password in the Password field.
 - Enter the database name in the Database field.

WHO Drug dictionaries using the Dictionary Management tool

In this section:

- [Prerequisites](#)
- [Load WHO Drug Dictionary](#)
- [Overwrite an Existing WHO Drug Dictionary](#)
- [Load WHO Drug Dictionary Format C](#)

Prerequisites

- Windows workstation is available to load the WHODrug data.
- The system has Oracle client installed, including the following:

```
SQLPLUS (Exe=sqlplus)
SQL*Loader (Exe=sqlldr)
```

- There is an updated TNSNAMES file and Oracle client to connect to the Oracle Argus Safety database.
- The format of the WHO Drug Dictionary Global data files is Text, and Chinese data files is CSV; and alternate rows are not blank.

Note:

WHODrug is loaded using sql*load with DIRECT=TRUE option. Because of sql*loader restrictions, **no one should have access** to the Oracle Argus Safety system while WHO-DRUG is being loaded.

- To display the WHO Drug Dictionary version in Oracle Argus Safety, the CFG_DICTIONARIES_GLOBAL.VERSION column fetches data from Version.txt file. If Version.txt file is missing during WHO Drug Dictionary load then WHO Drug Dictionary version is displayed based on the value available in CFG_DICTIONARIES.VERSION_NUMBER column only.

Load WHO Drug Dictionary



Note:

By uploading a version of WHODrug Enhanced, WHODrug Global, WHODrug Chinese, or other UMC products, you confirm holding a valid license granted by the UMC for the uploaded UMC product.

1. Open the Dictionary Management Tool and click **Who Drug Loader**.
2. Enter the SYSTEM or DBA user password, the database name, and click **OK**.
3. In the WHO Drug Dictionary Loader dialog box, do the following:
 - a. To load the dictionary into a separate schema, click **Load to New Tables**.
 - b. From the Dictionary Format drop-down, select an option.
 - For English dictionaries, select **Format B** or **Format B3**, or **Format C** or **Format C3**.
For information about format C, go to <http://who-umc.org>.
 - For Chinese dictionaries, select **Format B3 Chinese** or **Format C3 Chinese**.



Note:

- For Dictionary Format, **Format C3**, WHODrug schema will have the table named WHO_DRUG_C3_MASTER and WHO_DRUG_C3_MEDICINAL_PRODUCT, instead of table WHO_DRUG_C_MASTER and WHO_DRUG_C_MEDICINAL_PRODUCT. These table will have the DRUG_NAME as Varchar2 (1500). Besides, this schema will also have views as WHO_DRUG_C_MASTER and WHO_DRUG_C_MEDICINAL_PRODUCT which will point to the tables WHO_DRUG_C3_MASTER and WHO_DRUG_C3_MEDICINAL_PRODUCT but the Drug Name is updated to Varchar2 (250).
- For Dictionary Format, **Format B3**, WHODrug schema will have the table named WHO_B3_DRUG_DICT and WHO_B3_ATC_CODE, instead of table WHO_DRUG_DICT and WHO_ATC_CODE. These table will have the DRUG_NAME as Varchar2 (1500) and ATC_TEXT Varchar2 (110). Besides, this schema will also have views as WHO_DRUG_DICT and WHO_ATC_CODE which will point to the tables WHO_B3_DRUG_DICT and WHO_B3_ATC_CODE but the Drug Name is updated to Varchar2 (250) and Varchar2 (110).

- c. To create new user, click **Create User**. Enter the parameters and click **OK**.

- d. From the drop-down, select the **Dict Version**.
 - e. Click **Browse**, navigate to the dictionary files and click **Select**.
4. Click **Load**.
5. In the Tablespace Information section, select a **table** and an **index** from the drop-downs.
6. When the dictionary is loaded successfully, click **OK**.

Overwrite an Existing WHO Drug Dictionary

1. From the Dictionary Management Tool, click **Who Drug Loader**.
2. Enter the SYSTEM or DBA user password, the database name, and click **OK**.
3. In the WHO Drug Dictionary Loader dialog box, do the following:
 - a. Click **Overwrite**.
 - b. From the **Dictionary Format** drop-down, select an option.
 - c. From the **User** drop-down, select a user.
 - d. Enter the user password in the Password field; re-enter it in the Verify Password field.
 - e. From the **Current Version to Overwrite** drop-down, select the version to overwrite.
 - f. From the drop-down, select the **Dict Version**.
 - g. Click **Browse**, navigate to the dictionary files, and click **Select**.
 - h. In the Tablespace Information section, select a **table** and an **index** from the drop-downs.
 - i. Click **Load**.
 - j. View the WHO Drug Dictionary log file.
4. Click **OK**.

Load WHO Drug Dictionary Format C

For information about format C, go to <http://who-umc.org>.

1. Open the Dictionary Management Tool and click **Who Drug Loader**.
2. Enter the SYSTEM or DBA user password, the database name, and click **OK**.
3. In the WHO Drug Dictionary Loader dialog box, do the following:
 - a. To load the dictionary into a separate schema, click **Load to New Tables**.
 - b. Select Dictionary Format—**Format C** or **Format C3**.

 Note:

- For Dictionary Format, **Format C3**, WHODrug schema will have the table named WHO_DRUG_C3_MASTER and WHO_DRUG_C3_MEDICINAL_PRODUCT, instead of table WHO_DRUG_C_MASTER and WHO_DRUG_C_MEDICINAL_PRODUCT. These table will have the DRUG_NAME as Varchar2 (1500). Besides, this schema will also have views as WHO_DRUG_C_MASTER and WHO_DRUG_C_MEDICINAL_PRODUCT which will point to the tables WHO_DRUG_C3_MASTER and WHO_DRUG_C3_MEDICINAL_PRODUCT but the Drug Name is updated to Varchar2 (250).
- For Dictionary Format, **Format B3**, WHODrug schema will have the table named WHO_B3_DRUG_DICT and WHO_B3_ATC_CODE, instead of table WHO_DRUG_DICT and WHO_ATC_CODE. These table will have the DRUG_NAME as Varchar2 (1500) and ATC_TEXT Varchar2 (110). Besides, this schema will also have views as WHO_DRUG_DICT and WHO_ATC_CODE which will point to the tables WHO_B3_DRUG_DICT and WHO_B3_ATC_CODE but the Drug Name is updated to Varchar2 (250) and Varchar2 (110).

- c. To create new user, click **Create User**. Enter the parameters and click **OK**.
 - d. From the drop-down, select the **Dict Version**.
 - e. Click **Browse**, navigate to the dictionary files and click **Select**.
4. Click **Load**.
 5. In the Tablespace Information section, select a **table** and an **index** from the drop-downs.
 6. When the dictionary is loaded successfully, click **OK**.

J Drug dictionaries using the Dictionary Management tool

In this section:

- [Prerequisites](#)
- [Load J Drug Dictionary](#)
- [Overwrite an Existing J Drug Dictionary](#)

Prerequisites

- The system where these dictionaries will be installed has a minimum of 50 MB space.
- The Dictionary Management Tool is installed.
- An Oracle database instance is available.
- A SYSTEM or DBA user account is created.

Load J Drug Dictionary

The J Drug Dictionary loader in the Dictionary Management Tool now supports loading the English name from the English sub file that is part of J Drug Dictionary.

1. Open the Dictionary Management Tool and click **J Drug Loader**.
2. Enter the SYSTEM or DBA user password, the database name, and click **OK**.
3. In the J Drug Dictionary Loader dialog box, do the following:
 - a. Select **Load to New Tables** if a J-Drug dictionary has not already been loaded.
 - b. To create a new J-Drug user, click **Create User**, enter the parameters, and click **OK**.
4. In the Dictionary to Load section and do the following:
 - a. Select the dictionary version to be loaded from the drop-down.
 - b. Click **Browse**, navigate to the dictionary files and select the files.
5. In the Tablespace Information section, select a **table** and an **index** from the drop-downs.
6. Click **Load**.
7. Click **OK**.

 Note:

Oracle Argus Safety will use and display J Drug data from the latest J drug dictionary which is loaded in the database.

For the example, if JDrug_Aug_2015 dictionary and JDrug_OCT_2015 dictionary are loaded in the database, then Oracle Argus Safety will use data from JDrug_OCT_2015 dictionary.

Overwrite an Existing J Drug Dictionary

1. Open the Dictionary Management Tool and click **J Drug Loader**.
2. Enter the SYSTEM or DBA user password, the database name, and click **OK**.
3. In the J Drug Dictionary Loader dialog box, Loading Options section, do the following:
 - a. Select **Overwrite**.
 - b. Select the user from the **User** drop-down.
 - c. Enter the user password in the Password field; re-enter it in the Verify Password field.
 - d. Select the J Drug dictionary version to load from the **Dictionary Version** drop-down.
 - e. Click **Browse**, navigate to the dictionary files and select the files.
 - f. In the Tablespace Information section, select a **table** and an **index** from the drop-downs.
 - g. Click **Load**.
4. Click **OK**.

About the MedDRA Recoding tool

The below table displays the fields and the database tables affected by the recode activity.

Oracle Argus Safety Database Table	Location in the application
CASE_PAT_HIST	Oracle Argus Safety > Case Form > Patient Tab > Parent Section > Other Relevant History
CASE_EVENT	Oracle Argus Safety > Case Form > Events Tab > Event Information
CASE_PROD_INDICATIONS	Oracle Argus Safety > Case Form > Products > Products Indication
CASE_ASSESS	Oracle Argus Safety > Case Form > Events Tab > Event Assessment > Event PT (Description)/LLT
CASE_DEATH_DETAILS	Oracle Argus Safety > Case Form > Events Tab > Seriousness Criteria > Death Details > Cause of Death & Autopsy Details
CASE_LAB_DATA	Oracle Argus Safety > Case Form > Patient Tab > Lab Data
LM_PRODUCT	Argus Console > Business Configuration > Products and Licenses > Primary Indication
LM_LAB_TEST_TYPES	Argus Console > Code Lists > Lab Test Type
LM_EVENT_GROUP_TERMS	Argus Console > Code Lists > Event group terms
CASE_VACC_PRIOR_AE	Oracle Argus Safety > Case Form > Products > Vaccine prior adverse event
LM_ALWAYS_SERIOUS_TERM	Argus Console > Code Lists > Always Serious Term List
LM_LABELED_TERM	Argus Console > Business Configuration > Products and Licenses > Datasheet

For more information, see:

- [Recode MedDRA terms at the Enterprise level](#)
- [Logic to Recode MedDRA](#)

Recode MedDRA terms at the Enterprise level

For multi-tenant environment, the Dictionary Management Tool allows recoding of MedDRA terms at the Enterprise level.

The MedDRA Recoding tool displays an additional multi-select list of all active Enterprises. This lists all active Enterprise Short Names in the alphabetical order.

As per the recoding logic, cases are also re-coded to the MedDRA version that is configured in Console.

The MedDRA recoding tool only re-codes the items that match the selected Enterprises and values selected in the **Select the Source MedDRA version that was used for coding** list.

Logic to Recode MedDRA

1. Get the Lower Level Term (LLT).

For a case or LM data, if LLT (J) is different from the LLT (E), and either of them is moved to a different PT group in new MedDRA version, then the MedDRA Recode tool resolves the conflict by replacing LLT(J) with LLT(E) and recode as per the new MedDRA dictionary.

2. Check LLT_Code column in the MEDDRA_PREF_TERM_LLTT table to see if LLT is not current (LLT_CURRENCY = N).

Decisions:

- If LLT cannot be found in MEDDRA_PREF_TERM_LLT then record as exception to be noted in LOG file.
 - If for a record LLT(J) term is non-current as per the new upgrading MedDRA Dictionary but LLT(E) is current, then MedDRA recode only refreshes the hierarchy of both LLT(E) and LLT(J).
Note that for the records for which hierarchy is refreshed, the LLT Term's **text** and **currency** is also be refreshed based on the respective LLT codes.
If for a record, LLT(E) becomes non-current, then the MedDRA recode tool when recoded with the MedDRA J dictionary, replaces LLT(E) and LLT(J) with the PT code and recode if the **Process Non-Current Terms** checkbox is checked.
 - If LLT is current then keep LLT as it is.
 - If a current LLT can be found in previous step then continue with next step else go to 1 and select the next set of Terms.
3. Based on the LLT, get the Preferred Term (PT_CODE) from MEDDRA_PREF_TERM_LLT. Get the rest of the hierarchy from MEDDRA_MD_HIERARCHY, based on PT_CODE and PRIMARY_SOC_FG = 'Y'.
 4. Match all 5 levels of Code and Description and update the data, if required.
 5. Populate the following columns:
 - DICT_ID = Current MedDRA Dictionary ID, present under Case Form Configuration.
 - CODE_STATUS = 1 (displaying that this set of terms has been encoded).
 6. When you create an Event Group by selecting a term at PT level, and that event group is attached to a datasheet, the hierarchy stored in the datasheet is based on the Primary SOC flag, which is always current.

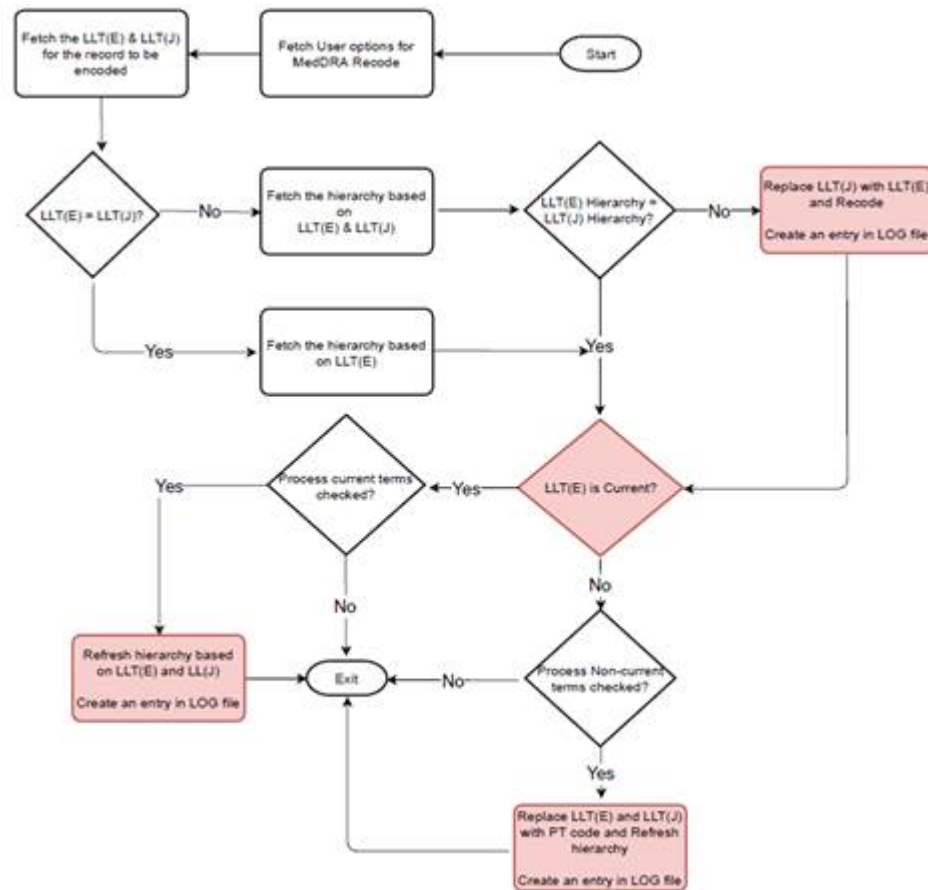
In the LM_LABELED_TERMS table:

- If only the English hierarchy is populated, then the application fetches data for the Japanese hierarchy based on the English hierarchy populated, and performs recoding based on the new MedDRA dictionary.
- If only the Japanese hierarchy is populated, then the application uses the PT code to populate the English hierarchy, and performs recoding based on the new MedDRA dictionary.
- If neither the English hierarchy, nor the Japanese hierarchy are populated in the table but the PT code or term is populated, then the application uses the PT code or term to populate both the English hierarchy and the Japanese hierarchy, and performs recoding based on the new MedDRA dictionary.

For case or LM data, if LLT(J) is different from LLT(E), and either of them is moved to a different PT group in the new MedDRA version, then the MedDRA Recode tool resolves the conflict by replacing LLT(J) with LLT(E), and recoding based on the new MedDRA dictionary.

For case or LM data, if MedDRA terms are coded with the English dictionary, then during MedDRA Recode, the Japanese hierarchy is populated based on the English hierarchy for both the case and LM data variables.

7. If you execute the MedDRA Recode with English MedDRA the preferences for executing will be limited as explained in the function flow for re-coding with J MedDRA.



See also:

- [About the MedDRA recode logs](#)

About the MedDRA recode logs

The MedDRA Recoding tool displays the following options for each case with the existing data elements after the case number in the XLS export or tab delimited file:

- Current Workflow State
- Current Workflow Group

These options are available for the end user logs.

The following log files are created with detailed old and new values:

Log filename	Scenario	Message
(Case Form) - MedDRA_Recode_Success_YYYY_M M_DD_HH_MIN	When LLT(E) is Non- Current	LLT(E) is non-current in target MedDRA dictionary: LLT(E) and LLT(J) replaced with PT
(LM Data) - MedDRA_Recode_Success_LM_YYYY _MM_DD_HH_MIN		

Log filename	Scenario	Message
(Case Form) - MedDRA_Recode_Success_YYYY_M M_DD_HH_MIN	When LLT(E) and LLT(J) not under same hierarchy	LLT(E) and LLT(J) not under same hierarchy in target MedDRA dictionary: LLT(J) replaced with LLT(E)
(LM Data) - MedDRA_Recode_Success_LM_YYYY _MM_DD_HH_MIN		
(Case Form) - MedDRA_Recode_Success_YYYY_M M_DD_HH_MIN	When LLT(E) is Non- Current and LLT(E) and LLT(J) not under same hierarchy in target MedDRA Dictionary	LLT(E) and LLT(J) not under same hierarchy in target MedDRA dictionary: LLT(J) replaced with LLT(E). LLT(E) is non-current in target MedDRA dictionary: LLT(E) and LLT(J) replaced with PT
(LM Data) MedDRA_Recode_Success_LM_YYYY _MM_DD_HH_MIN		

The log files have meaningful header information to reflect the selections made on the recode screen during execution. The following is the log file header format that appears in each recode log irrespective of the log file format:

Field	Description
Database Name	Displays the database name.
User Name	- For self service, displays the Argus user name of the user who initiated the MedDRA recode.. - For Dictionary Management Client/Server tool, displays SYSTEM.
Recode Mode	Displays the recode mode as View Only or Update as per your selection.
Enterprise(s)	Displays the Enterprise Short Name separated by comma in a multi-tenant environment, when multiple enterprises are selected.
Source MedDRA Version	Displays the source dictionary version selected in the Select the Source MedDRA Version that was used for coding drop down.
Target MedDRA Version	- For view-only mode, displays the target dictionary version selected in the Select the target MedDRA version that will be used to recode in View Only Mode drop down. - For update mode, displays the target dictionary version in the common profile switch. If recode is done for multiple enterprises, then populates the target dictionary version corresponding to the enterprise. For example, Ent1: MedDRA J Brows V24.1J, Ent2: MedDRA J Brows V25.1J.
Process Current Terms	Displays the current terms, if this option was checked.
Process Non-Current Terms	Displays the non-process current terms, if this option was selected.
Update dictionary version for coded terms where existing hierarchy is still current	Displays whether the dictionary version was updated for coded terms where existing hierarchy is still current.

About J Drug dictionaries

J Drug dictionaries contain the drugs details approved in Japan.

J drug is released by the maintenance organization of the Iyakuhinmei Data File (IDF). Delta update is basically released once a month and the whole dictionary is updated twice a year in April and October.



Note:

J-Drug Dictionary distributor organization (MT Kyogikai) is a different organization from Oracle thus there is a possibility that their specifications or procedures may change in future as per their own discretion.

The dictionary distribution organization name and contact are:

- Organization Name: MT Kyogikai
- Contact Information:
- URL: <http://www.iyaku.info/>
- TEL: +81-3-3230-2867
- FAX: +81-3-3239-3954
- e-mail: mtk@iyaku.info

In this section:

- [Create and Modify Required File](#)

Create and Modify Required File

J drug loader loads the following files using Dictionary Management Tool:

- `All_Data.txt`
- `formulationcode.txt`
- `drugnameenglish.txt`

All the files must be present to load the dictionary, and the file names must be same as mentioned above.

For more information, see:

- [Create All_Data.txt file](#)
- [Create formulationcode.txt file](#)
- [Create drugnameenglish.txt file](#)
- [Modify the.mdb file](#)

Create All_Data.txt file

Copy the **全件.txt** file received from MT Kyogikai to `All_Data.txt` without character code conversion. This file must be a file which contains all the drug data records. A file that contains only the delta (difference from the previous release) must not be used for `All_Data.txt`.

Sample `All_Data.txt` files:

```
"1114700","","6","外","","麻酔用エーテル","マスイヨエテル","麻酔用エーテル",
"マスイヨエテル","","","35000000000000000000","0","0000060","B","9705","3"
```

```
"1115F01","","4","注","","チアミラールナトリウム！","チミラールナトリウム]",
"チアミラールナトリウム！","1115403","","","31000000000000000000",
"0","0000080","C","9201","3"
```

Create formulationcode.txt file

The file `formulationcode.txt` is a text file containing the drug formulation code information. You need to create this text file on your own. The drug formulation information is provided from MT Kyogikai on a document titled *Drug Name Data File and English Name Sub File Summary*. The formulation code list section provides the contents of the `formulationcode.txt` file.



Note:

This file is not required when you upload a J Drug from Argus Console.

Format of the file `formulationcode.txt`:

- Physical file name: `formulationcode.txt`
- File format: CSV (Comma Separated Value) with 4 fields.
- Character Code: Shift-JIS code. (This file contains Kanji.)
- Field Information:

Field#1: Route of Administration --either of 1,4,6,8
(For example, 1=内用薬, 4=注射薬, 6=外用薬, 8=歯科用薬剤)

Field#2: Code --00, 10, 11, etc.

Field#3: Formulation name (Japanese)
(For example, 内服薬, 散剤, 末, etc.)

Field#4: Formulation name (English)
(For example, medicine, Powders, <null>, etc.)

Sample `formulationcode.txt`:

```
1,10,散劑,Powders
1,11,末,
1,12,散,
1,13,細粒,Fine granules
...
8,46,噴霧劑,Spray
8,47,パスタ剤,
8,50,貼付剤,Attach
8,70,注射剤,Injection
```

The complete `formulationcode.txt` file as of Feb.2011 is available at:

<https://support.oracle.com/epmos/main/downloadattachmentprocessor?parent=DOCUMENT&sourceId=1293240.1&attachid=1293240.1:formulationcode&clickstream=yes>

Create `drugnameenglish.txt` file

Copy the 英名.txt file received from MT Kyogikai and rename the file to `drugnameenglish.txt`. This file is added in order to support English Names in J dictionary.

Sample `drugnameenglish.txt`:

```
"0000040","111270001","FLUOTHANE","","","","",""
"0000060","1114700","ANESTHETIC ETHER","1","","","1010","B"
"0000080","1115F01","THIAMYLAL SODIUM","1","","","9806","C"
```

Modify the `.mdb` file

The current `.mdb` file shows only a single drop-down value for the release version on the J-drug dictionary loader. Modify this file to use the latest version of the dictionary.

1. Open the `jdrug.mdb` from the following location:

`disk:\Program Files\Oracle\Argus\DBInstaller`

A table appears with J_Drug table supported versions (second column).

2. To add a new version, modify the MedDRA Version column.

For example, if 2015-OCT is the last version added, add 2015-DEC, (note that you must append a comma).

Tables	ID	MeddraVersion	MeddraTableName
J_DRUG	150	,2007-APR,2012-APR,2014-APR,2014-AUG,2014-OCT,2015-APR,2015-OCT,2015-DEC	JPN_DRUG_DICT
J_DRUG_Constraint	151	,2007-APR,2012-APR,2014-APR,2014-AUG,2014-OCT,2015-APR,2015-OCT,	JPN_FORMULATION_CODE_LIST
J_DRUG_Ctl	231	,2007-APR,2012-APR,2014-APR,2014-AUG,2014-OCT,2015-APR,2015-OCT,	JPN_DRUG_DICT_ENG_SUB
J_DRUG_Index			
J_DRUG_Sqls			
J_DRUG_Versions			
MeddraBrowsersSql			
SQLloaderInfo			
WHO_B2_AFTER_LOAD			
	*	(New)	

- Similarly, modify other rows and tables wherever the previous version number exists.

Frequently asked questions

This chapter contains the most frequently asked questions about managing the dictionaries using the Console self-service options:

- [What are the prerequisites to load a dictionary?](#)
- [What are the mandatory files required to be zipped for a successful load?](#)
- [Are there any size restrictions for the dictionary files?](#)
- [Can I upload ZIP files from a remote or shared location?](#)
- [Why are the files zipped?](#)
- [Can I reuse the dictionary files?](#)
- [What is the MDB file?](#)
- [Does each dictionary type need a separate MDB file?](#)
- [From where can I get the MDB files for each dictionary?](#)
- [Do I need to upload the MDB file every load?](#)
- [When do I need to upgrade the MDB file?](#)
- [How do I know if my load is successful?](#)
- [What do I do if the dictionary loading process hangs?](#)
- [How can I load a dictionary in a multi-tenant environment?](#)
- [Can I work on cases or do other activities in Argus when loading a dictionary?](#)
- [Can I upload the same dictionary twice?](#)
- [Where is the dictionary files content stored?](#)
- [In which tablespace is the dictionary schema created? Can it be changed?](#)
- [How do I select the latest loaded dictionary for case coding?](#)
- [Is there a required downtime for MedDRA recode?](#)
- [What are the prerequisites for MedDRA recode?](#)
- [Why is the Update dictionary version for coded terms where existing hierarchy is still current field disabled when View Only is selected?](#)
- [How do I know if the recode is successfully completed?](#)
- [Can older recode logs be downloaded in self-service?](#)

What are the prerequisites to load a dictionary?

The prerequisites to load a dictionary are:

- Locally saved and zipped dictionary files
- Available MDB file
- A user with Dictionary Loader access
- Running the RelsysWindowsService.exe back-end service. For more information, refer to *Argus Safety Installation Guide*.

**Note:**

The application does not need to be restarted after loading and there is not a required downtime.

What are the mandatory files required to be zipped for a successful load?

The files that can be zipped are:

Dictionary type	Mandatory files (in ZIP) for a successful loading
MedDRA	soc.asc mdhier.asc lft.asc soc_hlgt.asc hlgt_hlt.asc pt.asc hlt.asc hlgt.asc hlt_pt.asc intl_ord.asc smq_list.asc smq_content.asc meddra_release.asc
JDrug	All_Data.txt drugnameenglish.txt

Dictionary type	Mandatory files (in ZIP) for a successful loading
WHODrug C and C3 Format	ATC.txt CCode.txt ING.txt MP.txt ORG.txt PF.txt PP.txt PRG.txt PRT.txt SRCE.txt SUN.txt ThG.txt UNIT.txt UNIT-L.txt UNIT-X.txt STR.txt Version.txt
WHODrug B2 and B3 Format	bna.txt ccode.txt ddsources.txt man.txt ing.txt ina.txt dda.txt dd.txt Version.txt

Are there any size restrictions for the dictionary files?

No, there aren't. All standard dictionary files are supported without restriction.

Can I upload ZIP files from a remote or shared location?

No, you can't. The dictionary files must be available in ZIP format on the user's local desktop machine.

Why are the files zipped?

The files are zipped because they are stored in the database, extracted and then loaded.

Can I reuse the dictionary files?

Yes, you can. The locally saved ZIP file can be used to load into different instances.

What is the MDB file?

The MDB file is a configuration file that is used to load the dictionary file contents into the Oracle Argus database. It also contains the version number list.

Does each dictionary type need a separate MDB file?

Yes, the following MDB files need to be used for the corresponding dictionary type:

- MedDRA MDB for MedDRA and MedDRA J
- JDrug MDB for JDrug
- WHODrug MDB for WHODrug and WHODrug Chinese

From where can I get the MDB files for each dictionary?

The MDB files are available in the directory: <Argus Installation path>\Oracle Argus\DBInstaller.



Note:

Periodically, Oracle releases MDB files with the newer versions and you can contact the Oracle Customer Support to get them.

Do I need to upload the MDB file every load?

No, you don't. You need to upload only the first time. Then, the MDB file is autopopulated based on the dictionary type.

When do I need to upgrade the MDB file?

You need to upgrade the MDB file when the expected version number does not appear in the dictionary version list.

How do I know if my load is successful?

You can download the logs, check the email status or the Status section on the Dictionary Loader window. Moreover, the new dictionary appears in the Common Profile Switches.

What do I do if the dictionary loading process hangs?

You need to extract the logs and raise a ticket on Oracle Customer Support.

How can I load a dictionary in a multi-tenant environment?

The dictionary loading is done using a default enterprise user and it is available across all the enterprises after one load.

Can I work on cases or do other activities in Argus when loading a dictionary?

Yes, you can. The load process is asynchronous and even if you log out, the loading process continues. Only the recoding activity cannot be performed when the dictionary is loading.

Can I upload the same dictionary twice?

No, you can't. A dictionary can be loaded only once. The Overwrite option can be used if the same dictionary needs to be modified.

Where is the dictionary files content stored?

The dictionary files are stored in a new automatically created schema. The password is randomly and automatically created, as well. The Argus_app user is automatically granted access to the new schema.

In which tablespace is the dictionary schema created? Can it be changed?

The tablespace details can be found in Argus Safety Windows Service bin folder, Service.config and they can be changed.

How do I select the latest loaded dictionary for case coding?

To select the latest loaded dictionary for case coding, navigate to Argus Console > System Configuration > System Management (Common Profile Switches) and select the new dictionary.

Is there a required downtime for MedDRA recode?

Yes, there is. The MedDRA recode process is a performance intensive activity and requires a downtime. The application is put in the System down for Maintenance mode. For more information, see [Configuring System Maintenance](#).

What are the prerequisites for MedDRA recode?

To recode the MedDRA dictionaries in Update Mode, set **Maintenance Mode** to **System down for Maintenance**. For more information, see [Prerequisites](#) and [Configuring System Maintenance](#).

The target dictionary should also be selected in Common Profile Switch.

Why is the Update dictionary version for coded terms where existing hierarchy is still current field disabled when View Only is selected?

The Update dictionary version for coded terms where existing hierarchy is still current field is by default available only when the Update check box is selected because this option updates the dictionary version for the terms that do not need recoding.

How do I know if the recode is successfully completed?

Once the recode process is completed, the Status section displays information on the recode, including the date and time. The latest recode log is also available for download to see the recode status, but the logs are not automatically saved. For more information on logs, see [About the log file generation](#).

Can older recode logs be downloaded in self-service?

No, they can't. Only the latest recode logs are available and can be downloaded by clicking the **Generate Log Files For Last Execution** button.

5

System Configuration

This chapter provides information about configuring the system as described in the following table:

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 Properties	This screen enables the administrator to configure field properties.
Local Affiliate 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 Configuration	This screen enables the administrator to configure SMTP for e-mails.
Enabled modules	This screen enables the administrator to segregate modules per enterprise.
Interchange Mapping	This screen enables the administrator to access the Interchange Mapping Utility in the Argus Console.

For more information, see:

- [Configuring Case Priority](#)
- [Configuring Field Validations](#)
- [Configuring System Management - Common Profile Switches](#)
- [Configuring Workflow](#)
- [Configuring System Numbering](#)
- [Configuring SMTP](#)
- [Configuring Field Properties](#)
- [Configuring Local Data Entry](#)
- [Enabling Argus Modules](#)
- [Configuring Interchange](#)
- [Configuring Message Profile for Interchange](#)
- [Configuring Argus Bridge for document management](#)
- [Configuring Translation Service](#)

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.

Priority	Serious	Case Assessment Unlisted	Causal	Other	First Report Due Date Due Soon	# Warning days	Advanced Conditions
☐ 1.	Yes	Yes	Yes	☐	☐		(None)
☐ 2.	Yes	Yes	Yes	☐	☐		(None)
☐ 3.	Yes	Yes	Yes	☐	☐		(None)
☐ 4.	Yes	Yes	Yes	☐	☐		(None)
☐ 5.	Yes	Yes	Yes	☐	☐		(None)
☐ 6.	Yes	Yes	Yes	☐	☐		(None)
☐ 7.	Yes	Yes	Yes	☐	☐		(None)

☒ Run all Case Priority Determination on Middle Tier

For more information, see:

- [Field Descriptions](#)

Field Descriptions

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

Field or Control Name	Description
Priority	Enables you to select the priority level whose criterion is to be configured. You 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 you 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 you 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.

Field or Control Name	Description
Case Assessment - Causal	Enables you 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 you 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 you 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 you 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 you to select an existing advance condition from the drop-down list.
AC Button	Enables you to create a new advanced condition set or modify an existing one.
Run All Case Priority Determination on Middle Tier	Enables you 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, Oracle 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:YYYYReason: 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.

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.

For more information, see:

- [Field Descriptions](#)

- [Modifying Field Validations](#)

Field Descriptions

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

Field or Control Name	Description
Field	Displays the name of the field.
Condition for Warning	Displays the advanced condition for warning.
Condition for Mandatory Exceptions	Displays the advanced condition for mandatory exceptions.
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 for Warning and Condition for Mandatory 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 Oracle Argus Safety Case Form unless IIS is reset.

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 Oracle Argus Web / Report Servers must be reset, in order to reflect the changes made in the 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 Dossier	Report Configuration	The Oracle Argus Dossier screen enables you to modify the customizable fields of Argus Dossier.

Section	Sub Section	Description
Argus Insight	—	If Oracle Argus Enterprise products are enabled, the Oracle Argus Insight URL can be provided here.
Argus J	E2B Reporting Device Report Responsible Officer	The Argus J Configuration screen enables you to modify the customizable fields on the Argus J form.
Argus Mart	—	If Argus Enterprise products are enabled, Oracle Argus Mart related settings can be configured here.
Background Services	—	This screen enables you to configure the Common Profile Switches that affect the behavior of Background Services.
Case Form Configuration	—	This screen enables you to configure Common Profile Switches that affect the behavior of the Oracle Argus application
Case Processing	Assessments Always Show Literature Data Auto Archiving Case Numbering Dictionary Browser Enable Local Unlocking Group Data Access Lot Number Processing Performance	This section enables you to configure the case processing fields and items.
Database	—	The database related parameters can be maintained here. Calculation functions for Case Seriousness, Listedness and Causality calculation.
Help	—	Centralized Online Help URL.
Local Labeling	LAM	The Local Labeling Configuration screen enables you to modify the options available through local labeling.
Network Settings	—	The Network Settings screen enables you to modify the settings on the Argus Safety Load Balancer Server, Argus Safety API Load Balancer URL, and Proxy.

Section	Sub Section	Description
Reporting	BIP Reporting	The Reporting Configuration screen enables you to modify the options available for reporting.
	E2B	
	eMDR	
	eVAERS	
	Expedited	
	Expedited - BfArM	
	Expedited - Canada	
	Expedited - CIOMS	
	Expedited - MedWatch	
	MedWatch Configuration	
	Periodic	
	Scheduling	
Security	Cryptography LDAP	The Security Configuration screen enables you to modify the options available for security.
Session Timeout	Session expiration time in minutes	The maximum idle time allowed for a user's session. Valid range for this value is 5-1440. Default value is 30 min. Note that long running processes like CDA are controlled through the table CMN_URL_ACCESS_GLOBAL where user can specify a timeout value local to that process. Further, the user would need to set the process as IS_LONG_RUNNING = 1. By default, the following are categorized as long running: '/REPORTS/CIOMSII/CIOMS2_SAVING.ASP' '/AUDITLOG/AUDITLOGLIST.ASP'; '/REPORTS/CDA/CDAGENERATE.ASP';
Single Sign-On	—	The Single Sign-On screen enables you to modify the options available for Single Sign-On such as enabling or disabling it, its HTTP Header, Logout URL, and using Oracle Access Server SDK for LDAP Validation. Note that in a SSO configured environment, for the SSO to take effect, the session timeout value should be set to maximum value.
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.

For more information, see:

- [Configuring Advanced Conditions](#)
- [Configuring Background Services](#)

- [Configuring Case Form \(System Management\)](#)
- [Configuring Case Processing](#)
- [Configuring Database](#)
- [Configuring Assessments](#)
- [Configuring Auto Archiving](#)
- [Configuring Case Numbering](#)
- [Configuring Lot Number](#)
- [Configuring Dictionary Browser](#)
- [Configuring Group Data Access](#)
- [Configuring WHO Drug](#)
- [Configuring Performance](#)
- [Configuring Local Labeling](#)
- [Configuring Network Settings](#)
- [Configuring User Interface](#)
- [Configuring Reporting](#)
- [Configuring Security](#)
- [Configuring Single Sign-On](#)
- [Configuring System Maintenance](#)
- [Configuring 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 or Control Name	Description
Number of rows to display per page on the Advanced Condition Search screen	Enables you to specify the number of rows to be displayed on the Advanced Condition search screen.

Field or Control Name	Description
Comma separated list of allowable parameters for custom advanced conditions	This feature allows the Advanced conditions to store and execute customer SQLs containing bind variables through the UI. The application supports the bind variables defined in a comma separated format. The bind variables defined here are case insensitive. This switch supports a maximum length of 1000 characters. In OOTB configuration, the following bind variables are supported: • P_CASE_ID • P_SEQ_NUM • P_REG_RPT_ID • P_REG_REPORT_ID • P_REPORT_FORM_ID

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 Background Services

This screen enables you to configure the common profile switches that affect the behavior of Background Services. Background Services are available only as the Default Enterprise user.

To view the list of field names associated with the Background Services section, click the **Background Services** folder in the left panel. The field names associated with the Background Services appear in the right panel.

Field Descriptions

The following table lists the fields available under Background Services:

Field or Control Name	Description
Number of cases to be processed by single Report Scheduling AG Process	Enter the number of cases that can be processed by a single instance of the Report Scheduling AG Process. The range of allowed values is 0-999. The default value is 50.
Number of cases to be processed by single Scheduling Check AG Process	Enter the number of cases that can be processed by a single instance of the Scheduling Check AG Process. The range of allowed values is 0-999. The default value is 100.
Number of reports to be processed by a single Auto Accept AG Process	Enter the number of reports that are processed for a single cycle for a single AG Process. The range of allowed values is 1-999. The default value is 10.
Number of retries to be done for an unsuccessful report to be picked for reprocessing by Auto Accept AG Process	If a report has not processed successfully, the application retries to process it before marking the report as a failure. Enter the number of times retry can be attempted. The range of allowed values is 1-999. The default value is 3.

Field or Control Name	Description
Number of minutes to wait for a unsuccessful report to be picked for reprocessing by Auto Accept AG Process	Enter the time interval for reprocessing of the report. The range of allowed values is 1-999. The default value is 60.

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.

Coding Web Service

The Case Processing Dictionary Browser common profile switches are segregated by enterprises to allow different configurations for different enterprises. However, the URL and

other configuration for WHO Drug and MedDRA web services remain in configuration XML on the Web Servers as per existing design and hence remain common across all enterprises.

In a multi-tenant installation, if the provider chooses to operate using Coding via web service, they should use the same web service across all enterprises.

Auto Encoding, Dictionary and 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 or Control Name	Description
Central Coding	You can independently turn On/Off Centralized Coding for individual enterprises from the Argus Console - System Management > Case Form Configuration by marking the checkbox next to the Events & Indications MedDRA dictionary version drop-down list. The enterprise can use its own MedDRA version using the Argus Console > System Management > Case Form Configuration > Centralized Coding > Centralized Coding Configuration.
Drugs	The Drugs dictionary list enables you to select 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.
Drugs(Chinese)	The Drugs(Chinese) dictionary list enables you to select the WHO Drug Chinese dictionary names only, and not WHO Drug Global dictionary names. By default, this drop-down list is blank.
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 or Control Name	Description
Auto Regulatory Scheduling	This enables the user to configure the manner in which Oracle Argus Safety handles the Auto-scheduling of Regulatory Reports. The available options are: • None • Always • Significant • Manual When the common profile switch is set to <i>Always</i>, the system does not wait for a lock to schedule reports, it tries to auto-schedule each time user the saves the case. However, the only criteria to run auto-scheduling algorithm is that the case must have product, event and event assessment.
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. Aware date and Due date of a scheduled report can be overwritten or retained with original dates based on the internal common profile switch "Scheduled Report Update". If Scheduled Report Update is set to Update to current aware date and new due date, the current Aware date is used and due date is updated based on the current aware date while overwriting a scheduled report. If Scheduled Report Update is set to Keep original aware date and due date the aware date/due date are not updated based on current aware date while overwriting a scheduled report. If the common profile switch Report Generation is set to Create as Follow-up then, system allows generation of follow-up reports irrespective of submission status of previously scheduled reports based on the settings made to the common profile switch Allow Report Generation.
Case Locking for Report	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.

Field or Control Name	Description
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 of Autonarrative	Selecting the Preventing Modification of Autonarrative check box will prevent users from modifying autonarratives.
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 the 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 the 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 Autonarrative 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 Autonarrative 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 or 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.

Custom Routines

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

Field or 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.

Field or Control Name	Description
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.
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.

Modify Data Lock Point

☒ **Enable Data Lock Point**
Data Lock Point Revision
☐ Use Last Completed Version
☒ Use Next Completed version (Includes Data Cleaning)

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

Field or 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.

Field or Control Name	Description
Use Next Completed Version (Includes Data Cleaning)	Enables you to use the next completed version that includes data cleaning.
Run Expedited and E2B Reports on DLP	Enables you to execute expedited and E2B reports on DLP database and these reports are scheduled on a previous aware date.

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



Note:

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 Always Show Literature Data
- Configuring Auto Archiving
- Configuring Case Numbering
- Configuring Dictionary Browser
- Configuring Duplicate Search
- Configuring Group Data Access
- Configuring Lot Number Processing
- Configuring Performance

Field Descriptions

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

Field or Control Name	Description
Create follow-up on unblinding	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

Field or Control Name	Description
Events to Display on Assessment Tab	The available options are: • Event Assessment will display all Events • Event Assessment will display Diagnosis Events only
Enable Local Unlocking	Provides a system level control permitting local users to locally unlock a case and make any corrections to the previously entered local data. Enables you to select whether to locally unlock a case or not. The available options are: • Yes • No
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.
Valid Attachment File Types	Allows users to attach files in Case Form with the file types mentioned in this parameter.

Field or Control Name	Description
SQL to prevent case unlock when reports are pending generation	Allows customization to prevent users from unlocking the case from Case Form, E2B, and LAM if there were reports pending generation. You can configure this behavior by adding a SQL or database function in the given text field. If the value returned is greater than 0, then the system shall behave as described below: If the Value of Allow forced unlock (Global and Local) is Yes, Report Status (Global or Local) is Pending (i.e. the value from SQL check returned > 0), a warning message is displayed. The case is unlocked using the existing "Locked Case" dialog if user selects "Yes" on the warning message. This means that the pending global reports will not be generated on unlock and may be overwritten or removed depending on case data on the subsequent global lock. If the Value of Allow forced unlock (Global and Local) is No, Report Status (Global or Local) is Pending (i.e. the value from SQL check returned > 0), the case is not unlocked and an error message is displayed. If the Value of Allow forced unlock (Global and Local) is N/A, Report Status (Global or Local) is Generated /Submitted (i.e. the value from SQL check returned 0 or no SQL has been configured), the case is not unlocked. If the value returned is 0 or no SQL has been configured, the system shall allow users to global unlock the case without any of the other checks. The default for this configuration will stop the users from unlocking the case if there are scheduled reports pending generation. DLP_EXPEDITED_E2B_REPORTS is set to 0 (i.e., DLP is not enabled for Expedited Reporting feedback). The checks for reports pending generation are applicable only when the parameter Run Expedited and E2B Reports on DLP is unchecked (i.e., DLP is not enabled for Expedited Reporting). Make sure that the name that is being used for the bind parameter is P_CASE_ID.

Field or Control Name	Description
Generate auto-narrative for the other language without user confirmation	This common profile switch helps to suppress user confirmation during generation of auto-narrative for the other language while the user performs the operation in the English side or Japanese side. Click Yes to generate or No (default) to not generate the auto-narrative. If auto-narrative is being performed prior to global lock: If a user is performing the auto-narrative from the Japanese side of the case form and if the auto-narrative template has any other language other than Japanese configured, and if the new common profile switch "Generate auto-narrative for the other language without user confirmation" is set to "No", the system shall first prompt the user if they wanted to generate the English and other language narratives as well. The system shall proceed with all the non-Japanese language narrative generation steps only if the user chose Yes to this dialog (note that existing generation steps and prompts still hold good) or if the new common profile switch "Generate auto-narrative for the other language without user confirmation" is set to "Yes. If they chose No to the user prompt, the system shall proceed with only Japanese narrative generation (note that existing generation steps and prompts still holds true). If they chose Cancel, the system shall not proceed with auto-narrative generation for any language. If a user is performing the auto-narrative from the English side of the case form and if the chosen Narrative template has Japanese language configured, and if the new common profile switch "Generate auto-narrative for the other language without user confirmation" is set to "No", the system shall first prompt the user if they wanted to generate the Japanese narrative as well. The system shall proceed with the Japanese language narrative generation steps only if the user chose Yes to this dialog (note that existing generation steps and prompts still hold good)) or if the new common profile switch "Generate auto-narrative for the other language without user confirmation" is set to "Yes". If they chose No to the user prompt, the system shall proceed with only the non-Japanese (English and all other languages except Japanese) narrative generation (note that existing generation steps and prompts still holds true). Note that the prompt shall not display if Japanese language was not configured in the template. If they chose Cancel, the system shall not proceed with auto-narrative generation for any language.
Truly Local Case (Note: Bind variable :P_CASE_ID must be used in SQL)	Provides a system level control allowing customers to define SQL or PL/SQL block or specify database function to test if a case with suspect Local (Japanese) License product is a Local PRPT case. This field is a multi-line text fields with a limit of up to 1000 characters. It is partitioned by enterprises for multi-tenant customers. The SQL or PL/SQL block or the database function shall accept a bind variable :P_CASE_ID representing the case from which this switch is being invoked. If the value returned from the configured SQL or PL/SQL block or the database function is > 0, the system shall consider the case with suspect products having local (Japanese) license as a Local PRPT case. If the value returned is 0, the system shall not consider the case a Local PRPT case (unless there is already a local report pending generation i.e., Scheduled or New data available report states). If there is no SQL or PL/SQL block or database function configured in this switch, the system shall consider that the switch returns a default value of 1. The system does not allow illegal data manipulations (e.g., UPDATE/INSERT/DELETE statements) to the underlying Argus schema via this switch. This switch is also used to determine if a report is a Local report.
Always show Literature Data section on Case Form	When configured to Yes, the application always displays the literature section in the Case Form and Book-in. Default: 0

Field or Control Name	Description
Enable Smart Duplicate Search	This common profile switch enables smart duplicate search. By default, it is set to Yes. Any changes made to this switch have the same impact on all the enterprises.
Threshold to display matching records having score of	This configuration option is an Enterprise-level score threshold displayed under the Smart Duplicate Search - Configuration section. By default, the record level score threshold is set to 50. When set, the system displays only records that have the matching score more than or equal to the value set. You can only input values between 0 and 99 in this field. If you enter a value greater than 99, the following error message is displayed: Enter a value between 0 and 99 for Score Threshold. If the Enable Smart Duplicate Search option is disabled, then this option is also disabled. The record level threshold option applies to the following windows: • Initial Case Entry • ICSR Pending • Local Affiliate Incoming Review
Maximum number of duplicate search records to be displayed	This configuration option is an Enterprise-level score threshold displayed under the Smart Duplicate Search - Configuration section. By default, the maximum number of records score threshold is set to 100. When set, the system displays only records that have the matching score more than or equal to the value set. You can only input values between 0 and 1000 in this field. If you enter a value greater than 1000, the following error message is displayed: Enter a value between 0 and 1000 for Score Threshold. If the Enable Smart Duplicate Search option is disabled, then this option is also disabled. The maximum number of records threshold option applies to the following windows: • Initial Case Entry • ICSR Pending • Local Affiliate Incoming Review

Backend configuration for Smart Duplicate Search

Control name	Description
Elimination Criteria	You can set the <code>DET_COLUMN</code> column value as Null for the <code>DUP_SEARCH_DATA_ZONES</code> table, where the <code>ZONE_NAME</code> element can be set to <code>CM_COUNTRY_ID</code>, <code>CM_RPT_TYPE_ID</code> or <code>CPI_PAT_GENDER_ID</code> to turn off elimination criteria for the following fields: • Country of Incidence • Report Type • Patient Gender
Weights	You can update the <code>Weight</code> column value to a valid integer value between one and ten for the corresponding <code>ZONE_NAME</code> element in the <code>DUP_SEARCH_DATA_ZONES</code> table. For example, if <code>DEFAULT_WEIGHT</code> is set to 1, you can increase this value depending on how much weight you want to give to your selected field.

Control name	Description
Thresholds	You can update the Thresholds column for the ZONE_NAME element in the DUP_SEARCH_DATA_ZONES table. For example, if the Thresholds for CM_INIT_REPT_DATE is {"name": "cm_init_rept_date", "value": "90", "default_value": "90", "unit": "days"} you can update it to {"name": "cm_init_rept_date", "value": "60", "default_value": "90", "unit": "days"} to decrease the threshold from 90 days to 60 days for the Initial Receipt Date field. You can update Thresholds only for the following date or numeric fields: • INIT_REPT_DATE (Initial Receipt Date) • SAFETY_DATE (Central Receipt Date) • ONSET (Event Onset Date) • PAT_DOB (Patient Date of Birth) • PAT_AGE (Patient Age)
Transposed Date	You can update the VALUE column to 0 when the KEY element is set to TRANSPOSE_DATE_ENABLED in the CMN_PROFILE table.

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 an action item code from the drop-down list in **Action Item Code when QC info is entered**. This code will be used to populate the Action Item Code field of the action item created by the system whenever a user adds QC information to a case through the Case form > Products tab. If you do not select any value from the list, then no Action Item Code will be set.
9. The Auto Upload Letters feature is no longer available. You are requested to select only the **Manually Upload Letters** option.
10. Click **Save** to save the changes made to this section.

Configuring Database

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

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

The field names associated with Modify Database appear in the right panel.

Field Descriptions

The following table lists the fields available under Modify Database:

Field or Control Name	Description
Database Server OS Timezone	The database server timezone can be specified here. This value can be configured during the Oracle Argus database installation. Note that the timezone selected here should be in sync with the database, web and transaction servers. For further information, see "GMT Offset Calculation" below.
Override Case Seriousness Calculation Function (Note: Default function shall be used if left BLANK)	If this configured in Common Profile Switches > Database > Modify Database, the configured function is executed.
 Note: Default function shall be used if left BLANK.	
Override Case Listedness Calculation Function (Note: Default function shall be used if left BLANK)	If this configured in Common Profile Switches > Database > Modify Database, the configured function is executed.
 Note: Default function shall be used if left BLANK.	
Override Case Causality Calculation Function (Note: Default function shall be used if left BLANK)	If this configured in Common Profile Switches > Database > Modify Database, the configured function is executed.
 Note: Default function shall be used if left BLANK.	

GMT Offset Calculation

The system uses the time zone of the DB server to perform GMT calculations. This time zone is initially loaded during the Oracle Argus database installation.

To set up the time zone:

1. Go to Argus Console > System Configuration > Database.
2. From the **Database Server OS Timezone** drop-down list, select a time zone.
3. Alternatively, update the DATABASE_TIMEZONE key in the CMN_PROFILE table.

Make sure that Argus is using the gss_util.gmt_offset function to derive the GMT OFFSET which impacts the calculation of GMT date and time.

Assume that Daylight Saving Time starts on the first Sunday of April at 2:00 AM and ends on the last Sunday of October at 2:00 AM.

To find out the time zone offset for the time zone regions, execute the following query:

```
SELECT tzname, tz_offset(tzname) offset, tzabbrev FROM gv$timezone_names;
----
```

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 or 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.

Field or Control Name	Description
Criteria for Event Level Assessment for Blinded Study	You can indicate if event assessment is required for all the blinded products configured in Study Configuration. The available options are: • Include datasheet/licenses for all the blinded study products • Include datasheet/licenses for the default blinded study product By default, this switch is set to Include datasheet/licenses for the default blinded study product.



Note:

If you have the **Include datasheet/licenses for all the blinded products** option set to perform assessment and if you use the same datasheet names across multiple study products, it might be difficult to distinguish between each study products in the Event Assessment section. If you want to identify products based on datasheets, it is recommended to revise the datasheet names to include product name/identifier.

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 or 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.

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

To view the list of field names, go to `Case Processing > Lot Number Processing` in the left panel. The field names associated with the Lot Number appear in the right panel.

The following table lists and describes the fields available under Lot Number Processing:

Field or 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 disallow.
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.

Field or Control Name	Description
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 Oracle Argus Safety 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 Oracle Argus Safety Product Families Lot Numbers.
 - **Yes:** This enables the system to query outside the Oracle Argus Safety system through a web service return the following parameters for Lot Number Validation
 - * Oracle Argus Safety 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 Dictionary 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.

A switch in Oracle Argus Safety enables you to use either local MedDRA Coding or Central System MedDRA Coding (Web Service Method).

- **Local (Default):** Current functionality of Dictionary 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 > Dictionary Browser` section, click the **Dictionary Browser** folder in the left panel. The field names associated with Dictionary Browser are in the right panel.

Field Descriptions

The following table lists the fields available under Dictionary Browser Configuration:

Field or Control Name	Description
Term Selection in Dictionary 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.
Allow User to Add Non-Current MedDRA Terms for	The available options are: • Case irrespective of Country of Incidence • Case where Country of Incidence is other than Japan
On change of LLT Term Sync English and Japan LLTs, irrespective of the currency	The available options are Yes or No. This profile switch is enabled only when the user configures the Allow User to Add Non-Current Meddra Terms for to Yes.

Use the following procedure to configure the Dictionary Browser.

1. Select the required option for Date to use for numbering year placeholder.
2. Click **Save** to save the changes made.

Dictionaries

All dictionaries are stored in database schema separately outside Oracle Argus Safety and Interchange schema. The Oracle Argus-supported dictionaries are:

- MedDRA
- MedDRA J
- WHO Drug
- J Drug

Only one copy of each dictionary version is maintained in the database and it is not segregated by enterprise. The dictionary version that is applicable for a particular enterprise/client is defined in these common profile switches: Case Form Configuration > Auto Encoding, Dictionary & Central Encoding. Since these switches are segregated by each Enterprise, these dictionaries can have different versions for different enterprises, as required. J Drug dictionary is not configured through Console common profile switches (Case Form Configuration > Auto Encoding, Dictionary & Central Encoding), and is internally maintained as single version, therefore, it remains a common J Drug dictionary for all enterprises.

Configuring Group Data Access

This screen enables you to configure the case processing fields and items for Group Data Access.

Field Descriptions

The following table lists the fields available under Group Data Access Configuration:

Field or Control Name	Description
Access on Patient Initials	The available options are: • Initials part of Patient Details access group • Initials part of Patient Information access group
Access on Patient DOB	The available options are: • Date of Birth part of Patient Details access group • Date of Birth part of Patient Information access group
Parent - Initials	The available options are: • Initials part of Parent Details access group • Initials part of Patient Information access group
Access on Parent DOB	The available options are: • Date of Birth part of Patient Details access group • Date of Birth part of Patient Information access group

Configuring WHO Drug

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

You can use either local WHO-Drug Coding or Central System WHO-Drug Coding (Web Service Method). To select an option:

1. Go to **System Configurations > System Management (Common Profile Switches)**.
2. From the left pane, go to **Case Processing > Dictionary Browser**.

3. On the right pane, under Argus Safety WHO Drug Coding Method section, select an option:
 - Local WHO Drug (Default): Uses the current functionality of WHO-Drug browser that uses the Local Dictionary in the Database.
 - Web Services: Returns the WHO-Drug fields via the configured Web Services.

The system enables the Use Local WHO Drug if Term not found by Web Services checkbox.

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 or Control Name	Description
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.
Maximum records to be displayed when type ahead field is double clicked	Enables you to configure the maximum number of records to be displayed when you double-click the Type Ahead field.
Auto-Generate Open Query Action Items during Case Save	Enables you to auto-generate open query action items during case save. The available options are Yes and No , with the default set to No .
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.

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 **Use Oracle Text for duplicate search querying**, as applicable.
3. Enter the time difference between each refresh (in minutes), under Refresh Oracle Text Index interval (in Minutes).
4. Enter the time (in military format) when the Oracle text refresh will begin, under Start Time for Oracle Text Refresh.
5. Click **Save** to save the changes made.

Configuring Local Labeling

This section enables you to configure the common profile switches for Local Labeling.

Configure Local Labeling

The Local Labeling Configuration screen enables you to modify the options available through local labeling. Go to `Argus Console > System Configuration > System Management (Common Profile Switches)` 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 or 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.

Configure Local Labeling 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 Oracle 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 Oracle Argus Affiliate field labels.
- The system tracks all field label updates in the audit log.

Field Validation Updates

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

- The existing Argus fields are under the Oracle Argus Safety folder structure.
- Refer to the table for LAM Event Info for the fields in the Field Validations.
- The Oracle Argus 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 **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 or Control Name	Description
Report Scheduling when Labeling Changes from the Local Labeling Screen	The available options are: - Report Scheduling will not be executed when the Local Labeling is changed. - Report Scheduling will occur for those Licenses where the Labeling has changed. - When this common profile switch is set to 1 (one), local labeling is done by AG Service and the AG Service locks the case before doing anything. - When this common profile switch is set to 0 (zero), local labeling is done live and it does not go through AG Service. In this scenario, the case is not locked.
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.
Report Scheduling for LAM	The available options are: - Perform live scheduling on screen. - Perform scheduling using AG service. - When this common profile switch is set to 1 (one), local labeling is done by AG Service and the AG Service locks the case before doing anything. - When this common profile switch is set to 0 (zero), local labeling is done live and it does not go through AG Service. In this scenario, the case is not locked.

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 Network Settings

The Network Settings screen enables you to modify the settings on the Argus Safety Load Balancer Server, Argus Safety API Load Balancer URL, and Proxy.

Configuring Argus Safety load balancer

1. Go to System Configuration > System Management (Common Profile Switches) > Network Settings.
2. In the Modify Network Settings section, enter the **Argus Safety Load Balancer Server** and **Argus Safety API Load Balancer URL**.

The **Argus Safety API Load Balancer URL** profile switch is available for the default enterprise. It is set at the global level and not specific to the enterprise.

If you have the Load Balancer setup, then enter the Load Balancer URL. Otherwise, enter the Argus web server URL with port 8091 (instead of 8033) . By default, this field is blank.

You must configure this profile switch. If it is configured incorrectly, the bridge configuration save and the case save operations fail or show unexpected result with generic errors.

Configuring network proxy

The proxy details configured for Argus are common for all the enterprises and do not change between enterprises.

To configure the proxy settings, go to `System Configuration > System Management (Common Profile Switches) > Network Settings > Proxy`, provide details for each field as listed in the following table.

Field name	Description
SSLStartMode	Determines how the component starts the SSL negotiation. The available options are: - Automatic—If the remote port is set to the standard plain text port of the protocol (where applicable), the class will behave the same as when SSLStartMode is set to sslExplicit. In all other cases, SSL negotiation will be implicit (sslImplicit). - Implicit—The SSL negotiation starts immediately after the connection is established. - Explicit—The class first connects in plaintext, and then explicitly starts SSL negotiation through a protocol command such as STARTTLS. - None (Default)—No SSL negotiation, no SSL security. All communication will be in plaintext mode.
Auto Detect Proxy	Checking this field lets the application detect the proxy automatically if applicable. This checkbox is visible for default enterprises. By default, this checkbox remains unchecked.
Proxy Type	Determines the type of proxy to connect through. The available values are: - None - No proxy (Default). - Tunnel - Connect through a tunneling proxy. ProxyPort is set to 80. - SOCKS4 - Connect through a SOCKS4 Proxy. ProxyPort is set to 1080. - SOCKS5 - Connect through a SOCKS5 Proxy. ProxyPort is set to 1080. This drop down is visible for default enterprises.
Proxy Host	Holds the name or IP address of the proxy server. This field is visible for default enterprises.
Proxy Protocol	Holds the HTTP_PROTOCOL component of proxy URL. Maximum length is 20 characters. This field is visible for default enterprises.
Proxy Port	Defines the TCP port for the proxy host. This field is visible for default enterprises.
Proxy Domain/UserName	If the Proxy Host is specified, this property along with Proxy Password is used to connect and authenticate to the given Proxy Server. This field is visible for default enterprises.
Proxy Password	If the Proxy Host is specified, this property along with Proxy Domain/UserName is used to connect and authenticate to the given Proxy Server. This field expects the password to be in encrypted state, use Cryptography Key Editor to encrypt the password. This field is visible for default enterprises.

Field name	Description
Use Proxy settings for ESM DTD Validation	Enables or disables the usage of Proxy settings for ESM. The available options are: • Checked (Enabled by default) • Unchecked This field is visible for all enterprises and is specific to each enterprise.
Use Proxy settings for SMTP/S	Enables or disables the usage of Proxy settings for SMTP/S. The available options are: • Checked • Unchecked (Disabled by default) This field is visible for all enterprises and is specific to each enterprise.

Configuring User Interface

You can configure the user interface, as per the options available. Go to `Argus Console > System Configuration > System Management (Common Profile Switches)`.

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.

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 or Control Name	Description
Allow User to regenerate reports	The available options are Yes and No.

Field or 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.

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 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 or Control Name	Description
Auto Accept Notes	Enables you 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.
Blind status during E2B report generation	The available options are: • Blinded • Unblinded
Default DTD	Enables you to select the Default DTD from the drop-down list box.
Default view for E2B(R3)	Specifies the default view of E2B(R3) reports in the ICSR viewer. Decoded, HL7, and XML are the available options.
Default viewing format of the E2B report (used in E2B(R2) reports)	The available options are: • SGML • CIOMS • MEDWATCH • DECODED VIEW
Default viewing format of the E2B(R3) report	The default viewing format of the E2B(R3) report will be applicable to MFDS E2B(R3) and NMPA E2B(R3) reports.
Drug assessment method (used by E2B/ Interchange module)	Enables you to incorporate the drug assessment method used by E2B/ Interchange module.

Field or Control Name	Description
File attachments allowed for ICH E2B(R3) Profile	Verifies the applicable files that can be attached with an E2B(R3) report generated using the ICH profile.
File attachments allowed for EMA E2B(R3) Profile	Verifies the applicable files that can be attached with an E2B(R3) report generated using the EMA profile.
File attachments allowed for MFDS E2B(R3) Profile	Verifies the applicable files that can be attached with an E2B(R3) report generated using the MFDS profile.
File attachments allowed for NMPA E2B(R3) Profile	Verifies the applicable files that can be attached with an E2B(R3) report generated using the NMPA profile.
Onset Date Calculation	Enables you to configure if the onset date is to be calculated based on any suspect drug or on the primary suspect drug only.
Send E2B nullification report	Enables you to send an E2B nullification report. You can select whether to automatically schedule it or to not send the report.
Enable stripping of line breaks in attachment data for EMA E2B(R3) profile	Enables you to strip line break characters in encoded attachment data. The parameter applies only to the EMA E2B(R3) Profile and has 'Yes' and 'No' values. The default value is 'Yes'.
Regional Drugs Dictionary	Enables you to select one from a drop-down list. The list values will emulate the WHO dictionaries list in <i>Case Form Configuration > Drugs</i> drop-down.

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. Enter the comments for the automatically generated notes, when an E2B is accepted, under Auto Accept Notes.
8. Click **Save** to save the changes made to this screen.

Configuring eMDR

The eMDR Reporting Configuration screen enables you to modify the options available for eMDR reporting.

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

To configure the fields associated with the Reporting section, click the **Reporting** folder in the left panel. The **eMDR** sub-folder is displayed in the left panel. Click this sub-folder to configure the reporting options. The configurable fields associated with eMDR appear in the right panel.

Field Descriptions

The following table lists and describes the fields available under eMDR:

Field or Control Name	Description
Default Timeframe for draft eMDR generation	Displays a time frame that the Draft report generation required for populating G7 (gtypeofreport). Without this information, eMDR throws a validation error and the report cannot be generated. The default setting for this parameter is 5. The allowed values for this parameter are 5, and 30. Based on the value entered, the corresponding NCI code is populated for data element Type of Report (G7) in eMDR.
File attachments allowed for eMDR	Verifies the files that are attached to an eMDR. Only configured file types are allowed to be attached to an eMDR.
Default view for eMDR	Specifies the default view of eMDR in ICSR viewer.

Configuring eVAERS

The eVAERS Reporting Configuration screen enables you to modify the options available for eVAERS 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 **eVAERS** sub-folder is displayed in the left panel.

Click this sub-folder to configure the reporting options. The configurable fields associated with eVAERS appear in the right panel.

Field Descriptions

The following table lists and describes the fields available under eVAERS:

Field or Control Name	Description
Default view for eVAERS	Enables you to select either XML View or HL7 view as the default view for eVAERS.
File attachments allowed for eVAERS	Enables you to specify the types of files which are allowed as attachments for eVAERS.
Allowed file size for eVAERS (in MB)	Enables you to specify the maximum file size (in MB) allowed in eVAERS.

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 you 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, you 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 you 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).
 - You can enter the number of days from 0 - # of days defined within the time frame.
 - If you 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 you 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 the **Expedited** sub-folder to configure the expedited reporting options. The configurable fields associated with Expedited Reporting open in the right panel.

Field Descriptions

The following table lists and describes the fields available under Expedited Reporting:

Field or 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)

Field or Control Name	Description
Allows Bulk Reporting screen 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
Allows Bulk Reporting screen to show Generated Reports Only	Enables the administrator to allow the Bulk Reporting screen to display only the generated reports.
Nomenclature System on EU Device Vigilance Form	Nomenclature system (Preferable GMDN)" box of EU Device Vigilance Form. By default, this common profile switch is set to 'GMDN'.
Default name of Regulatory Agency for Draft Expedited English Reports	This enables you 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 you to enter the text to display when a downgrade report is scheduled.
Auto Distribution Transmission Comments	Enables you 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.
Auto Distribution Submission Comments	Enables you 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 you to enable or disable the printing of the case version of expedited reports.
SQL mapping for CIOMS/CERFA/MHRA Spontaneous/EU EMEA Spontaneous/Spanish Clinical/Spanish Spontaneous Literature Report Source (Parameters: P_CASE_ID)	For more details on the default mapping, refer to the Mapping Document.

Field or Control Name	Description
Allow Generation of report	If you select Only when previously scheduled reports are submitted or marked for "submission not required" (default), the system retains the existing check for the previous reports that are in the Submission decision complete state. For example, the previous report has been either marked as Submitted or as Submission not required before a report can be generated. When the Even when previously scheduled reports are neither submitted nor marked for "submission not required" option is selected and the Create as Follow-up option is selected in Argus Console > System Configuration > System Management (Common Profile Switches) > Case Form Configuration > Report Generation section, the system removes the existing check for the previous reports that are in a Submission decision complete state. For example, the previous report has been either marked as Submitted or as Submission not required and the report can be generated irrespective of the previous report state (Generated, Approved, New Data Available states).

 Note:

When a previous report is in a **Deleted** state, it can be removed on subsequent case save and the current report can be generate.

When a previous report is set to the **Disapproved** state, no further follow-ups are scheduled.

When a previous report is set to the **No Longer Required** state, **Only when previously scheduled reports are submitted or marked for "submission not required"** option determines you to mark the report to **Submission not required** to generate the current report. **Even when previously scheduled reports are neither submitted nor marked for "submission not required"** option lets you generate the current report, but the change to the **No Longer Required** state of the previous

Field or Control Name	Description
	report does not determine you to mark the report for Submission not required.  Note: When you generate a report while the previous report is waiting a submission decision, the initial or follow-up sequence numbering in the Regulatory Reporting tab does not synchronize consistently with the report type data output within the report itself (for example, Type of Report/G7 in Medwatch).

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 **Default name of Regulatory Agency for New Draft Expedited Reports** from Analysis Tab of the Case Form from the drop-down text-box.
4. Enter the text in the Text to display as comment when a downgrade report is scheduled text-box, if applicable.
5. Enter the transmission comments in Auto Distribution Transmission Comments.
6. Enter the submission comments in Auto Distribution Submission Comments.
7. Select whether to enable or disable printing the case version of expedited reports in **Print Case Version of Expedited Reports (x.y.z)**.
8. Click **Save** to save the changes made to this screen.

BIP Reporting

Oracle Argus Safety uses the BI Publisher reporting technology for the PMDA (R3) Paper reports and Flexible Aggregate reports (DSUR, PBRER and PMAR). This screen contains the common fields that are needed for integrating the BI Publisher server with Argus Safety.

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

To configure the fields associated with the Reporting section, click the **Reporting** folder in the left panel. The **BIP Reporting** sub-folder is displayed in the left panel.

Click this sub-folder to configure the reporting options. The configurable fields associated with BIP Reporting appear in the right panel.

Field Descriptions

The BIP Reporting fields are grouped into Common and Aggregate reporting. The following table lists and describes the fields available under these sections:

Common

The fields under this section are common to both PMDA (R3) Paper Reports and Flexible Aggregate Reporting. These fields are critical to authenticate Oracle Argus Safety with BI Publisher.

Field or Control Name	Description
BIP Common User	Enables you to enter the name of the BIP common user.
BIP Common User Password	Enables you to enter the password of the BIP common user.

Aggregate Reporting

The fields under this section are applicable only to Flexible Aggregate Reports.

Field or Control Name	Description
Persist data in BIP Aggregate Temp Tables	Enables you to select whether to persist data in BIP Aggregate Temporary Tables. The available options are: • Yes • No
Number of days for which data of BIP Aggregate Temp Tables should be persisted	Enables you to specify the number of days for which data in BIP Aggregate Temporary Tables should be persisted.

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.

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 the **Expedited-BfArM** sub-folder to configure the expedited BfArM reporting options. The configurable fields associated with Expedited - BfArM Reporting appear in the right panel.

Field Descriptions

The following table lists and describes the fields available under Expedited - BfArM Reporting:

Field or 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 - Canada Reporting appear in the right panel.

Field Descriptions

The following table lists and describes the fields available under Expedited- Canada Reporting:

Field or Control Name	Description
SQL used to populate the "Health Canada assigned company identification number" field on the Canadian Device report form	This field enables you to enter the associated SQL syntax.
SQL used to populate the "Establishment License Number" field on the Canadian Device report form	This field enables you to enter the associated SQL syntax.
SQL used to populate the "Device Identification No" field on the Canadian Device report form	This field enables you to enter the associated SQL syntax.
SQL used to populate the "Age of Device" field on the Canadian Device report form	This field enables you to enter the associated SQL syntax.

Field or Control Name	Description
SQL used to populate the "How long was the device in use?" field on the Canadian Device report form	This field enables you to enter the associated SQL syntax.
Offset from GMT used to calculate Canada date/time fields (in hours)	This switch enables the GMT offset to the Submitted dates getting printed in Canadian Device Form.
SQL used to populate the "If "preliminary" only, anticipated date for the final report" field on the Canadian Device report form	This field enables you to enter the associated SQL syntax.
SQL used to populate the "Name of Health Care Facility" field on the Canadian Device report form	This field enables you to enter the associated SQL syntax.
SQL used to populate the "Name and Address for Manufacturer(A7)" field on the Canadian Device report form	This field enables you 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 you 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 you to enter the associated SQL syntax.
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 you 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 you 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 you 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 the **Expedited-CIOMS** sub-folder to configure the expedited CIOMS reporting options.

The configurable fields associated with Expedited - CIOMS Reporting appear in the right panel.

Field Descriptions

The following table lists the fields available under Expedited- CIOMS Reporting:

Field or Control Name	Description
CIOMS Form Selection	This enables you to select the CIOMS form to be used across the application for Expedited Reporting / Periodic Reporting.
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 you the option to clearly identify fields that have overflow information on the Additional Information page.
Print Patient ID, Study ID, Center ID in 26. REMARKS section of the CIOMS form	Enables you 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 you 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 you 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. Select the option for **CIOMS** report format to use.
5. Select the relevant **CIOMS form**, from **CIOMS Form Selection**.
6. 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 the **Expedited-MedWatch** sub-folder to configure the expedited MedWatch reporting options. The configurable fields associated with Expedited - MedWatch Reporting appear in the right panel.



Note:

The Medwatch Drug report uses Argus Interchange to define mapping rules and thus it does not use the following common profile switches: `Reporting > Expedited > MedWatch` and `Reporting > Expedited > MedWatch > MedWatch Configuration`.

Field Descriptions

The following table lists the fields available under Expedited- MedWatch Reporting:

Field or Control Name	Description
Value for Field E4 on MedWatch	Select the applicable value from the available options.
Data to print on follow up MedWatch Device form	The available options are: • All information (initial and follow-up) is displayed. (Previous Behaviour). • Only Display changed information from the initial report.

Field or Control Name	Description
Number from LM_REF_TYPES.REF_TYPE_ID for Reference Type containing Legacy Case Number (to print MedWatch forms)	This field enables you to select the required option from the drop-down list.
SQL used to print the BLA #	Enables you to enter the SQL query used to print the BLA#.
SQL used to print Unique Identifier (UDI #) in MedWatch Device Form	Enables you to enter the SQL query used to print the UDI# in MedWatch Device Forms.
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
License number on MedWatch Drug Report	This field enables you to select the option for License number on MedWatch Drug Report.
SQL mapping for MedWatch Literature Box 3. Report Source (Parameters: P_CASE_ID)	SQL mapping for the field: "This type includes cases from literature" for MedWatch. For more details on the default mapping, refer to the Mapping Document.
Value for Field G8 on MedWatch	Select the applicable value from the available options.

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. Select the option for License number on MedWatch Drug Report.
5. Add an SQL for BLA# and UDI#, if there is a need to change the default logic for these fields in MedWatch report.
6. Click **Save** to save the changes made to this screen.

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 or Control Name	Description
Firm Name as it Should Appear at the Top of Each Page	Enables you to enter the name of the reporting firm on the MedWatch form.
Use Manufacturer of the License Used for Report scheduling	Enables you to use the manufacturer of the license that was used for report scheduling, by checking this checkbox.
Date of FDA Approval to Appear on the First Page	Enables you to enter the FDA approval date of the manufacturer.
Disclaimer to appear at the Bottom of the First Page	Enables you to enter a brief disclaimer.
Default Text to Appear on H10 - MW device / H11- eMDR	Enables you to enter default text.
Address to be printed at the bottom of Second page of MedWatch Device Form	Enables you to enter the address to be printed at the bottom of Second page of MedWatch Device Form. The default address is as follows: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRASStaff@fda.hhs.gov
Reset MedWatch Numbering	Enables you 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 you 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 H10 - MW device / H11- eMDR.
5. Click **Reset MedWatch Numbering** to reset the sequence number that appears on the MedWatch form, for the manufacturer as required.

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 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 or Control Name	Description
Determine Primary Event for use in ICH PSUR/CTPR report	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 (First left most Diagnosis Related Serious Event with most weight on Diagnosis then relatedness and then seriousness).
Listedness grouping logic for ICH PSUR/CTPR report output	The available options are: • Primary Event (refer to Inclusion criteria of event for a product in the PSUR/CTPR switch). • Case level Listedness
Seriousness grouping logic for ICH PSUR/CTPR report output	The available options are: • Primary Event (refer to Inclusion criteria of event for a product in the PSUR/CTPR switch). • Case level seriousness

Field or Control Name	Description
Inclusion Criteria for cases in the ICH PSUR/CTPR report	The available options are: - Evaluate seriousness, listedness, relatedness, fatal across all diagnoses/events against product When this option is selected, the case inclusion criteria logic in ICH PSUR/CTPR scans all the diagnoses in the case and matches all the Seriousness, Listedness, Relatedness, Fatal values for the diagnosis in the case against the product(s) for which the report is being run, with the corresponding values selected by you in the Report configuration. When there are no diagnosis in the case, the system scans all the events in the case and matches all the Seriousness, Listedness, Relatedness, Fatal values for the events in the case against the product(s) for which the report is being run, with the corresponding values selected by you in the Report configuration. When multiple products are configured in the report, a match of all the Seriousness, Listedness, Relatedness and Fatal values against even one product-diagnosis is considered as a match for including the case. - Evaluate case inclusion based on following seriousness, listedness, causality option groups - Case Inclusion criteria for the ICH PSUR/CTPR report based on Seriousness OR Case Inclusion criteria for the ICH PSUR/CTPR report based on Causality OR Case Inclusion criteria for the ICH PSUR/CTPR report based on Listedness.
Determine Possible Causality from the causality score	This field enables you to enter a numeric value.
Determine Probable Causality from the causality score	This field enables you to enter a numeric value.
On PSUR, NDA, IND, Medical Review List Reports	The available options are: - Use Initial Receipt Date for date range search - Use Safety Date for date range search
Print footnote 'Non-Serious Listed' for non-serious listed cases in ICH PSUR report	The available options are: - Yes - No
Assessment of Listedness and Causality when both Licenses and Studies are selected in CTPR	The available options are: - Based on selected liscenses - Based on selected studies

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. 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 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 or 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 you 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 or 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. The default value is 3. Password rules: • The password should contain at least 2 non-alphanumeric characters. • The password should have at least 8 characters. • The previous 3 passwords cannot be repeated. • The account will be locked after 3 failed login attempts .
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. The default value is 2.
 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. The default value is 8. For example, if you enter 8 in this field, it configures the system to ensure that every password contains at least 8 characters.
Use Secure property for cookies	Enables you to select whether to use secure property for cookies.
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. The default value is 3. 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 or 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 or 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:

- Configured hashing algorithm to use - This setting determines the Hashtag algorithm that will be used in encrypting passwords.
- *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

You can determine to use the Single Sign-On feature by setting the common profile switch in Oracle Argus console.

To configure Single Sign-On:

1. Go to Argus Console > System Configuration > System Management (Common Profile Switches).
2. From the list of switches in the left navigation pane, click **Single Sign-On**.
3. Check the **Enable Single Sign-On** checkbox.
4. Enter the **Single Sign-On HTTP Header** that the Oracle Argus application uses for authentication.
This field can contain a maximum of 40 characters.
5. (Optional) Enter the **Single Sign-On Logout URL**.
6. (Optional) Check the **Enable Application Managed Idle timeout** checkbox to prompt the applications to timeout (logout) when idle time exceeds the time limit specified in the **Session expiration time in minutes** switch and you choose not to continue working. You are then redirected to the URL that is configured in the **Sign-On Logout URL**.
7. Click **Save**.

Modules that uses Single Sign-On feature:

The following table lists dialog boxes in the Oracle Argus Application that require passwords. In such cases, the system Single Sign-On feature redirects the password to Oracle Argus for validation. When single sign-on is enabled, the system locks the user account if the user enters

an incorrect password three consecutive times. You must then 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
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 **do not use** the Single Sign-On feature:

- Oracle Argus Safety Services
- Oracle Argus Interchange Services (ESM)
- Oracle Argus Interchange Mapping (ESM Mapping Utility)

Configuring Single Sign-On re-authentication

You can also configure Single Sign-On re-authentication. Make sure that the Service Provider IDM (for example, Oracle Access Manager) supports Re-Authenticate URL and sets the last re-authentication header every time a user is re-authenticated.

When configured, re-authentication is performed for critical activities, which requires user to re-authenticate to perform the operation.

To configure Single Sign-On re-authentication using Oracle Access Manager:

1. Go to Argus Console > System Configuration > System Management (Common Profile Switches).
2. From the list of switches in the left navigation pane, click **Single Sign-On**.
3. Check the **Enable Single Sign-On** checkbox.
4. Check the **Enable Re-Authentication** checkbox.

5. Select the **Oracle Access Manager** option.

6. Enter the following fields, and click **Save**.

- **Re-Authentication URL**—Enter the re-authentication URL of the corporate LDAP system. The URL must be in the following format:

`<protocol>://<hostname>:<port>/oamreauthenticate?redirect_url=`

(for example, `https://acme.idm.com:8787/oamreauthenticate?redirect_url=`).
- **Re-Authentication HTTP Header**—Auto-populated by default. The default setting is `OAM_LAST_REAUTHENTICATION_TIME`.
- **Re-Authentication HTTP Header Date Time Format**—Auto-populated by default. The default setting is `Dy Mon dd hh24:mi:ss TZD yyyy`.

If re-authentication is enabled, user association with LDAP is not required, and you can configure Oracle Argus Safety users without providing LDAP details.

Single Sign-On re-authentication has the following impact on the LDAP settings at the user configuration level, which you can access under `Console > Access Management > Argus > Users`:

1. The **Enable LDAP Login** checkbox is available, if either LDAP is enabled at the system level (under `Argus Console > System Configuration > System Management > Security > LDAP` node), or Single Sign-On re-authentication is enabled. If neither is enabled, then the checkbox is disabled.
2. The **LDAP Server Alias** drop-down list is disabled and blank when the **Enable Re-Authentication** checkbox is checked.
3. If both re-authentication and LDAP are configured, then priority is given to re-authentication.

To configure Single Sign-On re-authentication using Open ID Connect:

1. Go to `Argus Console > System Configuration > System Management (Common Profile Switches)`.
2. From the list of switches in the left navigation pane, click **Single Sign-On**.

3. Check the **Enable Single Sign-On** checkbox.
4. Check the **Enable Re-Authentication** checkbox.
5. Select the **Open ID Connect** option.
6. Enter the following fields, and click **Save**.
 - Authority URL
 - Redirect URI
 - Authorization Endpoint
 - Token Endpoint
 - Client ID
 - Client Secret
- [Error Messages](#)

Error Messages

Once the user is configured, the system automatically logs the user into the Oracle Argus Safety Application without requiring re-authentication 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 System Maintenance

To streamline operations and improve performance of the Oracle Argus Safety, some mandatory updates are applied, during which, the system must be made unavailable for use. This is done to prevent case updates and maximize processing power of the database to speed up the maintenance activity.

For the example:

Before MedDRA recode activity starts, it is recommended that users logout and not process cases.

The Global Admin users can control the availability of the system by setting the operational mode of the system. As this parameter has access at the global level, it is applied to all the web servers, and in case of multiple enterprises, it is applied to all the enterprises.

To set the operational mode of the system:

1. Go to Argus Console > System Management (Common Profile Switches) > System Maintenance.
2. Select one of the following options:
 - **System Live** (default)
Only Global Admin users can select this option.

When this option is selected, all the services like, AG services, ESM services, Windows services, DB Jobs, and others work as intended. Besides, login for all the users work as intended.
 - **System down for Maintenance**
Any user can select this option when required.

When this option is selected, all the following services come to a halt, and resume when the system is available again.

- Oracle Argus Interchange services, like E2B Transmit and E2B Import
- Oracle Argus Safety services, like AG services
- EOSU
- Auto Archiving
- Duplicate Search
- P_DLP_TRIGGER_STATE_CHECK
- PKG_PARALLEL_DB_PROCESSOR.PDP_MASTER
- OOTB Database Jobs (including PDP job and auto-archive job), and Oracle Cloud - extensibility jobs
- Oracle Argus Safety Windows Service making Dictionary Loading and Oracle Argus Dossier unavailable.

**Note:**

MedDRA Recode can be performed when the system is in maintenance mode.

The following message appears when you log in to Oracle Argus Safety, Oracle Argus Safety Japan, Oracle Argus Insight, Oracle Argus Affiliate, and Oracle Argus Unblinding:

```
System is currently down for maintenance. Please contact your system
administrator for more
information.
```

Only the Global Admin users can login the application in this mode, and can access the following operations:

- Access Oracle Argus Console.
- Open case forms and work on them.
- Book-In new cases via case form.
- Initiate MedDRA recoding from self-service.

**Caution:**

Oracle recommends that administrators plan the maintenance activity and inform the users before it is enabled. Administrators must evaluate the impact on custom jobs on non-Oracle maintained schemas and third party integrations during this mode.

Besides, users who have already logged-in to the system before beginning of the maintenance activity will be able to continue their work on the system.

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 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.

Search Case

Filter

Case Number

Value

Search

Group Membership

All

Only view locked Cases requiring Follow-up

Open

View Individual Group All

Total Number of Rows (19)

Displaying Rows 1-10

Page Size 100

Lock State	Priority SUSAR	Receipt Date Aware Date	Days Open/ Remaining	Case Number Workflow State / Group	Product Name Generic Name	Event PT Event Verbatim	SABR F, LT or H	Case Type Study ID	Reporter Type Country	Assigned To Owner		
		77-777-0000										
		77-777-0000										
	Initial	0	27-Apr-2020 27-Apr-2020	336 -321	2020-04-SPO-000004 Medical Review Administrator Group	RabiesVac-X RABIES VACCINE	Arthralgia joint pain	Y/Y/Y No	Spontaneous	Nurse US(New York)	veena (Unassigned)	
	Initial	0	27-Apr-2020 27-Apr-2020	336 -321	2020-04-LT-000008 Data Entry /	Penicillin PENICILLIN NOS	Ocular hyperaemia red eye	Y/Y/Y H	Literature	Nurse US(New York)	veena (Unassigned)	
	Initial	0	27-Apr-2020 27-Apr-2020	336 -306	2020-04-LT-000014 Data Entry /	Penicillin PENICILLIN NOS	No adverse event no adverse event	N/Y/Y No	Literature	Nurse US(New York)	veena veena	
	Initial	0	27-Apr-2020 27-Apr-2020	336 -306	2020-04-LT-000015 Data Entry /	Penicillin PENICILLIN NOS	No adverse event no adverse event	N/Y/Y No	Literature	Physician GERMANY	veena veena	
	Initial	0	27-Apr-2020 27-Apr-2020	336 -306	2020-04-LT-000032 Data Entry /	Penicillin PENICILLIN NOS	Ocular hyperaemia red eye	Y/Y/Y H	Literature	Nurse US(New York)	veena veena	
	Initial	0	27-Apr-2020 27-Apr-2020	336 -331	2020-04-SPO-000033 Data Entry /	RabiesVac-X RABIES VACCINE	Ocular hyperaemia red eye	Y/Y/Y No	Spontaneous	Nurse US(New York)	veena veena	
	Initial	0	27-Apr-2020	336	2020-04-SPO-000034	RabiesVac	No adverse event	N/Y/Y		Nurse	veena	

Routing Details

Print List

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.

- The Days Remaining Calculation in Worklist common profile switch enables you to select either of the following options:
 - **Use earliest due date of reports pending submissions** (default)

When...	...populate Due Soon date based on:
Auto-scheduling is done for the reports and the case contains scheduled reports.	Earliest due date of the report.
Auto-scheduling is done for the reports but the case does not contain any scheduled reports.	Latest aware date and duration as specified in the Due Soon Duration (in Days) for Worklist Calculation common profile switch.
Neither auto-scheduling is done for the reports nor likely to schedule a report.	Latest aware date and duration as specified in the Due Soon Duration (in Days) for Worklist Calculation common profile switch.
Auto-scheduling is not done for the reports but the reports are likely to be scheduled.	Earliest due date of the possible reports.

— **Use latest aware date**

When...	...populate Due Soon date based on:
Auto-scheduling is done for the reports, and may or may not contain any scheduled reports.	Latest aware date and duration as specified in the Due Soon Duration (in Days) for Worklist Calculation common profile switch.
Neither auto-scheduling is done for the reports nor likely to schedule a report.	Latest aware date and duration as specified in the Due Soon Duration (in Days) for Worklist Calculation common profile switch.
Auto-scheduling is not done for the reports but the reports are likely to be scheduled	Earliest due date of the possible reports.

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
Days Remaining Calculation in Worklist	The available options are: - Use earliest due date of reports pending submissions - Use latest aware date
Minimum length of the routing comment text length	The available options are: - None - Text field
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.

Field/Control Name	Description
% 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 Oracle 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.

For the 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, Oracle 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.

For more information, see:

- [Worklist Updates](#)
- [Configuring Case Workflow](#)
- [Worklist Intake](#)

Worklist Updates

Granular group permissions

The Worklist is driven by the group permissions defined for each user.

- Under group permissions, you can provide granular permissions to the following worklist options:
 - 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.

Worklist UDFs

To provide the ability to identify cases based on additional criteria, the Worklist > Open and Worklist > New screens provide two User Defined Fields (UDFs) of number type having at least one value configured in the **Selectable** list.

- These fields appear in Search Case section > Filter drop down and at the bottom section of the Worklist Grid.
- These UDFs are displayed for all users having access to the Workflow > New and Workflow > Open screens (not only the Workflow Manager).
- When a user selects any of the UDF from the **Filter** drop down, the **Value** field becomes a drop down, and lists all the values as used in the cases.

Configuring worklist UDFs

When you upgrade to Argus 8.4.3, these UDFs can be configured from the backend in the CMN_PROFILE_GLOBAL table with SECTION = SYSTEM, KEY = WORKLIST_UDF_FIELDS. The VALUE column remains blank by default.

 Note:

- Both UDFs must belong to the same table.
- This is a one-time configuration from the backend and no user-interface is available for this switch.
- This feature is not applicable to Global Worklists.

If you update the VALUE column, then this feature is enabled. Otherwise, this feature remains disabled and no UDFs are displayed in the Worklist screens.

To update the VALUE column, use the format as `TABLE NAME;COLUMN_NAME1,COLUMN_NAME2`. For example, `"CASE_ASSESS;ud_number_10,ud_number_11"`.

 Note:

The formatting must be strictly followed during configuration. Any mistake in the format (including semi-colon, comma) results in error during case save.

When these UDFs are configured, you must configure their labels in the LM_TRANSLATION_LABEL table.

 Note:

UDF labels configured from `Console > System Configuration > Field Properties` are used only for displaying in the Case Form. For the Worklist screens, the labels are picked from the LM_TRANSLATION_LABEL table.

- New Label IDs are added in the LM_TRANSLATION_LABEL table for English and Japanese labels.
- You must replace the following Translation ID for UDF 1 and UDF 2 to reflect correct labels in the Worklist Grid UDFs and Filter UDFs items in `Worklist > New` and `Worklist > Open`.

TRANSLATION_ID	English default label	Japanese default label
WL_CMN_UDF_FIELD_1	WL UD Field 1	WL UD Field 1(J)
WL_CMN_UDF_FIELD_2	WL UD Field 2	WL UD Field 2(J)

- If the labels are not replaced, then the default values are displayed in the Worklist screens.
- For legacy cases, you need to manually populate the data in the CASE_WORKLIST table.

Configuring the maximum cases routed at the same time

A configurable backend parameter, `CMN_PROFILE_ENTERPRISE.MAX_ROWS_SELECTED_ROUTING`, is introduced to set the limit of cases that can be routed at the same time. By default, it is set to 50. On selecting and routing more cases than configured, a warning message is displayed.

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.

Field Descriptions

The following table lists and describes the fields available under Total Number of Rows:

Field or 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.
Enable multi-lingual fields in locked case	Enables you to select the multi-lingual fields as editable even after locking (global or local) the case. By default, this check box remains unchecked.



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.

Code Lists Business Configuration Access Management System Configuration Tools

WORKFLOW

States Rules

Filter Criteria

From To A/C Name Group Normal Time/Max Time User Defined Attribute 1 User Defined Attribute 2

Data Entry	JP Data Entry	(NONE)	Administrator Group	1/2		
Data Entry	US Data Entry	(NONE)	usdataentry	17/5		
Data Entry	US Reporting	(NONE)	usdataentry	17/5		
JP Data Entry	US Medical Review	(NONE)	Administrator Group	/		
New Case	US Medical Review	(NONE)	Administrator Group	/		
New Case	US Reporting	Study_A/C	Administrator Group	/		
New Case	Data Entry	Case Number	usdataentry	/		
New Case	PSTEST1	PSTEST RULE	PS Central Group	/		
PSTEST1	PSTEST12	PSTEST RULE	PS Central Group	/		
smk1	smk2	(NONE)	ADMIN GROUP	/		
smk1	smk2	(NONE)	smk_group1	/		
UK Data Entry	UK Medical Review	(NONE)	UK Medical Review Group	88/17		
UK Medical Review	UK Data Entry	(NONE)	UK Data Entry Group	17/5		
UK Medical Review	UK Reporting	(NONE)	UK Reporting Group	17/1		
UK Reporting	US Reporting	(NONE)	US REPORTING	17/1		
US Data Entry	US Medical Review	Study	Administrator Group	/		
US Data Entry	US Medical Review	(NONE)	usmedicalreview	88/17		
US Medical Review	UK Medical Review	(NONE)	Administrator Group	/		

Add New Copy Delete Print

Modify Workflow Rules

From To Group Preferred State

Product Group Time(days) Norm. / Max. / Units Privileges to others

Advanced Conditions (None) Read-Only AC

Reason for Not Being Able to Route Restrict to Workflow Group

User Defined Attribute 1 User Defined Attribute 2 Global Lock Case on Route Local Lock Case on Route Require Password on Route

Save

Field Descriptions

The following table lists the field descriptions for this section.

Field or 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 Oracle Argus Safety.
Normal 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.
Max Time (days)	
	- 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.
User Defined Attribute 1 /	Lets a user define a custom attribute for a work flow rule such as logically grouping workflow rules. Used only for filtering purposes on the same screen.
User Defined Attribute 2	
Units	Enables you to specify the number of units.
Product Group	Enables you to associate a specific Product group as additional criteria for the workflow transition.
Restrict to Workflow Group	Enables you belonging to the identified workflow rule group to have case access rights, based on the definitions of only the identified group.

Field or Control Name	Description
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.
Global Lock Case on Route	Enables you to lock the case globally on routing. Users might need to enter a password when routing to the case.
Local Lock Case on Route	Enables you to lock the case locally on routing. Users might need to enter a password when routing to the case.
Reason for not being able to route	Enables you 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 you 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 Modify Workflow 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 **Global Lock Case on Route** checkbox, if required.
11. Select the **Local Lock Case on Route** checkbox, if required.
12. Select the **Require Password on Route** checkbox, if required.
13. Enter the number of days in the Normal Time (days) field.
14. Enter the number of days in the Max. Time (days) field.
15. Enter the number of units in the Units field.
16. Select the preferred state for the rule from **Preferred State**.
17. Select the relevant **Advanced Condition**, if any from the button.
18. Enter the reason for not being able to route, if applicable, under Reason for not being able to route.
19. Specify the access levels available to others from the **Privileges to others** drop-down list. The options available under this list are No Access, Read-Only and Read/Write.
 - 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.
20. 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.

21. Define custom attributes for a workflow rule under User Defined Attribute.
22. Click **Save** to save the changes made.

Worklist Intake

This section provides information about the Worklist Intake feature.

Pending tab

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 Oracle Argus Safety and Oracle Argus Affiliate cases in the Pending dialog.

The following table lists and describes the fields available for the worklist:

Field or 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

Field or Control Name	Description	Bookin Field	Property
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
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), 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 Oracle Argus Safety or Oracle Argus 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

Field or Control Name	Description	Bookin Field	Property
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
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:

Oracle 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.
 - 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, Oracle Argus Safety stores the document ID from the central document system. The file attachment will not be stored in Oracle Argus Safety.
- 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 Oracle Argus Safety or Oracle 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.
 - 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 Oracle Argus Safety, 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 Oracle Argus Safety, the Workflow Manager or Enterprise User can click **Reject Case** to reject cases from the Intake Worklist.

- Oracle Argus 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 (Oracle Argus Safety and Oracle Argus Affiliate) 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 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 for a case, a local affiliate case, or a case ingested via intake.

For more information, see:

- [Configuring Local Affiliate System Numbering](#)
- [Configuring Case System Numbering](#)
- [Configuring Intake System Numbering](#)

Configuring Local Affiliate 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.

To specify the case numbering preferences for the local affiliate cases:

1. Go to **System Configuration > System Numbering > Local Affiliate**.
2. Enter the fields as described in the following table.
3. Click **Save**.

Field Descriptions - LAM System Numbering

Field or 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.

Field or Control Name	Description
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. Alternatively, you can click on each placeholder in the order that you require for them to appear on the case. [YY][MM]-[###] is the default format.
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.

Configuring Case System Numbering

To specify the case numbering preferences:

1. Go to **System Configuration > System Numbering > Case**.
2. Enter the fields as described in the following table.

3. Click **Save**.**Field Descriptions - Case System Numbering**

Field or Control Name	Description
Manually Number Cases	Enables you 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 you in the numbering format.
Start at	Enables you to initialize the counter of the sequence number for automatic case numbering.
Separate sequence for each site	Enables you 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 you to separate the sequence numbering for cases by the report type of the case.
Separate sequence for each year	Enables you 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 you 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 you to reset the sequence numbering for cases for each different product abbreviation.
Numbering Format	Enables you 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. Alternatively, you can click on each placeholder in the order that you require for them to appear on the case. [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 booking of the case. • YY- Year: When selected, this uses the year of the Initial Receipt Date field of the case.

Configuring Intake System Numbering

For the adverse events reports uploaded in Oracle Safety One Intake, a unique identifier should be assigned. This screen enables you to specify the intake record numbering preferences.

For more information, see the *Oracle Safety One Intake Administration Guide*.

Configuring SMTP

The Oracle Argus Safety Service and the Oracle Argus Interchange Service use the SMTP configuration utility for e-mail transmission if it has been enabled and configured in Oracle Argus Safety. Case Letters are also sent using SMTP.

Oracle Argus Safety supports modern authentication for only Microsoft Office 365. Modern authentication is a method of identity management that offers more secure user authentication and authorization. To use this option, you must register Oracle Argus Safety in Azure AD and obtain required credentials to send emails.

To configure SMTP:

1. Navigate to `Argus Console > System Configuration > SMTP configuration`.
2. Check the **Enable SMTP** checkbox.
3. In the Server Configuration section, enter the following parameters:

Note:

Skip this step to configure SMTP for modern authentication.

- SMTP Server IP address or name
- Port number (Default value is 25)
- FQDN (Fully Qualified Domain Name)
- Valid e-mail address in the Global From Address field.
When e-mails are sent from Oracle Argus Safety, the From address for all e-mails is set to the e-mail specified in Global From Address.

4. To configure SMTP for modern authentication, perform the following steps:

Note:

Argus application supports modern authentication for only Microsoft Office 365. As a pre-requisite, Argus application needs to be registered in Azure AD to obtain required credentials like Client ID, Client Secret to send emails.

- a. In the Server Configuration section, enter a valid e-mail address in the Global From Address field.
- b. From the **Authentication** drop-down, select **Modern Authentication**.
The Modern Authentication Configuration section is enabled.

- c. Enter the following parameters:
 - Client ID: Registered Argus application client ID.
 - Client Secret: This field is masked similar to the password field.
 - Tenant ID: Token ID provided while registering.
 - Server Token URL: Server end point which defaulted by the system.
 - Authorization Scope: Scope of authorization defaulted by the system.
5. To mark sent emails as confidential, select the **Custom SMTP Header** checkbox.
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.
6. Click **Validate and Save**, to connect to the e-mail server as per the configuration data or in modern authentication mode. If the connection is successful, then the configuration data is saved and a test e-mail is sent. If the connection is not successful, the error is displayed in the Status field and the configuration is not saved.

 Note:

If Oracle Argus Safety needs to use the proxy set up for SMTP configuration, ensure that the Proxy setting is configured under System Configuration > System Management > Network Settings > Proxy.

Configuring Field Properties

This section enables you to change field label names and hide or display fields in the Case Form.

Select **System Configuration > Field Properties** to view the Case Form Field Configuration screen shown in the following illustration.

Field Name	Field Form Label	ICSR Field	Research Field	Hidden	Drug	Device	Vaccine
Case Central Safety Date	Central Receipt Date	No	No	No			
Case Classification	Classification	No	No	No			
Case Followup Data Clean up	Data Clean Up	No	No	No			
Case Initial Receipt Date	Initial Receipt Date	No	No	No			
Case Report Type	Report Type	No	No	No			
Case Requires Follow-up	Case Requires Follow-up	No	No	No			
Case Status	Case Status	No	No	No			
Country of Incidence	Country	No	No	No			
Date for Reports	Aware Date	No	No	No			
Date for Reports (J)	Aware Date	No	No	No			
Follow up Justification	Follow up Justification	No	No	No			
Global ID	Global ID	No	No	No			
Master Priority Level	Case Priority	No	No	No			
Medically Confirm	Medically Confirm	No	No	No			
User Defined Date 1	UD Date 1	No	No	Yes			
User Defined Date 10	UD Date 10	No	No	Yes			
User Defined Date 11	UD Date 11	No	No	Yes			
User Defined Date 12	UD Date 12	No	No	Yes			
User Defined Date 2	UD Date 2	No	No	Yes			
User Defined Date 3	UD Date 3	No	No	Yes			
User Defined Date 4	UD Date 4	No	No	Yes			
User Defined Date 5	UD Date 5	No	No	Yes			
User Defined Date 6	UD Date 6	No	No	Yes			
User Defined Date 7	UD Date 7	No	No	Yes			
User Defined Date 8	UD Date 8	No	No	Yes			
User Defined Date 9	UD Date 9	No	No	Yes			
User Defined Number 1	UD Number 1	No	No	Yes			
User Defined Number 10	UD Number 10	No	No	Yes			
User Defined Number 11	UD Number 11	No	No	Yes			
User Defined Number 12	UD Number 12	No	No	Yes			
User Defined Number 2	UD Number 2	No	No	Yes			
User Defined Number 3	UD Number 3	No	No	Yes			

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.

For more information, see:

- [Field Descriptions](#)
- [Adding User Defined Fields](#)
- [Configuring User Defined Fields](#)

Field Descriptions

The following table describes the fields associated with this section.

Field or Control Name	Description
Field Name	Enables you to view the field name. This is a read only field.
Field Form Label	Enables you 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.
Read Only	Enables you to make drug, device, or vaccine field read- only.
Drug	Enables you to make a field Read only in the Product tab, when the Oracle Argus Safety user chooses Drug option on the Product screen.
Device	Enables you to make a field Read only in the Product tab, when the Oracle Argus Safety user chooses Device option on Product screen.
Vaccine	Enables you to make a field Read only in the Product tab, when the Oracle Argus Safety user chooses Vaccine option on Product screen.
Hidden	Enables you 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.

ICSR Field	When checked, displays which fields are required for E2B reports.
Max Length	Displays the maximum data length allowed for the fields. This information is displayed for all fields except for Date and Codelist fields.
Null Flavors	This drop-down list displays the Null Flavor sets that are configured in Null Flavor codelist. Null Flavors are displayed in the Case Form field as per Null Flavor set associated.
* Safe Length	Allows you configure the safe length for all fields except for Date and Codelist fields. Safe length is populated by default for E2B R2 fields which have been extended as per the E2B R3 Regulation. This field is not used in the application for this release.
Selectable	When checked, it allows you to add or delete values when you select a numerical UDF. When unchecked, the system deletes the existing values when you click Save .
Parent Dropdown	Allows you to configure the parent-child dependency of User Defined Number fields from the same table. For child user defined number fields, each child field can have only one parent field. If the Parent Dropdown field is not selected in the child field configuration screen, then no dependancy is established. One Parent field can be tied to multiple child fields. This field is enabled when the Selectable checkbox is set. This field is set to blank by default.
Category	This column allows you to define a value that ties the parent and child records together. This is set to blank as a default and is a free-text field, with a limit of 20 characters.

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 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 ICSR Field 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 the Oracle Argus Safety 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 Properties`.
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 Oracle 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 Oracle 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
Field Type	Numeric (Text field type would not work)
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 number field:

1. Login to Oracle Argus Safety> Argus Console > System Configuration > Field Properties.
2. Select **User Defined Number** <N> at desired page (field label) from tree shown in the left pane.
3. Choose a value for **Hidden**.
If **Hidden** is marked as **No**, then the corresponding UDF drop down in the Case Form list all values as a regular User Defined Number fields.
4. Check **Selectable**.
 - a. Click **Add** and specify items stored in the drop-down in both English and Japanese if the field is multi-language, otherwise specify only in the English text box.
Enter a **Category** for the respective English and Japanese fields. By default, this field is blank.
The records are tied together only when an exact match of the Category is found.
 - b. In the **Parent Dropdown**, select the parent to define the parent-child dependency on another User Defined Number field from the same table.

This drop-down is enabled only when Selectable is checked, and is blank by default.

Each child User Defined Number has one parent only. But, a parent User Defined Number can be associated with multiple child User Defined Numbers.

If no parent is selected, then no parent-child dependency is created.

Go to **General tab > General Information** and check that the configured user-defined fields display the updated drop-down text.

Configuring Local Data Entry

Oracle Argus Safety supports a concept of global lock that indicates the readiness of case data for global reporting, and a concept of local data locks that indicates the readiness of case data for local reporting having fulfilled the local data entry and assessment needs.

The application allows local users to open a case for entering local data without globally unlocking the case and at the same time maintain the integrity of the "global" case data.

In order to achieve this:

1. The fields in the application are categorized into global and local fields. The local fields have been identified as local to one or more countries. The local fields for only Japan are supported in this release.
2. All Oracle Argus Safety Japan users are considered as Japan Local user in this release and as having access to edit the Japan local fields.

For more information, see:

- [About Local Fields](#)
- [Access Local Case Data Lock Functionality](#)
- [Process an Outlier](#)
- [Activate Local Locking in Oracle Argus Safety](#)
- [Activate Local Reporting in Oracle Argus Safety](#)

About Local Fields

A field is identified as a Local field to one or more countries based on a new attribute in the CMN_FIELDS table. The local fields for only Japan are supported in this release.

Customers can configure any field in the **Case Form > General, Patient, Products, Events** tabs, and in the **Analysis > PMDA** tab as a Local field for Japan through back-end updates to the CMN_FIELDS table.

The Enterprise copy configuration action will copy these updates as per existing functionality.

If a customer configures a field that could update global value as a local field, it is expected that the customers maintain the integrity of the global data by business SOPs or custom software processes.

All the fields in a case that is not a Local PRPT case are simply treated as global fields.

All Argus J users are considered as having access to edit the Japan local fields.

All Japanese text fields, including J User-Defined fields are considered as Local fields for Japan.

- All Japanese text fields are the fields that currently has separate _J columns.

- All fields from PMDA tab, PMDA Device Information section.

Oracle Argus Safety allows selection of secondary LLT (stored in LLT_J or LLT_CODE_J field) or Synonym (SYN_CODE_J) encoding using MedDRA J browser that does not change the base MedDRA hierarchy of English.

The **Event Assessment > Listedness** field in the tab for the licenses of the local country corresponding to the local user is considered as local field. However, this field is available for editing for the user only when the local user has listedness privilege for that local country assigned to them via the `User Group > Listedness Determination - Countries` access and the datasheet associated with that local country license is configured with **Global /No Local Assessment Required** checkbox as unchecked.

The Events tab > **Infection** and **Event Exclusion** checkbox are also considered as local field for Japan.

Any field where an update to a global field can occur is NOT considered as Local field.

All numeric fields, date fields, drop-down fields which share same data value for English and Japan sides are not considered as Local fields.

However, there are exceptions to this rule where some fields that contain global values are available for update to local users and in such a scenario, it is expected that the global value should be protected by customer's business SOPs.

Case Classification is such a field that can cause update to global value and it is available as a Local field in the application out-of-the-box.

Study section under General tab requires special handling by the application during local editing. Study Name, Study Description, Protocol Number, Clinical Compound Number and Center Name are local fields.

When the study is a configured study, all these fields are disabled for local editing except Center Name (J). Center Name (J) is available as an editable local field.

The Product Information section in Products tab requires special handling by the application during local editing. J Drug Code type and the corresponding J Drug Code/OTC Drug Code/Temporary Code (i.e., DRUG_CODE_TYPE_J, DRUG_CODE_J), J Generic Name and J Product Name fields are local fields.

Any field that is already editable after case lock will remain editable even after local lock.

An auto-narrative generation performed during Japan Local data entry (after global lock) only updates the J field value and does not update the English or any other language field value.

Access Local Case Data Lock Functionality

This section lists the different sections where the functionality for Local Case Data Lock has been documented in the Oracle Argus Safety documentation.

Refer to the following table for the list of features and the corresponding guides where they have been documented:

Local Lock Feature	Overview	Documented in
Local Locking and Local Unlocking - Configuration	Introduction of new switches: Allow Local Locking - to allow a local user to be set up with the privilege to locally lock or unlock a case. Enable Local Unlocking - to provide a system level control permitting local users to locally unlock a case and make any corrections to the previously entered local data.	Oracle Argus Safety Administration Guide > 2 Access Management > Configuring Users Oracle Argus Safety Administration Guide > 4 System Configuration > Configuring System Management - Common Profile Switches Oracle Argus Safety User's Guide > Global User Management
Changes to the Case Locking Mechanism in Argus Safety - Case Form Changes	Introduction of action icon - Local Lock - to allow a user to locally lock or unlock a case	Oracle Argus Safety User's Guide > 1 Getting Started > Quick Launch Toolbar
Changes to the Case Locking Mechanism in Argus Safety - Changes to global locking, One Step Global and Local Lock	Allow Global locking and triggering of global and local reports, and allow one step global and local locking	Oracle Argus Safety User's Guide > Locking a Case
Changes to the Case Locking Mechanism in Argus Safety - Changes to Global Unlocking - Configuration	Introduction of new switches: Allow Forced unlock (Global and Local) - to allow users to be set up with the privilege to forcibly unlock a case that been globally and/or locally locked but pending report generation. Allow Global Unlock on Pending Local Lock - to allow users to be set up with the privilege to forcibly unlock a case that is still pending a local lock.	Oracle Argus Safety Administration Guide > 2 Access Management > Configuring Users Oracle Argus Safety Administration Guide > 2 System Configuration > Configuring System Management - Common Profile Switches Oracle Argus Safety User's Guide > Global User Management
Changes to the Case Locking mechanism in Argus Safety - Changes to global unlocking - Case Form changes	Control globally unlocking a case based on local/global reports pending generation and /or cases pending local lock.	Oracle Argus Safety User's Guide > Unlocking a Case

Local Lock Feature	Overview	Documented in
Case Form changes - Local Reports Configuration - Local Reporting Rule and Local Reports	Configuring Local Reporting Rules and Local Reports.	Oracle Argus Safety Japan Administration Guide > 3 System Configuration > Configuring Local Reports - Local Reporting Rule and Local Reports
Triggering Local Reports - Changes to Report Scheduling and Generation Algorithm - Auto Scheduling	Changes to report auto-scheduling for scheduling local reports.	Oracle Argus Safety User's Guide > Report Scheduling - Auto-Scheduling
Triggering Local Reports - Changes to Report Scheduling Algorithm - Manual Scheduling	Changes to report manual scheduling for scheduling local reports.	Oracle Argus Safety User's Guide > Report Scheduling - Manual Scheduling
Triggering Local Reports - Changes to Report Generation Algorithm	Changes to report generation for generating local reports.	Oracle Argus Safety User's Guide > Triggering Local Reports - Report Generation Algorithm
Changes to Expedited Reports and Periodic Reports on DLP	Changes to DLP while generating local expedited and periodic reports.	Oracle Argus Safety Japan User's Guide > Reports

Process an Outlier

When a suspect product with local license is removed on a follow-up, the case remains a Local PRPT Case (Local Potential Reportable Case) until the corresponding nullification/downgrade local reports is generated.

If a customer wants to change Local Reports configuration data after being in production with this release, it is recommended that customers ensure that cases/reports under processing be completed before changing configuration data to avoid unpredictable results. Note that if a customer changes the Local Reports configuration data mid-way where the reports are mid-way processing (e.g., scheduled), the reports will be determined as local/global based on what type it was at the time when the report was scheduled and will be completed processing that way irrespective of current configuration even if inconsistent with the configuration. Also note that presence of local reports will determine that the case is local case.

It is also recommended that customers ensure that cases/reports under processing be completed before up taking the Local Locking feature and (thereby) installing the local lock configuration data (refer to [Activate Local Locking in Oracle Argus Safety](#)). Note that if the case was mid-way processing (e.g., case was open in data entry workflow) when customer up took the Local Locking feature, a subsequent case save will determine if the case is local or global.

Activate Local Locking in Oracle Argus Safety

In order to activate the Local Locking feature in Oracle Argus Safety, the installer provides the users with an option to install the underlying metadata that enables the local lock feature in the

application. A customer, who may not prefer to turn on the local locking feature due to existing business processes that already handle the local processing needs for a company, could choose not to install the metadata and thus not uptake the local lock feature in the application.

A separate database script is provided so that the user can run to turn on the Local lock feature after an upgrade or fresh install. On executing this script, it prompts the user to choose to turn on the local locking feature and uptake the Local Locking seed data.

The application assumes the default value of 1, parses the user input and installs the Local Locking seed data for each of the enterprise specified in the comma separated list.

Enter Local Reports Configuration Seed Data

A new table is seeded to identify Local Reports for Japan:

- **Country** — The seed data is the country id for Japan (from codelist Countries) for this release.
- **Reporting Destination** — The script prompts the customer to provide the default value of reporting destination for PMDA as Please enter Agency Name for the PMDA reporting destination as configured in the "Reporting Destination" codelist. This name will be used to identify Local Reports for all enterprises.
- **Report Form** — The seed data is the following Japan reports:
 - i. 医薬品 症例報告書 別紙様式 1・2 (Mktd 1, 2)
 - ii. 医薬品 研究報告調査報告書 別紙様式 3・4 (Mktd 3, 4)
 - iii. 医薬品 外国での措置報告 別紙様式 5・6 (Mktd 5, 6)
 - iv. 治験薬 症例報告書 別紙様式 1・2 (Inv 1, 2)
 - v. 治験薬 研究報告調査報告書 別紙様式 3・4 (Inv 3, 4)
 - vi. 治験薬 外国での措置報告 別紙様式 5・6 (Inv 5, 6)
 - vii. 報告様式8: 医療機器不具合・感染症症例報告書
 - viii. 報告様式10: 医療機器の研究報告調査報告書／外国措置調査報告書
 - ix. E2B

Enter Local Users Seed Data

The upgrade installer script prompts the user to choose if all the Argus J users will be updated to have local locking privileges.

Enter Local Fields Seed Data

Note that the CMN_FIELDS are always seeded as part of install/upgrade factory data to identify the Local fields for Japan and will be present irrespective of if the customer chooses local locking feature or not.

In case of Multi-tenancy, the customer input value is used to set the seed values across all enterprises.

This seeding of Local users data is audit logged with the system user.

After install/upgrade, if customer has turned on the local locking, the icons in the applicable screens start reflecting the local/global lock status of the case.

Activate Local Reporting in Oracle Argus Safety

The changes described below are applicable only when there are local reports configured in the application (i.e. there is data in the Local Reports Configuration table).

The Report Generation functionality does not generate any Japan Local reports, including the reports that were scheduled by the local reporting rules that were marked as **Active Moiety** or **Super Rules**, until a local lock occurs. The global reports are generated on global lock.

In `Case Form > Regulatory Reports` tab, the `Final` hyper link for a local report is NOT available for a case that is not yet locally locked (similar to the existing functionality for global report on a global unlocked case).

In `Case Form > Regulatory Reports` tab, the **Regenerate Report** menu for a local report is NOT available for a case that is not yet locally locked (similar to the existing functionality for global report on a global unlocked case).

The **Final** checkbox in `Case Actions > Case Open > Batch Print` dialog box will remain disabled and grayed out when any of the case selected is locally unlocked as it does today when a case is globally unlocked.

If report generation is invoked from the Batch Report Generation AG Service, the AG Service skips the case that is not yet locally locked similar to the existing global unlocked cases.

Note that `Worklist > Bulk ICSR Transmit > Re-Transmit` and `Re-Transmit Multiple Reports` put a failed report back in generation to be picked up for processing by Batch Report Generation AG Service. The above point will apply in this scenario.

If report generation is invoked from other AG Services listed below, the AG Service today ignores the global locked status and generates reports. This has been corrected so that the AG Service skips the case that is not yet globally locked when generating global reports similar to the existing Batch Report Generation AG Service. Similarly, the AG Services listed below skip the locally unlocked cases while generating local reports:

- Bulk Report Transmit
- Bulk Report Transmit Email
- Bulk Report Print
- Bulk Report Transmit Fax
- Bulk Report Transmit ICSR

Enabling Argus Modules

Use `Argus Console > System Configuration > Enabled Modules` menu option to enable or disable the usage of particular Oracle Argus modules such as Oracle Argus Affiliate, Centralized Coding, FAR, or Oracle Argus Interchange.

The the new `CFG_MODULES` table stores module names in individual columns. Enabling or disabling a module in the UI checks or unchecks the module flag in the table. For fresh installations, license keys are created in the table without any `CMN_PROFILE` key entries. Enabled modules are migrated per user setup during upgrade. `CMN_PROFILE` key entries are removed from the table as part of the upgrade.

The out of the box configuration of the following modules is as follows:

Product Name	Module Name	Enabled or Disabled
Oracle Argus Affiliate	Affiliate	Enabled
Oracle Argus Safety	BIP Aggregate Reporting	Disabled
Oracle Argus Safety	Centralized Coding	Disabled You need database add-on when you enable this module.
Oracle Argus Dossier	Dossier	Disabled
Oracle Argus Insight	Insight	Disabled
Oracle Argus Interchange	Interchange	Enabled
Oracle Argus Safety Japan	Japanese	Disabled
Oracle Safety One Intake	Intake	Disabled This checkbox is set during customer provisioning and enabled for the customers who have opted for Oracle Safety One Intake. This module have no impact on the Argus application.

The Reconciliation and the Documentum modules are no longer part of the configurations list.

Configuring Interchange

Use **Argus Console > System Configuration > Interchange** menu option to configure the Interchange service, manage the Interchange profiles and ICSR code translations, compare profiles, and view audit log information for the Interchange mappings.

This menu is available only if you have access to the ESM admin user role. For more details refer to the *Oracle Argus Interchange User's Guide*.

Configuring Message Profile for Interchange

You can configure the message profile for Oracle Argus Interchange web service.

Configure the message profile

1. Go to Argus Console > System Configuration > Webservice > MFDS.

Field Name	Value
Webservice Name	MFDS
Webservice URL	https://nedrug.mfds.go.kr/api/afgreptws?WSDL
User ID	
Auth Key	
Namespace	http://service.afgreprt.ws.ndii.mfds.gov/
Contract Name	AfgReprtServicePort
Soap Action	getLicenseInfo
Report Post Method	uploadAfgReprt
ACK Post Method	getAfgReprtTreatInfo
Request Elapse Time (in minutes)	480
ACK Polling Time (in minutes)	15
Request Retry Count	5

Note: Changing any configuration might impact the connectivity and submissions to MFDS.

2. Enter the values, and click **Save**.

Table 5-1 MFDS Web service - Field description

Field name	Default value	Description
Webservice Name	MFDS	Unique web service name to identify.
Webservice URL	https://nedrug.mfds.go.kr/api/afgreptws?WSDL	Web service URL provided by the authority.
User ID	Blank. No default value.	Valid login user ID of MAH/ Sponsor who is submitting the report.
Auth Key	Blank. No default value.	Valid authorization key of MAH/ Sponsor who is submitting the report.
Namespace	http://service.afgreprt.ws.ndii.mfds.gov/	Name space of the URL.
Contract Name	AfgReprtServicePort	Contract name as provided.
Soap Action	getLicenseInfo	Provides information about the web service request.
Report Post Method	uploadAfgReprt	Web service method to post xml.
ACK Post Method	getAfgReprtTreatInfo	Web service method to poll acknowledgment.
Request retry count	5	Retry count for failure in minutes.
Request elapse time	480	Elapse time for the service to poll again in minutes.
ACK polling time	15	Polling time for acknowledgment in minutes.

Configuring Argus Bridge for document management

Integrate the document management system to be used with Oracle Argus Safety by configuring the details in Console. By default, Documentum is supported out of the box. Any other document management system can be integrated through the API adapter.

You can access Bridge Configuration from Console > System Configuration > Webservice. This menu is visible only if you belong to groups with access set to Enabled on

the Webservice screen in Console > Access Management > Argus > Groups > Menus > Webservice.

To configure the Webservice for integration with any Document Management System:

1. Go to Console > System Configuration > Webservice > Bridge Configuration.
2. In the Service Assembly section, enter the following parameters:
 - a. In the **Service** drop down, select **Document Management**.
 - b. In the **Class Name** field, enter the class name available in the DLL.

 Note:

See the [Sample DLL](#) file for documentum integration.

- c. In the **Assembly File Name** field, enter the DLL file name created for the Document Management System.

 Note:

To use the default documentum class name, leave the **Class Name** and **Assembly File Name** fields blank.

- d. In the **Configuration JSON File**, upload the configuration file for any system: documentum or other. Before uploading the JSON file, replace the following parameters with your required values:

- {SERVER_URL}
- {SERVER_PORT}
- {THIRD_PARTY_REPO}
- {USERNAME}
- {PASSWORD}
- {CABINET_ID} with {category}

The sample tags mentioned here are applicable if you are using the default document adapter for documentum. If you are using any other system, then the JSON file may differ according to the custom adapter.

 Note:

See the [Sample Documentum Configuration JSON](#) file.

- e. In the **Service Status** field, status of the Document Management System appears as:
 - Not configured
 - Configured
 - Argus Safety API Load Balancer URL is not configured



Note:

You can configure the API Load Balancer URL option in the default enterprise. For more information, see [Configuring Network Settings](#).



Note:

These settings are applied at global level and not enterprise specific.

3. In the Service Settings section, enter the following parameters:
 - a. For the **Enable searching and attaching files already existing in External Storage to a case** radio button, select whether to enable search or to attach the existing files to a case that are available in the external storage.
 - b. For the **Enable storage of case attachment files** radio button, select whether to store case attachment files in the Argus storage or external storage.
 - c. For the **Enable storage of ICSR reports** radio button, select whether to store the ICSR reports in the Argus storage or external storage.
 - d. For the **Enable Storage of submitted expedited reports** radio button, select whether to store the submitted expedited reports in the Argus storage or external storage.
 - e. For the **Enable Storage of submitted periodic reports** radio button, select whether to store the submitted periodic reports in the Argus storage or external storage.
 - When the periodic reports are marked as Approved, report are stored in the document repository with a submission_succeed attribute marked as 0.
 - When the periodic reports are marked as Submitted, the report are updated in the document repository with the existing submission_succeed attribute marked as 1.
 - f. In the **Case Attachment Document Type** field, enter the type of attachment being uploaded.
 - g. In the **ICSR Document Type** field, enter the type of ICSR document being uploaded.
 - h. In the **Expedited Document Type** field, enter the type of expedited document being uploaded.
 - i. In the **Periodic Document Type** field, enter the type of periodic document being uploaded.
4. Click **Save**.
5. When the configuration is complete, perform an IISRESET for the settings to become effective.

Upload Document Management Adapter DLL file on a Web server

Follow the steps below to place the adapter DLL file created in step 2 above in the correct folder for each Web server:

1. Open the `argus.ini` file and navigate to the `ArgusInstallPath` folder location, for example: `C:\Program Files\Oracle\Argus\ArgusWeb\ASP\`.
2. From the `ArgusInstallPath` folder, go to the `Argus.NET\bin\AdapterBin` folder.
3. Copy the Document Management Adapter file inside the `AdapterBin > DOCUMENT` folder.

4. Go back to the `ArgusInstallPath`, but this time go back two folders to the Argus folder, for example: `C:\Program Files\Oracle\Argus`.
5. From the Argus folder, go to `API\Bridge\AdapterBin`.
6. Copy the Document Management Adapter file inside the `AdapterBin\DOCUMENT` folder.

Configuring Translation Service

Argus case processing user or medical reviewer can translate the narratives, company/sender comments, and other multi-lingual fields by calling the translation service through the translation adapter. This translation adapter can be integrated with Argus using configuration in Console. The configured translation adapter, auto-translates the text entered in the system to the target language instead of the manual process of translation outside Argus and then manually copying the translated text in to Argus.



Note:

This menu is visible only if you belong to groups with access set to Enabled on the Webservice screen in Console > Access Management > Argus > Groups > Menus > Webservice.

To set up the translation service:

1. Build the adapter

Based on the translation service to be used for translation, an adapter must be developed that includes generation of a DLL file and a configuration JSON file.



Note:

For more details, contact Oracle Support.

2. Configure the bridge for integration with translation adapter in Console.

- a. Go to Console > System Configuration > Webservice > Bridge Configuration.
- b. In the Service Assembly section, enter the following parameters:
 - i. In the **Service** drop down, select **Translation**.
 - ii. In the **Class Name** field, enter the DLL name.
 - iii. In the **Assembly File Name** field, enter the name of the adapter DLL file created via the configuration files on the web server to configure the translation adapter.
 - iv. In the **Configuration JSON File**, upload the configuration file created in Step 1 with `.json` extension containing configurations required by the Translation Adapter such as API URL, maximum character limit, delimiter, username, password, and so on.
 - v. In the **Service Status** field, the status of the translation adapter appears as:
 - Not configured (default)
 - Configured
 - Argus Safety API Load Balancer URL is not configured

 Note:

You can configure the API Load Balancer URL option in the default enterprise. For more information, see [Configuring Network Settings](#).

 Note:

These settings are applied at global level and not enterprise specific.

3. Enable the translation service

In the Service Settings section, check the **Enable Translation Service** checkbox. By default, this checkbox is unchecked.

 Note:

This option is specific to each enterprise. Any changes made to the translation capabilities impacts only the enterprise for which the changes are made.

4. Update the Language code list

Click **Save**.

The translation codes being used by the translation service configured in the translation adapter can be viewed or updated from the `Console > Code Lists > Flexible Data Re-categorization > Code List Name > Languages`. These translation codes appear under `Trans_Lang_Code` field.

- 5.** When the configuration is complete, perform an IISRESET for the settings to become effective.

To disable the translation service:

- 1.** Go to `Console > System Configuration > Webservice > Bridge Configuration`.
- 2.** In the **Service** drop down, select **Translation**.
- 3.** In the Service Settings section, deselect the **Enable Translation Service** checkbox.

 Note:

This procedure disables the translation service only for the specific enterprise. To disable the translation service for multiple enterprises, you must repeat the procedure for each enterprise respectively.

To Upload the Translation Adapter DLL file on each Web server

Follow the steps below to place the adapter DLL file created in step 2 of Translation service setup from above in the correct folder for each Web server:

- 1.** Open the `argus.ini` file and go to the `ArgusInstallPath` folder location. Folder example: `C:\Program Files\Oracle\Argus\ArgusWeb\ASP\`.
- 2.** From the `ArgusInstallPath` folder, go to the `Argus.NET\bin\AdapterBin` folder.

3. Copy the Translation Adapter file inside the AdapterBin > TRANSLATION folder.
4. Go back to the ArgusInstallPath, but this time go back two folders to the Argus folder.
File path example: C:\Program Files\Oracle\Argus.
5. From the Argus folder, go to API\Bridge\AdapterBin.
6. Copy the Translation Adapter file from inside the AdapterBin\TRANSLATION folder.

6

Code List Configuration

This chapter allows administrators to configure and maintain code lists in Oracle Argus Safety through Argus and the Flexible Data Re-categorization feature.

These are detailed in the following sections:

- [Configuring Code Lists > Argus](#)
- [Configuring Code Lists > Flexible Data Re-Categorization](#)

Configuring Code Lists > Argus

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 Oracle 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, Oracle 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 Oracle Argus Safety.
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 Routes of Administration information.
Study Center	This screen helps in capturing Study Center information.

For more information, see:

- [Configuring Autosignals](#)
- [Configuring Batch Reports](#)
- [Configuring Letters](#)
- [Configuring Justifications](#)
- [Configuring Electronic Transmission](#)
- [Configuring Event Groups](#)
- [Configuring Literary Citations](#)
- [Configuring Message Type](#)
- [Configuring Reporting Destination](#)
- [Configuring Routes of Administration](#)
- [Configuring Formulation](#)
- [Configuring Study Center](#)
- [Configuring Holiday Calendar](#)
- [Other Code List Items](#)
- [Configuring Dictionary Type](#)

Configuring Autosignals

This screen enables you to capture the Auto Signal information. Using this screen, you can define the criteria that triggers Autosignal within Oracle Argus.

For the 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 the required Code List folder to be configured. The details of this code list item appear in the right panel.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

The following table describes the fields associated with this section.

Field or 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.

Field or Control Name	Description
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.
 - Alternativley, 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.
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 Oracle Argus Safety Service. This screen displays a list of all the existing Batch Reports.

- By default the Batch reports shown are memorized reports. The Oracle Argus Safety user can see the list of scheduled reports for memorized reports, using the Memorized Reports option.
- to view the Code List page, select **Code Lists > Argus**, and click 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 the required Code List folder to be configured. The details of this code list item appear in the right panel.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

The following table describes the fields associated with this section.

Field or Control Name	Description
Title	This is the unique name for the batch report name.
Report	Enables you to select a report that has to be scheduled. • Report Regeneration • Memorized report
Product	Enables you to select a product for which the report is generated.
Frequency: Every Days.	Enables you to enter the number of days after which the report is to be generated. The value has to be greater than 0.
Next Run Date	Enables you to enter the next date from which the report has to be scheduled.
Advanced Condition	Enables you 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 you to select the type of the report.
Group	Enables you to select the group to which the report must be assigned.

Use the following procedure to configure Batch Reports

1. Click the **Report Title** (or row), to view the details associated with that report. The details appear in the Modify Batch Report section.
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.
17. Click **Save** to save the changes made to this section.

Configuring Letters

Oracle Argus Safety enables the customizing 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 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

For more information, see:

- [Field Descriptions](#)

Field Descriptions

The following table describes the fields associated with this section.

Field or Control Name	Description
Name	Enables you to specify the name of the letter as it will appear in the Letters menu.
Name (J)	Enables you to specify the Japanese name of the letter as it will appear in the Letters menu.
Edit Template	Enables you to open the letter (template) for editing. Use only WordPad for editing letter templates.
Regulatory Cover Letter	Enables you to indicate whether this letter template should appear in the Regulatory Rules dialog Cover letter drop-down list box. The available options are: No, Yes – RTF Format, and Yes – PDF Format.
Schedule - Letter	Enables you 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.
Return Email Address	Enables you 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.

Field or Control Name	Description
Advanced Condition	Enables you 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 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 the **Name** (or row), to view the details associated with that letter. The details appear in the Modify Letter Configuration section.
3. 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:

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.

Letter Placeholder for the IND Cover Letter

- You can define a placeholder for the IND_SIMILAR_EVENTS table. The system uses data from this table to populate the Case Number, Protocol Number, Subject ID, and Adverse Event terms for previously submitted cases reporting the same events.
- If no reports were submitted, the system prints `None Submitted` instead of the table. The placeholder only prints this information when it is used in the cover letter for the Regulatory Report. The system uses the license associated with the scheduled report to track other cases where the same product license was previously submitted for the same events in the current case.

Configuring Justifications

This screen enables you to capture justification information.

Oracle 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 the required Code List folder to be configured.
The details of this code list item appear in the right panel.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

The following table describes the fields associated with this section.

Field or Control Name	Description
Type	Enables you to configure the type.
Justification	Enables you to enter the justification.

Use the following procedure to configure justification.

1. Click 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 the **Type** (or row), to view the details associated with that justification. The details appear in the Modify Justification section.
3. 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 justification reason in Justification.
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.

CODE LIST MAINTENANCE

Organized by: Code List

Electronic Transmission Recipient Filter

Field: Contains: Value:

Total Number of Rows (2)

Name	Address	Country	Phone	Email
Rajani			9896208874	rajani.devenhalli@oracle.com.a@s.com
Yasna-Test			123124214	Fax

Add New Electronic Transmission Recipient

Name: Address: State/Province: Phone:

Title: City: Country: Fax:

Preferred Method: Postal Code: Email:

Help Text

This screen helps in capturing electronic transmission recipient information. Details of electronic transmission recipient such as name, title, address etc. are submitted here.



Tip:

The code list items are displayed in the left-panel. Click the required Code List folder to be configured. The details of this code list item appear in the right panel.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

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

Field or Control Name	Description
Name	Enables you to enter the name of Electronic Transmission Recipient.
Title	Enables you to enter the title of Electronic Transmission Recipient.
Address	Enables you to enter the address of Electronic Transmission Recipient.
City	Enables you to enter the city of Electronic Transmission Recipient.
State/Province	Enables you to enter the state/province of Electronic Transmission Recipient.
Country	Enables you to select your country.
Postal Code	Enables you to enter the postal code of Electronic Transmission Recipient.
Phone	Enables you to enter the phone number of Electronic Transmission Recipient.
Fax	Enables you to enter the fax of Electronic Transmission Recipient.
Email	Enables you to enter the email of Electronic Transmission Recipient.
Preferred Method	Enables you 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 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 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. Use the **Electronic Transmission Recipient** filter 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:

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.

For more information, see:

- [Terms tab](#)
- [Event Groups tab](#)
- [SMQ tab](#)

Terms tab

The following table describes the fields associated with Event Groups > Terms tab.

Field Name	Description
Event Group Name	Allows you to enter a new Event Group name.
Event Group Name (J)	Allows you 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 you 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.
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 corresponding 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 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 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.

[illegible]

 Tip:

The code list items are displayed in the left-panel. Click the required Code List folder to be configured. The details of this code list item appear in the right panel.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

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

Field or Control Name	Description
Journal	Configures the name of the journal where the citation appears. This is a required field.
Author	Configures the name of the author.
Title	Configures the title of the citation.
Volume	Configures the volume number of the journal where the citation appears.
Year	Configures the publication year of the journal where the citation appears.
Digital Object Identifier	Configures the digital object identifier.
Pages	Configures the number of pages in the journal where the citation appears.
Country of Publication	Captures the country of publication of the literature.
Study/Trial Classification	Captures the Study / Trial classification for the literature.

Use the following procedure to configure literary citations.

1. Click 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. 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 digital object identifier in the Digital Object Identifier field.
14. Enter the number of pages in the Pages field.
15. 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.

CODE LIST MAINTENANCE

Organized by: Code List

Message Type Filter: Field: Contains Value: Filter

Total Number of Rows (12)

Message Type	Description	Expedited / Periodic	Auto Submit	Display
backlog		Periodic	No	Yes
backlogd		Periodic	No	Yes
camiscr		Expedited	Yes	Yes
clscr		Periodic	No	Yes
clscr		Expedited	Yes	Yes
clscr		Periodic	Yes	Yes
Master		Expedited	Yes	Yes
Master Recoded		Expedited	Yes	Yes
nhivadminitemiscr		Periodic	No	Yes
pscr		Periodic	No	Yes
Recoded		Expedited	Yes	Yes
sapiscr		Expedited	Yes	Yes

Add New Message Type

Message Type: Description: Expedited: Mark as Auto Submit: Display: ☒



Tip:

The code list items are displayed in the left-panel. Click the required Code List folder to be configured. The details of this code list item appear in the right panel.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

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

Field or Control Name	Description
Message Type	Displays the message type for a report.

Field or Control Name	Description
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.
Display	Displays if the report needs to be displayed or hidden.

Use the following procedure to configure message type.

1. Click 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. 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. Click the **Expedited** checkbox if the message type is for an expedited report.
11. Click the **Mark as Auto Submit** checkbox if you wish to mark for auto submission.
12. Click the **Display** checkbox if you wish to display the message type.
13. 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.

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 the required code list folder to be configured. The details of this code list item appear in the right panel.

2. Click **Reporting Destination** on the left pane of the screen.

For more information, see:

- [Agency Information](#)
- [Local Company Contact](#)
- [Report](#)
- [Configuring EDI](#)
- [SMTP](#)
- [Configuring the Base Directory Path](#)

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 or Control Name	Description
Address 1	Enables you to enter the address of the regulatory contact in line 1.
Address 2	Enables you to enter the address of the regulatory contact in line 2.
Agency Name	Displays the name of the agency. This is a required field.
Agency Type	Enables you to select the agency type.
Allow WHO Drug / J Drug reporting	Enables you to schedule a report for either WHO Drug or J Drug reporting.
Attachments	Enables you to select single or multiple attachments. The default value is Single .
City	Enables you to enter the city of the regulatory contact.
Contact Type	• Manufacturer - Enables you to select manufacturer as the type of contact • Importer - Enables you to select importer as the type of contact • Distributor - Enables you to select distributor as the type of contact • Authorized Representative - Enables you to select the Authorized Representative as a type of contact.
Country	Enables you to enter the country of the regulatory contact.

Field or Control Name	Description
Country Code	Enables you to enter the country code of the regulatory contact.
Department	Enables you to enter the name of the department.
Email Address	Enables you to enter the email address of the agency.
Email Text Body	- Select - Enables you 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 you 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.
Ext	Enables you to enter the extension number of the regulatory contact.
FAX	Enables you to enter the FAX Number.
FAX Cover	Enables you to enter the FAX Cover.
First Name	Enables you to enter the first name of the regulatory contact.
Last	Enables you to enter the last name of the regulatory contact.
Middle	Enables you to enter the middle name of the regulatory contact.
Offline Recipient	Enables you to configure the regulatory agency as an offline agency.
Phone	Enables you to enter the phone number of the regulatory contact.
Postal Code	Enables you to enter the postal code of the regulatory contact.
Preferred Method	Enables you to select the preferred method of agency information. When you set the message profile to MedWatch, this parameter is set by default to Email .
Registration #	Enables you to enter the registration number.
Report for Investigational Licenses	Enables you to select if the reports are to be investigational always or only for clinical case or no marketed license. This field is set by default to Always .
Report for Marketed Licenses	Enables you to select whether reports are to be marketed as Always or only for the Spontaneous cases or no Investigational . This field is set by default to Always .
Report per Email	Enables you to enter the number of reports to be received in each email.
State/Province	Enables you to enter the state/province of the regulatory contact.
Title	Enables you to enter the title of the regulatory contact.
FAX	Enables you to enter the fax number of the regulatory contact.
Contact Type	Enables you to select the Authorized Representative, Manufacturer, Importer, or Distributor check box.

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:

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**.

When the message profile is set to MedWatch, then the **Preferred Method** is set by default to **Email**. When the **Preferred Method** is set to **Email** and the Agency's **Email Address** field is set to blank, then the following warning message is displayed: Agency Email Address cannot be blank. When the message profile is set to FDA MedWatch 3500A, then the following warning message is displayed: Email is the preferred method for this Profile.
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, Distributor, and Authorized Representative.
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 1 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 whether to send single or multiple attachments with emails through the **Attachments** drop-down list.
34. Select how the report is to be marketed from the **Report to be marketed** drop-down list.
35. The options in this list are Always or Spontaneous or No Investigational.
36. Select the **Allow WHO Drug / J Drug Reporting** checkbox to schedule the report for either WHO Drug or J Drug reporting.
37. 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.
38. 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 or Control Name	Description
Company Name	Displays the name of the company. This is a required field
Sender Type	Enables you to select the sender type.
Department	Enables you to enter the name of the department.
Email Address	Enables you to enter the email address of the agency.

Field or Control Name	Description
Lab Code	Enables you to enter the lab code.
Event Term on Expedited Reports	Enables you to select the event term on expedited reports.
Title	Enables you to enter the title of the local company contact.
First Name	Enables you to enter the first name of the contact
Middle	Enables you to enter the middle name of the contact.
Last	Enables you to enter the last name of the contact.
Address	Enables you to enter the address of the contact.
Phone	Enables you to enter the phone number of the contact.
Ext	Enables you to enter the extension number of the contact.
Country Code	Enables you to enter the country code of the contact.
FAX	Enables you to enter the fax number of the contact.
Ext	Enables you to enter the fax extension number of the contact.
Country Code	Enables you to enter the fax country code of the contact.
City	Enables you to enter the city of the contact.
State/Province	Enables you to enter the state/province of the contact.
Country	Enables you to enter the country of the contact.
Postal Code	Enables you 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. 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.

Report

This section lists the fields descriptions and configuration steps for the Report tab.

Add New Reporting Destination				
Agency Information	Local Company Contact	Report	EDI	SMTP
CIOMS I Form: ☐ Print Case References in the "26. REMARKS" section AI INTAKE ID B A+? Begin this is re. END BfA/M Report Number Companion Case ☐ Print Event Assessment in the "7 +13 DESCRIBE REACTION(S)" section ☒ Print Case Comment in the "7 +13 DESCRIBE REACTION(S)" section ☐ Print Company Comment in the "7 +13 DESCRIBE REACTION(S)" section ☐ Print Evaluation in light of similar events in the past in the "7 +13 DESCRIBE REACTION(S)" section				
MIR Report Format 				
☐ Transmit Non-Company product causality for study cases ☐ Transmit Non-Company product causality for non-study cases ☐ Apply EMA Special Rules ☐ Transmit WHO Medicinal Product ID				

Field Descriptions

The following tables lists and describes the fields on the Report tab.

Field or Control Name	Description
Print Case References in the "26. REMARKS" section	Enables you to select the case references to be displayed in the CIOMS I report. The selectable values are populated with the English attributes as configured in the Code Lists > Flexible Data Re-Categorization > Flexible Re-Categorization, REFERENCE_TYPES code list.
Print Event Assessment in the "7 +13 DESCRIBE REACTION(S)" section	Enables you to print the event assessment information in a tabular format in the CIOMS I report.
Print Case Comment in the "7 +13 DESCRIBE REACTION(S)" section	Enables you to print the case related comments in the CIOMS I report. The comment appeared as entered in Case Form > Analysis > Case Comment.
Print Company Comment in the "7 +13 DESCRIBE REACTION(S)" section	Enables you to print the company comments in the CIOMS I report. The comment appeared as entered in Case Form > Analysis > Company Comment.
Print Evaluation in light of similar events in the past in the "7 +13 DESCRIBE REACTION(S)" section	Enables you to print the analysis of the similar events in the CIOMS I report prefixed with text Analysis of Similar Events:.. The comment appears as entered in Case Form > Analysis > Evaluation in light of similar events in the past.
MIR Report Format	Enables you to select the MIR Report format from a drop-down list (PDF and XML).
Transmit Non-Company product Causality for study cases	When this checkbox is checked, the causality for non-study, non-company products in the study cases is transmitted in the E2B(R2) and E2B(R3) reports. When this checkbox is unchecked (default), the causality for non-study, non-company products in the study cases is not transmitted in the E2B(R2, R3) reports.
Transmit Non-Company product causality for non-study cases	When this checkbox is checked, the causality for suspect non-company products, non-study cases are transmitted. When this checkbox is unchecked (default), the causality for non-study, non-company products in the non-study cases is not transmitted in the E2B(R2, R3) reports.
Apply EMA Special Rules	When this checkbox is checked, special rules are applied to modify certain data for EU cases if the reports are sent for Agency/Partners from non-EU countries or if the country is not part of the countries list approved by EMA. This checkbox impacts E2B(R2), R2B(R3) and CIOMS-I reports. When you click on the Apply EMA Special Rules hyperlink, a pop-up appears having details of the impacted profile and elements with rule description.

Field or Control Name	Description
Transmit WHO Medicinal Product ID	Enables you to select whether to transmit WHO medicinal product ID or not in the E2B(R3) report. This checkbox is enabled when the Message Profile is set to any of the HL7 E2B(R3) profiles. Otherwise, the checkbox is unchecked and disabled.



Note:

This checkbox is added for future purposes. Currently there is no functionality associated with this checkbox.

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 or Control Name	Description
SGML/XML	Enables you to select whether to send the report in SGML or XML format. When the E2B(R3) Message profile is selected, then the XML radio button is selected by default and both SGML and XML radio buttons are displayed in read-only mode.

Field or Control Name	Description
Suppress ICSR transmission	Enables you to allow to suppress ICSR transmission. By default, this option is not checked.
Suppress ACK transmission	Enables you to allow to suppress the acknowledgment transmission. By default, this option is not checked.
Skip MDN polling	Enables you to allow to skip MDN polling for a given reporting destination. By default, this option is not checked.
Agency Identifier	Enables you to enter the routing ID configured in gateway for the sender community.
Secondary Agency/ Department Identifier	Enables you to enter Message Receiver Identifier information. The Message Receiver Identifier is the internal department within the agency which receives the report. For new and pre-existing destinations, this field is set to blank by default.
Identification Code	Enables you to enter the agency Duns code, a unique identification code that identifies the trading partner. This field is disabled for the E2B(R3), eVAERS, MIR, and eMDR profile. Populated with default values and is displayed in the read-only mode for the PMDA E2B R3 profile.
Code Qualifier	Enables you to enter the code qualifier here. The code qualifier is used to interpret the identification code. This field is disabled for the E2B(R3), eVAERS, MIR, eMDR, and PMDA E2B(R3) profiles.
Message Profile	Enables you to select a message profile among the list of message profiles displayed.
Mark as Auto Submit	Enables you to mark the report for auto submission.
Auto Accept ICSRs	Click this checkbox to auto accept ICSRs. This checkbox is visible only when case numbering is set to Automatic .
Submission date for ICSRs	Enables you to select the submission date for ICSRs. It is blanked out and disabled if user selects the eVAERS or eMDR profile in the EDI Tab.
ACK Profile	Enables you to select the acknowledgement profile. This field is disabled for the eMDR, MIR, and eVAERS profile. The PMDA E2B(R2) Ack profile is also available now.
Primary Receive Agency	Enables you to select the primary receiving agency.
Imported Cases are assigned to	Enables you to select the sites, 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.

Field or Control Name	Description
Initial Workflow State	Enables you 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.
XML Source Classification	The system enables you 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. 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. This field is disabled for the MIR profile.
Selection Source Classification	Enables you to select the source classification from the drop-down. This field is disabled for the MIR profile.
Transmit ICSR Attachments	Click this checkbox to transmit E2B attachments. If this checkbox is checked in the Reporting Destination Code List, case form attachments are sent to the specified reporting destination.
Attachment Classification	Enables you to select the attachment classification. This field is disabled for the MIR profile.
Local Company Contact Identification Code	Enables you to enter the company Duns code, a unique identification code that identifies the trading partner. This field is disabled for the E2B(R3), eVAERS, MIR, and eMDR profile.
Company Identifier	Enables you to enter the company identifier.
Code Qualifier	Enables you to enter the code qualifier here. The code qualifier is used to interpret the identification code. This field is disabled for the E2B(R3), eVAERS, MIR, and eMDR profile.
File Name	Enables you to specify the file name format for the files created by Interchange.
SGML Declaration File	Enables you to enter the SGML Declaration File. This field is disabled for the E2B(R3), eVAERS, MIR, and eMDR profile.
Maximum # of reports to include in the msg	Enables you to enter the maximum number of reports that will be transmitted in one message. This field is disabled for the eVAERS, MIR, eMDR, and PMDA Device profiles, and set to 1. This parameter can be used for English E2B(R2) reports. But in case of PMDA E2B(R2), this parameter should be left blank or set to 1. By default, when a new agency is created, this field appears as NULL for the profile selected as R3.
Method	Enables you to specify the method of submitting the report: Physical Media , Web services , or EDI Gateway .
Webservice Name	Enables you to select the webservice name configured in the system configuration. This drop-down is enabled only when Method is selected as Web Service. You must select MFDS as the web service name. If you select Interchange profile other than MFDS, an error message appears as only MFDS is configured as the message profile for web service.

Field or Control Name	Description
EDI Header Required	Enables you to generate the EDI Header. This field is disabled for the E2B(R3), eVAERS, MIR, and eMDR profile. Populated with default values and is displayed in the read-only mode for the PMDA E2B(R3) profile.
XML Version	Enables you to enter the XML Version. This field is disabled for the E2B(R3), MIR, and eMDR profile and set to 1.0. Populated with default values and is displayed in the read-only mode for the PMDA E2B(R3) profile.
URL for Message Schema	Enables you to enter the path where the message schema resides on the internet or enter full path if it is located on the disk. This field is disabled for the E2B(R3), eVAERS, MIR, and eMDR profile. Populated with default values and is displayed in the read-only mode for the PMDA E2B(R3) profile.
Encoding	Enables you to select the character set encoding used in XML. This field is disabled for the E2B(R3), eVAERS, MIR, and eMDR profile and set to UTF-8. Populated with default values and is displayed in the read-only mode for the PMDA E2B(R3) profile.
Allowed attachment file size per attachment (in MB)	Enables you to specify allowed attachment file size (in MB) for each attachment. This field is disabled for the MIR profile.
Allowed Report Size (in MB)	Enables you to specify allowed Report size (in MB). This field is disabled for the MIR profile.
URL of ACK Schema	Enables you to enter the path where the ACK schema resides on the internet or enter the full path if it is located on the disk. This field is disabled for the E2B(R3), eVAERS, and eMDR profile.
Interchange service to exclude Enterprise abbreviated name for folder creation	This checkbox appears only when the Base directory path for gateway folders common profile switch is configured with a base folder path. For more information on the base directory path, see Configuring the Base Directory Path. When this checkbox is unchecked, the Interchange service inserts the enterprise abbreviate name in the folder creation, resulting in folder structure, such as <i>Base folder path\Enterprise abbreviate name\Sub folder path configured in Agency</i> When this checkbox is checked, the Interchange service does NOT inserts the enterprise abbreviate name in the folder creation, resulting in folder structure, such as <i>Base folder path\Sub folder path configured in Agency</i> When this checkbox is marked for a new Reporting Destination, by default, the enterprise abbreviated name is populated in the fields as per the following format: • Incoming Folder: <i>Enterprise abbreviated name\Agency Name\Incoming</i> • Outgoing Folder: <i>Enterprise abbreviated name\Agency Name\Outgoing</i> • ICSR Attachment Outgoing Folder: <i>Enterprise abbreviated name\Agency Name\OutAttachment</i> If this flag is set for an existing Reporting Destination that has folders configured, the existing folders are retained. You can manually update the sub-folder as desired, or clear sub-folder path and tab out of Agency Name field to get the folder path auto populated as mentioned above.
Incoming Folder	Enter the path to the folder where incoming files are stored. For more information on the format of the folder creation path, see Configuring the Base Directory Path
Outgoing Folder	Enter the path to the folder where outgoing files are stored.
ICSR Attachment Outgoing Folder	Enables you to select the primary receiving agency that is used during ICSR import when there are multiple agencies with the same agency and company identifiers. This field is enabled only for E2B (R2) profiles.

Field or Control Name	Description
Suppress Auto-scheduling	If the checkbox for Suppress Auto-scheduling is marked for an Agency in the Reporting Destination codelist, the system does not schedule reports (Initial, Follow-up, Amendment, Nullification) for that specific Agency during Auto-scheduling (via AG services, Clicking on Auto-scheduling, Auto-scheduling of f/p reports for a manually submitted report). However, reports can be manually scheduled to the Agency that is set for Suppress Auto-scheduling.
Allow multiple reports for Investigational Drugs (Clinical Trial)	Enables you to schedule a report for each suspected Investigational drug for the case. The reporting categories applicable for this check box are DA, DB, DC and DD. By default, this check box is unchecked.



Note:

This field is applicable for PMDA reports only. Do not check this option for non-PMDA reports.

Allow multiple reports for Investigational Drugs (Research and Measure)	Enables you to schedule a report for each suspected Investigational drug for the case. The reporting categories applicable for this check box are DE, DF, DG. The check box is unchecked by default.
---	---



Note:

This field is applicable for PMDA reports only. Do not check this option for non-PMDA reports.

Allow Multiple Reports for Marketed drugs	Enables you to schedule a report for each marketed drug for the case.
---	---



Note:

This field is applicable for PMDA reports only. Do not check this option for non-PMDA reports.



Note:

For Oracle Argus Safety Japan users, an additional field called Message Profile 2 is displayed for the configuration of the PMDA J profile. This field is required for the PMDA agency to specify the PMDA J profile.

**Note:**

When the Message Profile is set to MedWatch, the following parameters are disabled:

- Auto Accept ICSR's
- ACK Profile
- Submission date for ICSR's
- Primary Receive Agency
- Imported Case are assigned to
- Initial Workflow State
- XML Source Classification
- Selection Source Classification
- Transmit ICSR Attachments
- Attachment Classification
- Allowed attachment file size (in MB)
- Allowed report size (in MB)
- MIR Report Format
- Incoming Folder xvi. Outgoing Folder
- ICSR Attachment Outgoing Folder
- Identification Code (Agency Information and Local Company Contact)
- Code Qualifier
- File Name
- SGML Declaration File
- Maximum # of reports to include in the msg
- Method
- Webservice Name
- XML Version
- URL for Message Schema
- Encoding
- URL for Ack Schema

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 or Control Name	Description
From	Enables you to enter the email address of the sender.
CC	Enables you to enter the email addresses to send email as CC.
BCC	Enables you to enter the email addresses to send email as BCC.
Delivery Receipt	Enables you to check this box to receive a delivery receipt.
Read Receipt	Enables you 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.

Configuring the Base Directory Path

A database only (not shown in the UI) global level common profile switch `BASE_DIR_PATH_FOR_GATEWAY_FOLDERS` is available for providing the base path for all incoming, outgoing and E2B attachments folders.

Users can configure the base directory path of a machine or network shared path through this switch. This path is suffixed with values provided in new configurations and all incoming, outgoing and E2B attachment folders are created under base directory only. This profile switch is mandatory for the Oracle cloud customers whereas it is optional for the on-premise customers. With this optional set up, on-premise customers can retain their existing folder structure when upgrading from older version of Oracle Argus Safety. Cloud customers would need to reconfigure their gateway folders based on the new architecture. When the `BASE_DIR_PATH_FOR_GATEWAY_FOLDERS` is set, make sure to create the base directory path along with the enterprise name.

For the example:

If `BASE_DIR_PATH_FOR_GATEWAY_FOLDERS` is set to `C:\BASE_DIR` for the enterprise `ENT_DEFAULT`, then the folder `C:\BASE_DIR\ENT_DEFAULT` is created.

If the Incoming Folder is set to `AGECNCY\Incoming`, Outgoing Folder to `AGECNCY\Outgoing` and ICSR Outgoing Attachment Folder to `AGECNCY\OutAttachment`, the actual incoming folder path would be `C:\BASE_DIR\ENT_DEFAULT\AGECNCY\Incoming`. The same standard applies for the outgoing and attachment folder too.

If the `BASE_DIR_PATH_FOR_GATEWAY_FOLDERS` is not set, the Incoming, Outgoing and Attachment folders could have the complete directory path.

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 **Route of Administration** list on the Products tab.
- Select `Code Lists > Argus` to view the Code List Maintenance screen.

The screenshot shows the 'CODE LIST MAINTENANCE' window. On the left is a tree view with 'Routes of Administration' selected. The main area is titled 'Routes of Administration Filter' and contains a table with 172 rows. The table has columns: 'Administration Route', 'Description', 'E2B Code', 'Display', and 'EDQM Term ID'. Below the table are fields for 'Add New Routes of Administration', 'Short Name', 'E2B Code', and 'Display' (checked), along with a 'Save' button.

Administration Route	Description	E2B Code	Display	EDQM Term ID
Auricular use	Auricular use	001	Yes	ROA-20001000
Auricular use custom	Auricular use custom		Yes	
Auto_1643051657	Test Description	111	Yes	
AutoE_1643052360	Test Description	111	Yes	
AutoE_This_is_test_string_to_perform_the_maximum_value_allow	AutoE_This_is_test_string_to_perform_the_maximum_value_allow	222	Yes	
AutoJ_This_is_test_string_to_perform_the_maximum_value_allow	AutoJ_This_is_test_string_to_perform_the_maximum_value_allow	222	Yes	
Buccal use	Buccal use	002	Yes	ROA-20002500
Buccal use custom	Buccal use custom		Yes	
Cerebral	Cerebral		No	
Conjunctival	Conjunctival		Yes	
Costal	Costal		No	
Cutaneous use	Cutaneous use	003	Yes	ROA-20003000
Dental use	Dental use	004	Yes	ROA-20004000
Drop	Drop For Injection		No	
Electro-osmosis	Electro-osmosis	005	Yes	ROA-20005000
Endocervical use	Endocervical use	006	Yes	ROA-20006000
Endotracheal	Endotracheal	007	Yes	ROA-20007000
Endotracheopulmonary use	Endotracheopulmonary use		Yes	ROA-20008000
Enteral	Enteral		Yes	ROA-20009000
Epidural use	Epidural use	008	Yes	ROA-20010000
Epileptical use	Epileptical use		Yes	ROA-20011000
Extracorporeal use	Extracorporeal use	009	Yes	ROA-20012000
Gastric use	Gastric use		Yes	ROA-20013000
Gastroenteral use	Gastroenteral use		Yes	ROA-20014000
Gingival use	Gingival use		Yes	ROA-20015000



Tip:

The code list items are displayed in the left-panel. Click the required Code List folder to be configured. The details of this code list item appear in the right panel.

Click the **Routes of Administration** folder in the left panel. The associated data appears in the Total Number of Rows section in the right panel.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

The following table describes the fields associated with this section.

Field or Control Name	Description
Administration Route	Displays information about the route of administration. It displays information about how the drug was administered. This is a required field.
Short Name	Displays the short name of the route.
Description	Displays a description of the route.
E2B Code	Displays the E2B Code of the route.
EDQM Term ID	Displays the EDQM Term ID of the route.



Note:

The EDQM Term ID field is automatically populated by the Dictionary Loader and is not editable by the users.

Display	Enables you to display the record in the 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. 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:

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 administration route in the Enter Administration Route field.
8. Enter a short name about the administration route in the Short Name field.
9. Enter the E2B Code of the administration route in the E2B field.
10. Select the **Display** checkbox to display the record in the Add field in the Products screen.
11. Enter the description about the administration route in the Enter Description field.
12. Click **Save** to save the changes made.

Configuring Formulation

This section enables you to configure the Formulation information.

The values entered here appear in the Formulation drop-down list on the Product screen.

Use the following procedure to configure the formulation.

1. From Argus Console, hover over Code Lists and select **Argus** to view the Code List Maintenance screen.

The screenshot shows the 'CODE LIST MAINTENANCE' interface. On the left, a 'Browser' pane lists various code list categories, with 'Formulation' highlighted. The main area on the right is titled 'Formulation Filter' and contains a table of existing formulations. The table has three columns: 'Formulation', 'Display', and 'EDQM Term ID'. Below the table, there are buttons for 'Add New', 'Copy', 'Delete', and 'Print'. At the bottom of the screen, there is an 'Add New Formulation' section with a text input field for the formulation name and a 'Display' checkbox.



Tip:

The code list items are displayed in the left-panel. Click the required Code List folder to be configured. The details of this code list item appear in the right panel.

2. Click the **Formulation** folder in the left panel. The associated data appear in the Total Number of Rows section in the right panel.
3. Click **Add New** to create a new formulation.
4. Enter information about the formulation in the Formulation field.
5. Select the **Display** check box to display the record in the Add field in the Products screen.
6. Click **Save** to save the formulation.

For more information, see:

- [Field descriptions](#)

Field descriptions

The following table describes the fields associated with this section.

Field or Control Name	Description
Formulation	Displays information about the formulations (cream, drop, capsule, etc.) available for a product.
Display	Enables you to specify the formulation associated with the Medicinal Product in the Product Configuration window, as well as in the Case Form Products tab.
EDQM Term ID	Displays the EDQM Term ID of the formulation.

 Note:

The EDQM Term ID field is automatically populated by the Dictionary Loader and is not editable by the users.

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 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 the required Code List folder to be configured. The details of this code list item appear in the right panel.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

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

Field or Control Name	Description
Center ID	Enables you to enter the Center ID.
Name	Enables you to enter the name of the center.
Address	Enables you to enter the address of the center.
Copy from Reporters	Enables you to copy the information from Reporters.
#	Displays the row count of the number of investigators.
Investigator	Enables you to enter the name of the investigator.
Phone	Enables you to enter the phone number of the investigator.
Fax	Enables you to enter the fax number of the investigator.
Notes	Enables you 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 Study Center section.
2. 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:

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 the required Code List folder to be configured. The details of this code list item appear in the right panel.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

The following table describes the fields associated with this section.

Field or 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. 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 additional 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 list.
Action Category	Enables you to create and describe an action item category required for a case. To configure an action item category, go to <code>Code Lists > Argus</code>, and from the left navigation pane, click Action Category. By default, no value is configured for this code list, and a message appears as <code>No records to display</code>. You can enter an action item category of up to 40 characters. Each action item category must be unique.
Action Taken	Enables you to capture Action Taken information. Action Taken information is required to capture information about steps taken when an adverse drug event occurs. The values that you enter in this field are read-only, and appear in the Dosage Regimen section on the Action Taken drop-down in <code>Case Form > Products tab</code> .
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 Category/Code/Description list of the Activities tab. Go to <code>Code List Maintenance > Code List > Argus</code> 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 different age groups. This data appears in Expedited and Periodic regulatory reports. The values that you enter in this field appear on the Patient Information Screen, and in the Age Group drop-down list. The Range values that you specify for new age groups must not contain numbering gaps or overlapping values.
Age Unit	Enables you to capture Age Unit information. An Age Unit displays time in periods such as Year, Month, Day, Hours, and so on. This data appears in the Expedited and Periodic regulatory reports. It also appears in the Age Unit drop-down, Gestation Period unit, and Device Age unit fields on the Patient Information screen, as per the settings made to the Age unit, Gestation Period unit, and Device Age unit flags in the Age unit codelist.

Code List Item	Description
Always Serious Term List	Enables you to select the report types you would like them always serious to run against. You can select specific Product Families to have the always serious terms run against. These values are not reset to No even if they do not satisfy the Always Serious Term criteria.
Anatomical Location	Enables you to capture information about the location where vaccinations are given. This data appears in the expedited and periodic regulatory reports. The values that you enter in these fields appear on the Anatomical Location drop-down list on the Vaccine screen.
Attachment Classifications	Enables you to capture the attachment classification that is used to describe attachment types. The values that you enter in these fields appear in the Attachment Classification section on the Additional Information screen. Attachment Classification that are marked as E2B Additional Doc can be configured to be sent as attachments while transmitting E2B(R2) and E2B(R3) reports.
Attachment Keywords	Enables you to capture information about the attachment keywords that are used to define an attachment type. The values appear in the Attachment Keywords section on the Additional Information screen.
Birth Type	Enables you to capture birth type information when capturing pregnancy information. This data appears in multiple regulatory reports and in the Birth Type drop-down list on the Pregnancy information screen.
Case Classifications	Enables you to capture Case Classification to help categorize cases.
Causality Category	Enables you to capture information about the causality type. This data appears in expedited and periodic regulatory reports and on the Event Causality drop-down list in the Event Assessment section on the Event screen.
Causality Method	Enables you to capture Causality Method information. It appears on the Case Form Event Assessment tab. The E2B report uses this information to determine the drug assessment method.
Causality Source	Enables you to capture Causality Source information. It appears on the Case Form Event Assessment tab. The E2B report uses this information to determine the drug assessment source.
Clinical Reference Type	Enables you to capture information about the clinical reference type. The Clinical Reference Type appears as a drop-down list in Study Configuration.
Condition Type	Enables you to capture information about the condition of the patient such as historical condition, current condition, historical drug, illness at the time of vaccination etc,. 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 (such as 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. The 'Countries Grouping' field enables you to create a group of countries. For example, to group all European Union member countries, you first create a country called 'EUROPEAN UNION'. You then select a European Union member country in the countries table, type 'EUROPEAN UNION' in its Countries Grouping field, and then click Save. Repeat the process for all European Union member countries. On screens where you need to enter a list of all European Union members, you can type European Union, and all countries in this group will be entered automatically. The 'Group 2 Country' checkbox enables you to add a Group 2 Country. This is required when the Due Date for expedited reports differs 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.
Date Ranges	Enables you to capture date range information as follows: • Description - Enables you to enter a description of the date range. • Duration - Enables you to specify the exact duration 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 (such as days, weeks, months, years, etc.) • Units—The unit of the duration (such as days, months, years). • 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 initial date of the date range. • End—The last 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.
Device Type	Enables you to capture information about patient device types. This data appears in expedited and periodic regulatory reports.

Code List Item	Description
Dosage Frequency	Enables you to capture information about how often medication is given (such as daily, bid, weekly, etc.) This information appears on the frequency drop-down list on the Products screen. - Frequency—Enables the user to specify how often the dose is given. - Number of doses per day—Enables the user to specify the number of doses administered each day. - Number of separate dosage—Enables the user 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 such as year, month, day, week (default), hour, minute.
Dosage Unit	Enables you to capture dosage units information. This information is required when capturing 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, it indicates that the current item is the dosage unit. - Lab Test Unit—When checked, it indicates that this is a lab test unit. - Display—When checked, it indicates that the Unit Name is displayed in the application. A new Strength Unit column has been introduced. Check the Strength Unit checkbox to capture strength unit information about the Dosage unit. For more information on the Factory data for Dosage Units codelist, see the <i>Argus_Safety_CaseForm_Console_Updates_Summary.xls</i>.
Ethnicity	Enables you to capture Race information of the patients. This information appears in periodic regulatory reports and eVAERS reports.
Evaluation Reason	Enables you to capture information about why the product is being evaluated. This information appears in the Evaluation Reason list on the <code>Case Form > Products</code> tab.
Event Frequency	Enables you to capture information about the frequency of the event. It includes categories such as intermittent, continuous, and single episode. The values entered 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 that 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 information 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 Information screen.
Fetal Outcome	Enables you to capture information about fetal outcome and includes information such as abnormal development or pre-natal complications. This data appears in expedited and periodic regulatory reports. The values entered here appear on the Fetal Outcomes drop-down list on the Pregnancy Information screen.
Formulation	Enables you to capture information about the formulations (cream, drop, capsule, etc.) available for a product. The values that you enter here, appear on the Formulation drop-down list on the Product screen.

Code List Item	Description
Gender	Enables you to capture gender information. This information appears in expedited and periodic regulatory reports. Column length is set to 25 to accommodate all gender values: Undifferentiated, Cisgender man/boy, Cisgender woman/girl, Transgender man, Transgender woman, Other or Decline to answer.  Note: The previous Intersex value has been renamed to Undifferentiated and the previous Undeclared value has been renamed to Decline to answer.
Ingredients	Enables you to capture information about the ingredients in the product. This includes the ingredient, the concentration, and the units of ingredients used to make the product. This information appears in expedited and periodic regulatory reports.
Institution	Enables you to capture information about the institutions and institutions IDs.
Intermediary	Enables you to capture information about intermediaries such as sales representative, licensee, regulatory authority or local affiliate. The values that you enter here, appear on the Intermediary drop-down list on the Reporters screen.
Interval Units	This codelist is used to maintain the interval units that are used as units for Age, Duration, etc.
Justifications	Enables you to capture justification information. You can enter reasons for overriding system determinations in the Justifications dialog box. The values that you enter here, appear in the Action Justification dialog.
Lab Assessment Terms	Enables you to capture the lab result assessment terms that define the terms that describe the patient's results on various lab tests (such as elevated, depressed, etc). This data is reflected in expedited and periodic regulatory reports. The values that you enter here, 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 whether it has normal, high, or low values. It can be coded as defined in the MedDRA dictionary. The values that you enter here, appear on the Lab Test drop-down on the Patient screen.
Lab Test Units	This codelist is used to maintain the units of measures used in Lab test.
Languages	This codelist is used to maintain the ISO codes of the languages in which text data entry can be made.
Literary Citations	Enables you to enter information about literary citations.
Local Evaluation Comment Type	Enables you to capture the category of a local comment such as French, German, English, etc. The values that you enter here, appear in the Analysis, Local Comment type.
Location	This codelist is used to maintain the Anatomical locations in which Vaccines are administered.
Manufacturer	Enables you to capture information about the product manufacturer. Manufacturer is required while capturing, 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.

Code List Item	Description
Medical Status	Enables you to capture medical information about patient status. This data appears in both the expedited and periodic regulatory reports. The values that 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 that you enter here, are marked as ICH Occupation, and 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 define the number of units in a package.
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 that 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 that you enter in this field appear on the Project ID field drop-down on the Study Configuration.
Purchased With	This code list is used to maintain the Funds from which Vaccine was purchased.
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 that you enter here, appear in the Type drop-down in the References section on the Additional Information tab.
Relation	This codelist is used to maintain the Reporter relation to the Patient.
Report Media	Enables you to capture Report Media information. The values that 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 that you enter here, appear on the Report Type drop-down list on the General Screen. The Considered cases for report type drop-down list determines whether a case is considered marketed or investigational for a given reporting destination. When creating a new case report type, the selected value is Marketed by default.
Reporter Information	Enables you to capture reporter information such as First Name, Last Name, and Occupation. You are also able to associate an institution with the Reporter.
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 that you enter here, appear on the Reporter Type drop-down list on the Product screen.
Reporting Destination Type	Enables you to capture information about the reporting destination. The values that 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 patient such as auricular, cutaneous, dental, and so on.

Code List Item	Description
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. You can also add investigators for each center. You can create a study center with the same center ID but with a different name and address.
Vaccinated At	This code list is used to maintain the Vaccination Facility Type information.

Configuring Dictionary Type

This section enables you to see information about the Dictionary Type.

From Argus Console, select **Code Lists**, then **Argus** and click the **Dictionary Type** folder to view the Dictionary Type screen.



Note:

The dictionary type information is part of factory data and it is not recommended to be altered.

For more information, see:

- [Field Descriptions](#)

Field Descriptions

The following table describes the fields associated with this section.

Field or Control Name	Description
Dictionary Type	Displays the list of dictionary types that can be loaded from the Dictionary Loader window.
Dictionary Configuration Type	Displays the type of dictionary configuration file associated with the dictionary type.
Display	Enables you to display the dictionary type in the MedDRA Loader window. The default value is Yes .

Configuring Code Lists > Flexible Data Re-Categorization

The Flexible data re-categorization feature allows Argus Safety and its associated applications such as Argus Mart and Argus Insight to handle the code list values in a much more flexible manner, as compared to the previously existing Argus Safety Code List database design.

Working with Flexible Data Re-Categorization

The Flexible Data Re-Categorization feature allows applications and customers to store and maintain all types of code list values in a single flat database table structure which shall be easier to maintain. This code list data storage design can be leveraged to easily add new and custom code lists or values by applications as well as customers without adding new database

tables and columns. This database structure was added in previous release of Oracle Argus Safety.

Argus Console provides a user interface that displays values for different code list languages for the flexible data re-categorization code list feature. This user interface helps add and remove custom languages for an existing code list, present in the flexible data re-categorization code list tables and also the flexibility of adding new code list items through this User Interface (UI).

However, this UI does not allow users to perform any modification for the languages which are maintained via the Console Code List feature. Any changes done to the values through this user interface are audit logged.

The Flexible Data Re-Categorization feature allows administrators to manage and display the existing and new code list items.

For more information, see:

- [Flexible Code Lists](#)
- [Flexible Re-Categorization](#)
- [Add custom values to a flexible code list](#)

Flexible Code Lists

To access Flexible Data Re-Categorization:

1. Go to `Argus Console > Code Lists > Argus > Flexible Data Re-Categorization`.

The following table describes the fields associated with this section:

Field Name	Description
Code List Name	This is the unique name of code list which can be used in the application and reporting for fetching the values of a code lists. This is mostly derived from the source Oracle Argus Safety code list names. However, it can be different in some scenarios as per the customer need.
Code List Description	This is the description of code list which can be used to define the purpose of this code list.
Source	Argus: All the code lists which are part of Oracle Argus Safety factory configuration and can be edited using standard Argus Console code list UI show the source as 'Argus'. Custom: Any code lists added as part of factory data which cannot be modified from Argus Console standard code list UI are considered as custom. Any code list added by customers has source as 'Custom'.

2. This page is used to add new values or view existing code list values in the code lists.
 - Click **Add New** to add a new flexible code list item.
To make any changes, users can select a code list, modify values in the given text boxes, and save those changes for modification.
 - Click **Delete** to delete an existing flexible list item.
 - Click **Copy** to copy an existing flexible list item.
3. Click **Save** to save the new or existing flexible code list item information.

Flexible Re-Categorization

To access Flexible Re-Categorization:

1. Go to Argus Console > Code Lists > Argus > Flexible Re-Categorization.

The following table describes the fields associated with this section.

Field Name	Description
Code List Name	This is a drop-down list that displays all the available flexible code lists for selection.
Attribute Name	This is the language Decode context for selected code list which can have language code and other properties of code lists. The following are possible values for this field for the factory data rows which will be populated based on the current code list factory data. Customer can add more language/type values for the new code list items that they create from flexible re-categorization screen, based on their usage: • en: English display value for a code list item • jp: Japanese display value for a code list item • cn: This attribute provides Chinese text used in NMPA E2B(R3) reports. It is present in the Formulation, Route and Manufacturer flexible codelists. • E2B: E2B code value for this code list item • RPT: Display value for Reports • ISOA2: A2 country code for the country code list items • ISOA3: A3 country code for the country code list items • EN_ABBRV: This is used for defining abbreviation values. • SM: This decode context is used by Oracle Argus Mart while populating data into the SM tables. • UCUM_CODE: UCUM code value for this code list item. This is used in E2B(R3) and eVAERS reports. • E2B_R3: E2B(R3) value for this code list item. This is used in E2B(R3) and eVAERS reports. • VAERS_CODE: VAERS Code value for this code list item. This is used in eVAERS and VAERS report mapping. • NCI_CODE: NCI code value for this code list item. This is used in eVAERS reports. • MDFS: MDFS code value for this code list item. This is used in MDFS E2B(R3) reports. • NMPA: NMPA code value for this code list item. This is used in NMPA E2B(R3) reports. • MEDWATCH: MedWatch code value for this code list item. This is used for MedWatch drugs. • EU Data Protection: to identify countries listed by EMA that provide adequate protection to EU data.
Code List Display Value	This is the re-categorized display value for the code. This display value shall be based on a code list, code, and language combination.
Add Attribute	Enables you to add a language attribute.
Remove Attribute	Enables you to remove a language attribute.
Attribute Name	This is the language Decode context for selected code list which can have language code and other properties of code lists.

Field Name	Description
Code	This is the first column in the grid for all flexible code lists. This column displays the internal id for the existing 'Code' list value. For custom code list, the application always populates the code columns with system generated unique sequence value for the selected code list. It is possible for customers to provide a custom 'Code' value for any of the new rows. This value is always unique for a code list.
<All Language Attributes>	All the language attributes are displayed as a new column in the grid with Primary attribute being the first one after the Code column.
Right-click > Make Primary	Allows you to make the selected language attribute as the primary attribute. The primary attribute column is moved as the first attribute in the grid after the 'Code' column. This configuration is available every time the user opens the same flexible code list.
Right-click > Make Preferred	Allows you to mark the selected cell values corresponding to selected language attribute as Preferred in the database. Preferred values are displayed with an asterisk (*) in the grid for easy identification. At any given time, only one value can be marked as preferred within matching values for a language attribute.
Export to Excel	Enables you to export all the values of selected code list into an excel file.
Batch Attribute Update	A collapsible interface, this option displays the list of all attributes available for the selected code list in Flexible re-categorization screen. It also provides a text box called Code List Value, where users can enter the required display value of the code list for the selected attribute.

- This page is used to add new values or view existing code list values in the code lists.
- Click **Edit**. The grid cells of corresponding row become editable for all the attributes added in that code list by the user.
On clicking Edit, a green tick mark is displayed, along with a red colored, cross icon.

Click the **green tick mark** to temporarily save the grid values (until saved into database by clicking Save button). The selected row comes out of Edit mode.

Click the **red colored cross icon** to discard any changes made to the selected row. The selected row comes out of Edit mode.

On changing the value of a preferred cell, its preferred status is removed upon saving the grid values.
- Click **Delete** to allow the users to delete an entry from the flexible code lists. The Delete icon is enabled for only custom code lists, for which protected flag is set to 0 in CODE_LIST_CODE_ATTRIBUTES table. Click this icon to delete all the attribute values corresponding to the selected row from the database.
- The **Display** checkbox is checked by default (except for hidden entries), for a new row added into the flexible code list.
- Click **Save** to save all the changes made on flexible code list screen.

The following Code Lists are used/provided for BIP Aggregate Reports:

- REPORT_TEMPLATE**: This code list is used for managing various BIP report templates available in the system (OOB + Custom) and assign an Oracle Argus periodic configuration (ICH PSUR or CTPR) using which user want to execute this report template. Whenever a new report template is added in BIP, this code list should be modified for providing report template name, its path and corresponding Oracle Argus configuration.
- ADHOC_LINE_LISTING**: All the LISTNAME added in adhoc_line_listing code list are available in the UD Summaries tab of periodic reports configuration for attaching the memorized reports to a particular line listing section of periodic report. User can renames

these using flexible re-categorization user interface. System provides four adhoc line listings by default which can be increased using this code list if you have more adhoc line listing sections in your report. Once configured, use Oracle Argus UI for attaching the UD summaries with line listings of your custom report.

- **SOC_DISPLAY_ORDER:** Use this code list to reorder the printing of SOC in various tabulations.
- **AGGREGATE_REPORT_FORMAT:** Use this code list to define the report formats which you want to use with BIP reports execution. Make sure to use only those formats which are supported by BI Publisher.
- **DOSAGE_STRING_FORMAT:** This code list can be used to restrict/add the dosage string formats which should be available while BIP report execution. More dosage string formats can be added with the help of custom code. The following dosage string formats are provided out of box which print values for dosage string as mentioned in the EN attribute.

Code	EN
Do	Dose
DoFo	Dose, Formulation
DoFoFr	Dose, Formulation, Frequency
DoFoFrRt	Dose, Formulation, Frequency, Route
DoFoRt	Dose, Formulation, Route
DoFr	Dose, Frequency
DoRt	Dose, Route

- **UNIQUE_PATIENT_ID_FORMAT:** This code list is used to restrict/add the dosage string formats which should be available while BIP report execution. More dosage string formats can be added with the help of custom code. The following dosage string formats are provided out of box which print values for dosage string as mentioned in the EN attribute.

Code	EN
CePt	Center, Patient
InPt	Investigator, Patient
Pt	Patient
StCeInPt	Study, Center, Investigator, Patient
StCePt	Study, Center, Patient
StCnCeInPt	Study, Country Name, Center, Investigator, Patient
StCnCePt	Study, Country Name, Center, Patient
StCoCeInPt	Study, Country ISO Code, Center, Investigator, Patient
StCoCePt	Study, Country ISO Code, Center, Patient
StInPt	Study, Investigator, Patient

- **LABELING_ALGORITHM:** Use this code list to define new labeling algorithm with the help of custom code. Please see labeling algorithms for more information on out of the box algorithms.
- **EVENTSERIOUSNESS:** This code list is provided as part of factory data and is used for printing the actual value of seriousness defined against a serious event.

- **ORGAN_IMPAIRED_HLT:** This code list is added for defining the high level terms which needs to be scanned through to find out if event reported falls under organ impairment section or not. This can be used in custom reports.
- **BIP_DFLT_VALUES:** This code list used for configuring the default values for some of the important fields which are used in various grouping and tabulations. For example, how to handle/print an event without and SOC. Value configured in this code list corresponding to SOC will be used in PBRER/DSUR tabulation for events with undefined SOC.

The following Code Lists are used in reports, such as E2B(R3), eVAERS, VAERS, MIR, eMDR and NMPA reports:

Code List	Description
AGE_UNIT	This code list enables you to capture Age Unit information. An Age Unit displays time in periods such as Year, Month, Day, Hours, and so on with E2B and UCUM code information.
CAUSALITY_SOURCE	This code list lets you capture the source from which the causality information was derived, along with the EU_CODE attribute. For each custom value that you add, you must enter the value of the associated EU_CODE attribute in order to populate this info in the EMA E2B report. The values that can be entered for the EU_CODE attribute need to be in the range 1-6, as permissible values for EVCTM are 1-3, and permissible values for EVHUMAN are 3-6
CAUSALITY_CATEGORY	This code list lets you capture the category of the causality information with the EU_CODE attribute.
CAUSALITY_METHOD	This code list lets you capture the method by which the causality information was derived.
* CODE_SYSTEM	For the current release, this codelist is not used in the application (Case Form, Reports).
COUNTRY	This code list maintains the list of Countries with the ISO A2, ISO A3, GENC3, EEA, and EU Data Protection attributes. The EU Data Protection attribute enables you to identify the EEA approved countries. It must be set to 1 for the following countries: • Andorra • Argentina • Canada • Faroe Islands • Guernsey • Israel • Isle of Man • Japan • Jersey • New Zealand • Korea, Democratic People's Republic Of • Korea, Republic Of • Switzerland • United Kingdom • Uruguay
DEVICE_AGE_UNIT	This code list enables you to capture Device Age Unit information. Device Age Unit displays time in periods such as Year, Month, Day, and Hours with eMDR code information.
DEVICE_SUBCOMPONENTS	This code list enables you to maintain information about subcomponents that are part of a medical device, featuring the CLINICAL SIGN IMDRF CODE and DEFINITION attributes.

Code List	Description
DOSE_UNITS	This code list is used to maintain the units of measures used in Dose with E2B and UCUM code information.
ETHNIC_GROUP	This code list is used to maintain information about Ethnicity data of Patient or Parent with NCI Codes information and NMPA information.
ETHNICITY	This code list is used to maintain Race information along with NCI Codes information and NMPA information.
EVALUATION_REASON	This code list is used to maintain the List of reasons for not evaluating devices with NCI Codes information.
FORMULATION	This code list enables you to capture information about the formulations (cream, drop, capsule, and so on) available for a product with NCI Codes information.
GENDER	This code list is used to maintain the Gender with E2B, NCI and MedWatch Codes information.
INTERVAL_UNITS	This code list is used to maintain the interval units that are used as units for Age, Duration, and so on.
LAB_TEST_UNITS	This code list is used to maintain the units of measures used in Lab test.
LANGUAGES	This code list is used to maintain the ISO codes of the languages in which text data entry can be made. It also stores translation codes for different languages that are used by the translation adapter for translation.
LOCATION	This code list is used to maintain the Anatomical locations in which Vaccines are administered.
LOCATION_EVENT_OC CURRED	This code list is used to maintain the locations where the events occurred. This data is used in the eMDR and the MedWatch Device report.
MANUFACTURER	Enables you to capture information about the manufacturer name. This data appears in expedited and periodic regulatory reports.
MEDIATYPE	This code list maintains the file types that can be sent as attachments in E2B(R3) reports with the ICH, FDA, EMA, PMDA, and PMDA Device attributes to indicate if attachment types are allowed for these agencies.
MEDICAL_DEVICE_INF O	This code list is used to maintain the risk class of the medical devices.
MILITARY_STATUS	This code list is used to maintain the details of the Military status of the Patient such as Active Duty, Reserve, National Guard, TRICARE Beneficiary, and Other with NCI Codes information.
NULL_FLAVOR	This code list stores the different null flavors such as UNK, NA NASK, and ASKU. Null flavor sets are attributes in the Null Flavor codelist which are used to create sets with various combinations of Null Flavors. The Null flavor set can be assigned to Case Form fields in Field Properties Configuration and users can select the Null flavors associated with a Null Flavor set as a part of Case Form data.
PRODUCT_IDENTIFIER _TYPE	This code list identifies the type of Product name being used such as Medicinal Product Identifier (MPID), Pharmaceutical Product Identifier (PhPID).
PRODUCT_NAME_PAR TS	This code list specifies the name of a product as a separated component such as container name, form name, device name, invented name, scientific name, trademark name, intended use name, scientific name and so on.
PURCHASED_WITH	This code list is used to maintain the Funds from which Vaccine was purchased.

Code List	Description
RELATION	This code list is used to maintain the Reporter relation to Patient.
REPORTER_INFORMATION	This code list is used to maintain the Reporter information such as First Name, Last Name, and so on.
RISK_CLASS_TYPE	This code list captures a list of values for the risk class type with attributes such as MDR and IVDR.
REPORTER_OCCUPATION	This code list is used to maintain the Occupation with NCI Codes and Device Operator information.
ROUTE	This code list enables you to capture information about how a drug is administered to a patient such as auricular, cutaneous, dental and so on with E2B and NCI Codes information.
SPANISH_STATES	This code list lets you capture the states of Spain with the STATE_CODE attribute.
ITALIAN_STATES	This code list lets you capture the states or proviances of Italy with the STATE_CODE attribute.
SPECIALIZED_PRODUCT_CATEGORY	This code list is used to maintain details of the Product category details as per FDA specifications such as Convenience Kit of Co-Package, Prefilled Drug Delivery Device/System, Drug/Biologic Combination, and so on with NCI Codes information.
US_STATES	This code list lets you capture the states of USA with the STATE_CODE attribute.
VACCINATED_AT	This code list is used to maintain the Vaccination Facility Type information.

Add custom values to a flexible code list

1. Click **Argus Console**.
2. From **Code Lists**, select **Flexible Data Re-Categorization**.
3. On the FLEXIBLE CODE LIST MAINTENANCE page on the right, in the Flexible Re-Categorization Code Lists section, select the flexible code list that you want to add custom values to.
4. To avoid the creation of a duplicate custom value, verify that the value doesn't already appear in the Total Number of Rows section.



Tip:

The number that appears in parentheses is the number of existing custom values for the flexible code list.

5. Click **Add New**.
6. In the Total Number of Rows section, enter information as necessary for the new custom value.
7. Click the green check mark (✓).
8. To add additional custom values, repeat steps 4 to 6.

Accessing Tools

This section explains the EDQM Term List Loader utility, the Dictionary Loader option, the MedDRA Recode option, and the ICSR Length report (features and purpose).

For more information, see:

- [EDQM Term List Loader utility](#)
The EDQM Term List Loader utility can be used to load the EDQM Standard Terms database in Argus, to maintain a local repository for the EDQM Standard Terms database, and to synchronize the Argus code list for Routes of Administration and Dose Forms.
- [Dictionary Loader field descriptions](#)
The Dictionary Loader option is used to load new MedDRA, WHODrug, WHODrug-Chinese, and J Drug dictionary files, as well as to overwrite them.
- [MedDRA Recode field descriptions](#)
The MedDRA Recode window is used to recode the already coded MedDRA terms to the MedDRA dictionary version configured in System Configuration. It supports recoding in multi-tenant environments.
- [Report Features](#)
The report prints the code list items that exceed E2B(R2) length specifications and also lists code list data that has codes not matching with codes required for the E2B(R2) report.
- [Viewing the ICSR Length Check Report](#)
This section enables you to view the ICSR Length Check Report.

EDQM Term List Loader utility

The EDQM Term List Loader utility can be used to load the EDQM Standard Terms database in Argus, to maintain a local repository for the EDQM Standard Terms database, and to synchronize the Argus code list for Routes of Administration and Dose Forms.

The Argus Console application provides the EDQM option for Dictionary Management on the Tools tab of the menu bar.

When Argus Console is accessed from the Global homepage, this utility is accessible only from the default enterprise.

This utility is available only to the users with the Global Admin role configured in User Management.

The EDQM Term List Loader Utility can be used to:

- Load the EDQM Standard Terms database in Argus.
- Maintain a local repository for the EDQM Standard Terms database.
- Synchronize the Argus code list for Routes of Administration and Dose Forms.

This utility needs to be used to load the standard dictionary provided by EDQM accessed through EDQM API.

Field descriptions

Field	Description
Dictionary File	Provide the ZIP file that contains the JSON files from the EDQM Standard Dictionary. The JSON files that belong to RoA and Formulation need to be extracted from the EDQM website and zipped before uploading.
Note: We recommend you to follow the dictionary files naming convention.	
Argus Code List mapping to Concept Class	The data from the Route of Administration and the Dose Formulation fields indicate the EDQM concept class terms mappings to Argus Code list.
Routes of Administration	This field is used to specify the concept class that needs to be considered to populate the EDQM Term ID in the Route of Administration codelist. The Routes of Administration codelist uses terms with ROA concept class. The default data populated in this field is ROA.

Field	Description
Dose Formulation	This field is used to specify the concept class that needs to be considered to populate the EDQM Term ID in the Formulation codelist. The default values are: • PDF - Pharmaceutical Dose Form • CDF - Combined Pharmaceutical Dosage Form • BDF - Basic Dose Form • PFT - Patient Friendly Term If a term belongs to multiple concept classes, the EDQM Term ID, populated in the Formulation codelist, is based on the concept class order specified in this box. Removing any concept class or changing the order from this list might result in incorrect resolution of the EDQM Term ID that may affect reporting. The changes made to concept class are effective only for successful load. For example, the Lozenge term is present in multiple concept classes as PDF-10321000, BDF-0058, PFT-13220. If the default order is retained, after a successful EDQM load, the application maps Lozenge onto the PDF-10321000 EDQM Term ID in the Formulation codelist because PDF appears first in the priority order. If the PDF concept class is removed and placed after BDF in the list, then the application maps Lozenge onto the BDF-005 EDQM Term ID. The user should not remove any concept class from the Route of Administration and Dose Formulation fields.
Notification Email Address	The user provides the list of email addresses that will receive notifications regarding the status of EDQM Load process. The email message contains the changes done to Argus Code List such as new term addition, existing term updates, and term status changes. The email address of the logged-in user is populated by default. You can enter multiple email address separated by a semicolon.
Load	When a user clicks the Load button, the EDQM standard dictionary loads the local repository and updates the Routes of Administration and Formulation codelists if the system identifies any changes. During EDQM load, the display attribute is turned off for all the new terms added to code list, and the deprecated terms as per the latest dictionary files. The EDQM local repository is common to all enterprises in a database. Loading synchronizes the codelist for each enterprise based on the files uploaded using the utility.
Cancel	The Cancel button enables the user to halt the loading process that is in progress.
Status	The Status box is refreshed automatically, displaying the progression of the Load process.

For more information on EDQM, refer to the *Usage of EDQM Routes of Administration (RoA) and Dose Forms (DF) Best Practices* document.

Dictionary Loader field descriptions

The Dictionary Loader option is used to load new MedDRA, WHODrug, WHODrug-Chinese, and J Drug dictionary files, as well as to overwrite them.

Field	Description
Load New	Load the new dictionary version into the database. It loads the data in the Dictionary ZIP files selected into the newly created database schema.
Overwrite	Overwrite an existing dictionary schema in the database.
Dictionary File [.zip file containing dictionary Data]	Allows you to select the local path of the ZIP file that contains the dictionary files. You can select MedDRA, WHODrug or JDrug ZIP files.
Select	Opens the dialog box to select the ZIP file path.
Dictionary Type	This field is autopopulated for MedDRA. For other ZIP files, a drop-down list with the supported dictionary types codelist appear.
Configuration File	This is autopopulated with the latest uploaded MDB file for the dictionary type and with the date and time of the latest load.
Upload New Configuration File	Allows you to select and upload an MDB file from the local directory. The MDB file is used to load that dictionary type.
Select	Opens the dialog box to select the local MDB file path.
Upload	Uploads the selected MDB file.
Version	Select the version from the list of versions provided based on the selected MDB file. This field is autopopulated only for MedDRA based on the meddra_release.asc file.
Notification Email Address	Enter the email address where an email, with the load status, either success or failure, and the log file details, is sent. This field is autopopulated with the email address of the logged-in user from the user setup in Access Management.
Load	Start the dictionary loading process.

**Note:**

You can provide multiple email addresses separated by semicolon (;).

Field	Description
Cancel	This field is enabled only when a new load or an overwrite process is in progress. When clicked, you can cancel the loading or the overwrite process and you can roll back the loading. The load cancellation can be done only if the load hasn't finished updating the database tables. An email is sent if the loading or the overwrite is canceled.
Last Updated on	Displays the dictionary type, the date and the time in GMT of the latest successful load process.
Status	Displays the load process status for the current operation.
Log History	Presents a list with the latest three loaded dictionaries, the dictionary type, the date and the time in GMT.
Download	Downloads the log file for the selected run in the local system.

MedDRA Recode field descriptions

The MedDRA Recode window is used to recode the already coded MedDRA terms to the MedDRA dictionary version configured in System Configuration. It supports recoding in multi-tenant environments.

Fields	Description
Enterprises	Displays a list with all active enterprises in alphabetical order.
Select the Source MedDRA Version that was used for coding	Allows you to select the version that needs to be recoded. This list is autopopulated with the already loaded MedDRA dictionaries versions.
Coding Data Update/View Options (Currency determined at LLT level only)	Select the coding updates options: • Process Current Terms (Using Primary SOC Path): checks for the currently encoded terms that are current in the new dictionary. • Process Non-Current Terms (Using Primary SOC Path): checks for the currently encoded terms that are now non-current in the new dictionary. • Update dictionary version for coded terms where existing hierarchy is still current: updates the dictionary version for the terms that do not need recoding because they match the target term.
Update	Updates the Argus encoded events in the source version to the target version selected in Common Profile Switch and creates an Audit Log entry.
View Only	If you select this option, the application does not update any Argus rows and does not create any Audit Log entries.

Fields	Description
Select the target MedDRA version that will be used to recode in View Only Mode	Select the target dictionary name from the list used for recoding.
 Note: This field is available when the View Only option is selected.	
Output Log File	Select the format of the generated log, either as a delimited text or an Excel file.
Generate Log Files For Last Execution	Download a zipped file that contains all eight log files. The file is downloaded in the browser default download path. The log file specifies the enterprise short name and every log record processed for a particular enterprise.
Status	Displays information about the recode, the date and the time.

Report Features

The report prints the code list items that exceed E2B(R2) length specifications and also lists code list data that has codes not matching with codes required for the E2B(R2) report.

When Oracle Argus Safety 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.

This report does not provide the length check and Code check validations pertaining to E2B(R3), eVAERS, and eMDR reports.

The report contains the following as illustrated:

ORACLE HEALTH SCIENCES	ICSR Reports 13-SEP-2017 17:38 GMT +5.5
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ICSR Report Data Check Errors & Warnings As of 13 September 2017

List Maintenance	
1.	ICH-ICSR V2.1 MESSAGE TEMPLATE
2.	ICH-ICSR V2.1 MESSAGE TEMPLATE - EMA
3.	ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA
4.	ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA PIP

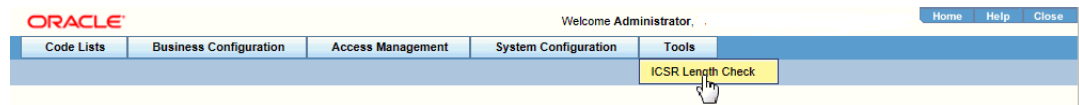
Validation Type	Data Element	DTD Element	Case Form Field	Actual Error Message	Profiles	LM Data
Length Check Validation	A.2.3.1	STUDYNAME	List Maintenance / Clinical Studies / Description	Field value exceeds the ICSR item's maximum field length. Actual Data Entered = 259, DTD Length = 100, Data Truncated = 159	1, 3	CEL-234-002
	A.2.3.1	STUDYNAME	List Maintenance / Clinical Studies / Description	Field value exceeds the ICSR item's maximum field length. Actual Data Entered = 449, DTD Length = 100, Data Truncated = 349	2	CEL-234-001
	A.2.3.1	STUDYNAME	List Maintenance / Clinical Studies / Description	Field value exceeds the ICSR item's maximum field length. Actual Data Entered = 274, DTD Length = 100, Data Truncated = 174	2	CEL-234-002
	A.2.3.1	STUDYNAME	List Maintenance / Clinical Studies / Description	Field value exceeds the ICSR item's maximum field length. Actual Data Entered = 434, DTD Length = 100, Data Truncated = 334	1, 3	CEL-234-001
Other Validation	A.1.2	OCCURCOUNTRY	General Information / Country of Incidence	Invalid E2B Code - WW	1, 2, 3, 4	WORLD
	A.1.2	OCCURCOUNTRY	General Information / Country of Incidence	Invalid E2B Code - EU	1, 2, 3, 4	EUROPEAN UNION
	A.1.2	OCCURCOUNTRY	General Information / Country of Incidence	Invalid E2B Code - RA	1, 2, 3, 4	ASIA

Viewing the ICSR Length Check Report

This section enables you to view the ICSR Length Check Report.

Use the following procedure to view the ICSR length report.

1. Select **Tools > ICSR Length Check**.



2. The ICSR Length Check PDF report opens in a separate window.

ICSR Report Data Check Errors & Warnings
As of

List Maintenance	
1.	EMA-21-OP
2.	ICH-ICSR V2.1 MESSAGE TEMPLATE
3.	ICH-ICSR V2.1 MESSAGE TEMPLATE - EMA
4.	ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA
5.	ICH-ICSR V2.1 MESSAGE TEMPLATE - FDA PIP

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	Field value exceeds the ICSR item's maximum field length. Actual Data Entered = 2000, DTD Length = 100, Data Truncated = 1900	1, 2, 3, 4	BEGINTHISSTUD END
	A.3.1.3b	SENDERTITLE	List Maintenance / Regulatory Authority / Local Company Contact / Title	Field value exceeds the ICSR item's maximum field length. Actual Data Entered = 27, DTD Length = 10, Data Truncated = 17	1, 2, 3, 4	EMA_R2
	A.3.1.3b	SENDERTITLE	List Maintenance / Regulatory Authority / Local Company Contact / Title	Field value exceeds the ICSR item's maximum field length. Actual Data Entered = 27, DTD Length = 10, Data Truncated = 17	1, 2, 3, 4	ESM FDA 1
	A.3.1.3b	SENDERTITLE	List Maintenance / Regulatory Authority / Local Company Contact / Title	Field value exceeds the ICSR item's maximum field length. Actual Data Entered = 27, DTD Length = 10, Data Truncated = 17	1, 2, 3, 4	ICH_R3
	A.3.1.3b	SENDERTITLE	List Maintenance / Regulatory Authority / Local Company Contact / Title	Field value exceeds the ICSR item's maximum field length. Actual Data Entered = 27, DTD Length = 10, Data Truncated = 17	1, 2, 3, 4	FDA_PIP

Administrator



Page 1 of 11

**Tip:**

This report compares the lengths of the code list elements with the maximum ICSR 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 ICSR length.

8

Using Advanced Conditions

This section discusses how to create and use Advanced Conditions. If you **do 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.

Oracle 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.

For more information, see:

- [Features within Advanced Conditions](#)
- [Using Advanced Conditions](#)
- [Creating Advanced Conditions](#)
- [Creating a Query Set of Advanced Conditions](#)
- [Rename Query Sets](#)
- [Use the Advanced Conditions from the Case Selection Dialog Box](#)
- [Use the Advanced Conditions Library](#)
- [Case Series \(former Hit List\) Tab](#)

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 the **Select** lookup to view/edit/create the Advanced Condition in the Advanced Condition dialog.

Note:

Only trusted users should be given access to the Advanced Condition, as users with this access will have complete access to the information in the Argus schema.

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.

This displays a confirmation dialog.

2. 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.
3. If you select No, the Advanced Condition Set dialog is displayed.

Advanced Condition -- Webpage Dialog

Advanced Condition Set - [BCG-001 study]

Name: BCG-001 study Description:

Advanced Condition Case Series

Properties

- ACTIVITIES
- ADDITIONAL INFORMATION
- ANALYSIS
- EVENTS
- GENERAL
- MEDDRA DICTIONARY ALL SOC
- MEDDRA DICTIONARY PRIMARY SOC
- MedDRA SSC (Special Search Category)

Conditions

- equal to
- not equal to
- greater than
- greater than or equal to
- less than
- less than or equal to
- missing
- exists
- begins with
- Contains
- does not contain

Field: Value: Select i Add Insert

Criteria ☒ Share with other users Permissions Delete Show SQL New

Property	Conditions	Value
Study ID	equal to	BCG-001

Save As Save OK Cancel

 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.

4. 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.

5. 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".

6. Under Value, enter the value which will apply to the property, or select an appropriate value from the list, as applicable.
7. If the condition created in steps 3 through 5 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*.

8. Click **Add** to add the newly created condition to the advanced condition.
9. Repeat steps 2 through 6 to add more conditions to the advanced condition.

10. When each of the required conditions for the advanced condition is entered, click **Save**.
11. 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.
 - Argus 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`

IMPORTANT! Customers should cleanup the aggregate case series data (such as `cfg_adv_cond_hitlist` and related tables) from the Advanced Condition Library which are no longer used or are not likely to be required in future.

With each periodic execution, the number of aggregate case series can keep growing in the system and it is up to the customers to manage these case series either by deleting them manually or by deploying an Oracle job.

 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.

For more information, see:

- [New Action Type Fields and Field Description](#)

New Action Type Fields and Field Description

Field or 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 you to configure an Advanced Conditions Rule for creating the Query Type Action Item in the case.	User Selectable

Field or Control Name	Description	Property
User Group	Enables you 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 you 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 you 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 you to generate open queries when he/she saves the case.
 - No (Default) - When you click **No**, the system **does not** generate open queries in the case when you save the case.
 - Yes - When you click **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. A dialog that prompts for the creation of an advanced condition query set opens.
2. Click **Yes** to create a set of advanced conditions by linking together those advanced conditions that have been defined previously.
3. 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.

Advanced Condition -- Webpage Dialog

Advanced Condition Set - [BCG-001 study]

Name: BCG-001 study Description:

Advanced Condition Case Series

Properties

- ACTIVITIES
- ADDITIONAL INFORMATION
- ANALYSIS
- EVENTS
- GENERAL
- MEDDRA DICTIONARY ALL SOC
- MEDDRA DICTIONARY PRIMARY SOC
- MedDRA SSC (Special Search Category)

Conditions

- equal to
- not equal to
- greater than
- greater than or equal to
- less than
- less than or equal to
- missing
- exists
- begins with
- Contains
- does not contain

Field: Value: Select Add Insert

Criteria ☒ Share with other users Permissions Delete Show SQL New

Property	Conditions	Value
Study ID	equal to	BCG-001

Save As Save OK Cancel

- 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. The SQL supports the list of parameters as defined in the profile switch *Comma separated list of allowable parameters for custom advanced conditions*.

- Select an appropriate set operator from the **Set Operator** list. This set operator will link this advanced condition to the next advanced condition.
- To add the next advanced condition to the query set, click **Add**.
- Repeat steps 4 through 6 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.

8. When each of the advanced conditions for the query set is entered, click **Save**.
9. Enter a name for the advanced condition and click **OK**.

 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.

Rename Query Sets

You can save and retrieve sets of search criteria (advanced conditions), and add, edit, or delete them.

You can select and rename a query set on the Advanced Condition screen based on the permissions to modify the advanced condition. When you open an advanced condition or query set, the query name is displayed in the Name field.

- To enable the **Save** button, in the Name field, enter an advanced condition name.
- To record changes to the advanced condition name, click **Save**.
The query set is saved with the new name and description, and the Query Set drop-down list is refreshed.
- To update the changes to the query set name, click **Save**.
- When you click **New**, all the values in the Name, Description, and Query Set fields are cleared.

Use the Advanced Conditions from the Case Selection Dialog Box

Users can view a list of Cases that satisfies an Advanced conditions from the Case Open screen.

1. Select **Case Actions > Open**.
2. You can do the following:
 - Use a set of previously saved criteria.
 - Select the appropriate set of criteria from the **Advanced Condition** list.

- Select the set of criteria from the **Advanced** list, and click the adjoining Advanced Condition icon.
- Add a new condition to a set of criteria.
- Create a new advanced condition by associating logical operators (like AND, OR) with items from the Case Form.

Use the Advanced Conditions Library

From the Utilities drop-down menu, select **Advanced Conditions Library**.

From this screen, you can:

- Create a new advanced condition
- Reassign an advanced condition
- Set advanced condition permission levels
- Modify an existing advanced condition
- Delete an advanced condition
- Print a list of advanced conditions

To search for an existing query sets or advanced conditions, enter the search criteria, and click **Search**.

Case Series (former Hit List) Tab

The Case Series (former 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 Case Series (former 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 case series (former Hit List)	Add and enter the Case ID
Remove a case from the Case Series (former Hit List)	Remove
Save the Case Series (former Hit List) result for future use	Store Advanced Condition (former Hit List)
Retrieve results of the saved Case Series (former Hit List)	Retrieve Advanced Condition (former Hit List)
Save the Case Series (former Hit List) as a text file	Export
View SQL for Query	Show SQL
Run a Query	Find Now

Data Privacy

The Oracle Argus Safety application provides various methodologies to protect data between different sites, user groups, and users. This chapter discusses personally identifiable information (PII) and the methods to protect it.

For more information, see:

- [Personally Identifiable Information](#)
- [Personally Identifiable Information and Application Behavior](#)

Personally Identifiable Information

PII (personally identifiable information) or SPI (sensitive personal information), as used in information security and privacy laws, is information that can be used on its own or with other information to identify, contact, or locate a single person, or to identify an individual in context. PII is any data that could potentially identify a specific individual. Any information that can distinguish one person from another and can be used for de-anonymizing anonymous data can be considered PII. The application protects the sensitive PII data as per user access.



Note:

All PII is personal data, but not all personal data is PII.

In Oracle Argus Safety, the following data is considered as PII:

- Patient Initials
- Patient Date of Birth
- Parent Initials
- Parent Date of Birth

The PII Data can be controlled via user group accesses and common profile switches. The user group accesses that can be used to control the PII data fields are:

- Case Patient - Patient Information
- Case Patient - Patient Details
- Case Patient - Parent Information
- Case Patient - Parent Details

These user groups accesses are found under `Argus Console > Access Management > Groups`.

In the Case Form, the patient and parent fields are grouped under the Information/Details sections as shown below.

Patient Information and Details Sections

The screenshot shows the 'Patient' tab in a software interface. The 'Patient Information' section includes fields for Title, First Name, MI, Last Name, Initials, Address 1, Address 2, City, State, Country, Postal Code, Phone Number, and Email Address. There are checkboxes for 'Protect Confidentiality' and 'Child Only Case'. The 'Patient Details' section includes fields for Date of Birth, Age 2, Units, Age Group, Height, Weight, Gender at Birth, Current Gender, Pregnant, Date of LMP, Breastfeeding, Occupation, Age at Vaccination, Units (at Vaccination), Ethnic Group, Military Status, and Pregnant at time of Vaccination. There are also text areas for UD Text 1 through UD Text 9. A 'Race Information' table is visible on the right, showing one entry: 'African American'.

Parent Information and Details Sections

The screenshot shows the 'Parent' tab in the same software interface. The 'Parent Information' section includes fields for Title, First Name, Middle Name, Last Name, and Parent Initials. The 'Parent Details' section includes fields for Date of Birth, Age, Units, Height, Weight, Gender, Date of LMP, Parent Breastfeeding, Age at Vaccination, Units (at Vaccination), and Ethnic Group. There is a 'Medical History' text area. A 'Race Information' table is visible on the right, showing zero entries.

The fields are controlled through the user groups as shown in the table below.

Group Access Name	Value	Case Form Behavior	Impacted Case Form Fields
Case Patient - Patient Information	Modify View No Access	User can add/ modify all the fields User can only view the fields The fields are hidden and inaccessible	Patient Information - Title - First Name - Middle Name - Last Name - Address 1 - Address 2 - City - State - Postal Code - Country - Email Address - Protect Confidentiality

Group Access Name	Value	Case Form Behavior	Impacted Case Form Fields
Case Patient - Patient Details	Modify	User can add/modify all the fields	Patient Information • Initials
	View	User can only view the fields	Patient Details • Date of Birth • Age and Age Units • Age Group • Weight and Units • Height and Units • Gender at Birth • Current Gender • Pregnant • Date of LMP • Breastfeeding • BMI • Body Area • Occupation • Age At Vaccination and Units • Ethnic Group • Military Status • Country • Pregnant at time of Vaccination
	No Access	The fields are hidden and inaccessible	
Case Patient - Parent Information	Modify	User can add/modify all the fields	Parent Information • Title
	View	User can only view the fields	• First Name • Middle Name • Last Name
	No Access	The fields are hidden and inaccessible	
Case Patient - Parent Details	Modify	User can add/modify all the fields	Parent Information • Initials
	View	User can only view the fields	Parent Details • Date of Birth • Age and Age Units • Weight and Units • Height and Units • Gender • Date of LMP • Parent Breastfeeding • Age At Vaccination and Units • Ethnic Group • Medical History
	No Access	The fields are hidden and inaccessible	



Note:

The initials field is located under the Information sections, but still controlled through the Details access group.

This default behavior can be overridden using a set of common profile switches. The switches located at `Argus Console > System Configuration > System Management (Common Profile Switches) > Case Processing > Group Data Access` are used for this purpose. These switches help the *Initials* and *Date of Birth* fields to be controlled via the alternate user groups as shown below.

Switch Name	Use	Default Value
Access on Patient Initials	Sets the <i>Patient Initials</i> either to be part of Patient Information or Details Group	Initials part of Patient Details Access Group
Access on Patient Date of Birth	Sets the <i>Patient Date of Birth</i> either to be part of Patient Information or Details Group	Date of Birth part of Patient Details Access Group
Access on Parent Initials	Sets the <i>Parent Initials</i> either to be part of Parent Information or Details Group	Initials part of Parent Details Access Group
Access on Parent Date of Birth	Sets the <i>Parent Date of Birth</i> either to be part of Parent Information or Details Group	Date of Birth part of Parent Details Access Group

Personally Identifiable Information and Application Behavior

This section provides details about the impacted areas and their behavior.

Case Form Print, Case Summary and Medical Summary Reports

The Case Form Print, and the Case and Medical Summary reports display PII data fields only based on the user group access and common profile switches setup.

Case Form Title Bar

For certain report types, the case form title bar displays the Patient initials. These will now be visible based on user group access and common profile switches.

Case Revision

Case Revisions display PII data based on the user group access and common profile switches.

Audit Log Report

The Audit Log reports displays the PII data based on the user group access and common profile switches. If the main user group (`Argus Console > Access Management > Groups > Patient Information`) is restricted, the new user group access and common profile switches will be ineffective.

System Reports

Both the Patient and Parent PII data in the system reports are controlled only through `Argus Console > Access Management > Groups > Patient Information`. The sub-level user group access and common profile settings do not have any effect.

Duplicate Search (Book-in, Local Affiliate and ICSR Pending)

The Duplicate search result displays the PII data based on the user group access and common profile switches.

Case Copy and Audit Logging

Case Copy and the Audit Log continue to handle PII data even when the fields are hidden or read-only.

Copy Patient Information from Reporter

Patient initials are copied from the reporter only when the Patient initials field is visible and editable.

Patient/Parent Initials Automatic Calculation

The Patient or Parent Initials are automatically calculated when the Patient or Parent initials field is visible and editable.

Accept ICSR/Affiliate Acceptance (Interchange and LAM)

The Accept ICSR/Affiliate Acceptance dialogs and reports work as in the existing version of Argus Safety. These modules do not follow the PII restrictions levied by user group access setting and common profile switches.

The following sections provides a sample of the Case Form behavior between two users who have been set up for PII Data Privacy.

User Details	Access Settings
User 1	User ID: usr_pat_info Group: Patient_info_group Access Setting: Case Patient - Patient Information: No Access Case Patient - Patient Details: Modify
User 2	User ID: usr_pat_det Group: Patient_det_group Access Setting: Case Patient - Patient Information: Modify Case Patient - Patient Details: No Access

No changes to the common profile set up from the default values.

With the above set up when user 1 and user 2 logs into the application, the application behaves as following:

Logged in User	Application Behavior
usr_pat_info	In the case patient tab, all the fields under Patient-Information group are hidden except Initials, Child Only case and Country fields.
usr_pat_det	In the case patient tab, all the fields under Patient-Details group are hidden. Patient Initials, Child only Case and Country fields are hidden too.

Sample Documentum Configuration JSON file

```
{
  "rest_url_scheme": "http",
  "rest_url_host": "{SERVER_URL}",
  "rest_url_port": {SERVER_PORT},
  "rest_repo": "{THIRD_PARTY_REPO}",
  "username": "{USERNAME}",
  "password": "{PASSWORD}",
  "category_mapping": [
    {
      "category": "attachment",
      "cabinet": "{CABINET_ID}",
      "object_type": "case_attachment"
    },
    {
      "category": "icsr",
      "cabinet": "{CABINET_ID}",
      "object_type": "argus_report"
    },
    {
      "category": "expedited",
      "cabinet": "{CABINET_ID}",
      "object_type": "argus_report"
    },
    {
      "category": "periodic",
      "cabinet": "{CABINET_ID}",
      "object_type": "argus_report"
    }
  ]
}
```

Sample DDL file for Documentum integration

```
using System.Collections.Generic;
using System.IO;

namespace Oracle.Argus.Bridge.Service.Contracts
{
    /// <summary>
    /// Document adapter template that the integration hub will use to query
    the content management system.
    /// </summary>
    public interface IDocumentAdapter
    {
        /// <summary>
        /// Logger interface for debugging. Bridge API will provide a wrapper
        to existing Argus logging functionality.
        /// </summary>
        ILogger Logger { get; set; }

        /// <summary>
        /// Dictionary containing adapter configuration details to connect to
        content management system.
        /// </summary>
        string DictionaryConfig { set; }

        /// <summary>
        /// Checks if the adapter can connect to the third-party content
        management system.
        /// </summary>
        /// <returns></returns>
        bool IsAlive();

        /// <summary>
        /// Pushes the document object into the content management system.
        /// </summary>
        /// <param name="attributes">Special attributes that help describe
        the document</param>
        /// <param name="fileData">File byte array data</param>
        /// <param name="fileName">Complete title of a file and file
        extension</param>
        /// <returns>ID of newly created document object</returns>
        string PushDocAsync(IDictionary<string, object> attributes, byte[]
        fileData, string fileName);

        /// <summary>
        /// Fetches the file data from content management system.
        /// </summary>
        /// <param name="ecmId">ID of document object</param>
        /// <returns>Stream of file data of document object</returns>
        Stream RetrieveDoc(string ecmId);

        /// <summary>
        /// Fetches the file data from content management system.
```

```

        /// </summary>
        /// <param name="ecmIds">Array of IDs of document object</param>
        /// <returns>Byte array of file data of document objects</returns>
        IEnumerable<byte[]> RetrieveMultiDoc(string[] ecmIds);

        /// <summary>
        /// Updates the special attributes of a document object.
        /// </summary>
        /// <param name="ecmId">ID of document object</param>
        /// <param name="dictAttr">Any combination of special attributes</
param>
        /// <returns></returns>
        string UpdateDocAsync(string ecmId, IDictionary<string, object>
dictAttr);

        /// <summary>
        /// Searches document objects with search request.
        /// </summary>
        /// <param name="dictSearchAttr">Any combination of special
attributes</param>
        /// <param name="lstDisplayAttr">List of document attributes to
attach with search record</param>
        /// <returns>IDs and display attribute values of matching document
objects</returns>
        IList<IDictionary<string, object>> SearchDoc(IDictionary<string,
object> dictSearchAttr, IList<string> lstDisplayAttr);

        /// <summary>
        /// Deletes the document object from content management system.
        /// </summary>
        /// <param name="ecmId">ID of document object</param>
        /// <returns>Status of deletion</returns>
        string DeleteDocAsync(string ecmId);
    }
}

```