Oracle Argus Safety
User's Guide

Release 8.4.3

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ORACLE®

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Preface

This preface contains the following sections:

- Documentation accessibility
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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

To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.

Cloud customers receive support assistance through Support Cloud

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface of Oracle Life Sciences Support Cloud (https://hsgbu.custhelp.com/)

- Japanese interface of Oracle Life Sciences Support Cloud へようこそ (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit Life Sciences Support | Oracle or visit Oracle Accessibility Learning and Support if you are hearing impaired.

On-premises customers receive support assistance through My Oracle Support

Oracle customers that have purchased support have access to electronic support through My Oracle Support. For information, visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info or visit http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs if you are hearing impaired.

1
Know your basics

In this chapter:

- Product overview
- Log in
- Change your password
- Begin on the Personal Argus Status page
- Use the Quick Launch Toolbar
- Use field validations
- Acceptable date formats
- Use other (than English) language text
- Enter reasons for missing (Null Flavor) data
- Dynamic workflow indicator
- Case form user preferences
- Scale and Layout
- Integrate with Oracle Argus Insight
- ETL status for enterprise products
- Log out
- FAQs

Product overview

Argus Safety is a complete pharmacovigilance software system designed to solve the pharmaceutical industry's toughest regulatory challenges. Argus Safety supports drug safety business processes from an easy-to-understand user interface.

Log in

1. Open your browser and enter the URL for Oracle Argus Safety in the address bar.

   > ✎ **Note:**
   >
   > Contact your System Administrator for the Oracle Argus Safety URL.

2. When the login screen opens, perform the following:

   a. Enter username and password.

   b. Select a value from the **Database** drop-down list.

   c. Click **Login**.

Autofill password: If the password save option is enabled in modern browsers, Oracle Argus Safety allows to select a saved password during the login. When you type the username, the Password field displays the hidden password for the selection and you can log in without actually typing the password.

> **Note:**
>
> We recommend that you don't use the password save option.

The default Home page set by the Administrator appears. This can be the Personal Argus Status page or one of the worklists, depending on user preferences defined in the Argus Console.

> **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.

Scale and layout

- The supported screen scale (zoom) is 100%. If the scale is not set to 100%, it may lead to distortion or truncation of the user interface.
- The recommended layout (display resolution) is minimum 1280 x 1024.
- Depending on the medium of device used (monitor, laptop, etc.) the supported layout may vary. Set the resolution according to your monitor settings.

> **Note:**
>
> Disable the pop-up blocker in the browser's advanced settings. Disable **Save and fill addresses** in your browser's settings.

Change your password

1. Hover over the **Utilities** menu, and click **Change Password**.
2. Enter your current password in the **Old Password** field.

3. Enter the new password in the **New Password** field, and confirm the new password by re-entering it.

4. Click **OK**.

> **Note:**
>
> This capability is available when the user ID and password are maintained in Oracle Argus Safety and does not apply if your Oracle single sign-on is enabled.

Begin on the Personal Argus Status page

The Personal Argus Status page displays the cases assigned to you, your Contact Log entries, your pending action items, and any overdue action items.

- To view your assigned cases, check the **Cases Assigned** checkbox.
- To view your Contact Log entries, check the **Contact Log Entries** checkbox.
- To view your pending action items, check the **Action Item Entries** checkbox.
- To view your overdue actions items, check the **Overdue Action Items** checkbox.

> **Note:**
>
> If the Personal Argus Status page is not your Home page, hover over the **Dashboards** menu and click **Personal Argus Status**.

Use the Quick Launch Toolbar

The Quick Launch Toolbar is on the top right side of the screen.

Figure 1-1   Quick Launch Toolbar

Place the cursor over each icon to view the tool tip, which describes the role of each icon.

> **✏ Note:**
>
> Shortcut keys are driven by a combination of common profile switches and menu access rights. For the example:
>
> ```
> The Case Save shortcut/icon is visible only to users who have been granted
> access to save the case in the group configuration. If the menu option is
> disabled in the group configuration for a user, the respective shortcut /icon
> is also removed.
>
> Certain shortcuts/icons such as Field Validation are enabled only through a
> common profile switch. Shortcuts/icons that are driven through common profile
> switches are global to all users and are not controlled by group permissions.
> ```

Icon	Tool Tip	Description
	New Case	Displays the **Initial Case Entry** dialog box.
	Open Case	Displays the **Case Search** dialog box.
	Worklist	Displays the **Worklist** dialog box. If no default Worklist option is defined, then **Worklist - New** is displayed.

Use field validations

1. Click the icon next to a field to view its corresponding Field Justification dialog box.

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

    - Enter a specific reason.
      OR

    - Select a standard reason from the message box.

3. Click **OK** to overwrite the field justification warning.

   The orange icon changes to green.

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

- A red icon signifies that a mandatory validation check has not been met.You need to correct the data entry before being able to save a case.

- An orange icon signifies that an optional validation check has not been met. You need to enter justification but can then continue to save the case.

Acceptable date formats

Several fields in the Oracle Argus Safety user interface enable you to enter dates. Fields that accept full dates appear in the *dd-mmm-yyyy* format.

Appropriate formats for entering English dates are as follows:

- DDMMMYYYY where MMM is the three-character abbreviation for the month (such as MAR, APR, JUN, and so on.)

- DDMMMYY where MMM is the three-character abbreviation for the month and YY is the two-digit numeric value for the year (such as 09, 10, and so on.)

- DDMMYYYY where MM is the two-digit value identifying the month (such as 01 = January, 02 = February, etc.) and YYYY is the four-digit value for the year.

The dot (.), dash (-) and backslash(/) are acceptable separators.

Use other (than English) language text

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

> **✎ Note:**
>
> When a case is in a specific workflow state, for which the parameter **Enable multi-lingual fields in locked case** is set in the workflow configuration, then the Multilingual dialog boxes are enabled for data entry, even when the case is locked globally or locally.
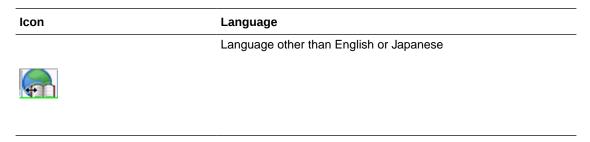
To enter text in a language other than English:

1. Click the **English language** icon.

2. Use the pane associated with English to enter the English language text. Select the required language from the **Select Language** drop-down list to enter text in that language.

3. After completing text entry, you can perform a spell-check for the text.

The table below displays icons representing different languages.

Icon	Language
	English
	Japanese

Icon	Language
	Language other than English or Japanese

For more information, see:

- [Text translation](#)
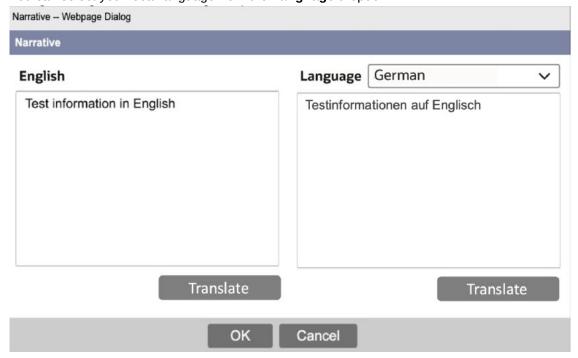
Text translation

You can use the multilingual dialog box to translate text from English to any local language and vice-versa.

> **Note:**
>
> Translation from one local language to another local language is not supported.

You can select your local language from the **Language** dropdown.

The **Translate** buttons are available in the multilingual dialog box only if the **Enable Translation Service** option is enabled in Argus Console > System Configuration > Webservice > Bridge Configuration > Translation. If that option is disabled, the **Translate** buttons are not visible on the screen.

The **Translate** button is also disabled when there is no text entered in any of the language textboxes (English /Selected Language), as seen below:

If you clear the entered text from either one of the language textboxes, or if you do not select a language from the dropdown list, then the **Translate** buttons are disabled.

Multilingual dialog supported fields

The following fields in Argus support translation by using the multilingual dialog box:

No.	Case Form/ Console location	Field name
1	General tab > Reporter Information	Reporter Institution
2	General tab > Reporter Information	Reporter Notes
3	General tab > Reporter Information	First Name
4	General tab > Reporter Information	Middle Name
5	General tab > Reporter Information	Last Name
6	Patient tab > Patient Information	Patient Notes
7	Patient tab > Patient Information	Initials
8	Patient tab > Relevant Tests	Patient Relevant History Tests
9	Patient tab > Other Relevant History	Relevant History Notes
10	Patient tab > Pregnancy Information	Delivery Notes
11	Parent tab > Other Relevant History	Parent Relevant History Notes
12	Products tab > Product Information	Product Name
13	Products tab > Product Information	Product Generic Name
14	Products tab > Product Information	Product Notes
15	Products tab > Product Indication	Product Indication as reported
16	Products tab > Product Details	Related Device Comments
17	Products tab > Device > Device Information	Device Comments
18	Events tab > Event > Event Information	Event Description as reported
19	Events tab > Event > Details	Event Details
20	Events tab > Event > Cause of Death and Autopsy Results	Death Cause as reported
21	Analysis tab > Analysis > Case Analysis	Evaluation in light of similar events in the past

No.	Case Form/ Console location	Field name
22	Analysis tab > Analysis > Case Analysis	Case Comment
23	Analysis tab > Analysis > Case Analysis	Abbreviated Narrative
24	Analysis tab > Analysis > Case Analysis	Narrative
25	Analysis tab > Analysis > Case Analysis	Company Comment
26	Console > Business Configuration > Studies	Study Description

Enter reasons for missing (Null Flavor) data

Null Flavors are used to describe the reason for missing data. ICH E2B(R3) and regional agencies such as CBER, EMA, MFDS, and PMDA have published guidelines on the allowed Null Flavors for various fields that are part of the E2B(R3) report. A Null Flavor set is a collection of Null Flavors. Sets are provided by default for various combinations of Null Flavors in the Flexible Re-categorization Codelist.

Null Flavor data can be selected for fields in the Case Form by clicking on the Null Flavor button ( ) next to the fields. On clicking the button, a drop-down list appears and allows you to select Null Flavor data as configured in the Field Properties Configuration in the Argus Console. The background color of the NF button changes (from grey to blue) when a Null Flavor is selected from the drop-down list.

When the Case Form field has data and the user clicks the button, the system displays a warning message that data will be cleared on switching to the Null Flavor field. The data is cleared or retained based on user confirmation. When data pertaining to the field is received, Null Flavor data can be overwritten by actual data by clicking the NF button.

Dynamic workflow indicator

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

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

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

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

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

Case form user preferences

The application lets you return to the same location on the tab after you tab to a different form. For the example:

```
You are on the 8th reporter in the Reporter Section on the General tab and move to
another location in the application. When you return to the General tab, you are
automatically directed to the 8th Reporter as it was the last Case Form location that
you accessed before moving out of the Case Form.
```

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

Quick navigation

Each page displays the navigation flow to access the page.

Shortcut Key	Output
CTRL+SHIFT+#	Directs to the tab indicated by the # entered. (1=General tab, 2=Patient tab, etc.)
ALT+SHIFT+#	Directs to the sub-tab as indicated by the # entered (= Product 1, Product 2, etc.)

> ✏ **Note:**
>
> The maximum # for the sub entities is 10 which pertains to ALT+SHIFT+1 for the first entity within the tab till ALT+SHIFT+0 for the 10th entity within the tab.

Scale and Layout

The supported scale (zoom) is 100%. Consider the following:

- Distortion or truncation of UI display of Argus may occur if scale is not set to 100%. The recommended display resolution is minimum 1280 x 1024.

- Depending on the device used (monitor/laptop/etc.), the supported layout may vary. Set the resolution according to your monitor settings.

Disable the Pop-up blocker in the **Advanced** settings section of your browser.

Disable the **Save and fill addresses** option in the **Settings** section of your browser.

Integrate with Oracle Argus Insight

Oracle Argus Safety has the following integration points with Oracle Argus Insight. All these integration points operate within the same enterprise for both Oracle Argus Safety and Oracle Argus Insight.

> **Note:**
>
> This integration is available only to Argus Enterprise Edition users.

- **Case Series Sharing**: In case of multi-tenant installations, Oracle Argus Safety > `Case Actions > Case Open screen > Result from Argus Insight` imports the active case series for the user from the same enterprise partition of Oracle Argus Insight which is currently opened in Oracle Argus Safety.

- **Oracle Argus Insight Application Launch**: The Oracle Argus Insight button in the main Argus Navigation bar opens the same enterprise partition of Oracle Argus Insight which is currently opened in Oracle Argus Safety.

For more information, see:

- Sharing a case series in Oracle Argus Safety with Oracle Argus Insight
- Sharing a case series in Oracle Argus Insight with Oracle Argus Safety

Sharing a case series in Oracle Argus Safety with Oracle Argus Insight

1. In the Case Search dialog box, search for and select a case in Oracle Argus Safety.

2. Open Oracle Argus Insight.

   The system writes the case series belonging to the alert to the Argus case-sharing table.

3. Check **Make Active from Argus** to make the Case Search dialog box case series active in Oracle Argus Insight.

4. If Oracle Argus Insight was already open, the Active Case series in Oracle Argus Insight is replaced with cases from Oracle Argus Safety.

Sharing a case series in Oracle Argus Insight with Oracle Argus Safety

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

1. Hover over the **Case Actions** menu and click **Open**.

2. Click **Result from Argus Insight** to create a search result with the same cases as the Active Case series in Oracle Argus Insight.

ETL status for enterprise products

You can view the data migration status (ETL) from the Argus Safety source system to the Enterprise Edition application target systems: Argus Insight, Argus Mart, and Argus Analytics. This ETL status is displayed in a dashboard. The ETL Status dashboard is available for both Argus English and Argus Japan users.

To view the ETL status, click `Dashboards > ETL Status.`

> **Note:**
>
> This menu option appears only when it is enabled from `Argus Console > Access Management > Groups > Menus > File > ETL Status.`

- The ETL Status dashboard displays the most recent row from the frequently executed ETL processes.
- For Argus Safety Standard Edition, a message appears as `No ETL runs available.`
- For Argus Safety Enterprise Edition, both new installations and post upgrade:
  - ETL status of the subscribed products is displayed. Unsubscribed product row does not appear in the dashboard.
  - When an ETL is not started, or no records are present for the product, then **Not Started**status is displayed.

> **Note:**
>
> When the ETL logs are cleaned up, the **Not Started** status is displayed in the dashboard.

General information—field descriptions

Field	Description
Product	Displays the name of the Enterprise Edition application: • Argus Analytics • Argus Insight • Argus Mart > **Note:** > If any product is not integrated, then that option is not displayed.
Database Name	Displays the database names of the enterprise product.
ETL Type	Displays the ETL execution type. • Initial—Performed initially, a full copy of the data set is transferred from the source to the target system. • Incremental—Performed on regular basis, changes made to the ICSR cases in the Argus Safety source database are captured from the last migration, including new records, updates to existing records, and deletions.

Field	Description
Start Date (GMT)	Displays start date and time of the initial or incremental ETL execution. Date is displayed in the DD-MMM-YYYY H24:MM: SS GMT format. **✎ Note:** When the ETL Status is Not Started, the Start Date column remains blank.
End Date (GMT)	Displays end date and time of the initial or incremental ETL execution. Date is displayed in the DD-MMM-YYYY H24:MM: SS GMT format. **✎ Note:** • When the ETL status is In-Progress, Not Started, or Unknown, the End Date column remains blank. • When the ETL status is Completed or Failed, the End Date displays the date and time. • For Argus Insight, when the ETL status is Failed, the End Date column remains blank.
Status	Displays the data migration status. • Green circle—ETL execution has completed successfully. • Yellow circle—ETL execution is in-progress. • Red circle—ETL execution has failed and stopped due to errors. • Blue circle—ETL execution has not started. • Grey circle—ETL execution status is unknown and cannot be retrieved due to communication link error. When the status is Failed (red circle), an error link appears in the Status column. Click this error link to view details.
Refresh	Click **Refresh** to retrieve the recent ETL execution status from the respective databases.

Log out

In the upper-right corner of any page, click **Logout**.

FAQs

- [What happens if I enter a wrong password?](#)
- [Why can't I change my password?](#)
- [How do I get help?](#)

- [How do I view contents of the generated PDF when it contains uncommon or unsupported characters?](#)
- [How do I trigger autocalculation?](#)
- [How do I generate batch reports?](#)

What happens if I enter a wrong password?

The password is case-sensitive.

If you enter an incorrect username or password several consecutive times, based on the current settings, Oracle Argus Safety then performs one of the following:

- Disables the **Login** button and displays a warning message.
- Locks your account. If this occurs, you must contact your company Administrator to unlock your account. If you are still unable to login, please contact My Oracle Support.

> **Note:**
>
> The number of failed login attempts for log in of is configurable from `Argus Console > System Configuration > System Management (Common Profile Switches) > Security > Number of consecutive failed login attempts before account is locked out.`

> **Note:**
>
> In all other places in Oracle Argus Safety where you are prompted to enter a password for critical operations like lock, unlock, route, delete, if the failed log in attempts reaches three, the session will expire, but your username will not be locked.

> **Note:**
>
> The application sends an email for **Invalid Log-in** entries to a pre-configured email address that specifies the username used for Login along with the terminal from where the user tried to login to the system.

> **Note:**
>
> If you still cannot log in and you do not receive the **Login Error** dialog box, verify that the **Pop-up Blocker** functionality is disabled for your browser.

Why can't I change my password?

You may have exceeded the number of wrong entries. Ask your Administrator to reset your password.

If you are logged in and the password change has not been accepted, hover over the **Utilities** menu and select **View the Error Log** under **Logs** for details.

How do I get help?

To get task-based help, click **Help** on the top-right frame of the window. This takes you to the respective product page on Oracle Help Center.

To get field-level help on the Case Form, double-click the label associated with the field to obtain information about that field.

How do I view contents of the generated PDF when it contains uncommon or unsupported characters?

When the report generated from Oracle Argus Safety is viewed in Google Chrome or Microsoft Edge, there is a possibility that some characters are missing in the output. To view the generated PDF that may contain characters in language other than English, make sure the Acrobat reader extension is enabled in your browser. Save the generated PDF to your local drive, and use Acrobat reader to view the contents.

How do I trigger autocalculation?

In general, you trigger autocalculation when you use the Tab key to move from field to field. Some examples of autocalculation include check box selection and case save.

How do I generate batch reports?

The **Batch Reports** dialog displays a list of those batch reports that have been scheduled for generation.

To view a list of batch reports:

1. Select **Batch Reports** from **Utilities** in the menu bar.
2. The system opens the **Batch Reports** dialog box with a list of batch reports along with their report titles and next run dates.

To delete a batch report from the list:

1. Select the check box corresponding to the batch report to delete.
2. Click **Delete**.

2
Enter case data

In this chapter:

Create a new case

When your company receives new adverse event data, you need to enter this information and check for duplicates before saving a case in Oracle Argus Safety.

You can create a new case by doing either of the following:

- Select **Case Actions**, and click **New**.
- Select **Worklist**, and click **Intake**.

For more information, see:

Enter a new case

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

To enter a new case:

1. On the Home page, hover over the **Case Actions** menu and click **New**.

2. On the Initial Case Entry page, enter the mandatory information (fields with a red flag) and click **Continue**.

3. Click **Search** to confirm this is not a duplicate case.

4. A list of cases that match the criteria you entered on the form is displayed along with their duplicate search score. Review the search results for a duplicate case.

If a duplicate case exists, open the case to enter further information related to the existing case. Click the link associated with the case.

> **✎ Note:**
>
> If the **Enable Smart Duplicate Search** switch is enabled in `Console >`
> `System Configuration > Common Profile Switches > Case`
> `Processing > Duplicate Search`, then the application uses the smart
> duplicate search algorithm to execute duplicate search on the Initial Case Entry
> screen, else the existing duplicate search algorithm is used.
> Besides, the **Score** field appears in the result only when this switch is enabled.

5. If a duplicate case does not appear, click **Continue** in the Initial Case Entry form to display the BookIn and Attachments and References sections.

   When a duplicate search is performed, the system remembers the results until the user logs out of the system or performs a duplicate search again. When the Bookin screen is opened, the search results from the last search are displayed again.

6. Enter the relevant information in the following sections:

   • Under **Reported Causality**, select the reporter's assessment of causality. The causality relationship is the causal relationship between the clinically most important event and the suspect drug that is entered in the Initial Case Entry form.

   • For **Seriousness Criteria**, check the appropriate checkboxes to indicate the seriousness of the case, as appropriate.

   • **Attachments and References**

   To insert a file attachment

   a. Click **Add** on the Attachments and References tab.

   b. Enter the Classification and Description, as applicable. Select **File Attachment** from the drop-down list and click **Add**.

   c. On the File Attachment -Web page dialog box, double-click **Browse** and navigate to the relevant file. Click **OK**.

      Contact your system administrator to configure this location.

   To insert a URL Reference

   a. Select **URL Reference** from the drop-down list.

   b. Enter the URL after `http://`.

   To search for and insert a document

   a. Select **Documentum Link** and click **Add**.

   b. The **Document Lookup** dialog box is displayed.

      You can search for a document from the database by specifying a search criterion in this dialog box.

7. Click **BookIn**.

   Once clicked, this button is hidden from the screen. The button is enabled only if the Save operation fails or when the case is booked-in successfully.

8. If the application has been configured to generate a case number automatically, it is generated now.

If the case number is not automatically generated, enter it according to your company guidelines.

9. When the case creation message appears, click **Yes**.

> **Note:**
>
> If you click **Yes**, the Case Form page appears. You can now enter case data.
>
> If you click **No**, the case is saved and closed. You can open the case and enter data at any time.

Initial case entry—fields descriptions

Field	Description
Initial Receipt Date	Enter the complete date on which your company became aware of the case. The Receipt Date cannot be entered as a partial date.
Central Receipt Date	Enter the date on which this information was received by Central Safety.
Country of Incidence	Select the country where the adverse event occurred. This may or may not be the reporter's or the patient's country of residence.
Report Type	Select the item that best describes the type of report. This determines the fields that are made available for entering case information. The report type also impacts duplicate search. For example, selecting **Sponsored Trial** makes the **Study ID** and **Protocol ID** fields available. The Administrator can adjust the information in this list.
Study ID(applicable to clinical trial cases only)	Click **Select** to choose the study ID from the **Clinical Trial Selection dialog box**.
Center ID (applicable to clinical trial cases only)	Click **Select** to choose the **Center ID** from the **Clinical Trial Selection dialog box**.
Initial Justification	The values of this field are configurable through the standard Justifications dialog box. This field is reflected in the General tab of the Case Form and is also available for duplicate searching for cases. Click the green dot to view and select justifications from the Justification dialog box.
Product Name	If the adverse event(s) are associated with more than one product, each additional product can be added from the Case Form. Enter the most suspect product here. Click **Select** to search for a product from the **Trade Name Product Lookup** dialog box. Several items are automatically entered on the Case Form based on the product selected here.
Generic Name	This field can be used to enter the generic name of the product. This field is automatically entered when a product is selected from the **Trade Name Product Lookup** dialog box.

Field	Description
Batch/Lot #	In this field, you can enter the batch or lot number in a free-text form to search for duplicate cases. The search is performed on the following case fields: • Drug > Dosage Regimens > Batch / Lot # • Device > Device Information > Lot • Vaccine > Vaccine Information > Batch / Lot #

> **Note:**
>
> The **Dose #** field from Vaccine > Vaccine Information > Vaccine History is not included in the search.

Field	Description
Description as Reported	Enter a brief verbatim description from the reporter describing the event that is most clinically important in the case. The icon denotes that the event is encoded. Click the icon to populate the MedDRA hierarchy dialog box.
Onset Date/Time	Enter the date/time for the onset of adverse event symptoms.
ID	Enter the value to search for a Reporter Reference number, Case Reference, and Case number.
Journal and/or Title	These items are applicable to literature cases only. Click **Select** to choose a journal and/or title from the Literature Reference dialog box. The Administrator can adjust this list.

Check for duplicates

1. Enter the information related to the case in the Initial Case Entry form.

2. Select the **Receipt Range Limits** option to check for duplicates based on the dates entered in the form and click **Search**.

   If the **Enable Smart Duplicate Search** switch is enabled in `Argus Console > System Configuration > Common Profile Switches > Case Processing > Duplicate Search`, then the application search records based on the Smart Duplicate Search algorithm, otherwise the existing duplicate search algorithm is used.

3. Review the list to determine if any case contains duplicate information.

For more information, see:

• Receipt range—fields descriptions

• Smart duplicate search

Receipt range—fields descriptions

Field	Description
No date	90 days before System Date and 2 days after System Date.
Full Onset Date	10 days before Onset date and 90 days after Onset Date.

Field	Description
Full Initial Receipt Date	60 days before Initial Receipt Date and 60 days after Initial Receipt Date.

> **Note:**
>
> This default date range for searching on Initial Receipt Date can be disabled by un-checking the **Receipt Range Limits** option on the **Initial Case Entry** dialog box.

Field	Description
Partial Onset Date	Based on the Full Date Range - if only the year is entered, the date range becomes: 10 days before the end of the previous year and 90 days after the end of the year.
Partial Initial Receipt Date	Based on Full Date Range - if only a year is entered, the date range becomes: 60 days before the end of the previous year and 60 days after the end of the year.

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

Smart duplicate search

The smart duplicate search considers all the values present in the incoming record or search criteria to find the potential matching records. It returns the matching case record, even if some of the values in search criteria do not match as those values do not contribute to total match score.

The application uses this algorithm only when the **Enable Smart Duplicate Search** switch is enabled in `Argus Console > System Configuration > Common Profile Switches > Case Processing > Duplicate Search`, and displays a record match score in the **Score** field. By default, the search result is sorted in the descending order of the score.

If the **Enable Smart Duplicate Search** is not enabled, the duplicate search does not return a record even if a single criteria does not match. For example, if all the search criteria values are matching to a record except patient age, then the duplicate search does not return this case record, while the smart duplicate search fetches this record in the search results for a total match score above the predefined score threshold. Hence, the smart duplicate search reduces the number of search iterations making the process more efficient.

> **Note:**
>
> This switch is global that is, any changes made to this switch impacts all the enterprises.

Score Threshold

A threshold value is defined in `Argus Console > System Configuration > System Management (Common Profile Switches) > Case Processing > Duplicate Search`. While searching for a case record, the smart duplicate search algorithm displays matching records having a score of predefined threshold or more. The threshold is also referred as the record level score threshold.

> **Note:**
>
> This switch is set at the Enterprise level. Any changes made to this switch impacts only that enterprise.

Smart search algorithm

The smart search algorithm use fuzziness such that you can enter all the search criteria at once and the records are returned based on the total score. It is possible that one or more of the search criteria does not match a record in the result, but still appears in the results list, if the total score is higher than the configured threshold.

For example, if the record threshold is 50, then only matching cases with score of 50 or more are displayed in the list.

The following are the main features provided by the smart search algorithm:

*   **Numerical Scoring** - Smart Search algorithm applies numerical scoring to the numeric and date fields, so that, the entered search criteria matches the value in the case record, if the value is within pre-defined threshold.
    For example, for a threshold of 1 month, the patient age of 12 months should match 11 months. Similarly, for a threshold of 15 days, the Event Onset date 10-Jan-24 should match 20-Jan-2024.

    The lower is the deviation between the search criteria and the matching value, higher is the score contribution, and vice-versa.

*   **Soundex** - A feature to match misspelled text fields or names with similar sounds is available using the **Full Search** check box on the Initial Case Entry screen.

*   **Weighted Matching** - Each matching attribute contributes differently to the scores based on the pre-configured weight.
    For example, if Patient DOB has more weight configured than Patient Age, then the Patient DOB field contributes more to the total score than the Patient Age field.

*   **Transposed Date Matching** - Transposed date, that is, date with day and month swapped is also considered as a match with more score to an original date than the transposed date.
    For example, Patient DOB: 10-Jan-2024 matches 01-Oct-2024.

> **Note:**
>
> – Date thresholds are applied to date as well as transposed date.
>
> – Date limits are calculated based on the input date and not based on the transposed date.
>
> – Records with transposed date are considered if they are within the date limits, else they are excluded. For example:
>   For the initial receipt date of 03-Jan-2024, the receipt range limit is 04-Nov-2023 to 03-Mar-2024. In this case, the transposed date 01-Mar-2024 falls within the date limits calculated from 03-Jan-2024.
>
>   Whereas, in case of the initial receipt date of 10-Jan-2024, the receipt range limit is 11-Nov-2023 to 10-Mar-2024 and the transpose date 01-Oct-2024 does not fall within the date limits. Hence, the record with the transposed date is not considered as a match.

*   **Exclusion Criteria** - This is to ensure that there are no performance issues. If any of the following fields do not match, then the record is excluded from the search results:

    – Report Type

    – COI

    – Gender

    – Initial Receipt Date

> **Note:**
>
> As the above fields are part of the exclusion criteria, and hence these fields do not contribute to the match score, and do not show up in the Match Score Explanation screen. However, the Initial Receipt Date field is an exception as this field contributes to the match score as well as appear in the Match Score Explanation screen due to numerical scoring.

Match Score

To understand the score value, from the duplicate search results, click **Score** of the selected record. The Match Score Explanation screen appears with the fields for which search criteria has been entered.

The Match Score Explanation screen shows comparison of the values, which are searched with the corresponding values in the matching case record. You can also view the contribution of each field to the total match score along with the match type, that is, if it is an exact match, similar values, or no match; so as to take a decision on whether the incoming record is a duplicate or follow-up of the selected record or not.

> **Note:**
>
> The match score also depends on the number of search terms. The significance of number of terms in the search criteria diminishes with the increase in search terms. However, for a lower number of search terms like searching only by Reporter's First Name as the search criteria may return a very less score (as low as 5), even on the exact match. Hence, Oracle recommends to search with more basic available information for the case rather than searching on only one field.

If the Reference ID or case number matches, then this field is prioritized over the rest of the fields and the case record is considered as a match with 100 score ignoring the match score contribution for rest of the fields. Match Type is the Camel Casing in this scenario.

Total score for the record is rounded off to a whole number, and hence there can be round off error between the sum of individual field scores and total score.

Reference ID field, if available in the search criteria, is always the first field in the Match Score Explanation screen.

Field name	Description
Search Criteria	Displays the values in the search criteria or incoming record being searched against. > **Note:** > > Only duplicate search fields that are checked and have values in the incoming record or search criteria are displayed. > > Exclusion Criteria fields are not displayed in the Match Score Explanation screen as these fields do not contribute to the total score. > > The Initial Receipt Date field is always displayed, if entered as search criteria or present in the incoming record.
Selected Record	Displays the value for the matching case record. For example, if the search criteria matches Patient First Name, then only First Name is displayed under Selected Record. • In case of no match, Patient First Name and Last Name are displayed separated by space. • If only Patient First Name or Last Name is available, then non-blank values are displayed. • If Patient First Name and Last Name, both are blank, then Patient Initials are displayed. If patient initials are also unavailable, this field is left blank.
Score	Displays individual contribution to the total score by each field. It helps to understand how much each field has contributed for the record to be a match. Individual field score is rounded-off to 2 decimal places.

Field name	Description

Match Type	Displays type of the values that are matched:
	• **Priority Match** - If the fields with high priority matches, like Reference ID.
	In case a record is a priority match, the Match Type is displayed as N/A as well as Score for rest of the fields in the search criteria.
	• **No Match** - A criterion that is used during the search, but the searched value do not match the value in the duplicate search result case record being assessed.
	• **Exact Match** - A criterion that is used in the search, where the value in the duplicate search result case record being assessed matches exactly.
	• **Similar Values** - A criterion that is used in the search, where the intent of the values match, but are reported or captured as other similar values that are close to the value searched (such as dates within range, age ranges, Soundex, etc.). For example:
	  – Soundex: "Johnson" vs "Jonsen"
	  – Misspelling: "Headahce" vs. "Headache"
	  – Date Range match: "20-Nov-2023" vs "21-Oct-2023"
	As Argus uses Oracle Text which is designed to match information based on the text (word) entered, if there are fields with same value and are variants, then also the record is considered as a similar match, and assign them with same score. For example, if a record has symptom as Rash, and the other one has Severe Rash, then both the records are considered as similar match, and assigned same score.

Initial case entry—BookIn dialog box

- You can enter the attachment classifications and their descriptions on the Initial Case entry dialog box.

- The values entered in the **Classifications** and **Description** fields are transferred after the cases have been booked.

- When you book in a clinical trial case and select a study where the country of incidence value does not match the list of countries defined in the study configuration, a warning message appears.

- Right-click the row, and select one of the following:

  – View Case Summary

  – Print Medical Summary—Displays the Medical Summary report PDF. If you do not have access to the Medical Review dialog box, the Medical Summary Report is hidden.

  – Print—Launches the Case Form print dialog box. If you do not have access to the Case Form print dialog box, the Print Case option is hidden.

Accept incoming cases

The Intake function enables you to view a list of incoming attachments in the Worklist View where you can select an attachment for creating a case.

To access the Worklist > Intake page, hover over the **Worklist** menu and select **Intake**.

For more information, see:

- View pending case
- View rejected cases

View pending case

Use Pending tab to create a case, reject a case, and so on. Users other than Workflow Managers can reject a case from the Intake Worklist.

Field	Description
Priority	Allows the user to view the priority of the case.
Case Type	Allows the user to view report type information.
Reporter Type	Allows the user to view the Reporter type for the Primary Reporter in the case.
Group	Allows for the current group owner or Unassigned group to be assigned to the case.
Central Site/LAM Site	Allows the user to view the current Site (Oracle Argus Safety or Oracle Argus Affiliate) of the Case - If there are no Sites defined, ALL users can access the case attachment.
Attachment Name	Allows the user to view the attachment which is associated to the case.
Classification	Allows the user to view the attachment classifications which is associated with the case.
Description	Allows the user to view the attachment description which is associated with the case.

View rejected cases

Field	Description
Generic Name	Allows the user to view the generic name of the suspect product in question.
F, LT or H	Allows the user to view Fatal, Life-Threatening or Hospitalized cases.
Reporter Type	Allows the user to view the Reporter type for the Primary Reporter in the case.
Country	Allows the user to view the Country of incident.
Classification	Allows the user to view the attachment classifications which is associated to the case.
Description	Allows the user to view the attachment description which is associated to the case.
Rejected Date	Allows the user to view the date when the case was rejected.

Enter general information

The General tab captures the case information in categorized sections for category-specific information. It also enables you to enter or view information such as the type of report, literature information, and so forth.

- If a priority has not been assigned to a case, the Case Priority field is hidden.
- If a case owner has been assigned to the case, the name of the case owner appears at the top of the Case Form.

For more information, see:

- General information—field descriptions

- Enter study information
- Enter reporter information
- Enter literature information

General information—field descriptions

Field/Control Name	Description
Report Type	Select a report type that determines the availability of fields relating to clinical studies and literature references.
	The **Clinical Study** report prompts for information relating to the study, and literature-based reports enable to select the journal and reference on which the case is based.
Country	Select the country where the adverse event occurred.
Initial Receipt Date	Enter the date your company became aware of the case. Oracle Argus Safety uses this date throughout all reports.
	This date can be changed only prior to regulatory report submission.
Central Receipt Date	Enter the date on which this information was received by Central Safety.
Medically Confirm	Specify whether the case was medically confirmed or not, by a healthcare professional.
Initial Justification	Enter the initial justification reason.
	The entry in this field is displayed as per the reason entered when the case is being booked in.
Amendments/Follow-ups	On sorting by follow-up received dates, the serial number still displays the order of entering the follow-ups. The follow-up information can be sorted by:
	• Serial Number
	• Follow-up Received Date
	• Central Received Date
	Click the header to sort in ascending or descending order. By default, the sorting is in descending order of the Follow-up Received Date.
	You can add up to 500 enteries using the **Add** button.
Follow-up Received Date	To enter the date on which amendment or follow-up information was received by your company, click **Add**.
	You can select whether the case has significant follow-up information by confirming the message: `Is this follow-up significant?`.
	When sorting on follow-ups, by default, the dates are sorted in descending order.
Safety Received	Enter the date on which follow-up information was received by Central Safety. This field is disabled for an amendment and any prior data in this field is cleared.
Significant	Check this checkbox if the follow-up is significant.
Data Clean up	Check this checkbox to mark the follow-up as a Data Clean up version.
	This version is used in the Data Lock Point for Case Versioning in and System Reports.
	This field is disabled for an amendment and any prior data in this field is cleared.
Amendment	Specify if the case was updated without adding any new information.
	This checkbox is enabled irrespective of whether the Significant checkbox is checked.

Field/Control Name	Description
Amendment/Follow-up Justification	Select a pre-defined justification for Amendment or Follow-up.
	Click the icon to view the standard justifications dialog box. The justification entered in the Amendment field is also populated in this field.
	You can select a pre-defined justification from this dialog box or enter a new justification.
Case Requires Follow-up	Check this checkbox, if the case requires follow-up information.
	When this field is checked, an action item is scheduled automatically for the current user to request follow-up information.
Classification	Select up to 50 case classifications used to categorize a case.
	To enter additional case classifications, click **Add**.
	When the **Classifications** field is hidden, the classification section is hidden on the Case Form.

Enter study information

1. To choose from the available list of study information, click **Select**.

2. In the Clinical Trial Selection dialog box, enter Project, Study, and Center information.

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

3. Click **Search**.

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

4. Choose the study information from the list, and click **Select**.

   The details of the selected Study Information are added to each field in the Study Information section.

   For more information, see:

   • Study information—field descriptions

Study information—field descriptions

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

Field/Control Name	Description
Blinding Status	The status is auto-populated based on the type of study.
	You need special access rights to use any of the **Broken By** entries.
	✏ **Note:** The Unblind Case dialog box appears when you try to unblind a study. For **Not Blinded** studies, saving the case or generating a report, you can enter the actual drug (vs. placebo) given to the patient.
Observe Study Type	The value selected from this drop-down list is populated in the Case Form Study Section when the Clinical Study is selected.
Unblinding Date	Auto-populates when the blinding status is changed to **Broken by Sponsor** or **Broken by Investigator**.
	If you double-click the date in this item, the Unblind Case dialog box is displayed. A significant follow-up is added and follow-up received date is populated with date.
	The unblinded date is not editable in the Unblind Case dialog box when blinded status is changed to **Broken by Sponsor** whereas it is editable when the blinded status is changed to **Broken by Investigator**.

Enter reporter information

Enter the information about the person providing the case-related information.

- The Reporter Rearrangement dialog box displays the number of Reporters present in the case. It displays the First Name and Last Name, followed by the Reporter Type in brackets, as entered in the reporter information dialog box.

- To view all the Reporters, click the **Quick Launch** icon.

- To view the details of the selected Reporter tab, click a **Reporter Name**.

- To add a new reporter, click the New tab. You can add a maximum of 100 reporters.

- The Primary Reporter is identified by the **Reporter** icon on the Reporter Information tab.

For more information, see:

- Add reporter information
- Reporter information—field descriptions

Add reporter information

1. In the Reporter Information section, click **Select**.

2. In the Reporter Lookup dialog box, enter the search criteria, and click **Search**.

   - All filter criteria you have entered on the Reporter Look Up dialog box are saved as user preferences while it populates the reporter information on the General tab.

      – If you have reporter information in the case, the information appears in the Reporter Lookup dialog box and search is performed.

– After performing the search the search criteria is retained as user preferences. The next time you perform a search, these preferences appear.

– When you log out, the user preferences are retained and are available the next time you log in.

– To clear all the values in the filter elements, click **Clear**.

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

3. From the search results, select the reporter information, and click **Select**.

   The selected, pre-defined information is added to the fields.

Reporter information—field descriptions

Field/Control Name	Description
Reporter Notes	Click this button to enter free text notes relating to this reporter.
	This field supports multiple language entries. Click a flag, select the language tab, and enter information.
Institution	Enter the institution's name.
	This field supports multiple language entries. Click the multi-language icon to display the languages window, select the target language from the drop-down list at the top, and enter the text in the language fields.
Institution ID	Enter the reporter's institution ID.
	This field value is populated based on the Institution ID selected for the Reporter from the Reporter Lookup dialog box. This field also allows to manually enter or update the value directly in the Case Form irrespective of the value specified in the Institution field for the reporter.
	Manually entered **Institution** and **Institution ID** field values are allowed in the Reporter Information section even if they are not specified or linked to each other as per Console Institution code list.
Protect Confidentiality	If this checkbox is checked, the name and address of the reporter does not appear on regulatory reports and the reporter's information displays `NAME AND ADDRESS WITHHELD`.
	The MSK null flavor appears in the eVAERS report when this checkbox is checked. MSK is populated only when the data element contains some data and is not null.
Primary Reporter	Only one primary reporter is permitted per case. The primary reporter is the reporter whose name appears on the regulatory reports. The tab that identifies the primary reporter is displayed in blue as compared to the other reporter tabs.
Correspondence Contact	If this checkbox is checked for a reporter, the reporter's address information is used in letters. You can select more than one reporter as the correspondence contacts for the case.
Reporter ID	If known, enter the **Reporter ID**. This completes the Case Form reporter fields.
Reporter Type, Report Media, and Intermediary	These lists are maintained by the administrator.
(New) Tab	Creates details for a new reporter.

Enter literature information

You can enter a literature reference for a case manually or you can enter pre-defined literature information.

1. From the list of available literature, click **Select**.

2. In the Literature Reference dialog box, select a reference in the list, and click **Select**.

   The details of the selected literature information are added to each field in Literature Information.

Enter patient information

You can enter patient information such as the patient's past medical history and current conditions, and laboratory tests and test results.

For more information, see:

- Enter current medical status
- Copy patient information from reporter information
- Patient information—field descriptions
- Enter patient notes
- Enter patient details
- Enter patient death details
- Enter other relevant history
- Enter lab data—lab test and test results
- Enter additional test information
- Enter parent information

Enter current medical status

1. In the Case Form > Patient tab, click **Current Medical Status**.

2. From the items in the form, select the options that apply to the patient.

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

3. To save the current medical status, click **OK**.

Copy patient information from reporter information

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

To copy the reporter information, click **Patient Info From Reporter**.

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Patient information—field descriptions

Field/Control Name	Description
Child only Case	If this checkbox is checked, then the pregnancy [Detail] button is accessible from the Parent information tab only and no longer through the Patient tab directly.
Current Medical Status	Captures details about the history and the current condition of the patient from the dialog box.
	The items that appear in the Current Medical Status dialog box are mapped to the fields for the German BfArM tab on the Analysis tab. Changing the values on the BfArM tab does not affect these items.
Name (Title, First Name, MI, Last Name)	During book-in, the patient name is transferred to the relevant name and initials fields. If the Patient Name or Initials are three characters or less, this is transferred to the Initials field.
Number of Patients	Enter the number of patients involved in the adverse event.
Pat. ID	Enter the Patient Identifier number.

> **Note:**
>
> This field appears for clinical trial cases only.

Tip: This field can be used while searching for cases in the Case Selection dialog box.

Field/Control Name	Description
Protect Confidentiality	If this check box is selected, the patient's name and address will not appear on any of the regulatory reports and the patient's information will show the word PRIVACY.
	The MSK null flavor appears in the eVAERS report for patient's name and address when this check box is selected. MSK is populated only when the data element contains some data and is not null.
Randomization #	Determines which drug was administered to the patient during the course of the study.

> **Note:**
>
> This field appears for clinical trial cases only.

Tip: This field can be used while searching for cases in the Case Selection dialog box.

Field/Control Name	Description
Sponsor Identifier	Enter the Sponsor Identifier of the patient.

> **Note:**
>
> This field appears for clinical trial cases only.

Tip: This field can be used while searching for cases in the Case Selection dialog box.

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Enter patient notes

Click to enter free text notes relating to the Patient. If there is no text data for Patient Notes, from the **NF** drop-down list, select **Null Flavor**.

> **✎ Note:**
>
> This field supports multiple language entries. Click the 🏴 icon to translate your data from English to a different language or vice-versa.

 Icon is displayed when there is no data in Patient Notes and NF data.

 Icon is displayed when there is data in Patient Notes or NF data.

Enter patient details

Enter patient information, including pregnancy data.

Table 2-1   Patient Details—Field Descriptions

Field	Description
Gender at Birth	Enter the patient's gender at the time of their birth.
	The available values for this field are controlled through MEDWATCH attribute in the GENDER flexible code list as configured in Argus Console.
Current Gender	Enter the patient's gender they identify with.
	The available values for this field are controlled through MEDWATCH attribute in the GENDER flexible code list as configured in Argus Console.
Ethnic Group	Enter the patient's ethnic group such as Hispanic or Latino, Not Hispanic or Latino, and so on.
Military Status	Enter the details of the Military status of the Patient such as Active Duty, Reserve, National Guard, TRICARE Beneficiary, and so on.
Race	Select the patient's race. You can capture up to 5 Race using the Add and Delete buttons. > **✎ Note:** > You cannot select the same Race more than once.
Pregnant at time of Vaccination	Select **Yes** if the patient is pregnant at the time of vaccination.

For more information, see:

• [Enter pregnancy information](#)

Enter pregnancy information

1. From the **Pregnant** drop-down list, select **Yes**.

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

   The Pregnancy Information section appears.

2. Enter the available pregnancy information in the form.

3. Click **OK**.

4. In the Neonate Information section:

   - To delete neonate information, right-click the neonate, and click **Delete**.

   - The changes are tracked to the neonate information in the audit log.

The following list describes the fields on the Pregnancy Information and Neonate form.

Field/Control Name	Description
Gestation Period	Enter the gestation period when the reaction or event was observed in the fetus. Select a unit for the gestation period from the accompanying drop-down list.
Number of Fetus	Enter data for a baby who is born to the patient.
	To make an additional entry, click **New**.
Prospective/ Retrospective	Select if the information was Prospective or Retrospective.
	A prospective information is one where the company hears of the case *before* the baby is born to the patient who took the drug.
	In a retrospective case, a company gets to know *after* the baby is born.
Delivery Notes	Enter baby delivery details.
	This field supports multiple language entries. Click the multi-language icon to display the languages window, select the target language from the drop-down list at the top, and enter the text in the language fields.

Enter patient death details

Enter information about the death of a patient. For more information, see:

- Event death details—field descriptions

Event death details—field descriptions

Field/Control Name	Description
Autopsy Done?	If Autopsy Done is set to No or Unknown, the Autopsy Results Available is shown as **No**.
Autopsy Results Available?	The **Autopsy Results Available?** field is enabled only if the **Autopsy Done?** field is marked as **Yes**.
	If **Autopsy Results Available?** is changed to **No,** and **Autopsy Result** rows exist, you will be asked to delete the rows first. Click **Yes** to delete the data.

Field/Control Name	Description
Add	Click this button to add a **Cause of Death** and **Autopsy Results** row. ✏ **Note:** You can add multiple records, up to 50 entries.
Delete	Deletes a highlighted row.

Enter other relevant history

Enter information related to past drugs administered on Patient, and Current Medical condition of the patient.

To copy the Other Relevant History rows, select the row, and click **Copy**.

For more information, see:

- Other relevant history—field descriptions

Other relevant history—field descriptions

Field or Control Name	Description
Copy	Enables you to copy a row. After you copy the row, the focus will be on the newly copied row.
Add	Enables you to add a row to the relevant history. After you add the row, the focus will be on the new row.
Delete	Enables you to delete a row from the relevant history.
Start Date	Enter the start date of the condition. You can enter a partial date if the actual date is not available. You can also choose not to enter a date. ✏ **Note:** If you click **Add** but do not enter a date, the **Date** column is removed. Once the date is entered and a test is associated with the date, you cannot clear the date but can only modify it. To remove the date column, individually delete all the cells in that **Date** column.
Stop Date	Enter the stop date of the condition. You can enter a partial date if the actual date is not available. You can also choose not to enter a date. If you select **Ongoing** as **Ye** or **Unknown**, the Stop date is cleared and disabled.
Age and Units	Age and Age units are enabled only for condition type with **Patient Other Relevant Therapy** being set.
Family History	Check this checkbox if this relevant history is reported to be present in another family member. The **Family History** checkbox is enabled only for Condition types that are mapped to **Medical History Episode** in the **Condition Type** codelist.

Field or Control Name	Description
Substance Information	Displays the substance name, term ID, and strength unit of the Product separated by commas. If there are multiple records, they are displayed in subsequent rows.
Name Part	Displays the name part and name part type information. If there are multiple records, they are displayed in subsequent rows.
	Click **Name Part** button to enter Product Name Part Type and Product Name Part details.
Product Name Parts Information	Displays the Product Name Part information. Enabled only for condition type with **Patient Other Relevant Therapy** being set.
Version	Displays the Date or Version of the Product Identifier. Enabled only for condition type with **Patient Other Relevant Therapy** being set.
Coded PT/ Description of condition LLT/ Indication PT/ Reaction PT	Enter a term to describe the condition. You can either manually encode or auto-encode if you have been so configured by the Administrator.
	In manual mode, type the description (for example, Fever).
	In Auto-encode mode, enter a partial description and press ENTER or TAB.
	The appropriate coding dialog box appears.
	In either mode, click **Encode** and modify the encoding. If the condition type is historical drug, the encoding will be done with WHO drugs.
Product Identifier Type/ Product Identifier Version/ MFDS Product Code/WHO Medicinal Product ID/Notes	Displays the type of Product Identifier such as MPID, PhPID, and so on. Enabled only for condition type with **Patient Other Relevant Therapy** being set.
	Displays the Date or Version of the Product Identifier. Enabled only for condition type with **Patient Other Relevant Therapy** being set.
	Enables you to add the MFDS assigned Product Code.
	Both MFDS Product Code and WHO Medicinal Product ID fields are enabled only when the **Condition Type** is set to value configured for **Patient Other Relevant Therapy** as **Yes** in Codelist > Condition Type.
	These fields are disabled, when the **Condition Type** is set to value configured for the **Medical History Episode** as **Yes** in Codelist > Condition Type.
	When drug is encoded using the WHO-DD C3 format then the Medicinal Product ID is populated in the **WHO Medicinal Product ID** field. If the drug is encoded but already has a value entered in the **WHO Medicinal Product ID** field, then the value from the Drug Coding browser is overwritten into the **Medicinal Product** ID field.
	When the drug is encoded using any other WHO-DD format where the Medicinal Product ID is not available or displayed in the Drug browser, then the Medicinal Product ID is not populated in the WHO Medicinal Product ID field and remains Null. If you have entered any data in the **WHO Medicinal Product ID** field, then it is removed when drug is encoded using any other WHO-DD format where Medicinal Product ID is not available.
Encode	Click this button to encode the term. Encode is used in multiple contexts such as coding with MedDRA for reactions and indications, and coding for products using WHO drug browser.

> **Note:**
>
> To view the complete MedDRA hierarchy for the encoded term, click the encoding status icon.

Field or Control Name	Description
Indication PT and Reaction PT	This field is visible on the case form only if the condition type selected in the List maintenance is **Patient Other Relevant Therapy**.
Ongoing	Indicates whether the condition is continuing. If it is set to **Yes** or **Unknown**, the Stop date is disabled.

Enter lab data—lab test and test results

The maximum number of lab test data on the Case Form is 1500.

1. To enter a Lab Test Name:

    a. Click **Add Test**.

    b. Enter the description, and click **Search**.

    c. From the search result, select a name.

2. To select a Lab Test Group, click **Select**.

    A list of the lab test that matched the selected group appears.

    If lab test data is already in the case form, the lab test group is appended after the last lab test.

3. To add more rows of Lab Test Data, right-click an empty cell, and click **Add**.

4. To copy a Lab Test Data, right-click the row to be copied, and click **Copy**.

5. To delete a Lab Test Data, right-click the row to be deleted, and click **Delete**.

6. To arrange entries in a specific order, click the **Order** icons.

7. You can sort Lab data in chronological order by Date of the Test and alphabetically by the Test Name.

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

8. To view the hierarchy of the Event Term, click the **view** icon.

9. To view Notes in a Zoom dialog box, click the **view** icon.

10. To arrange the Lab Test Data, click the arrow button to move data to left or right.

    This is available only when the Lab Test is entered for the same date.

For more information, see:

• Lab data—field descriptions

Lab data—field descriptions

Field/Control Name	Description
Norm Low/Norm High	The **Test Name** list can retrieve details of the normal range for the test selected (if the administrator has entered the normal range into the list). Otherwise, enter the values manually.

Field/Control Name	Description
Result/Units	Enter the test result, including units, and select a term to describe the qualitative assessment of the results. The administrator can modify the list of possible assessments.
	If test results cannot be expressed in Result/Units or Assessment, enter the data in **Notes** field.
	You must enter Lab test result by using Results/Unit, Assessment or Notes fields, and not in all the fields. Regulatory agencies may send rejection for ICSR if data is sent in all formats.
Assessment	Select a qualitative assessment term to describe the lab test results.
More Info Available	Check this checkbox if there is additional information is available for this Lab test in Additional Info tab.

Enter additional test information

Enter additional information about any relevant tests, such as toxicology.

Enter parent information

The Parent Information tab is similar to the Patient tab.

However, in the Other Relevant History section, the Family history, Age, and Units fields are unavailable.

Enter product information

Enter and view details for products and dosage regimens. This tab contains the name of the drug that has been entered here. For Blinded Studies, the Blinded Product Name field appears in the tab.

If you do not have access to view unblinded information on the Case Form, some of the fields are hidden.

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

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

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

For more information, see:

- Search for products
- Enter time measurement information
- Enter drug information
- Enter device information
- Enter vaccine information

Search for products

You can perform the following search:

- Product Browser based search
- WHO Drug Browser based search

Product Browser based search

1. In the Products tab, click **Select** adjacent to the product name.

   The Product Browser dialog box appears.

2. Click the displayed entities.

   The hierarchy above and below the entity being searched is also displayed. For the example:

   ```
   If Product Name is searched, it displays the Product Name as well as the Family Name
   and Trade Name.
   ```

3. Search for Products based on the following criteria:

   - Ingredient
   - Family
   - Product Name
   - Trade Name—Searches the License Trade Name

4. To select all the search criteria, select the **Full Search** checkbox, and click **Select**.

5. Select a product from the search result.

6. To remove the entered search criteria, click **Clear**.

WHO Drug Browser based search

1. To open the WHO Drug Coding dialog box, click **Encode** adjacent to the product name.

2. In the Drug Coding dialog box, the dictionary is loaded based on the configuration of the Case For Configuration common profile switch as mentioned here.

   From the Case Form Configuration dialog box where the dictionaries are selected for encoding, select either the WHO Drug B format or the WHO Drug C format.
   When you select **WHO Drug** from the Drug Coding window, the **Chinese Trade Name** and **Chinese Generic Name** are auto-populated in the `Product tab > Product Name and Generic Name` fields in the multi-language window for Chinese language.

   These fields are auto-populated only when the Chinese WHO Drug dictionary is loaded, and set in the WHO Drugs (Chinese) common profile switch.

3. Enter the search criteria, and click **Search**.

   You can search for a product based on:

   - Trade Name
   - Total Rows (#) - Total number of records are displayed as per the search result next to Trade Name.
   - Formulation/Strength (sequence 3 and sequence 4) of the product.

- Country—The Sales Country Code of the Product as defined in the WHO Dictionary.

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

  - Formulation

  - Country

  - Strength

  - MAH

  - Generic

  - Medicinal Product ID

  - Product Type

4. To copy the selected drug to the Product tab, click **Select**.

5. To close the selection dialog box without making any updates to the Product tab, click **Cancel**.

6. To perform a full search from the WHO Drug browser, select **Full Search**.

   - By default, an exact search is performed (e.g., CUREALL)

   - You can use the percent (%) sign to perform wildcard searches (e.g., CUREALL%)

   - If you click Full Search, the full search is performed (e.g., %CUREALL%)

7. To clear the search criteria you entered, click **Clear**.

8. You can sort the results on all the fields.

Enter time measurement information

You can enter seconds in the following fields:

- `Argus > Case Actions > Open > (Select a Case) > Event tab > Event sub tab > {event description} sub tab > Event Information section` (middle of screen)

  - Onset From Last Dose field

  - Duration field

  - Onset Latency field

- `Argus > Case Actions > Open > (Select a Case) > Products tab > Product sub tab > {Product Name} sub-sub tab (drug) > Dosage Regimen section` (lower 1/3 of screen)

  - Duration of Regimen

- `Argus > Case Actions > Open > (Select a Case) > Products tab > Product sub tab > {Product Name} sub-sub tab (drug) > Product Details section` (lower 1/3 of screen

  - Duration of Administration

  - Time between First Dose/Primary Event

  - Time between First Dose/Primary Event

- Any number following by the letter "s" defaults to "#sec."

- The seconds entered in the form are interpreted in the following formats, where:
is a number from 0 to 9

  #s—changes the format to # sec.

  # s—changes the format to # sec.

  # sxx

  where:

  x is other letters—that changes the format to # sec

- The Temporal View and the Case Form printout display the seconds.

- The E2B import and export case functions support seconds and M2 Validation for the defined fields.

Enter drug information

In this section:

- Product information—field descriptions
- Enter product indications on the drug tab
- Enter Quality Control information
- Enter dosage regimens
- Enter product details
- Enter study drug information

Product information—field descriptions

This section enables you to enter information about the drug being used for the case.

Table 2-2   Product Information

Field or Control Name	Description
Product Name	Enter the name of the product using the **Select** button or by entering a partial product name. Type a partial product name and press TAB. This displays the Product Selection dialog box.
	If only one product is found, this information is entered without showing the dialog box. If no match is found in the company product list, the WHO Drug Dictionary is searched for a possible match through the WHO Drug Dictionary dialog box. If a match is still not found, the text you initially typed in, is used as is.
	If the study is blinded, the **Blinded Name** of the clinical study is displayed in this field. After unblinding, the selected study's **Product Name** for Unblinded cases is not shown.
	This field supports multiple language entries. Click the multi-language icon to display the languages window, select the target language from the drop-down list at the top, and enter the text in the language fields.
	Note: Editing the base entry in English/Japanese is disabled for product names.
Select	Displays the product selection dialog box.
	Select a product from the list of company products click **Select**.
	The relevant fields are added to the Case Form.
Encode	Click **Encode** to retrieve the code.
• Suspect • Concomitant • Treatment/Other	Make a selection for the product you are entering. The drug types indicate the involvement of the product with the adverse event(s) reported for the case.
	Suspect indicates that the product may have caused the adverse event(s).
	Concomitant indicates drugs that are taken with the suspect drug.
	Treatment/Other is the drug taken to treat the adverse event.

Table 2-2   (Cont.) Product Information

Field or Control Name	Description
Generic Name	Enter the generic name of the drug in a manner similar to the **Product Name**. If the study is blinded, the **Generic Name** is replaced with the **Study Name** of the product. > ✏ **Note:** > This name is entered based on the selected company product. If the study is blinded, the **Blinded Name** of the clinical study is displayed in this field. After unblinding, the selected study's **Product Name** for Unblinded cases is not shown. This field supports multiple language entries. Click the multi-language icon to display the languages window, select the target language from the drop-down list at the top, and enter the text in the language fields. > ✏ **Note:** > Editing the base entry in English/Japanese is disabled for generic names.
Product Identifier Type	Auto-populates based on the selected license in the `Argus Console > Studies Configuration > Product > License` drop down. This field is populated only for the new cases being created and on reselecting the products. For the existing cases, this field is not updated and remains the same unless a product is selected again. Not even if configured in Argus Console. If the selected license does not have Product Identifier Type in Console, then this field remains blank. If a License's Product Identifier Type is changed in Console and saved, the cases with that license does not reflect the new value unless the product is reselected.
Product Identifier	Auto-populates based on the selected license in the `Argus Console > Studies Configuration > Product > License` drop down. This field is populated only for the new cases being created and on reselecting the products. For the existing cases, this field is not updated and remains the same unless a product is selected again. Not even if configured in Argus Console. If the selected license does not have Product Identifier in Console, then this field remains blank. If a License's Product Identifier is changed in Console and saved, the cases with that license does not reflect the new value unless the product is reselected.
MFDS Product Code	Enables you to enter the MFDS product code for the drug. This field is treated as a blinded field.

Table 2-2   (Cont.) Product Information

Field or Control Name	Description
OTC Product	Check this check box if the product administered was an over-the-counter (OTC) 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 `Console > Studies Configuration`. 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 `Console > Studies Configuration`. When unblinded at case level, data is enabled irrespective of the product selected in the Study Drug drop-down.
Compounded Product	Check this check box if the product administered was compounded.
Company Drug Code	Displays the licensed country for the selected company product.
Obtain Drug Country	Country the drug is licensed in.
Drug Code	Enter the WHO-DRUG code.
WHO Medicinal Product ID	Displays the Medicinal Product ID associated with the selected WHO drug. For company products, this field is updated based on the data available in license configuration. If not available, this field is updated based on the data available in product configuration. For non-company products, this field is updated based on the selected WHO Drug.
Formulation	Select the formulation of the product. The form in which the drug was administered (liquid, tablet, capsule, and so on.) **Note:** This field is entered based on the product. Contact your administrator to adjust this list.
Drug Authorization Country	The country where the drug is licensed.

Table 2-2   (Cont.) Product Information

Field or Control Name	Description
Market Authorization Holder	Captures the name of the Marketing Authorization Holder of the product that was administered.

> **Note:**
>
> For study products, this field is fetched based on the primary license number selected in the `Console > Business Configuration > Studies > Product > License` drop-down list.

Authorization Type	Captures the Authorization Type of the product that was administered such as IND, BLA, PLA, and so on.

> **Note:**
>
> The **Authorization Type** field length was changed from 5 to 10 characters.
> For study products, this field is fetched based on the primary license number selected in the `Console > Business Configuration > Studies > Product > License` drop-down list.

Authorization Number	Captures the Authorization Number or License Number of the product that was administered.

> **Note:**
>
> For study products, this field is fetched based on the primary license number selected in the `Console > Business Configuration > Studies > Product > License` drop-down list.

Authorized Representative	Select a manufacturer name from the manufacture codelist.
Manufacturer	A different Manufacturer can be selected from the drop-down list and can still be kept as a company product.

Table 2-2   (Cont.) Product Information

Field or Control Name	Description
Concentration	Indicates the amount of the drug that was administered. After a drug and formulation have been entered, select the concentration from the list, or enter the concentration. If this information is changed manually, the product is marked as a non-company product. **Note:** This field is entered based on the chosen product. The concentration cannot be modified for a Study drug.
Interaction?	Indicates whether the case involves a drug interaction.
Contraindicated?	Indicates whether the drug was administered contrary to its indication.
Drug Not Administered	Check this check box if no drug was administered on the patient.

Table 2-3   Substance Information

Field or Control Name	Description
Substance Name	Displays the Ingredient's name.
Strength	The Strength of the substance used in the Product.
Unit	The drug unit (such as mg, tsp, and so on).
MFDS Ingredient Code	Enables you to enter the MFDS ingredient code for the drug. This field is treated as a blinded field.

Note:

Drug Authorization Country, Authorization Type, Authorization Number, and Marketing Authorization Holder data are populated from the Argus Console for company products.
For Study Products, the system populates the Authorization Type, Authorization Number, and Marketing Authorization Holder data based on the Primary license number selected in the `Argus Console > Studies Configuration`. When unblinded at the case level, Authorization Type and Authorization Number data is not accessible for users with restricted access to unblinded data.

The application supports printing of the new fields added to the **Product Information** tab.

Enter product indications on the drug tab

Enter information about the indicator of the adverse event, like:

- Reported Indication—Reported reaction

- Coded Indication—Code for the reaction

Both the values could be different or same.

Table 2-4   Product Indication—Field Description

Field/Control Name	Description
Reported Indication	By default, the value of this field is populated with the Product Indication from the Product Configuration, if set up. If not, you can enter a term into the Reported Indication field. ✏ **Note:** Oracle Argus Safety automatically encodes this information. You can also click **Encode** to open the coding dictionary dialog box.
Coded Indication	This field is populated with the encoded term when you enter data in the reported indication field and tabs out.
Encode (Indication)	Opens the MedDRA Browser with the term already populated from the **Coded Indication** field. To view the complete MEDDRA hierarchy for the encoded term, click the **Encoding Status** icon.
Add	Adds a new Indication row. Only two indications are visible at a time
Delete	Click this button to delete the selected Indication row.

Enter Quality Control information

To enter quality control information, click **Quality Control**.

When you enter information in this section, an action item is automatically created in that case with text `Case Product Product Name sent for QC requires follow up.` This action item is assigned to the you.

If you do not intend to create any action item, then it adds a date in the `Product > Quality Control > QC Result Date` field.

You can set the Quality Control section in the minimized form as default, by selecting the **Always minimize Quality Control section on case form** common profile switch as **Yes**.

The **Action item code when QC info is entered** common profile switch is used to set the action item code as selected in this switch. If this switch is left blank, then no action item code is set.

Field Name	Description
Quality Control Safety Date	Enter the Quality Control department reference number for the analysis.
Quality Control Cross Reference	Enter the Quality Control department reference number for the analysis.
# CID Number	Control Identification Number

Field Name	Description
PCID Number	Product Control Identification Number
Lot Number	If the Lot Number entered is incorrect, a Lot Number Lookup dialog box is displayed, that allows you to select from the existing lot numbers.
Quality Control Result Date	Enter the date the result of the analysis was received by the Quality Control department.
Quality Control Result	Enter a text explanation as necessary. Use the zoom icon to open the zoom notes and view or edit the text.

Enter dosage regimens

Field or Control Name	Description
Stop Date/Time	Enter the stop date and time of the dosage. Entry of time information is optional, and you can enter partial dates.

> **Note:**
>
> If no Stop Date is entered, **Onset from Last Dose** is calculated from the **Event Onset Date** and the most recent Stop Date or the most recent Start Date.

Field or Control Name	Description
Ongoing	Select this checkbox if the drug treatment is ongoing.
	The **Stop Date**, **Duration of Regimen**, and **Last Dose** fields are removed if this checkbox is checked.
Outside Therapeutic Range	Check this checkbox if the drug has not been used in accordance with the label or has been used for outside the Therapeutic Range.
	Contact your administrator for further company-specific information on the use of this field.
Duration of Regimen	This value is calculated based on regimen start and stop dates (if full dates are entered for the start and stop dates). If the value is entered manually, the duration units (for example: minutes, hours, days, months, or years) must also be entered along with the actual duration.

> **Note:**
>
> Contact your administrator to set the duration to be inclusive or exclusive. In Inclusive mode, the starting day counts in the calculation of the duration; in Exclusive mode, it does not.

Field or Control Name	Description
Dose Description	This value is entered by using the values from **Dose**, **Dose Units**, and **Frequency**. If necessary, you can change this value.
	If Dose, Units, or Frequency information is changed, this value will be recalculated.
Daily Dosage	This value is calculated based on the dose and frequency. It can be manually overwritten. If either the dose or the frequency fields are blank, this field is not calculated automatically.

Field or Control Name	Description
Regimen Dosage	This value is calculated based on the daily dose, duration, and frequency. This total can be overridden. If the daily dose is blank or the frequency fields are 0, this field is not calculated automatically.
Regimen Dosage Unit	This value is derived based on the **Daily Dose Units**.
Accidental Exposure	Select the type of Accidental Exposure from the list. A non-modifiable list of items is provided for this list.
Pack Units	Select the package presentation information of the product. Contact your administrator to adjust this list.
(New) Tab	Click this tab to create a new dosage regimen entry.

Enter product details

Field or Control Name	Description
First Dose	The earliest regimen start date.
Last Dose	The latest regimen stop date.
Duration of Administration	Calculated automatically if full dates are available for the first and last doses.
Total Dosage	Calculated based on daily dose and duration.
Time Between First Dose/ Primary Event	The time from the first dose to primary event onset.
Time between Last Dose/ Primary Event	The time from the last dose to primary event onset.
Total Dose to Primary Event	The cumulative dose to the time of the event.
Action Taken	Select a term. If you select **Dose Increased** or **No** change, the dechallenge and rechallenge fields are disabled. Contact your administrator to adjust this list.
Dechallenge Results	Indicates the drug stopped for the purpose of determining if it was the drug that caused the adverse event.
Date	Enter the date the dechallenge was carried out.
Gestation Period at Exposure	**Gestation Period at Exposure** is automatically calculated for all Products in the case by using the formula: Date of First Dose of the respective Product – LMP Date. It is calculated only if full dates are available for both fields. If the First Dose occurs before the LMP Date, then this field is not populated with any data.
Taken Previously / Tolerated	Select a response from the list.
Rechallenge Results	Make a selection based on whether the drug was taken again. If **Pos** or **Neg** or **UNK** is selected for the **Rechallenge** field, the following fields are enabled: • Rechallenge Start Date/Time • Rechallenge Stop Date/Time • Rechallenge Outcome
Start Date/Time	Enter the date and/or time when the rechallenge was started.
Stop Date/Time	Enter the date and/or time when the rechallenge was stopped.

Field or Control Name	Description
Specialized Product Category	Select specialized FDA product categories such as combination products, compounded and repackaged products used in eVAERS reports.
• Abuse • Batch and lot tested and found within specifications • Batch and lot tested and found not within specifications • Counterfeit • Drug taken beyond expiry date • Drug taken by the father • Medication error • Misuse • Occupational exposure • Off label use • Overdose • Tampering • FDA Additional Information on Drug	Select the corresponding check boxes to provide information on the drug populated as Additional Information on Drug [G.k.10.r] in the E2B(R3) reports. Select the FDA specific additional information on the drug.
Related Device Comments	Enter the details about the devices used with the drug that caused an adverse reaction. When entering data entries, only up to 2000 characters are allowed. Multi-language data entry is supported. This field is also displayed in the Japanese split-screen of the case form. A separate data entry field is applicable when using the Japanese language. **Note:** This field is visible only in the **Drug and Vaccine** tab, under the **Product** tab.

Enter study drug information

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

To mark a product as a study drug:

1. Right-click any suspect product in the case.

2. To mark the current product as a study drug, select **Make Study Drug**.

When you mark a product as a study product, then the following changes are observed in the Product tab:

• The drug type is disabled to make the product a **Concomitant** or **Treatment/Other** option.

• **Study Drug** is a read-only field that contains the product name selected by you.

You can add a study drug for an unblinded or not blinded study case.

To add a new study drug:

1. Open the unblinded or not blinded study case.

2. On the **Product** tab, right click any product in the case.

3. Select the **Add Study Drug** option.

Enter device information

In this section:

- Enter product information

- Enter Quality Control information on the Device tab

- Enter product indications

- Select product delivered by device

- Enter device component information

- Device information—field descriptions

Enter product information

Enter the following information in the Device tab:

M/W Info dialog box

The MW Info dialog box allows you to enter the following device information:

- **Is this a single-use device that was reprocessed and reused on a patient?**—Indicate whether the device was labeled for single use. If the question is not relevant to the device being reported (for example, an X-ray machine), leave the select box cleared.

- **Reprocessor Name**—Enter information for Address 1, Address 2, City, State, Country, Postal Code, Fax, and Email Address.

- Select if the device was an **Adverse Event** or a **Product Problem**.

- **Type of Follow-up Report**—Select a checkbox that describes the nature of the follow-up (supplemental) report:
  Correction—Changes to previously submitted information.

  Additional information—Information concerning the event that was not provided in the initial report because it was not known/available when the report was originally submitted.

  Response to FDA request—Additional information requested by FDA concerning the device/event.

  Device Evaluation—Evaluation/analysis of the device.

- **Device Evaluated by Mfr**—Select the **Not returned to mfr.** checkbox if an evaluation could not be made because the device was not returned to or made available to the manufacturer.
  Select **Yes** if an evaluation was made for the suspect medical device. You can attach a summary of the evaluation and select **Yes, Summary Attached**.

  If an evaluation of a returned suspect or related medical device was not conducted, check the **No** checkbox and attach an explanation or provide an appropriate code from the coding manual (Part II, Subpart A).

- **Reason for Non-Evaluation**—Enter the reason for the device not being evaluated by the manufacturer.

- **Other Reason for Non-Evaluation**

- **If remedial action initiated, check type**—Select the applicable actions. If other, specify the type of action in the space provided (for further reference, see 21 U.S.C. 360h and 21 CFR part 803).

- **Usage of Device**—Make a selection to indicate whether the use of the suspect medical device was the initial use, reuse, or unknown.

- **USC 360i(f) correction/removal reporting number**—Enter the number that the FDA assigned to the corrective action. If the FDA has not yet assigned a number, the internal number assigned to the action by the company is used.

- **Additional manufacturer narrative**—Check the checkbox (if applicable) and enter any additional information, evaluation, or clarification of data presented in previous sections.

- **Corrected Data**—Check if the data is corrected.

EU/CA Device dialog box

The EU/CA Device dialog box allows you to enter the device information. Fields are marked by either an EU flag or a Canadian flag to indicate which entity is mapped to the field.

- **Associated Devices**—Enter the associated devices with the device.

- **Associated Accessories**—Enter the associated accessories with the device.

- **Firmware version**—Enter the firmware version.

- **Periodic Summary Report (PSR) ID**—Enter the PSR ID, if any.

- **Identification of Notified Body involved in Conformity Assessment**—Enter identification number of the Notified Body involved in the conformity assessment procedure (if any) and the date(s) of the attestation(s).

- **Remedial Action by HC Facility**—Enter the remedial action taken by the Healthcare facility.

- **Update to Initial Report (Follow-up Report)**—Check if the Follow-up report must be updated to an Initial report.

- **Availability of Device**—Select whether the device was Destroyed, Returned to Manufacturer/Importer, or Neither.

- **Current location of device**—Enter the present location of the device that was involved in the incident.

- **Other**—This field is enabled when you select Other in the **Current location of the device** drop-down.

- **Final Report**—Check if this is the final report.

- **MIR Report Type**—Select the MIR report type as Follow-up Report, Final (Reportable), or Final (Not Reportable).

- **Rationale for Not Reportable**—Enter the reason why the considered report is not reportable. This field is enabled when the MIR Report Type is selected as **Final (Not Reportable)**.

- **Where was the device purchased**—Enter the establishment where the device was purchased.

- **Root cause confirmed**—Select an option.

- **Risk assessment**—Specify if the risk assessment has been reviewed and is adequate. Select an option as Reviewed and Adequate, Reviewed and Not Adequate, or Not Reviewed.

- **Rationale**—Enter the reason for why a review is not required. This field is enabled when the Risk assessment is selected as **Not Reviewed**.

- **Results of Assessment**—Enter the results of assessment.

- **Marketed Device Variant/Subset**—Enter the value for device variant or subset.
  The valid values are:

  0 – Model

  1 – Software

  2 – Other Variant

  3 – Lot/Batch

Similar Incidents dialog box

Similar incidents occurring with the same device type or variant of a given manufacturer with the same investigation finding (IMDRF investigation finding; Annex C) and the same medical device problem (IMDRF medical device problem; Annex A) have to be reported to National Competent Authorities (NCA) and European Commission (EC).

Identification and computation of the count of similar incidents is done outside the application. The application captures the fields for the provided results.

- **Similar Incident Device Category**—Select the device or device variant used for identification of the similar incidents.

- **Details of the Device Category**—Enter the details of the selected device or device variant.

- **Criteria for Number of Devices on the Market**—Select the criteria used for the number of devices in the market.

- **Other**—This field is enabled only when you select **Other** in the **Criteria for Number of Devices on the Market** field. Describe the criteria.

- **Similar Incident Analysis Based on**—Select the details based on the similar incident analysis.

- **Rationale**—This field is enabled only when you select **Other IMDRF Annex** or **Other Inhouse Codes** in the **Similar Incident Analysis Based on** drop-down.

- **Inhouse Medical Device Problem Code and Term**—Enter the most relevant in-house medical device problem code and term used for identification of similar incidents. This field is enabled only when you select **Inhouse Codes** in the **Similar Incident Analysis Based on** drop-down.

- **Inhouse Evaluation Result/Findings Code and Term**—Enter the most relevant in-house root cause evaluation code and term used for identification of similar incidents. This field is enabled only when you select **Inhouse Codes** in the **Similar Incident Analysis Based on** drop-down.

- **Start Date**—Enter the start date for the period for which the analysis of similar incidents is performed.

- **End Date**—Enter the end date for the period for which the analysis of similar incidents is performed.

- **No of Similar Incidents in Incident Country**—Enter the number of similar incidents occurred in the incident country.

- **No of devices in Incident Country**—Enter the number of devices in the incident country.

- **No of Similar Incidents in EEA+CH+TR**—Enter the number of similar incidents that occurred in European Economic Area, (EEA), Switzerland (CH), or Turkey (TR).

- **No of devices in EEA+CH+TR**—Enter the number of devices in European Economic Area, (EEA), Switzerland (CH), or Turkey (TR).

- **No of Similar Incidents in World**—Enter the number of similar incidents that occurred in world.

- **No of devices in World**—Enter the number of devices in the world.

- **Comments**—Enter the comments for identification of similar incidents.

Enter Quality Control information on the Device tab

This section applies to the Quality Control information on the Device tab and to the Quality Control information on the Drug tab. For more information, see Enter Quality Control information.

Enter product indications

See Enter product indications.

Select product delivered by device

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

Enter device component information

Field or Control Name	Description
Component Name	The device component name used in the product.
IMDRF Code	Select the IMDRF code for the medical device component via lookup.
Component Term ID	The device component term ID of the device component used in the product.
Version	The Date or Version of the device component term ID of the device component used in the product.
Batch Lot #	The batch lot number of the device component name used in the product.
Add	Adds another row.
Delete	Deletes the highlighted row.

Device information—field descriptions

- You can enter up to 10,000 characters in the **Additional Manufacturer Narrative** field.

Enter the following **Product Information** in the Device tab:

Field or Control Name	Description
Catalog #	Under Catalog#, enter the exact catalog number as it appears in the manufacturer's catalog, device labeling, or accompanying packaging.
Implant facility	Enter the healthcare facility where the device was implanted.
Explant facility	Enter the healthcare facility where the device was explanted.
UDI System	The UDI System captures the unique identification type of the given device. The valid values are: • GS1 – Global Standards 1 • HIBCC - Health Industry Business Communications Council • ICCBBA - The International Council for Commonality in Blood Banking Automation
Unique Identifier (UDI) #	Under Unique Identifier (UDI) #, enter any other applicable identification number (for example: component number, product number, part number, bar-coded product ID). Data is entered in such a way to handle the UDI Device identifier and UDI Production Identifier fields.
UDI -DI	Enter the UDI device identifier.
UDI-PI	Enter the UDI-Product identifier.
Unit of Use UDI-DI	Enter the Unit of Use UDI-DI.
Serviced by Third Party	Enables you to capture whether the device was serviced by a third party. The possible values are: • Yes • No • Unknown
FDA Exemption Number	This field is available for the eMDR report and provides a number provided by the FDA. This field enables you to track the approved exemptions or variances of the adverse event reporting.
Operator of Device	Select the type of person operating or using the suspect medical device on the patient at the time of the event such as Health Care Professional, Patient, Paramedic and so on.
If Other	If the operator of the device is other, enter the operator of the device.
Malfunction Type	Make a selection to indicate the type of reportable event. For an event associated with a malfunction, the FDA refers to applicable sections in 21 CFR Part 803 reporting guidelines.
Device Outcome	The values in this drop-down are derived from the standard Device outcome codelist.
Device Outcome Detail	This field is enabled when the Device Outcome field is set to Other.
Device Comments	Allows you to enter details about the device.
Device Available for Evaluation	Indicate whether the device is available for evaluation. Also, indicate whether the device was returned to the manufacturer and if so, the date of the return.
CE Marked	Select whether the device is CE Marked or not. This information is preloaded from License information for a case booked manually, through E2B or LAM, and can be modified as needed.
Similar Device	Check this check box when you report similar devices to FDA. You must report similar devices when a device causes reportable malfunction and it is likely that malfunction can occur in similar devices. Similar devices are identified in a case when this check box is checked along with the **Drug not administered** check box being checked and Product Type set to **Treatment/Other**.

Enter the following **Malfunction Information** in the Device tab:

Field or Control Name	Description
Reported Malfunction	Enter the malfunction as entered by the reporter.
Determined Malfunction	Enter the malfunction as determined by the company.
Listedness	Enter the listedness of malfunction in respect of the device.
Reportable	Select the reportability of the malfunction.

Enter the remaining fields:

Field or Control Name	Description
Patient Problem and Device Problem Information	This section captures the problem details for a device. It contains the following fields: • FDA Code (for patient problem) (read-only) • Patient Problem (read-only) • FDA Code (for device problem) • IMDRF Code • Device Problem Term Patient Problem and related FDA code are read-only fields and code select option was removed. Any legacy data available can be viewed here. Use the Device Problem lookup to select the device problem information, like device problem, FDA code, and IMDRF code.
MedWatch Info	In Case Form, the `Analysis > MedWatch Info` tab only shows the existing records. This section underwent the following changes: • The **Add** and **Select** buttons were removed. • The application allows you to delete existing codes, if required.
Evaluation/Investigation Code Information	To enter the applicable codes from the categories listed, click **Select**. It contains the following fields: • FDA Code • IMDRF Code • Method/Type Term • Result/Findings Term • Conclusion Term Follow the instructions in the dialog box to enter the evaluation codes. Conclusion codes must be entered even if the device was not evaluated.
Health Impact Information	This section captures the health related information. It contains the following fields: • Clinical Sign IMDRF Code • Health Impact Term
Device outcome	This field is derived from the standard Device outcome codelist.
Device outcome details	This field captures the device outcome details when the **Device Outcome** field is set to **Other**.
Device Comments	This field allows to enter details about the device.

EU/CA device dialog box—field descriptions

Field or Control Name	Field Length	Field Type
NCA Reference Number	100 characters	Alphanumeric
Identify to what other NCA's this report was also sent	2000 characters	Alphanumeric

Field or Control Name	Field Length	Field Type
Number of Patients Involved	3 characters	Numeric
Number of Devices	3 characters	Numeric
User facility reference number	21 characters	Alphanumeric
Remedial Action by HC Facility	1000 characters	Alphanumeric
Usage of Medical Device	N/A	Checkbox
Other	15 characters	Alphanumeric
Update to Initial Report (Follow-up Report)	N/A	Checkbox
Final Report	N/A	Checkbox

When you select the **EU/CA Device** option, the fields on the Case form are printed. A track of the fields and any updates are maintained in the audit log.

Enter vaccine information

In this section:

- Enter product details
- Enter prior adverse events information
- Enter product information
- Complete vaccine administration form
- Enter vaccine history

Enter product details

This section is the same for the Product Details section under all the tabs - in the Drugs tab, Device tab, and the Vaccine tab.

See Enter product details.

Enter prior adverse events information

1. Enter the relevant vaccination information items in the form.
2. Click **OK**.

Enter product information

Field or Control Name	Description
Include in VAERS Block	Select the VAERS Form block that this vaccine needs to be printed in.
• Suspect • Concomitant • Treatment/Other	Make a selection for the product you are entering. The drug types indicate the involvement of the product with the adverse event(s) reported for the case. • **Suspect** indicates that the product may have caused the adverse event(s). • **Concomitant** indicates drugs that are taken with the suspect drug. • **Treatment/Other** is the drug taken to treat the adverse event.

Field or Control Name	Description
Generic Name	Enter the generic name of the drug in a manner similar to the **Product Name**.
	if the study is blinded, the **Generic Name** is replaced with the **Study Name** of the product.
	This name is entered based on the selected company product.
Formulation	Select the formulation of the product. Contact your administrator to adjust this list.

> **Note:**
>
> This field is entered based on the product.

Drug Authorization Country	Displays the licensed country for the selected company product.
Concentration	After a drug and formulation have been entered, select the concentration from the list, or enter the concentration. If this information is changed manually, the product is marked as a non-company product.

> **Note:**
>
> This field is entered based on the selected product. The concentration cannot be modified for a Study drug.

Units	Select a concentration unit.
	Contact your administrator to adjust this list.
Interaction?	Indicates whether the case involves a drug interaction.
Contraindicated?	Indicates whether the drug was administered contrary to its indication. Make the appropriate selection to indicate whether the drug was contraindicated in this case.

Complete vaccine administration form

The following are the fields for **VAERS Form-1 Use Only:**

Field or Control Name	Description
Resp. Physician	Enter the name of the physician responsible for the patient.
County	Enter the county where the patient was vaccinated.
State	Enter the state where the patient was vaccinated.
CDC/FDA VAERS #	Enter the verification number.
Purchased With	Select an item from the list to describe how the vaccine was purchased.

The following are the fields for **Vaccine Facility Information**

Field or Control Name	Description
Facility Name	Enter the name of the facility where the vaccine was administered.
Country	Enter the country of the facility where the responsible physician works.
Facility Type	Enter the facility type where the patient was vaccinated.
Facility Military Flag	Indicates whether or not the vaccination facility was a Military facility.

Enter vaccine history

Field or Control Name	Description
Route of Admin	Enter the route of administration or a short code for the route of administration. Contact your administrator to adjust this list.
Anatomical Location	Select the anatomical location of the vaccination. Contact your administrator to adjust this list.
Block 14	If this box is checked, this Vaccine History will be printed in the VAERS Form Block 14.
Add	Adds a new Indication row.

> ✎ **Note:**
>
> Only two indications are visible at a time.

Delete	Click this button to delete the selected Indication row.

Enter event information

You can enter or view details for adverse events for a case using this tab. It has the following sub-tabs:

- Events tab
- Event Assessment tab
- Product-Event Details tab

For more information, see:

- Events tab—field descriptions
- Enter data on the Event Information tab
- Enter event coding information
- Enter seriousness criteria
- Enter event assessment information

Events tab—field descriptions

Field	Calculation
Total Dosage	The sum of all Total Regimen Dosages.
First Dose to Onset	The system calculates this value based on the First Dose Stop date and the event onset date if present.
	If any regimen start date is null, the system sets the First Dose to Onset to null.
	The system uses only complete date entries for the regimen start and stop date/time fields to calculate First Dose to Onset.
	The user can overwrite this field.
Last Dose to Onset	The system calculates this value based on the last dose stop date and the event onset date if present.
	If the regimen start date is null, the system sets the Last Dose to Onset is to null.
	The system uses only complete date entries for regimen start and stop date/time fields to calculate the Last Dose to Onset.
	The user can overwrite this field.

- You **can** change the listedness for a drug at the individual level.

- The field labels for the Event Assessment tab can be updated and configured on the Argus Console.

- If the Death Seriousness criteria on the Event tab are unchecked, the event outcome reverts to empty and is not set to fatal.

- The MedDRA LLT term selection behavior across the Case Form is based on the profile switch value configured in the **Allow User to Add Non-Current MedDRA Terms for** and **On change of LLT Term Sync English and Japan LLTs, irrespective of the currency.**

- The system populates the **To be coded** value on the MedDRA pop-up window when you check the green checkbox for the MedDRA hierarchy. This applies to the areas where the **MedDRA** dialog box appears.

- The Event to Exclude from Report field enables you to identify information to not include in a PMDA Expedited report.

  – When this checkbox is checked, enter a justification for this action in the Reason to Exclude from the Report dialog box.
  The system places a symbol to the right of the field.

  – The system does not retrieve events that are excluded from a report as part of CSPSR (Clinical Study Periodic Safety Report) unless it has been configured to include them.

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

Enter data on the Event Information tab

The Event information tab lets you encode adverse events, record criteria for event seriousness, and display results of automated assessments that determine whether events are listed in data sheets. It also lists the licenses for the data sheets.

For more information, see:

Event information—field descriptions

Field or Control Name	Description
Relationships	Click the **Relationships** button to view the Diagnosis-Event Relationships dialog box. This allows you to group symptoms and signs with diagnoses. This requires at least two events and a diagnosis.
Description as Reported	Enter the verbatim term used by the reporter, or patient, to describe the adverse event. As you type, the term is copied under **Description to be Coded**. Verbatim English translations of foreign languages may also be entered here.
Term Highlighted by Reporter	Indicate whether the primary source reporting the event considered it a major concern. If the information was not explicitly provided, the term is not considered a highlighted term. The seriousness of the reaction/event must be based on the ICH E2A criteria. Selecting **Yes** does not mark this case as **Serious**.
Description to be Coded	You can modify the verbatim term in this field. For the example: `The original term can be split, or enhanced with an anatomical location. Contact your system administrator to prevent manual encoding of the description. If automatic encoding is enabled, the term can be auto-encoded to the included term level.`
Onset Date/Time	Enter the date/time when the event started. Enter a partial date if the full date is not available.
Onset from Last Dose	This field is calculated from the event onset date and most recent stop date listed in the dosage regimen details of the suspect drug(s). You can also enter or modify the field manually. This field is removed if the dosage regimen is ongoing.
Duration	This field is calculated from the event start and stop dates. You can also enter or modify the duration manually.
Onset Latency	This field is calculated from the earliest first dose date of the suspect drug(s) to onset date. You can also enter or modify the duration manually. Onset Latency = Onset Date - First Dose.
Receipt Date	Enter the date on which information about this event was received by your company. In Flexible Aggregate Reporting, this field is used to filter the events that fall out of the reporting period.
Patient Has Prior History?	Indicate whether the patient has had a prior history or has suffered from the same event in the past.
Intensity	Select the category of severity of the event. Contact your system administrator to adjust this list.
Frequency	Select the frequency of the event from the list. Contact your system administrator to adjust this list.
Outcome of Event	Select the outcome of the event. Contact your system administrator to adjust this list. If **Fatal** is selected, **Death** is selected in the list of seriousness criteria. If the **Death** checkbox is subsequently cleared, the outcome still remains fatal.

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Review a diagnosis-event relationship

You can group events in a case, and/or associate them with particular diagnoses. Your company may determine these or they may be reported to it. This helps in interpreting and reviewing individual case reports. You can also enable the reporting of diagnoses only while retaining database records of individual event terms.

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

The case must contain at least two events and, at least, one diagnosis. The events related to a diagnosis are listed on top in this dialog box and the symptoms are indented to the diagnoses. You can group events together and associate them with individual diagnoses.

Associate a symptom with the diagnosis

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

For the example:

```
Defining a diagnosis-event relationship can clarify an adverse event report. Suppose an
initial case report describes a patient suffering from Somnolence, Sore Throat, and
Fever.
AE #     Diagnosis AE Term (Associated AEs)
 1          Somnolence
 2          Sore Throat
 3          Fever
For reports on all events, they would appear on a CIOMS-I form as:
```

- Somnolence [SEDATION]

- Sore Throat [SORE THROAT NOS]

- Fever [PYREXIA]

```
Suppose a Follow-up report then supplies information that the patient also had
neutropenia, and had been diagnosed as suffering from agranulocytosis (the cause of the
sore throat and fever). The somnolence was considered to be coincidental, and unrelated
to any other adverse events.
Neutropenia and agranulocytosis would be entered into the system, and a diagnosis-event
relationship established as follows:
```

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

```
These events would appear on a CIOMS I form as:
```

- AGRANULOCYTOSIS

- [AGRANULOCYTOSIS] [SORE THROAT],

- [PYREXIA NOS], [NEUTROPENIA]

- Somnolence [SEDATION]

```
This immediately provides a clear clinical picture of the case.
```

Auto-populate event information

The MedDRA application searches the term dictionary for a match at the Lower level or at the Synonym level. If a match is found, the following fields are automatically populated:

- Term code
- Preferred Term
- Included Term
- High Level Term
- Group Term
- Body System/SOC

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.

Enter event coding information

The Event Coding section enables you to enter information about the event.

Field or Control Name	Description
System Organ Class (SOC) (Code)	Displays the body system or System Organ Class. This item is automatically entered from the event dictionary used and cannot be edited.
High Level Term (Code)	Displays the high-level group term when using the MedDRA coding dictionary. This field is not shown when coding with WHO-ART and cannot be edited.
High Level Term (Code)	Displays the High Level Term when the MedDRA coding dictionary is used. This item is not displayed when event encoding is done using the WHO-ART dictionary and cannot be edited.
Preferred Term (Code)	Displays the preferred term. This item is automatically entered from the event dictionary used and cannot be edited.
Included Term (Code)	Displays the lower level term code. This item is entered from the event dictionary used and cannot be edited.
Clinical Sign IMDRF Code	Enter the IMDRF code for Clinical Sign via lookup.

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Enter seriousness criteria

Field/Control Name	Description
Death	Displays the Death Details dialog box

> **✎ Note:**
>
> If you un-check the **Death** option in the **Seriousness Criteria**, you are required to confirm the deletion of the death details.

Field/Control Name	Description
Hospitalized	Displays the Event Hospitalization dialog box.
Other	Check this checkbox to enter explanatory text. You must mandatorily enter text, specifying the **Other** Seriousness Criteria.

For more information, see:

- Enter death details
- Enter hospitalization details
- Select nature of event
- Enter event notes

Enter death details

1. Check the **Death** checkbox under **Seriousness Criteria**.

    The form for Event Death Details appears.

2. Enter information for the items in the form.

3. Click **OK** to save the entered Death Details.

> **✎ Note:**
>
> When Seriousness criteria Death is unchecked, the system displays a message `Do you wish to delete the Death Details?` On confirming, the Death date (NF or date) and Autopsy details are cleared.

Enter hospitalization details

1. Check the **Hospitalized** checkbox under Seriousness Criteria.

    The form for Hospitalization Details appears.

2. Enter information for the items in the form.

3. Click **OK** to save the entered Hospitalization Details.

Select nature of event

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

Enter event notes

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

Enter event assessment information

The **Event Assessment** tab enables you to capture causality and listedness information for a case. Causality can be captured for both company and non-company products for study cases.

You can enter labeling information in the Event assessment page manually or it can be determined automatically. Labeling data is entered for all licenses pertaining to company suspect products against all the events present in the case. In clinical trial cases, labeling information can be entered for non-company products that are part of Study configuration.

A pre-requisite for auto-labeling is to have active datasheet versions associated with the Product licenses in the License configuration screen.

Non-clinical trial cases

Labeling is assessed based on the latest datasheet revision and by using the below logic:

- If the event entered in the case is present in the latest datasheet revision, then the **Labeled** field is populated.

- If the event entered in the case is not present in the latest datasheet revision, then the **Unlabeled** field is populated.

- If the Product license is not configured with a datasheet or associated with a datasheet that is not activated even once, then the **Unknown** field is populated for labeling information and **Unspecified** is populated for the datasheet name and revision #/name is not displayed.

- Overall listedness for the datasheet is populated as **Listed**, **Unlisted**, and **Unknown** based on the labelling information of all licenses within a product.

Clinical trial cases

The Study Configuration screen allows you to set the datasheet revision for licenses associated with study products.

If datasheet revision is set for the licenses in the Study configuration, then event assessment is computed based on datasheet revision that is configured or prior datasheet versions, based on the below logic:

- If the event entered in the case is present in the datasheet revision, then xx configured for that product license in Study

  – If the Onset date is later on equal to the activation date (the datasheet revision that is configured in Study), then the event assessment is performed using that revision. If there are multiple datasheet revisions with the same activation date, then the system takes the most recent revision into consideration.

- If the Onset date is prior to the activation date, then the system matches the Onset date of the event with the activation date of the previous revision number, and this continues until it finds an Onset date later or equal to the activation date. It is not recommended to have the Onset date set earlier than the activation date of all revisions, however if this scenario occurs, then the datasheet revision does not get listed in the event assessment and listedness assessment for that license is displayed as Unknown.

- If the event entered in the case is not present in the datasheet revision configured in Study but present in prior version such as xy and if the Onset date of the event is later the datasheet revision xy's activation date, then the datasheet revision xy is considered for listedness evaluation and the **Labeled** field is populated.

- If the event entered in the case is not present in the datasheet revision xx configured in Study and its prior versions, then datasheet revision xx is considered for listedness evaluation and the **Unlabeled** field is populated.

- Overall listedness for the datasheet is populated as **Listed**, **Unlisted**, and **Unknown** based on the labelling information of all licenses within a product.

- If there are conflicting listedness within same datasheet for Product, the system displays the *** symbols for Overall listedness for the datasheet.

The listedness assessment for clinical trial cases is based on the same logic as non-clinical trial cases in the following situations:

- For non-study products within a Study case;

- Study products for which datasheet revisions are not configured in Study configuration;

- Company study products in non-company clinical trial cases;

- Company products that are part Blinded study and are marked as open labeled products.

> **Note:**
>
> If the Onset date is not specified in the Event section, then the initial received date is considered. If the Onset date is set at an imprecise date, then the system considers June as the missing month and 15 as the day for missing day component and thus matches the Onset date with Activation date and then performs the event assessment.

When a blinded user (User Information > Protect From Unblinded Information) opens a blinded case, or opens an unblinded case with blinded study, then the `CaseForm > Events > Event Assessment` tab appears as follows:

- License information is blinded.

- Datasheet name is blinded.

- Listedness information is retained as-is.

Assess listedness for blinded clinical cases

When the **Include datasheet/licenses for the default blinded study product** common profile switch is selected in `Argus Safety Console > System Configuration > System management > Case Processing > Assessments > Criteria for Event Level Assessment for Blinded Study`, then:

- Event assessment for default blinded product is evaluated.

- – If a primary license is configured in the Study configuration, then the event assessment is performed for the primary license product.

  – If no primary license is configured in the Study configuration, then the event assessment is performed for any of the blinded product.

- Datasheets and licenses for all the blinded products configured in the Study configuration against the default blinded case product are displayed in the `Case Form > Events > Events Assessment` tab.

> **✎ Note:**
>
> When a blinded study case is created, then a blinded product is added.

- – The datasheet name, revision and licenses are displayed for each blinded product separately against the common blinded case product that is displayed in the first column.

  – The datasheets and licenses are grouped together for each blinded product.

- If any of the blinded product is non-company product, then a single record is displayed as per the blinded drug to capture listedness.

  – For a non-company study product in the Event Assessment tab, the **Datasheet** column display Unknown and no link is associated with text displayed.

  – For non-company study product in the Event Assessment tab, the **License** column display text as (Mkt:) followed by the product name as appeared in the Study configuration. There is no link associated with the text displayed.

- If the blinded product is the only non-company product or all the blinded products are non-company products; i.e. none of the blinded product has datasheet/license information, then a single record is displayed to capture listedness at product/event level.

- If a blinded case created prior to this release is opened with the existing event assessment, then the Event assessment tab displays the datasheet and licenses for blinded product evaluated at the time of re-calculation of event assessment. It does not contain the additional datasheet and license information for all the blinded products from study configuration against the blinded product.

- Click on **Recalculate** to perform re-calculation of event assessment. If multiple blinded products are encountered in the Study configuration, then the Event Assessment tab displays additional datasheet and license against blinded product including the listedness evaluation. However, selecting WHO Drug Recalculate in listedness goes back to Unknown.

- After the case is unblinded and a study product is selected, the event assessment is recalculated. After unblind, event assessment records for the selected drug are retained and the event assessment records for non-administered products are deleted from the case.

> **✎ Note:**
>
> This common profile switch does not impact behavior for the blinded user on the Products tab.

All cases

Datasheet revision number/name and activation date is displayed as per the datasheet revision that was used for listedness computation and it is displayed against each of the licenses grouped under the datasheet.

Withdrawn date plays a role in listedness determination and this logic is common to both Clinical and Non-Clinical trial cases.

If a product license has a withdrawn date, then the following logic is applied:

1. If withdrawn date >= initial received date, then the system performs the event assessment displays the License number and Revision number/name.

2. If initial received date > withdrawn date, then the license does not get listed in event assessment and its corresponding assessment is not shown.

3. If all licenses within product are withdrawn, then the Datasheet name is shown as Unknown and Overall Product listedness is displayed as Unknown.

4. If Products has both withdrawn and non-withdrawn licenses and are associated with same datasheet, then datasheet name associated with Active licenses are displayed and Overall Product listedness are displayed based on the active licenses instead of Unknown.

5. If Products has both withdrawn and non-withdrawn licenses and are associated with different datasheet, then the logic specified in c) and d) are used for displaying datasheet name and Overall listedness is based on active license.

For more information:

- Event assessment tab—user actions
- Filter event assessment details
- Enter product-event details

Event assessment tab—user actions

User Action	Result
Click Datasheet column's + icon	The system does the following: • Datasheet revision name and number, along with the activation date that was used for listedness determination is displayed against the licenses. • On the License column, all licenses that are associated with the datasheet are displayed. • Labelling information that corresponds to the Product licenses is displayed. • The License column also displays an icon. You can click the icon to hide individual product licenses, datasheet revisions and labelling information and only the overall listedness for the datasheet is displayed.
Click Product Name link	You can navigate to Case Form > Products > selected Product.
Click Event Description link	You can navigate to Case Form > Events > selected Event.
Click Datasheet Description link	Displays the activation date, revision name, revision number of the latest datasheet revision on which the listedness assessment was made. Click **Export** to get a listing of all labeled terms in an Excel file.
Click Datasheet revision number/name link	Displays the activation date, revision name, revision number of the latest datasheet revision on which the listedness assessment was made. Click **Export** to get a listing of all labeled terms in an Excel file.

Event assessment—field descriptions

Field or Control Name	Description
Recalculate	Refreshes the Event Assessment section with the newly entered data if new suspect products or events are entered, or the Event Relationship is modified.
Product	Populated when events are entered in the Products tab and appears as: • First Line - Product Name • Second Line - Generic Name
Causality as Reported/ Source/ Method/ Result	Provides the source of causality as reported such as Investigator, Healthcare Professional, and so on. Provides the method used for causality determination. Provides the result of the causality assessment.
Causality as Determined/Source/ Method/ Result	Provides the source of causality as determined such as Sponsor, MAH, and so on. Provides the method used for causality determination. Provides the result of the causality assessment.
Other Causality / Source/ Method/ Result	Provides the source of causality from any additional source such as NCA. Provides the method used for causality determination. Provides the result of the causality assessment.

> **Note:**
>
> The previous three causality fields can be set up for:
> • Company suspect products in all cases.
> • Suspect non-company products in study and non-study cases.

Field or Control Name	Description
Event	Populated when events are encoded and appears as: • First Line - Event PT (Verbatim) • Second Line - LLT
D/S	Displays the Diagnosis/Symptom details by D or S.
Seriousness Severity Duration	Displays the seriousness, severity, and the duration of the event.
Listedness	Indicates whether the system found the event on the datasheet for this product. This field is enabled for company products and non-company study drugs.

Filter event assessment details

Only the assessment rows that match the selected criteria appear in the filtering results.

Field or Control Name	Description
Product	The Product filter drop-down list contains the **All**, **Company Product(s)** and **Non-company Product(s)** options. You can filter on all the products which are present in the Event Assessment dialog box or you can filter on only company products or only non-company products.
Event PT(Description)/LLT	Contains a drop-down list of values of distinct Event PT. You can filter on all the products which are present in the Event Assessment dialog box.

Field or Control Name	Description
D/S	Contains a drop-down list of values of D for Diagnosis or S for Symptoms.
Datasheet	Contains a drop-down list of values of distinct Datasheets.

Enter product-event details

The Product-Event Details tab enables you to capture causality information for a case.

Field or Control Name	Description
Event	Populated when events are encoded and appears as: • First Line - Event PT (Verbatim) • Second Line - LLT
Onset from First Dose	This date is defined as the earliest regimen start date to Onset and is completed automatically. The date calculation is based on the Case Form Calculation for Inclusive or Exclusive.
Onset from Last Dose	This date is defined as the latest regimen stop date to Onset and is completed automatically. The date calculation is based on the Case Form Calculation for Inclusive or Exclusive.
Total Dose to Event	This value is calculated based on daily dose and duration.

Add attachments to your case

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

• When you click the hyperlink and a reference case is present, the system opens a case number irrespective of the selected reference type when you clicked the hyperlink.

• If no sites are defined for the attachments classification, the system permits **all** users to view the attachments on the Additional Information tab.

• The system permits Workflow Enterprise to view **all** attachments across **all** sites.

• You can send different Case Form attachments to different agencies, based on the **Attachment classification** specified to the Receiving Agency in the Reporting Destination Codelist in the Oracle Argus Console. For more information, refer to the *Oracle Argus Safety Administration Guide*.

• After the records in **Notes and Attachments** are sorted, if the following options are invoked without closing the case, the sort order is respected in these modules:

– Case Form Print

– Medical Review

– Copied Case

For more information, see:

• Enter additional information for the attachments

• Sort attachments

- Search for Documentum links

- Attach files to a case

- Enter keywords

- Attach references to a case

- View and print attachments

Enter additional information for the attachments

Notes and Attachments- field description

Field or Control Name	Description
Notes and Attachments	Lets you sort column headers to sort the records based on the fields in the Notes and Attachment section.
Classification	Select a classification that describes the attachment. Contact your system administrator to adjust this list.
	Refer to the Oracle Argus Interchange User's Guide for details about Attachment Classification usage in sending attachments in electronic reports.
Incl. Reg. Sub	Check this checkbox to merge PDF attachments within the Case Form. The **Incl. Reg.** checkbox identifies the attachments to be included as an appendix to Expedited reports. On checking this checkbox, the Expedited reports - CIOMS I, CIOMS I (Local), US FDA MedWatch 3500 Drug and 3500 A Device print an appendix page before each attachment. This is added to the case, and marked as Inc. Reg. Sub checked.
	The checkbox is available only if a PDF is selected as an attachment.
Literature Reference	Select the Literature that is related to the attachment. Attachments that have Literature reference are transmitted as inline attachments for the data element C.4.r.2 in the E2B(R3) report.
Attach File	Inserts a file attachment into the case. Maximum file size is 4 GB.
Attach Documentum Link	This option is visible only if Documentum is available.
	Click **Searching for Documentum** to search for and attach Documentum.
References Type	Select a reference type from the list, for example, a parent-child link. Contact your system administrator to adjust this list. For description of each reference type, see Reference Type descriptions.
ID #	Enter the case number of the case that is to be referenced.
	Click **Select** to search for the case that is to be referenced. You can also use this field to record the reference number for external cases.
Select	Opens the Case Selection dialog box for the selected ID.

Table 2-5   Reference types and their description

Reference Type	Used in Report	Description
Parent-Child Link	E2B	Add the parent-child link between cases.
MHRA Report Number	All	Add the report number of the submission made to MHRA.
EMEA Report Number	All	Add the report number of the submission made to EMEA.
E2B Report Duplicate	E2B	Add details of the duplicate E2B report.
E2B GP Medical No.	E2B	Add the medical number provided by the specialist.

Table 2-5   (Cont.) Reference types and their description

Reference Type	Used in Report	Description
E2B Specialist No.	E2B	Add the medical number provided by the general practitioner.
E2B Authority Number	E2B	Add the Worldwide Unique Case Identification assigned by the regulator.
E2B Company Number	E2B	Add the Worldwide Unique Case Identification assigned by the non-regulator.
E2B Other Number	E2B	Add the Worldwide Unique Case Identification assigned by the non-regulator.
E2B Linked Report	E2B	Add details of the linked report.
HTTP/URL Reference	All	Add the http or url references as part of the case.
Patient Link	All	Use if the multiple cases are reported in the context of same patients.
MHLW Identical Case Num	All	Stores case numbers of identical cases sent to MHLW.
MHLW Registration ID	All	Stores the Registration ID assigned by MHLW.
Local Event Number	All	Add the local event number that was used to create a case in Oracle Argus Safety.
MHLW Completion Report ID	All	Stores the Completion ID assigned by MHLW for the report sent for the case.
DEC ID	All	
Spanish Local Id	All	Add the reference number provided by the Spanish Agency on report submission.
Health Canada File Number	All	Add the reference number provided by Health Canada on report submission.
Source Case	All	Add details of the source case that was used to create the current case in Oracle Argus Safety.
PMDA Document Number	PMDA	Stores details of the documents received from PMDA.
EUDAMED Reference No.	MIR	Add the reference number as provided by EUDAMED.
Historical Ref.	All	Add details of the historic references related to the current case in Oracle Argus Safety.
Other NCA Local Ref. No.	MIR	Add the local reference number as provided by NCA.
Other EUDAMED Ref. No.	MIR	Add the reference number as provided by EUDAMED.
Other Mfr Ref. No.	MIR	Add the reference number as provided by the manufacturer.
NCA local FSCA Ref. No.	MIR	Add the FSCA reference number as provided by NCA.
EUDAMED FSCA Ref. No.	MIR	Add the FSCA reference number as provided by EUDAMED.
Mfr FSCA Ref. No.	MIR	Add the FSCA reference number as provided by the manufacturer.

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Table 2-5   (Cont.) Reference types and their description

Reference Type	Used in Report	Description
Regulatory Ref.	All	Add details of the regulatory references related to the current case in Oracle Argus Safety.
E2B Hospital Record No.	E2B	Add the hospital record number.
Companion Case	All	Add details of the companion case.
MW 3500A Mfr. Rpt. #	All	Add the report number of the submission made to FDA in MedWatch format.
BfArM Report Number	All	Add the report number of the submission made to BfArM(Germany).
PEI Report Number	All	Add the report number of the submission made to PEI(Germany).
Cross Reported IND	All	Add a reference number of the abbreviated new drug.
UF/Importer Report #	eMDR	This is the unique identifier used by the user facility or the importer for this report. For a follow-up report, the UF/Importer report number must be identical to the number assigned to the initial report.

Sort attachments

Field	Description
Keywords	On clicking this column header for the first time, records are sorted in the ascending order (alphabetically) of the *Keywords*.
Date	On clicking this column header for the first time, records are sorted in the ascending order (chronologically) of the *Date*.
Description	On clicking this column header for the first time, records are sorted in the ascending order (alphabetically) of the *Description*.

Search for Documentum links

1. Click the **Attach Documentum Link** button to open the Documentum Lookup screen.

2. Enter the desired search criteria as per Type Name, Attribute Name and Search String, and click **Search**.

3. Select the desired link from the row displaying the search results.

4. Click **Select** to select the link from the list.

Attach files to a case

1. In the Notes and Attachments section of the Additional Info tab, click **Attach File** to open the Attachment dialog box.

2. Click **Browse** to locate a file attachment.

3. Select the file and click **OK**.

Enter keywords

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

To attach keywords to a case:

1. Go to the Notes and Attachments section and click **Select**.

2. When the system opens the Attachment Keywords dialog box, select a keyword from the **Select a keyword to add to the list** drop-down list.

   The system displays the selected keywords in the Keywords field.

3. Click **OK**

Attach references to a case

1. Locate the References section and click **Select**.

2. When the system opens the Case Search Criteria dialog box, enter the search parameters and click **Search.**

3. When the system displays the search results in the Total Number of Rows section, select the desired search criteria from the list, and click **Select** to view details about the selected case.

View and print attachments

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

- As footers on all printouts (except letters).

- In the following format: dd-mmm-yyyy hh24: mm: ss.

To print case attachments:

1. Click the **Description** link to display the attachment.

2. When the system opens the letter, click **Print** to print it.

Review local labeling

1. Hover over the Worklist menu and select **Local Labeling**.

2. When the system opens the Local Labeling screen, select the appropriate information as necessary.

- Filtering by Product Family: You can filter products in the Event Assessment dialog box based on the selected product families. Click the magnifying glass icon to filter the search results by product family.

- The system displays the number of cases currently in view and automatically updates the range based on the page size specified in the Search dialog box (read-only). For the example:

  ```
  If you select 100, the system divides the displayed rows into groups of 100 cases.
  ```

- Events assessment can show all listedness values. By default, it shows listedness **only** for the core datasheets and countries you have permission to access.

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- Diagnosis - The **Diagnosis Filter** contains a drop-down list with the following values:

    – D (Diagnosis)

    – S (Symptoms)

    – In the Events Assessment dialog box, you can filter on either the diagnosis or the symptom.

- By default, the system displays all events with the **<ALL>** option.

- Datasheets

    – The **Datasheets** drop-down list contains a list of distinct datasheets.

    – Displays the revision number and the date on which Datasheet was made active.

    – All the blank datasheets display as a single row of **Unspecified**.

    – When you click the **Datasheet** hyperlink, the system displays the datasheet notes.

- Licenses

    – The **Licenses** drop-down list contains a list of distinct countries for the licenses.

    – All licenses not associated with a datasheet appears under **Unspecified** and are aligned with the datasheet view.

    – When you click the **Licenses** hyperlink, the system displays the license references.

- The **Process** button triggers all the applicable rules (both global and local) for the country/ license type for the licenses that are assessed through this screen.

For more information about Local Labeling, see the *Oracle Argus Affiliate User's Guide* for Worklist - Local Labeling requirements.

Enable local data entry for Japan

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.

For more information, see:

- Enable local data entry
- Access local case data lock functionality
- Process an outlier
- Activate local locking in Oracle Argus Safety

Enable local data entry

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](#)

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 Oracle Argus Safety Japan 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 a 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 a 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 an update to the 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.

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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.

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 Oracle 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 Oracle 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 Oracle 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

Local Lock Feature	Overview	Documented in
Changes to the Case Locking mechanism in Oracle 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
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 a 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 or 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 or 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 a local case.

It is also recommended that customers ensure that cases or 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.

For more information, see:

- Enter local reports configuration seed data
- Enter local users seed data
- Enter local fields seed data

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 below:

  ```
  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

x. PMDA Device XML

Enter local users seed data

The upgrade installer script prompts the user to choose if all the Oracle Argus Safety Japan 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 or upgrade, if the customer has turned on the local locking, the icons in the applicable screens start reflecting the local or global lock status of the case.

3

Process case data

In this chapter:

- Access cases
- Process cases
- Review cases
- FAQs
- What if

Access cases

In this section:

- Search for a case
- Search for a case assigned to you

Search for a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Search Criteria page, enter criteria for your search in any of the following fields:

   - **Search For**—Select a parameter from the drop-down list and provide a search value in the adjacent text field.

     > 💡 **Tip:**
     >
     > You can select the **Pri/Stdy/Othr/Cntr/Rptr/Pat** option from the **Search For** drop-down to simultaneously search for a value that you specified in the field adjacent to **Search For** by all these parameters: Project ID, Study ID, Other ID, Center ID, Reporter ID, and Patient ID.

   - **Date Range**—Select a parameter from the drop-down list, or enter a custom date range in the **From** and **To** fields, and click **OK**.

     > 💡 **Tip:**
     >
     > Select the **Follow-up** radio button to search by follow-up dates, including significant and non-significant event dates.

   - **Product Family**—Select a product category from the drop-down list.

3. To use a new advanced condition query set as criterion for your search, select **New** from the **Advanced Condition** drop-down list or click the **AC** button. See Create a single filter.

4. If necessary, check the **Full Search** checkbox and enter a value in the field adjacent to **Search For** to search for cases that contain the specified value in any word order or combination.

5. Click **Search**.

6. From the search results list, click a Case ID link.

Search for a case assigned to you

1. On the Home/Personal Argus Status page, check the **Cases Assigned** checkbox.

> ✎ **Note:**
>
> If the Personal Argus Status Page is not your default home page, go to the **Dashboards** menu and click **Personal Argus Status**.

2. From the list of cases assigned to you, click a Case ID link.

   Alternately, enter the exact case ID of the case in the **Case Quick Launch** field, and click **Open**.

Process cases

In this section:

- View assigned and unassigned cases
- View the case workload for one or more individuals or sites
- View the workflow status for cases
- Route a case to another workflow state
- Route multiple cases to another workflow state
- Add a follow-up event to a case
- Unblind cases to a study
- Copy a case
- Lock or unlock a case
- Delete a case
- Undelete a case
- Formally close a case
- Print case details for a case
- Print letters and attachments for a case

View assigned and unassigned cases

1. Hover over the **Worklist** menu, and do one of the following:

   - To view unassigned cases and new worklist items that were assigned but not accepted by users, click **New**.

   - To view cases that were assigned and accepted by users, click **Open**.

2. On the New/Open page, enter the required information, and click **Search**.

3. To select a case by its number, enter a value in the **Case Number** field.

   Alternately, choose a filter from the available filters list.

> ✎ **Note:**
>
> Oracle Argus Safety doesn't include open cases that are assigned to you in the search results.

View the case workload for one or more individuals or sites

1. Hover over the **Dashboards** menu, and click **Case Workload**.

> ✎ **Note:**
>
> The **Case Workload** option displays only if you are a Workflow Manager.

2. In the **Load Balancing Dashboard** section, click the + (plus sign) character next to a parameter top expand it.

   - **Week Forecast**—Displays the number of cases that Argus Safety estimates for the selected workflow state or group in the next five days.

   - **Refresh**—Refreshes the number of cases that appear in the Load Balancing Dashboard every number of minutes you specify.

View the workflow status for cases

1. Hover over the **Dashboards** menu, and select **Worklist Status**.

2. Enter search parameters in the search case fields, and click **Search**.

3. To view cases in a specific workflow state, click a bar graph and perform a select from the drill-down menu.

> ✎ **Note:**
>
> The number of cases displayed changes as cases are updated during case processing.
> Oracle Argus Safety saves your preferences when you return to the **Workflow Status**.

4. To apply additional filters, click **More Filtering** and use the **Ctrl + Shift** keyboard keys to make multiple selections.

> **Note:**
>
> If you don't apply other filters, the **Default Report Configuration** filter shows cases for the current month. The cases are evaluated based on their **Aware Date** value.

5. To go to a specific worklist screen, double-click the **Bar Graph**.

Example 3-1   Sample filter options

- **Site**—Displays active sites except LAM sites in the **Argus Code List**.

- **Workflow State**—Displays active workflow states except **Archived** or **Closed** in **Utilities - Configuration**.

Route a case to another workflow state

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Open page, select the options to use as criteria for your search and click **Search**.

3. From the search results list, click a **Case ID link**.

4. From the Case Form, select the **Activities** tab.

5. To route the case to the next workflow state, do the following:

   a. Select **Route**.

   b. From the Case Routing dialog box, select the state to which to route the case from the **Route to Next State** drop-down list.

   If there is a single match for the next logical workflow state, then that workflow state is displayed by default in the **Route to Next State** drop-down.

   > **Note:**
   >
   > You can view states that are assigned to sites in the Workflow Configuration only if you are an Enterprise Workflow Manager.

6. To route the case to the previous workflow state, do the following:

   a. Click **Return**.

   b. Enter your password in the Case Routing dialog box.

   c. Select the user or group the case will be returned to from the **Route to User** drop-down list.

7. Enter a routing comment in the **Comments** field.

   Alternately, click **Select** and choose a pre-defined routing justification from the **Select a standard justification** drop-down list.

8. Click **OK**.

9. In the Case Routing dialog box that opens, click **OK**.
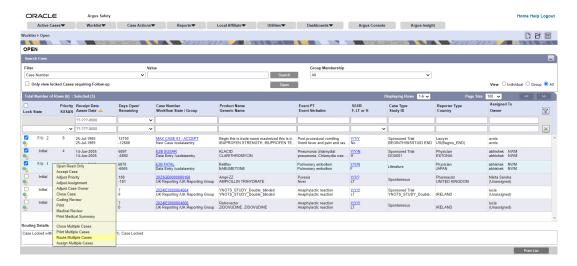
> **Note:**
>
> If a case is routed to multiple workflow states or groups, it is counted multiple times in the Week Forecast.

Route multiple cases to another workflow state

1. You can route multiple cases to another workflow state from:

   - `Worklist > New`

   - `Worklist > Open`

   - `Case Actions > Open`

   For `Case Actions > Open`, you can either select a single case or multiple cases.

2. Select multiple cases and then right-click.

3. Select the **Route Multiple Cases** option.

> **Note:**
>
> You can select the **Route Multiple Cases** option only if you have the Workflow Manager role assigned.

4. If the **Enable Checklist on Route** option is set in `Console > User Configuration`, then the **Checklist** based on the workflow rule is displayed under the **Current State** and **Date** values.

5. If all selected cases are in the same workflow state, then you can select the next workflow state from the list displayed in the **Route to Next State** dropdown. The default value is set to **Current**. If there is only one next logical workflow state match, then that workflow state is displayed by default in the **Route to Next State** dropdown.

6. In the **Route to User** dropdown, you can select from a list of users. If there is a single workflow rule that matches for the next logical workflow state for all selected cases, then the dropdown will display the user list in accordance to the Group configured in that workflow rule. If not, all users irrespective of configured groups are displayed.

7. In the **Password** field, enter your password. You are required to re-authenticate when the **Require Password on Route** option is set in `Console > System Configuration > Workflow > Rules` and when you select any matching workflow rule that is displayed above the dotted line in the **Route to Next State** dropdown.

Add a follow-up event to a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Open page, select the options to use as criteria for your search and click **Search**.

3. From the search results list, click a **Case ID** link.

4. If the case is locked, unlock the case by clicking the **Lock** icon () in the Quickstart tool bar at the top right of the Case Form.

5. From the General Information section, in the Follow-ups sub-section, click the **Add** button.

6. In the Case Form Operations dialog box, choose if the follow-up event is a significant one by clicking the **Yes** or **No** button.

7. Modify the system date values in the Follow-up Received and Central Received fields as required for the event.

8. To add a justification for adding the follow-up event to the case, check the **Amendment** checkbox.

   In the Amendment/Follow-up Justification dialog box, enter a comment and click **OK**.

9. To add more than one follow-up event to the case, click the **Add** button again and redo steps 5 to 7.

Unblind cases to a study

You can perform expedited unblinding (case by case or one case at a time) or unblind cases in bulk after end of study.

To unblind a case:

1. Hover over the **Utilities** menu, then **Argus Unblinding**, and select **Unblinding Lite**.

2. In the Unblinding Lite dialog box, select a study from the drop-down list.

> **Note:**
>
> The Unblinding Lite dialog box does not include cases that are globally or locally unlocked, or pending local or global report submission.

3. Select **Drug Received** from the drop down for the case to be unblinded.

4. To add information on dosage, under the Dosage column, click **Select** for the corresponding case ID.

5. In the Dosage Regimens dialog box, click **Add** and enter the drug dosage information.

6. To display cases that are still in blinded status belonging to the selected study, check the **Display only unbroken cases** check box.

7. Click **OK**.

To unblind cases in bulk:
Hover over the **Utilities** menu, then **Argus Unblinding**, and select **Unblinding Advanced**.
A list of all the configured EOSU Profiles specific to the user enterprise appears.
For information on creation of new profile and execution of the profile, see the Chapter Argus Unblinding.

Unblinding Advanced - Fields description
You can sort and search cases based on the following fields.

Field Name	Description
Profile Name	Displays the profile name.
Study ID	Displays the Study ID associated with the profile.
Last Modified	Displays the last modified date and time of the profile. Time stored in GMT in the database is reflected in the local user time-zone on UI.
Last Run	Displays the last run date (completed dry-run or update) of the profile. Time stored in GMT is reflected in the local user time-zone on the UI. If the profile was never executed, the column value remains blank.
Status	Displays the latest status of the profile corresponding to the last run. The screen refreshes with the latest status only on reloading the Unblinding Advanced page. The following are the available statuses: • Dry-Run In Progress • Dry-Run Completed • Dry-Run Failed • Update In Progress • Update Completed • Update Failed • Not Executed

Copy a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Search Criteria page, select the options to use as criteria for your search and click **Search**.

3. From the search results list, click a Case ID link.

4. Hover over the **Case Actions** menu and click **Copy**.

5. On the Case Copy - Webpage page, enter the number of copies to create and click **Yes**.

6. On the Case Copy page, select the sections from the case to copy.

   To copy the entire case, click **Select All**.

7. Click **Copy**.

> **Note:**
>
> Oracle Argus Safety copies any blank values from the case to the case copy.

8. In the Case Routing dialog box:

   a. From the **Route to Next State** drop-down list, select a value to represent the workflow state for the copied case.

   b. From the **Route to User** drop-down, select a user or user group to return the case to.

   c. In the **Comments** field, add a justification for the copy action.

      To add a standard text as justification, click **Select**, choose the standard text from the Routing Justification dialog box and then click **OK**.

   d. Click **OK**.

9. If automatic case numbering is disabled, on the Case Form for the copied case, enter a case ID.

Lock or unlock a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Search Criteria page, select the options to use as criteria for your search and click **Search**.

3. From the search results list, click a Case ID link.

4. From the Case Form, select the Activities tab.

5. From the Case Lock/Close section, click **Lock** or **Unlock**.

6. In the Case Locking/Unlocking dialog box, enter your Oracle Argus Safety password in the **Password** field.

7. To add a justification for the case lock or unlock, enter data in the **Notes** field.

8. If you are unlocking a Case Form, click either button to choose the focus page for significant or non-significant follow-up events:

   • **Significant F/U**—The **Follow-up Received Date** on the General tab, with the **Significant** checkbox checked.

   • **Non-significant F/U** — The **Follow-up Received Date** on the General tab, with the **Significant** checkbox unchecked.

9. Click **OK**.

> **Note:**
>
> You can also lock and unlock a case by clicking the **Lock** icon () in the Quickstart tool bar at the top right of the screen.

Delete a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Open page, select the options to use as criteria for your search and click **Search**.

3. From the search results list, click a Case ID link.

4. Hover over the **Case Actions** menu a second time, and click **Delete**.

5. In the Action Justification dialog box, enter a justification in the **Please enter a justification for performing this action** field.

   Alternately, click **Select** and choose a pre-defined justification from the **Select a standard justification** drop-down list.

6. Enter your password in the **Password** field.

7. Click **OK**.

> **Note:**
>
> Once you delete a case, users can no longer access it from the Oracle Argus Safety application.

Undelete a case

1. Hover over the **Utilities** menu, and select **Case Undelete**.

2. On the Case Undelete page, enter search values in the fields from the **Case Search Criteria** section and click **Search**.

3. Check the checkbox for the case number to restore and click **Undelete**.

4. In the Action Justification dialog, enter a justification in the **Please enter a justification for performing this action** field.

   Alternately, click **Select** and choose a pre-defined justification from the **Select a standard justification** drop-down list.

5. Click **OK**.

Formally close a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Search Criteria page, select the options to use as criteria for your search and click **Search**.

3. From the search results list, click a Case ID link.

4. From the Case Form, select the Activities tab.

5. From the Case Lock/Close section, click **Close**.

6. Enter your password in the Case Closure dialog box.

7. Click **OK**.

> **Note:**
>
> Formally closing a case isn't the same as closing the Case Form for the case and returning to the previous page.
>
> To modify the details of a formally closed case, you must first re-open it by providing your password.
>
> You don't need to unlock a locked close case before you close it.

Print case details for a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Open page, enter the search criteria for a case and click **Search**.

3. From the search results list, click a Case ID link.

4. Hover over the **Case Actions** menu, and click **Print**.

   To print the Case Form for the case:

   a. Select **Case Form**.

   b. From the Print Case dialog box, check the checkbox for each section to print or check the **Select All** checkbox.

   c. If you don't want the print to include product information for the case, check the **Blind Study Product** checkbox.

   d. Click **Print**.

   To print the Medical Summary for the case:

   a. Click **Print Medical Summary**.

   b. From the medical summary report, select **File** and then **Print**.

Print letters and attachments for a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Open page, enter the search criteria for a case and click **Search**.

3. From the Case Form for the case, select the Additional Information tab.

4. Click the **Print Case** icon (🖨) at the top of the page.

5. In the Print Case dialog box, select the tab corresponding to the item type to print (Letters or Attachments).

6. Click the **Description** link for a letter, or the **Classification** link for an attachment to view the item in Adobe Acrobat.

7. Click the **Print File** icon at the bottom.

> **Note:**
>
> Letters are the only Oracle Argus Safety printouts that don't include date/time information in the footer section.

Review cases

For more information, see:

- View correspondence contacts for a case
- Generate a letter on a case
- Track correspondence for a case
- View case action items
- View revisions for a case
- View the audit log for a case
- View the coding status of a case
- Perform a medical review of a case
- Perform a coding review of a case
- Perform a regulatory submission review of a case

View correspondence contacts for a case

1. Hover over the **Worklist** menu, and select **Contacts**.
2. On the Contacts page, enter case information in the fields as necessary.
3. From the results list, click a Case ID link for which to view correspondence contacts.

Generate a letter on a case

1. Hover over the **Case Actions** menu, and click **Open**.
2. On the Case Selection page, enter the search criteria for a case and click **Search**.
3. From the results list, select a case.
4. From the Case Form for the case, click the Activities tab.
5. In the Contact Log section, click **New Letter**.
6. From the Custom Letter Templates dialog box, select a letter template and click **OK**.
7. From the Save Letter dialog box, click **Yes** and modify the application generated letter as appropriate.

   Alternately, click **No** to save the Oracle Argus generated letter as is.
8. In the Attach Letter for Case dialog box, click **Browse** and navigate to the location of the saved letter.

> **Tip:**
>
> You can then modify the value in the **Date Sent** field in the Contact Log to schedule an action item for the letter.

The following table describes the meaning/status of various letter icons.

Icon	Status
	Scheduled letter is awaiting to be sent
	Letter is overdue (Date Open > System Date)
	Indicates email success status
	Click this button to open a message editor

Track correspondence for a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Open page, enter the search criteria for a case and click **Search**.

3. From the results list, select a case.

4. From the Case Form for the case, click the Activities tab and select **Contact Log**.

View case action items

1. On the Home or Personal Argus Status page:

   • To view your pending action items, check the **Action Item Entries** checkbox.

   • To view action items for a specific case, click a case number link and then select the Activities tab.
   You can view the details in the Action Items section.

2. From the **Worklist** menu, select **Action Items**.

   • To view details for a specific case action item, enter search criteria in the relevant fields:

     – **S/U/R**—Select the case-level assessment values for the case that contains the action items as Serious, Unlisted, Related.

     – **Action Item Code**—Select the case action item code.

     > **Note:**
     >
     > You can modify the **Description** value that the application uses for the selected action item code as required.

     – **Action Item Category**—Allows you to filter the action items. Select a value from the dropdown list. This dropdown lists values based on the selected Action Item Code for which action item category is configured in the Action Category code list.

- Check the checkbox corresponding to the type of case action item to view:
  - To view only case action items with due dates before the current date, check the **Overdue Action Items** checkbox.
  - To view only query-type case action items, check the **View Query Action Items** checkbox.

View revisions for a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Open page, enter the search criteria for a case and click **Search**.

3. From the search results list, right-click a Case ID link and select **Case Details**.

   Alternately, open the case and select **Case Revisions** from the **Case Actions** menu.

4. From the Case Details dialog box, click the plus sign (+) next to **Revisions**.

5. Click the **Revision History** text to view all the revisions for the case in the Audit Log Details dialog box.

6. Click an entry under **Revision History**.

> 💡 **Tip:**
>
> For descriptions of the icons associated with the revisions, see What are the lock states for a case?

7. From the Audit Log Details dialog box, to view details for a specific revision in read-only mode, select the revision from the revisions list.

> 💡 **Tip:**
>
> You can also view revisions for a case by selecting **Case Revisions** from the **Case Actions** menu.

View the audit log for a case

1. Hover over the **Utilities** menu, and select **Logs**.

2. Select **View Audit Log**.

3. Enter or select search criteria for the log in the Search Conditions section and then click **Search**.

4. Click the **Action item** icon ( ) for a case.

5. In the Audit Log Details dialog box, to view details for revisions made on the case on specific date, select the date entry at the bottom of the dialog.

   Alternately, check the checkbox next to the Revisions Date column to view a listing of revisions made on the case through all the dates.

> **Note:**
>
> Audit log is done for case data only that can be viewed from Case Revisions > View Audit log > Category > Cases. Audit log of reports is not covered in case revisions or case audit log data.

View the coding status of a case

1. Hover over the **Worklist** menu, and select **Coding Status**.

2. On the Coding Status page, enter case search criteria.

   > **Note:**
   >
   > To filter cases by an advanced condition, click **Advanced**. Select the advanced condition and click **OK**.

3. Note the coding status icon for the case.

   For a description of the icons associated with the coding status, see What does the coding status icon indicate for a case?

Perform a medical review of a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Selection page, enter the search criteria for a case and click **Search**.

3. From the results list, select a case.

4. Hover over the Case Actions menu and click **Medical Review**.

5. In the Medical Review - Case Form dialog box, to add a narrative to the case:

   Manually fill in the Narrative text box.

   > **Tip:**
   >
   > To enter the narrative in a specific language, click the icon representing the language above the text area.

   Alternatively, to fill in the Narrative text box with text from an auto narrative template, click **Generate**.

   a. In the Custom Auto Narrative Templates dialog box, select a template from the list of available templates and click **Append**. To replace the selected template with a new auto generated narrative template, click **Replace** instead.

   b. To add information in addition to the narrative, click the **Case Comment** icon ( ).

   c. If the case has events that are encoded using the MedDRA dictionary, select either **D** for Diagnosis or **S** for Syndrome from the D/S field.

    d. To switch to data sheet view and display the License column, click the + (plus) icon for Datasheet.

    Revision number and date on which the Datasheet was made active are also displayed.

6. To view a read-only version of the case, click the Temporal View tab.

    a. Filter the data categories to appear in the Event Assessment section by checking the corresponding checkboxes in the Display Options section.

    b. To view details for an event listed in the Event Assessment section, click the **Info** icon for the event.

    c. Enter information about any relevant tests performed in the Relevant Tests field in the associated section.

7. To attach notes and other items to the case, or to create cross-references to other cases, click the Action Items/Addl Info tab.

Perform a coding review of a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Selection page, enter the search criteria for a case and click **Search**.

3. From the results list, select a case.

4. Hover over the Case Actions menu and click **Coding Review**.

5. Click **Product Information** and review the existing information about the case.

6. To change information about the case:

    a. If the product is not a predefined company product, select a value from the **Formulation** list.

    b. Enter a value for the indication as reported in the Reported Indication field.

    c. Enter the indication to be coded in the Coded Indication LLT field.

    d. To display the associated coding dictionary, click **Encode**.

7. Click **Action Items** and review the existing action items for the case.

    To add an additional action item for the case:

    a. Enter the date an action item was created for the case in the Date Open field.

    b. Select an action item code from the Code list.

    c. Select a group to be responsible for the action item from **Group/Responsibility**.

    d. Enter the date on which the action item must be completed in the Due field.

    To mark an existing action item for the case as completed, enter the completion date in the Completed field.

Perform a regulatory submission review of a case

1. Hover over the **Case Actions** menu, and click **Open**.

2. On the Case Open page, enter the search criteria for a case and click **Search**.

3. From the search results list, click a Case ID link.

4. From the Case Form, select the Analysis tab.

5. To view differences in narratives for the case, in the Case Analysis section, click **Show Difference**.

> **Note:**
>
> The **Show Difference** button is enabled only if at least one previously locked version exists for the case.

6. To create a MedWatch 3500A Drug Report, select the MedWatch Info subtab.

   a. Enter the following details in block B:

   • If the product caused an adverse event in a patient, in Block B, select **Adverse Event**.

   • If a product defect or malfunction lead to the death or serious injury of a patient, select **Product Problem**.

   • If a malfunction or problem of the product caused the death or serious injury of a patient, select both **Adverse Event** and **Product Problem**.

   b. In block C, enter medication data in Suspect Medications.

   c. Enter the following information in block G:

   • Match all report sources in Reporter Type by checking the corresponding **Report Source** check boxes.

   > **Note:**
   >
   > If the country of incidence isn't the US, the value **Foreign** appears by default.
   > If the primary reported on the General tab is a health care professional, the value **Health Professional** appears by default.

   • Alternately, select **Other** and enter the necessary text.

   • Enter the PLA number in STN# Pre-1938/OTC Product.
   - If the product pre-dates 1938, select **Pre-1938**.

     - If the product is an over-the-counter product, select **OTC product**.

7. To review information about the history and the current condition of the patient and generate the BfArM 643 form, select the BfArM Info subtab.

> **Note:**
>
> If available, Oracle Argus Safety uses the relevant information from the Current Medical Status Form on the Patient tab to fill in the fields on the BfArM Info tab.

   a. Enter a causality or modify the existing value from the **Causality** drop-down list.

   b. Select or modify the existing values that apply to the patient from the drop-down lists in the Check One in Each Category section.

8. To assess imputability for the suspect product, select the AFSSAPS Info subtab.

a. Check one or more check boxes in **AFSSaPS Information**.

> 💡 **Tip:**
>
> Check the **Autres** check box to enable the corresponding field.

b. Enter a description in Future Actions.

FAQs

- What is a case owner?
- Can I reassign a case to another owner?
- When does a case become open?
- How do I create a query-type action item for a case?
- What happens to a query-type action item after its due date has passed?
- How can I view a summary of all the open cases?
- How can I view a summary of cases with open action items?
- When can I formally close a case?
- What happens to a study if I unblind the cases that are associated with it?
- How can I track which case revision contains significant follow-up information for the case?
- How can I interpret the differences between two narratives for a case?
- What other case details can I retrieve from the Routing Comments log?
- Can I view the original case from a copied case?
- What are the lock states for a case?
- Can I apply a local lock on a case that already has a local lock for another country?
- If I am an Oracle Argus Safety Japan user, can I enter local data, copy or modify a case that has a global lock?
- If I am an Oracle Argus Safety Japan user, can I apply both a local and a global lock on a Local PRPT case that I entered?
- Can I change the outcome of a case as part of my medical review for the case?
- Can I change the causality for a case during my medical review?
- What do the case assessment values stand for?
- Who is the MDR contact person?
- How does Oracle Argus Safety set the Receipt Date for a case?
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- Which actions can I perform on a saved letter?
- Can I edit or remove a letter after it was sent for a case?
- If I change the Date Sent value for a letter, must I also change the Due Date for the action item associated with the letter?

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- Where can I view action items for letters?
- Why do only some action items for a case appear as Sent in Letter?
- Can I auto-generate a letter for a case?
- Which actions can I do on an auto-generated letter?
- What does the coding status icon indicate for a case?
- Why does a border appear for a coding action item for a case?
- Why is there a green dot in the Notes area of a case summary?
- Why do only some user names appear in bold in the Case Workload?
- Why does the (SUSAR case icon) icon appear as the lock state icon for a case?
- Why do some letter icons from the Contact Log have an exclamation mark?
- Why does an asterisk (*) symbol appear next to the username for some users in the Case Routing dialog?
- How to attach multiple files to a single letter for follow ups?

What is a case owner?

A case owner is the first user to accept a case after book-in. This user has the right to assign the case to another user.

Can I reassign a case to another owner?

Yes, you can reassign a case to another user if you are a Workflow Manager and the initial owner of the case.

When does a case become open?

Oracle Argus Safety assigns the Open state to a case when the user accepts their assignment to the case.

How do I create a query-type action item for a case?

Based on the advanced conditions rules for the query-type action item, Oracle Argus Safety generates an open query-type action item when you save a case or when you click the **Generate Query** icon on the **Quick Launch** toolbar for a case.

The Due Date for the query-type action item is the System Date plus the Due Date (in days) as defined in the codelist. Similarly, the Open Date is the system date on the day the Query was created for the case.

What happens to a query-type action item after its due date has passed?

Once the due date for a query-type action item has passed, Oracle Argus Safety:

- Closes the query-type action item, if it doesn't meet the criteria of the Advanced Conditions for the case.
- Attempts to resolve the open query-type action item in the Case Form without creating a new action item with the same name.

How can I view a summary of all the open cases?

To view a summary of all the open cases in PDF format, hover over the Dashboards menu and select **Open Case Summary**. Cases in the summary are sorted in ascending order as per the number of days each case has been open.

How can I view a summary of cases with open action items?

To view a summary of cases with open action items in PDF format, on your Personal Argus Status page, hover over the Dashboards menu and select **Open Action Items**.

When can I formally close a case?

You can formally close a case only if the following conditions are met:

- You have access rights to the case.

- Action items for the case are complete.

- Expedited regulatory reports for the case are submitted.

- Expected follow-up information for the case was received.

- The case isn't locked.

Closing a case is the final stage of the case workflow. After a case is closed, Oracle Argus Safety archives it.

What happens to a study if I unblind the cases that are associated with it?

If you unblind cases that are associated with a study that is complete and single or double blinded, Oracle Argus Safety sets the **Blinding Status** value of each case to **Broken After Study**.

How can I track which case revision contains significant follow-up information for the case?

Oracle Argus Safety uses the following designations for items in the Audit Log Details dialog box:

- **(S) F/U**— Significant follow-up information was attached to the case.

- **(NS) F/U**—Non-significant follow-up information was attached to the case.

Users can mark follow-up information as significant or non-significant on the General Information tab of the Case Form for the case.

Each company can use its own definition of what significant follow-up information represents.

How can I interpret the differences between two narratives for a case?

Oracle Argus Safety uses the following conventions to signal the differences between two narratives on the Show Difference page:

- **Strikethrough red text with yellow highlight**—Narrative text that was removed.

- **Regular text with green highlight**—Narrative text that was added.

What other case details can I retrieve from the Routing Comments log?

In addition to user justifications for case routing, the Routing Comments log also includes details of any lock or unlock action that a user did on the case, even if that user was a system user such as the AG Service.

Note that the log displays only one entry if a global/local lock or a global/local unlock is applied at the same time to the case.

Can I view the original case from a copied case?

Yes, to view the original case, open the case form, and select the Additional Information tab for the copied case. The original case appears highlighted in the References section.

What are the lock states for a case?

Oracle Argus Safety uses the following states for a locked case:

- **Local Locked** ( )— The case requires follow-up. Any user who tries to access the case will be required to either view it as read-only, or unlock of the case at the local level.

- **Local Unlocked** ( )— The case is available to other local users.

- **Global Locked** ( )— The case requires local reporting.

- **Global Unlocked** ( )— The case doesn't require local or global reporting.

- **Global Locked and Local Locked** ( )— The case is a Local PRPT case and is locked at both local and global levels for all local countries for the case.

- **Global Locked and Pending Local Lock** ( )— The case is a Local PRPT case and is locked at global level but pending a local lock for any local country for the case.

Can I apply a local lock on a case that already has a local lock for another country?

Yes. You can apply a local lock on case that already has a local lock only if:

- **Enable Local Unlocking** is set to **Yes** for your tenant.

- There are no local reports pending for the case in the country for which the initial local lock was applied.

If I am an Oracle Argus Safety Japan user, can I enter local data, copy or modify a case that has a global lock?

Yes, you can enter local data, copy, or modify a case that has a local lock. However, you can't change the **Classification** value or generate local reports for the case.

If I am an Oracle Argus Safety Japan user, can I apply both a local and a global lock on a Local PRPT case that I entered?

Yes, you can apply both a local and a global lock on a Local PRPT case in one step if you select the **Perform Local lock additionally for a Local PRPT case** option in the Case Locking dialog box.

If this option isn't available, contact your Administrator to set the value for **Enable Local Unlocking** to **Yes** for your tenant.

Can I change the outcome of a case as part of my medical review for the case?

Yes, you can change the value of the **Case Outcome** field based on your medical review for the case.

Oracle Argus Safety sets an initial value of the **Case Outcome** field based on the outcome values of events from the Events tab of the case.

Note that changing the outcome for the case doesn't change the outcome value for any of the events for the case.

Can I change the causality for a case during my medical review?

Yes, if values already exist in the Causality as Reported and Causality as Determined fields on the Medical Review page, you can change them during your medical review.

- Oracle Argus Safety automatically adds the text that was added to Reported Causality when the case was booked in. You can select a different value for **Causality as Reported**, respectively override the text in **Causality as Determined** if you have the necessary access rights.

- Your Administrator is responsible for maintaining the list of available causalities for a case and for defining which causalities can be reported.

What do the case assessment values stand for?

Oracle Argus Safety uses the following assessments values for a case:

- **S**—Serious
- **U**—Unlisted
- **R**—Causality
- **A**—Unknown
- **F**—Fatal
- **LT**—Life Threatening
- **H**—Hospitalized

Who is the MDR contact person?

The Medical Device Reporting (MDR) contact person is the designated contact for the device user facility or distributor and the person the FDA conducts MDR correspondence with. This individual may not be an employee of the facility.

How does Oracle Argus Safety set the Receipt Date for a case?

Oracle Argus Safety sets the value of the Receipt Date field based on the state of the **Display Initial Receipt Date always** option.

- When the **Display Initial Receipt Date always** option is enabled, and there is follow-up information for the case, Oracle Argus Safety uses the value from the Initial Received Date field.

- When the **Display Initial Receipt Date always** option is disabled and follow-up information exists for the case, Oracle Argus Safety uses the value of the latest Follow-up Received Date regardless of the significance of the information.

How does Oracle Argus Safety set the Aware Date for a case?

If follow-up information exists for a case, Oracle Argus Safety uses the value of the latest significant follow-up information as the Aware Date for the case.

If follow-up information doesn't exist for a case, Oracle Argus Safety uses the value of the Initial Receipt Date field as the **Aware Date** for the case.

How does Oracle Argus Safety set the Date Received value for a case?

The Date Received value is the latest Follow-up Date value for the case.

- If there are multiple Follow-up Date values, then the Date Received value is the oldest Follow-up Date value that exists for the case.

- If there is no Follow-up Date value for the case, then the Date Received value is the initial Receipt Date value for the case.

Which actions can I perform on a saved letter?

You can view saved letters in the Uploaded letters folder.

You can edit a saved letter by clicking the corresponding email button in the **Contact Log** and then editing it in the message editor.

Can I edit or remove a letter after it was sent for a case?

After a letter is sent, you can no longer edit it. You can only remove it manually.

If I change the Date Sent value for a letter, must I also change the Due Date for the action item associated with the letter?

No. Unless the action item that is associated with the letter has already been completed, when you change the Date Sent value for the letter, Oracle Argus Safety also updates:

- The Due Date for the associated action item, to match the new Date Sent value.

- The number of days for the action item that is specified in the letter configuration.

Where can I view action items for letters?

You can view action items for letters for a case in the Action Items section on the Case Form for the case. You can view action items for letters across cases on the Action Items page from your personal worklist.

Why do only some action items for a case appear as Sent in Letter?

Action items that appear as **Sent in Letter** are query-type action items for the case.

Can I auto-generate a letter for a case?

No. For Oracle Argus Safety to auto-generate a letter after you save a case, contact your system administrator.

Based on settings, Oracle Argus Safety can:

- Auto-generate a letter after a specific number of days since an adverse event is reported for a case.

- Auto-generate a follow-up action item for you to follow up with a correspondent after the letter is sent.

Auto-generated letters are sent to the first correspondence contact by default.

Which actions can I do on an auto-generated letter?

You can view auto-generated letters in the Contact Log section of the Case Form for a case.

You can view or print an auto-generated letter by double clicking the letter icon in the **Contact Log** section and selecting the associated action from the Letter Preview dialog.

What does the coding status icon indicate for a case?

The coding status icon indicates the state of the term to be coded for a case.

- **Red cross mark** ()—The term was coded.

- **Green check mark** ()—The term was successfully coded.

- **Grey hourglass** ()—Oracle Argus Safety submitted the term to Central Coding, but didn't yet receive a result.

- **Red stop sign** ()—Oracle Argus Safety submitted the term to Central Coding but received an error either from Central Coding or from Argus.

Why does a border appear for a coding action item for a case?

A red border indicates that the respective action item was completed for the case. Oppositely, a green border indicates that the respective action item wasn't completed for the case.

Why is there a green dot in the Notes area of a case summary?

The green dot that appears in the **Notes** area is an option for the related field. You can click the dot to revert to the initial automatic value for the field, or view previous overriding notes.

Why do only some user names appear in bold in the Case Workload?

User names that appear in bold in the Case Workload are online users who can view the Online Help icon.

Why does the (⬆) icon appear as the lock state icon for a case?

The (⬆) icon denotes that the case is a Suspected Unexpected Serious Adverse Reaction (SUSAR) case.

Why do some letter icons from the Contact Log have an exclamation mark?

Letter icons that have a green exclamation mark indicate letters that were successfully sent.

Letter icons that have a red exclamation mark indicate letters that are overdue.

Why does an asterisk (*) symbol appear next to the username for some users in the Case Routing dialog?

The asterisk (*) symbol next to a username denotes that the user who entered the routing justification for a case has since received the **Disabled** status in Oracle Argus Safety.

How to attach multiple files to a single letter for follow ups?

1. In the RPT_TRANSMIT_EMAIL_ATTACH table, insert records from backend with the same ID as in the RPT_TRANSMIT_EMAIL.ID column created for the letter.
2. Configure letter from `Argus Console > Code Lists > Argus > Letter Configuration`.
3. Go to `Case Form > Activities > Contact Log > New Letter`.
4. Select **Configured Letter**, and save.
5. Click **Email Letter**, enter the required email address in the **To** field, and send.

What if

- The Medical Review page appears empty for a Case Form
- The narrative text for a case contains blank spaces or placeholders
- I can't change the assessed seriousness of a case
- I can't change the determined listedness of a case
- I can't select the language I need for my text narrative?

The Medical Review page appears empty for a Case Form

The fields on the Medical Review page are user-defined. To view them, you must first enable the desired fields from Analysis page in the Case Form. The system saves the selection as a default and uses it when you open the Medical Review page for other case.

The narrative text for a case contains blank spaces or placeholders

Blank spaces or placeholders can appear when the narrative text for a case is auto-generated. Oracle Argus Safety displays blank spaces for placeholders that are missing data, and actual placeholders if the placeholders are incorrect.

Contact your Administrator to amend the template for the auto-generated narrative text, or to enable auto-generated narrative text to be modified.

I can't change the assessed seriousness of a case

If any Seriousness Criteria was selected for any Event on the Event page for the case, Oracle Argus Safety automatically sets the value of **Case Serious** to **Yes**. To override this value, contact your Administrator to receive access rights.

I can't change the determined listedness of a case

Oracle Argus Safety automatically sets the value of the Listedness Determination field based on the value of entries from the Event Assessment section on the Events tab of the case.

- If any of the entries appear as 'unlisted', the value of Listedness Determination is **unlisted**.
- If all the entries appear as listed, the value of Listedness Determination is **listed**.
- If all the entries have an unknown value, the value of Listedness Determination is **unknown**.
- In all other cases, the value of Listedness Determination is blank.

To override this value, contact your Administrator to receive access rights.

I can't select the language I need for my text narrative?

If the icon representing the language you need to enter narrative in does not appear for your case, contact your Administrator to set up the respective language in the application.

4

Filter cases with advanced conditions

In this chapter:

Create a single filter

1. From the **Case Actions** drop-down menu, select **Open**.

2. In the **Case Search Criteria** section, from the **Advanced Condition** drop-down list, select **New**.

   You are asked to confirm whether you want to create a query set (a set of filters).

3. To create a new single filter, in the Confirmation dialog box, click **No**.

4. Enter Name and Description of the new filter.

5. Select the types of values for the filter:

   - To include values from the codelist, select **From Code List**.

   - To include values from the case data, select **From Case Data**.

6. From the Properties navigation tree, select a field name or item to use as a filter.

7. From the **Conditions** list, select a relational operator to establish a relation between the field name and the value.

8. Repeat from step 5 to step 7, until all the filters are added.

   Use the logical operators (AND and OR) to control whether all the selection criteria must be met for the case to be retrieved or that any one of the conditions must be met.

9. Click **Save**.

10. Click **Yes** if you want to share the filter with other users.

    See also, Share filters with other users.

11. Click **OK**.

Create a set of related filters

1. From the **Case Actions** drop-down menu, select **Open**.

2. In the Case Search Criteria section, from the **Advanced Condition** drop-down list, select **New**.

   You a asked to confirm whether you want to create a query set (a set of filters).

3. To create a set of filters by linking a previously defined filter, in the Confirmation dialog box, click **Yes**.

4. To add a filter, click **Add**.

5. When the new row appears in the filter selection area, do one of the following:

   • To add an existing filter, click the **Lookup** icon (), click **Filter**, from the search result select a filter, and click **OK**.

   • To enter a new filter criteria, click **AC**, and follow the procedure to Create a single filter.

6. From the **Set Operator** list, select an operator to link your filters.

   This set operator links this filter to the next filter.

7. Repeat from step 4 to step 6, until all the filters are added.

8. Enter the Name and Description of the new filter.

9. Click **Save**.

Share filters with other users

Sharing filters with other users is possible only if access of the User group is defined in Argus Console through Access Management.

1. From the **Case Actions** drop-down menu, click **Open**.

2. Click the **Lookup** icon () next to the **Advanced Condition** drop-down list.

3. To find a filter, from the drop-down list, select an option.

   • **Contains**—Search the filters that contain the entered criteria.

   • **Starts With**—Search all the filters that start with the entered criteria.

4. In the text box, enter the search criteria, and click **Filter**.

5. From the search result, select a filter, and click **AC**.

6. In the Advanced Condition Set dialog box, check the **Share with other users** checkbox.

7. Click **OK**.

> 💡 **Tip:**
>
> - If a filter is not shared with other users, the filter does not appear in the list for any user except the Administrator and the user who created it.
> - If the filter is shared, all users in the system can view the filter, but **cannot** modify it.
> - You **cannot** stop sharing a filter, if the filter is in use in the system.

Modify a filter

1. From the **Case Actions** drop-down menu, click **Open**.

2. Click the **Lookup** icon (🔍) next to the **Advanced Condition** drop-down list.

3. To find a filter, from the drop-down list, select an option.

    - **Contains**—Search the filters that contain the entered criteria.

    - **Starts With**—Search all the filters that start with the entered criteria.

4. In the text box, enter the search criteria, and click **Filter**.

5. From the search result, select a filter, and click **AC**.

6. Update the filters, and click **Save**.

> ✏️ **Note:**
>
> To save the changes as a new filter, click **Save As**.

Use filters to view the case series list

1. From the **Case Actions** drop-down menu, click **Open**.

2. Click the **Lookup** icon (🔍) next to the **Advanced Condition** drop-down list.

3. To find a filter, from the drop-down list, select an option.

    - **Contains**—Search the filters that contain the entered criteria.

    - **Starts With**—Search all the filters that start with the entered criteria.

4. In the text box, enter the search criteria, and click **Filter**.

5. From the search result, select a filter, and click **OK**.

6. On the Case Open page, click **Search**.

Export the case series list to a spreadsheet

1. From the **Case Actions** drop-down menu, click **Open**.

2. Click the **Lookup** icon (🔍) next to the **Advanced Condition** drop-down list.

3. To find a filter, from the drop-down list, select an option.

   - **Contains**—Search the filters that contain the entered criteria.

   - **Starts With**—Search all the filters that start with the entered criteria.

4. In the text box, enter the search criteria, and click **Filter**.

5. From the search result, select a filter, and click **AC**.

6. In the Advanced Condition Set dialog box, go to Case Series tab.

7. To list the cases that match the filter, click **Find Now**.

8. Select the cases from the list.

9. To save the list, click **Store Case Series**.

> ✎ **Note:**
>
> You must save the list before exporting.

10. Click **Export** to export the cases in CSV format.

Import a case series list from the spreadsheet and save

1. From the **Case Actions** drop-down menu, click **Open**.

2. Click the **Lookup** icon (🔍) next to the **Advanced Condition** drop-down list.

3. To find a filter, from the drop-down list, select an option.

   - **Contains**—Search the filters that contain the entered criteria.

   - **Starts With**—Search all the filters that start with the entered criteria.

4. In the text box, enter the search criteria, and click **Filter**.

5. From the search result, select a filter, and click **AC**.

6. In the Advanced Condition Set dialog box, go to Case Series tab.

7. Click **Import**.

8. Enter the description to import the cases and click **OK**.

9. Browse the file to be imported and click **OK**.

10. Click **Store Case Series** to save it for later use.

> ✎ **Tips:**
>
> - You can import an XLS, XLSX or TXT file with **one** column containing case numbers.
> - When you upload a text file, each line in the file is considered a **complete** case number.
> - If a case is missing (cannot be found) or has been deleted, a message appears.
> - If the same case has been entered multiple times; only one entry is retained for the same and rest are ignored after the import process is complete.
> - For **case series**, the import process, imports 1000 cases/60 seconds.

Find filters

1. From the **Case Actions** drop-down menu, click **Open**.

2. To open the Advanced Condition Lookup dialog box, click the **Lookup** icon (🔍) next to the **Advanced Condition** drop-down list.

3. To find a filter, from the drop-down list, select an option.

   - **Contains**—Search the filters that contain the entered criteria.
   - **Starts With**—Search all the filters that start with the entered criteria.

4. In the text box, enter the search criteria, and click **Filter**.

5. From the search result, select a filter, and do one of the following:

   - To list the selected filters in the **Advanced Condition** drop-down list, click **OK**.
   - To view the details for the selected filter in the Advanced Condition dialog box, click **AC**.
   - To close the Advanced Condition Lookup dialog box without saving changes, click **Cancel**.

Access filters from the Advanced Condition Library

1. From the **Utilities** drop-down menu, select **Advanced Condition Library**.

2. From the list of filters, select a filter, and from bottom-right of the page, click an option:

   - To create a filter, click **New**, and do one of the following:

     – Create a single filter (skip step 1 and step 2).

     – Create a set of related filters (skip step 1 and step 2).

   - To modify an exiting filter, click **Modify**.
     See also, Modify a filter (skip step 1 and step 2).

   - To delete a filter, click **Delete**.

   - To print a list of filters, select the filters, and click **Print List**.
     To print the entire list of filters, check the checkbox from the heading, and click **Print List**.

3. To find filters for a specific time period:

   a. From the **Date Range** drop-down list, select an option. Or, enter date range in the From and To fields.

   b. From the **View** options, select **Advanced Condition**.

   c. Click **Search**.

FAQs

- [What is an advanced condition?](#)
- [What is an advanced condition query set?](#)
- [How do the logical operators work?](#)
- [How do the set operators work?](#)
- [What is a case series (formerly Hit list)?](#)

What is an advanced condition?

An advance condition is a filter that can be a complex or non-standard query where that uses field-level data or dictionary terms as criteria to search cases. These queries act as filters to search for cases.

What is an advanced condition query set?

An advanced condition query set comprises two or more filters combined to create a more complex filter. These query set act as filter to search for cases.

How do the logical operators work?

You can use the AND and OR logical operators to set the conditions of when the filter is used.

- The AND operator returns only those cases that match both the conditions in a filter. No case is found if one of the condition match in the filter.
- The OR operator returns cases that match either or both the conditions in a filter. No case is found if none of the condition match in the filter.

How do the set operators work?

You can use the UNION, INTERSECT, and MINUS set operators to combine multiple conditions in a filter.

- The UNION operator returns cases found in either filter.
- The INTERSECT operator returns only those cases that are found in each filter.
- The MINUS operator returns cases that are found in either of the filters, but not in both filters.

What is a case series (formerly Hit list)?

A case series is the search result of a filter or set of filters. See also:

- Export the case series list to a spreadsheet
- Import a case series list from the spreadsheet and save

What if

- I am unable to find a filter
- I am unable to view cases that match the filter criteria
- I am unable to view values of a codelist
- While adding a value to a property, the Select button is disabled

I am unable to find a filter

You may not have the access rights to use the filters. Only users with execute rights for a filter can view the filters in the drop-down list.

If you do have the access rights, you can find your filters either by using the **Lookup** icon (🔍) (see Find filters) or from the **Advanced Condition Library** (see Access filters from the Advanced Condition Library).

I am unable to view cases that match the filter criteria

When using a set of filters to search cases, the search result is also dependent on the values entered for Date Range fields and the Initial/Follow-up selection. Therefore, if a case is not part of the Date Range for the filter, the case does not display when you click **Search**.

I am unable to view values of a codelist

The values in the Code List are configured by the administrator in Argus Console. To configure these values, refer to the *Oracle Argus Safety Administration Guide.*

While adding a value to a property, the Select button is disabled

The **Select** button is enabled only for a property whose value is a term that can be coded.

- For MedDRA related terms, the MedDRA browser appears.
- For other terms, the Product browser appears.

5

Code an adverse event term

In this chapter:

- Autocode a term
- Manually code a term
- FAQs
- What if

Autocode a term

1. Open a case.
2. Select **Events**.
3. In the Event Information section, under Description as Reported, enter the term to code exactly as it was reported and then press the `Alt+Tab` keys on your keyboard.

   The coding details for your term appear in the Event Coding section.

   If autocoding did not succeed in finding a coding for your term, see Manually code a term.
4. To print the selected coding as a PDF report:
   a. Press **Encode**.
   b. Select the coded LLT term.
   c. Press **Print**.

Manually code a term

1. Open a case.
2. Select **Events**.
3. In the Event Information section, under Description as Reported, enter the term to code exactly as it was reported and then press the `Alt+Tab` keys on your keyboard.

   If autocoding did not find a coding for your term, the MedDRA Browser dialog box opens.
4. In the MedDRA browser dialog box, perform the following:
   a. In the LLT field, refine the description of your search term using a wildcard character (%), an alternative term, or a company-specific synonym that matches your term, and then press the `Alt+Tab` keys on your keyboard.

   > 💡 **Tip:**
   >
   > To view a specific LLT, click the **LLT** entry.

   b. To print the selected coding as a PDF report, press **Print**.

    c. To accept the current LLT selection as the coding for your term, double-click the **LLT** selection or press **Select**.

The coding details for your term appear in the Event Coding section.

FAQs

Which dictionaries does Argus Safety support?

Oracle Argus Safety supports MedDRA, MedDRA J, WHO Drug Global and Chinese, and J Drug dictionaries. The application maintains a single version of each dictionary in the database.

In multi-tenant environments, each tenant can have its own versions of each dictionary. The J Drug dictionary is the only dictionary version that is common to all the tenants.

What is the MedDRA browser?

The MedDRA (Medical Dictionary for Regulatory Activities) browser is a utility that you can use to code a term such as a disease, sign, or a symptom with an internationally standardized medical term. This is a way to ensure consistent drug terminology in the Oracle Argus Safety application.

The MedDRA browser appears when you create an Advanced Condition (also known as a filter) or when you enter case details in the Adverse Event Form. You can also access the MedDRA browser from the Utilities menu.

What are the five levels of the MedDRA dictionary?

The MedDRA dictionary hierarchy is a categorization of medical terminology. The five levels of the dictionary are System Organ Class (SOC), High Level Group Term (HLGT), High Level Term (HLT), Preferred Term (PT), and Lowest Level Term (LLT).

The lower the level of the dictionary, the more precise the medical terminology becomes. Preferred Terms (PTs) represent medical terms you can use as the end result for coding.

For the example:

```
If the term to code is "queasy," the preferred equivalent medical term (PT) is "Nausea"
in the context of the following hierarchy:
System Organ Class (SOC) = Gastrointestinal disorders
High Level Group Term (HLGT) = Gastrointestinal signs and symptoms
High Level Term (HLT) = Nausea and vomiting symptoms
Preferred Term (PT) = Nausea
Lowest Level Term (LLT) = Feeling queasy
```

What is a synonym?

A synonym is a term or a combination of terms that nearly or exactly match the meaning of the term to code. Each organization defines its own list of synonyms for coding. To add a term to the list of synonyms, contact an Administrator.

What is autocoding?

Autocoding is an Oracle Argus Safety feature that Administrators can enable for terms to be automatically coded using the MedDRA dictionary. If autocoding is not enabled in the Oracle Argus Safety application, or if autocoding does not find a match for your term in the MedDRA dictionary, you must manually search and select a coding for your term in the MedDRA browser.

What happens if you don't enable autocoding?

If autocoding is not enabled in Oracle Argus Safety, you must manually search and select a coding for your term in the MedDRA browser.

What are Standard MedDRA Queries (SMQs)?

Standard MedDRA Queries are predefined sets of MedDRA terms that you can use to retrieve codings in the MedDRA browser. SMQs are developed and validated by the CIOMS Working Group and are updated for each MedDRA dictionary version.

What is a full search?

When you run a full search, the MedDRA browser retrieves terms that contain your search term in any word order and combination. Alternatively, MedDRA retrieves only terms that start with your search term.

What is a non-current term?

A non-current term is a term that you can no longer use for coding, but is retained in the Oracle Argus Safety database for historical data retrieval. A coding term can become non-current if it is vague, ambiguous, outdated, truncated, misspelled, or derived from a terminology that is incompatible with MedDRA.

Non-current terms appear next to an asterisk symbol (*) at the LLT level in the MedDRA coding browser and in the search results list.

How can I view details for a coded term?

To view details for a coded term such as the dictionary version it was coded against, or SOC, HLGT, HLT, PT, LLT level values, click the **green check mark** next to Event Coding on the Case Details or new Advanced Condition form.

How can I narrow my search in the MedDRA browser?

To narrow your search for a coding, you can use one of the following options in the MedDRA browser:

- To search for the term in a specific Standard MedDRA Queries (SMQs) category, select the category from the **MedDRA SMQ** drop-down list. To search for the term across all dictionary levels, enter the term in **Search All Levels** and press the `Enter` key on your keyboard.To search for the term against any combination of terms that includes your term, check **Full Search**.To search for the term also against codings that may not be included in the selected dictionary version, click **Include Non-current terms**.

Why does a dictionary coding appear highlighted in yellow in the MedDRA browser?

A yellow highlighted coding in the MedDRA browser represents the primary System Organ Class (SOC) path for a term with more than one path or SOC.

Why can't I use the Export button to export a coding?

The Export functionality is reserved for Administrators.

What is Null Flavor data?

Null Flavors are used to describe the reason for missing data. ICH E2B(R3) and regional agencies such as CBER, EMA, MFDS, and PMDA have published guidelines on the allowed Null Flavors for various fields that are part of the E2B(R3) report. A Null Flavor set is a collection of Null Flavors. Sets are provided by default for various combinations of Null Flavors in the Flexible Re-categorization Codelist.

Null Flavor data can be selected for fields in the Case Form by clicking on the Null Flavor button ( ) next to the fields. On clicking the button, a drop-down list appears and allows you to select Null Flavor data as configured in the Field Properties Configuration in the Argus Console. The background color of the NF button changes (from grey to blue) when a Null Flavor is selected from the drop-down list.

When the Case Form field has data and the user clicks the button, the system displays a warning message that data will be cleared on switching to the Null Flavor field. The data is cleared or retained based on user confirmation. When data pertaining to the field is received, Null Flavor data can be overwritten by actual data by clicking the NF button.

What if

- [Autocoding is not enabled in my application](#)
- [Autocoding is unsuccessful](#)

- I receive a "No Records Found" message when I manually code a term
- The coding I previously used for a term now features an asterisk and can no longer be selected in the MedDRA browser, as it is labeled as non-current

Autocoding is not enabled in my application

If your Administrator did not enable autocoding in the application, you must manually search and select a coding for your term in the MedDRA browser.

Autocoding is unsuccessful

If your Administrator enabled autocoding, but autocoding did not find a coding from the MedDRA dictionary for your term, the MedDRA Browser dialog box appears on the screen for you to manually search and select a coding for your term.

To attempt autocoding a second time, refine the description of your search term in the LLT field using a wildcard character (%), an alternative term, or a company-specific synonym that matches your term.

The application populates the fields in the Event Coding section with the details of a MedDRA coding match.

I receive a "No Records Found" message when I manually code a term

If you received a `No Records Found` message when manually coding your term in the MedDRA browser, you can refine the description of your search term in the LLT field using a wildcard character (%), an alternative term, or a company-specific synonym that matches your term.

The coding I previously used for a term now features an asterisk and can no longer be selected in the MedDRA browser, as it is labeled as non-current

If one of your active cases contains an adverse event term that has been coded with a term that now appears next to an asterisk symbol (*), you must code the term a second time for the respective case, or ask an Administrator to recode the term for you using the MedDRA recoding tool.

6

Manage your Expedited Report submissions

This chapter lists tasks related to preparing, submitting and tracking compliance for Expedited Reports (ICSRs - Individual Case Safety Reports).

For more information, see:

- Schedule an Expedited Report
- Submit your Expedited Reports
- Track your Expedited Report submissions
- Manage your Incoming ICSRs
- FAQs

Schedule an Expedited Report

In this section:

- Schedule a report manually
- Auto-schedule a report
- Create unscheduled Expedited Reports or batch print reports
- Review a draft Expedited Report
- Review your scheduled reports
- View Expedited Report status

Schedule a report manually

1. Open the case for which the report has to be scheduled.
2. When the system displays the Case Form for the selected case, select **Regulatory Reports**, and then select **Schedule New Reports**.
3. When the system opens the Schedule New Expedited Report dialog box, enter the appropriate information in the fields in the dialog box:

Field	Description
Aware Date	If an Aware Date is appended with '(A)' in the drop-down list, it is used to denote the aware date of an Amendment.
	The resulting expedited report **Due Date** is based on the selected **Aware Date** and the duration of the **Due Date** section.
	The selected Aware Date has no impact on the Actual Due Date if the user specifies an absolute **Due Date**. For instance, selecting a date in the **Due Date** field causes the report to be due on the specified date, regardless of the selected **Aware Date**.
	This drop-down list is only populated and enabled after a license has been selected. The Aware Dates are displayed in descending order of the Current Aware Date.

Field	Description
Protect Confidentiality of Patient and Reporter	If this check box is checked, the patient's name and address will not appear on any of the regulatory reports, and the patient information will show the word **PRIVACY**.
	For non-US cases, the application also displays MSK null flavor in the eVAERS report when this check box is checked. MSK is populated only when the data element contains some data and is not null.

4. Click **OK**.

To view all scheduled reports, go to **Reports**, then select **Compliance**, and click **Expedited**. Alternatively, you can go to **Worklist**, and select **Reports**.

Auto-schedule a report

1. Open the case for which the report has to be scheduled.

2. Select **Regulatory Reports**, then select **Auto Schedule** or **Auto Schedule Device**.

Reports will be scheduled against the reporting rules which have been set up by the administrators.

Create unscheduled Expedited Reports or batch print reports

You can use the Batch Reports function to schedule and generate reports for multiple cases. Before using this function, verify that no cases or reports are open.

1. Select **Reports**, then select **Compliance**, and select **Expedited**.

2. Click **Batch Print or Create Report** and search for the case for which the expedited report has to be scheduled.

Table 6-1   Expedited Reports - Fields and Fields Description

Field	Description
Suspect Product	Displays the Trade Name for which the report has been scheduled. A (+) displayed at the end of the Product Name denotes that more than one Suspect Company Product exists.
	For Reports which were scheduled for the Device, the Device name gets displayed.
F / LT	Denotes Fatal / Life Threatening
	If the case is both **F** and **LT**, only **F** is displayed.
	If the case is neither **F** nor **LT**, **No** is displayed.
7/15	Displays 7 if the report is due within 7 days.
	Displays 15 if the report is due in more than 7 days.

3. When the system displays the search results, select the locked cases for which the expedited report is to be scheduled.

4. Click **Batch**.

5. When the system opens the Batch Print or Create Reports dialog box, enter the appropriate information and click **OK**.

The system generates the unscheduled expedited report. The Expedited Batch Printing dialog box supports printing Batch CIOMS, Medwatch, and VAERS on Oracle Argus Safety Web locally.

> **Note:**
>
> The **Batch print or create Reports** for E2B reports is supported for locked cases only. These reports are generated as only final report with **Run at** option enabled, and **Save with case, mark as submitted** checkbox as checked and disabled (default) for E2B reports.

Table 6-2   Batch Print or Create Reports dialog box—Fields and Field Description

Field	Description
Format	Enables you to print reports **As Draft** or **As Final**.
	• The **Print As Final** option is available **only** if all the selected cases are locked.
	• If **Print As Final** is selected, then the option **Save with case, mark as submitted** is also available as a checkbox option.
	• Click the options **Print As Final** and **Save with case, mark as submitted** to generate final Regulatory Reports and create a submission record with each case identical to the current functionality.
	• Click the options combination of **Print As Final** only (and not Save with case, mark as submitted) to generate final Regulatory Reports without creating a submission record with each case.
	• If the report is associated with a blinded study, select the **Blind study product** checkbox.
Destination	Check the **Printer** checkbox to print the report.
Protect Confidentiality of Reporter and Patient	Check this checkbox to hide the Reporter and Patient information on the expedited reports.
Scheduling	• If **Run Now** is selected, all the selected reports run against all selected cases and a PDF is generated. The **Run Now** option is visible only when a MedWatch, MedWatch Drug, CIOMS, or VAERS form is selected on the Batch Expedited Report screen. If you select an unlocked case, the report gets printed in draft form only and is not saved.
	• Select **Run at** and enter the appropriate date and time when the generation of reports should occur.
Due Date	You can select parameters for the report due date calculation. This option is available for final reports with the **Save with case, mark as Submitted** checkbox set.

Review a draft Expedited Report

1. Open the case for which you want to view a draft report.

2. Click the Regulatory Reports tab.

3. From the Total Number of Rows tab, locate the relevant report and click **Draft** to view the report.

4. Alternatively, click the **Draft Report** icon on the top right of the screen.

    a. From the View Draft pop-up, select the Report Form, Destination, and Product.

    The Report Form drop-down displays the list of expedited reports and the **Destination** drop-down displays the list of reporting destinations configured in Console. Based on the report form and destination, the products are displayed as explained below:

- For the Drug Report Forms, the left most suspect product with the drug license that matches the agency country is displayed as default.

- For the Device Report Forms, the left most suspect product with the device license that matches the agency country is displayed as default.

- For the Vaccine Report Forms, then left most suspect product with the vaccine license that matches the agency country is displayed as default.
When no product with license matches to the license type and agency country in the case, then the primary suspect product is displayed, that is left most suspect product in the Product tab.

- For the Drug Report Forms, the drug license with earliest award date of the selected product that matches the agency country is used to generate reports.

- For the Device Report Forms, the device license with earliest award date of the selected product that matches the agency country is used to generate reports.

- For the Vaccine Report Forms, the vaccine license with earliest award date of the selected product that matches the agency country is used to generate reports.

b. Click **OK**.

The report is generated in the draft mode.

Review your scheduled reports

The Regulatory Reports tab enables you to view all scheduled reports.

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

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

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

- The system displays the time component for the date generated on the `Case Form > Regulatory Reports` tab using the IE offset of the client machine for the display.

- The system displays the time component for the date generated on the Report Details using the IE offset of the client machine for the display.

- When you manually schedule an Expedited report, the system places the word, **Manual**, in the Notes field along with the current notes information.

When a case is opened in read-only mode, the application enables you to view the final report whether generated, approved, or submitted.

For more information, see:

- Review a list of your scheduled reports
- View your scheduled reports

Review a list of your scheduled reports

- Go to **Reports**, then select **Compliance**, and then select **Expedited Reports**.

You can print draft expedited reports from the **Batch Print** or **Create Reports** without printing DRAFT on the reports from the Case Open or the Reports | Compliance | Expedited Reports dialog box.

View your scheduled reports

- To view scheduled reports, hover over the **Worklist** menu and select **Reports**.

When the system opens the Reports screen, enter the appropriate information as necessary.

Report filter options

- The search results appear in the Report Details dialog box and permit the user to enter the approval notes that are applied to all selected reports. The system skips any reports selected by the user that have the following statuses:
    - Scheduled
    - Disapproved
    - Approved
- The system hides the reports fields from the report details dialog box and **does not** permit the user to access or modify any other tabs.
- The system hides the **Route** button to prevent users from modifying the **Report Status**.

Option	Description
Reporting Destination	Displays the report destination (agency) for which the report is scheduled.
Report Status	Displays the status of the report as **Approved**, **Generated** or **Scheduled**.
Report Form	Displays the description of the report.
Filtering Reports	You can click the respective magnifying glass icons to filter reports based on **Destination**, **Product Family**, and **Country of Incidence**. The system displays the standard lookup dialog box.
By Destination	The **Report Destination** filter multi-selection screen list contains the names of all agencies as configured in the Oracle Argus Safety **Regulatory Authority** CodeList.
By Product Family	The **Product Family** filter multi-selection screen contains a list of all product family names as configured in the Oracle Argus Safety **Products** codelist.
By Country of Incidence	The **Country of Incidence** filter multi-selection screen contains a list of all available countries.

View filter results

The **Total Number of Rows** section displays the result based on the selected filter criteria with following details:

Field	Description
Selected	Allows the user to select one or more reports, on which actions can be performed.
Suspect Product	Displays the trade name for which the report has been scheduled. A "+" displayed at the end of a **Product Name** indicates that more than one **Suspect Company Products** exist. A **Device Name** is also displayed for those reports which were scheduled for the Device.
Diagnosis	Displays the Primary Event Diagnosis PT.

Field	Description
Event Verbatim	Displays the event verbatim (verbatim as reported) of the Primary Event.
F or LT	Indicates whether a case is fatal or life threatening as follows: • F identifies a Fatal (F) case • LT identifies a Life Threatening (LT) If any of the above are present together, then Fatal takes precedence followed by **LT**. If the case is neither of the above, **No** is displayed.
7/15	Displays 7 if the report is due within 7 days. Displays 15 if the report is due in more than 7 days.
Report Form	Displays the description of the report. Click the link to view the **DRAFT** report PDF.
Initial / Follow-up (#)	Displays if the report is **Initial** or **Follow-up**. If it is a Follow-up, the follow-up number is printed.
Downgrade	Displays **Yes** if the report is a **Downgrade** report.
View Report	Enables the user to view the report as a PDF.
Local Labeling	Enables the user to view the local labeling dialog box. • This option is available only if the user has access to Local Labeling within the groups to which the user belongs to. • The Local Labeling can also be viewed by clicking the local labeling icon that is displayed next to S/U/R.

View Expedited Report status

1. To review the status of expedited reports, select **Dashboards**, and then select **Expedited Report Status**.

2. In the Search Case section, enter the parameters, and click **Retrieve**.

3. To view a list of cases, click the relevant section of the pie chart or bar chart.

> **Note:**
>
> When you have access to Expedited Report Status, you also have access to the Report Due Soon dashboard.

Submit your Expedited Reports

In this section:

• Generate an Expedited Report

• Approve your report

• Transmit an ICSR

• Transmit several ICSRs at once

• Print your reports

• Store Expedited Reports in Documentum

Generate an Expedited Report

You can generate a report using either of the following procedures.

Method 1: Generating a report

1. Verify that the relevant case has been locked and the required report has been scheduled.

2. Open the selected case to display its associated Case Form.

3. Open the report from the Regulatory Reports tab of the Case Form.

4. When the system opens the Regulatory Reports details for the selected case, locate the relevant report and click the **Final** link to generate the report.

Method 2: Generating a report

1. Verify that the relevant case has been locked and the required report has been scheduled.

2. Select **Case Actions**, and then click **Open** to view the Case Open form.

3. Click **Search** to view cases matching the search criteria.

4. When the system displays the search results, click the **Lock State** icon and select **Case Details**.

5. When the system opens the Argus Safety Case Details dialog box, open the Scheduled Regulatory Reports folder and select the relevant regulatory report.

> **Note:**
>
> - You do not need to lock the case to preview a report in draft mode.
>
> - If you have access rights to view or print blinded information, you are prompted to select whether you would like to view a blinded or unblinded version of the report. If your access rights disallow you from viewing or printing unblinded information, you can view only a blinded version of the expedited report. The following items are not displayed when viewing a blinded version of the expedited report:
>   - Clinical Treatment Given (Study Drug field)
>   - Study Drug Formulation and Concentration
>   - Study Drug Dose, Daily Dose and Route
>   - Study Drug Batch/Lot # and Expiration Date
>
> - If the case is locked you can generate the report from the `Worklist > Reports`, `Reports > Bulk Reporting`, and `Reports > Compliance > Expedited` screens.

Approve your report

1. Open the case associated with the report that needs to be approved.

2. When the system opens the Case Form, click the **Regulatory Reports** tab to displays the case details.

3. Click the icon associated with the report you wish to approve and select **View Report Details**.

4. When the system opens the Report Details dialog box, click the Routing tab.

5. When the system opens the Routing tab, select **Approved** from the **State** drop-down list and click **Route**.

6. When the system opens a dialog box, enter the required information and click **OK** to approve the report.

Transmit an ICSR

To transmit reports one by one, select Reports Detail Dialog, and click the Transmit tab.

- Go to **Case Actions**, then click **Open**, and select **Regulatory Reports**. Left-click on the Status icon, and select **Transmit**.

- Go to **Report**, then select **Compliance**, and select **Expedited**. Left-click on the **globe** icon to show the report details, and select **Transmit**.

The Transmit tab enables you to transmit a case electronically.

1. Select the recipient from the **Available Recipients** list.

2. Select the transmission method from the **Method** list.

3. Enter any comments under Comments.

4. Click **Transmit**.

Transmit several ICSRs at once

To transmit several reports at a time, go to **Reports** and select **Bulk Reporting**, then select **Print Regulatory Report** and click **Transmit**. Select the cases you wish to transmit, and click **Transmit** at the bottom of the screen.

The Bulk Transmit function lists the status for all transmission events against your assigned cases.

To view the Bulk Transmit page, hover over the Worklist menu and select **Bulk Transmit**.

For more information, see:

- Filter reports
- User options
- View routing details

Filter reports

The **Total Number of Rows** section displays the search result based on the filter criteria.

Field	Description
Report Form	Displays the description of the report. Click the link to view the DRAFT report PDF.
Recipient Company	Displays the name of the company of the report recipient
Date Created	Displays the date on which the report was created.
Date Sent	Displays the date on which the report was transmitted to the recipient.

Field	Description
# of Pages	Displays the number of pages in the report.
Attempts	Displays the number of attempts made to transmit the report. If you are using Right Fax, the value of this field is displayed as 0 even if the Right Fax had attempted it multiple times. This is an unsupported feature in Right Fax.
Sender	Displays the name of the sender of the report.
Lock State	Displays the lock status of the report.
Sender Agency Name	Displays the name of the agency that has generated the report
Status	Displays the Report Status such as **Scheduled**, **Generated**, and so on.

User options

Option	Description
View Transmission	Displays the report in a PDF format.
Mark report as Submitted	Marks the report for the selected row as submitted.
	This option is displayed to only those users who have the access rights to mark a report as submitted.
Remove transmission	Failed transmissions can be removed using this option as it removes the transmission log entry from the list.
	A report whose status is pending cannot be transmitted.
Re-transmit	This options allows reports to be re-generated and re-transmitted if report generation had failed earlier. For failure in other stages of report transmission, this option performs only retransmission.
Submit Multiple Reports	Multiple reports that are selected from the list can be marked as submitted simultaneously.
Re-transmit Multiple	The status of multiple reports that are selected from the list can be changed to **pending**, and those reports can be re-transmitted.
Remove Multiple Transmissions	Transmission of multiple reports that are selected from the list can be removed.

View routing details

Enter routing details in the text box.

Reports that appear in the Bulk Transmission section or the Bulk Print section do not display in the Reports section of the Worklist.

Print your reports

The Bulk Print function displays a separate list for all Bulk Print events against reports.

1. Hover over the **Worklist** menu and select **Bulk Print**.

2. When the system opens the Bulk Print page, enter the appropriate information.

For more information, see:

- Bulk print user options

Bulk print user options

Option	Description
Remove Print Job	Removes the print job entry from the list. A report whose status is pending cannot be printed.
Re-print	This option is displayed if the selected row has a status of failure or success. Select this option to change the status back to pending and the re-print the report.
Submit Multiple Reports	Multiple reports that are selected from the list can be marked as submitted simultaneously.
Re-print Multiple	The status of multiple reports that are selected from the list can be changed to **pending**, and those reports can be re-transmitted.
Remove Multiple Print Jobs	Print jobs of multiple reports that are selected from the list can be removed.

Store Expedited Reports in Documentum

Oracle Argus Safety lets you store your Expedited Reports in Documentum.

- Mark an Expedited Report as **submitted** from within Oracle Argus Safety to insert the report into the Documentum system as a PDF.

- If the report is to be transmitted via fax or email, Oracle Argus Safety Service marks the report as a successful submission in Documentum only **after** the fax or email transmission has succeeded.

Track your Expedited Report submissions

In this section:

- Track ICSR outgoing status
- View ICSR transmit status
- ICSR Pending screen icons
- Track your failed ICSR imports

Track ICSR outgoing status

1. To monitor the Outgoing messages and Acknowledgements, go to **Utilities**, then select **ICSR**, and click **ICSR Transmit Status**.

2. In the Search Reports section, enter the search criteria, and click **Search**.
   The search results appear in the Total Number of Rows section.

   If the Agency is selected as **Any**, the search results display all ICSR messages and acknowledgements for all receivers.

View ICSR transmit status

The Bulk ICSR Transmit function displays only those ICSR Reports that are awaiting submission (not in submitted state) when transmitted from Bulk Report By Form to the Trading partner.

1. Hover over the **Worklist** menu and select **Bulk ICSR Transmit**.

   The Bulk ICSR Transmit page appears with following tabs:

   - Reports—Displays the status of individual ICSR Reports that are in the process of being transmitted.

   - Messages—Displays the status of ESM Messages which may contain multiple reports.

   For E2B R2 and R3 batch XML, the XML messages are displayed in the Utilities > ICSR > ICSR Transmit Status screen as a single record with a MSD icon. When you click the MSG icon, the Message Acknowledgement Status - Webpage Dialog window opens. On the window you can see the report number and authority/ company number values from the first ICSR in the XML file.

2. Once reports have been successfully submitted and marked as submitted, they no longer show when you go to **Worklist** and select **Bulk Transmit**, when you go to **Worklist** and select **Bulk Print**, or when you go to **Worklist** and select **Bulk ICSR** transmit. To find a list of all successfully submitted cases, go to **Reports**, then select **Compliance**, and click **Submitted**.

3. Alternatively, go to **Utilities**, then select **ICSR**, and click **ICSR Transmit Status**.

   On the Reports screen, in the Search Criteria section, you can filter by using the **Local Message #** criteria. This allows you to filter for reports that belong to a particular batch by providing the batch number.

   > ✏️ **Note:**
   >
   > If you selected the eMDR, eVAERS, or PMDA XML values in the Report dropdown, then the Local Message# field is disabled.

For more information, see:

- Search for reports
- Search for ESM messages
- View search results

Search for reports

On the Reports tab, select the options to search for reports.

Field	Description
Report	Select the type of report from the drop-down list, as applicable.
	To view the transmission status of the report, select one of the following reports from the list: • E2B • eVAERS • eMDR • PMDA Device
Message Type	Select a pre-defined message type.This field is set to **ichicsr** and is disabled if report is set as eMDR or eVAERS.
Periodic Report	This field is enabled for message type that are marked as **Periodic** in the Message type codelist.
	This field is disabled for eVAERS and eMDR.

Field	Description
Range	Select a date range.
Search button	Triggers search based on the search criteria.
Only show transmissions that have reached a failure state	Check this checkbox to search for only those transmissions that have a failed status.
Show all transmissions (submitted and unsubmitted) having a error ACK	When this checkbox is checked by the user during the Search action, the system brings back any ICSR report that has received an error ACK (acknowledgement), irrespective of whether it has been marked as submitted or not.
	When this checkbox is checked, the checkbox **Only show transmissions that have reached a failure state** is automatically unchecked.
Only show not suppressed transmissions	When this is option is checked, the system displays ICSR reports for agencies, which are not marked for ICSR suppression.
	This option is checked by default. Users can uncheck this option to view all ICSR reports for all agencies irrespective of being marked for ICSR suppression.

> **Note:**
>
> The suppressed ICSR records have EDI In status displayed in grey color as the physical file is not generated.

Field	Description
Stage Legend	Shows the status (through colors) corresponding to each stage.

Search for ESM messages

On the Messages tab, select the options to search for ESM messages.

Field	Description
Report	Select E2B, eVAERS or eMDR from the drop-down list to view the transmission status of these reports.
Agency Trading Partners	Enter the agency or trading partner.
Transmit Date Range From	Select the transmit date range.
Range	Select a range to auto-populate the Start Date and End Date.
	The **Range** option is cleared if the Start Date or End Date is changed.

View search results

The Total Number of Rows section displays the search result based on the search criteria.

If the ICSR report in a result set row was already submitted, the system does not display the following pop-up windows:

- Remove Transmission
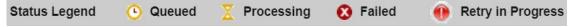
- Re-Transmit
- Mark as Submitted
- Re-Transmit Multiple
- Submit Multiple Reports
- ICSR Transmission History

For the same record above, the system, however, keeps the View Report Details and View ICSR Report menus enabled.

Option	Description
View Acknowledgement (Read only)	Displays the Acknowledgment report.
	This menu option is not displayed if ACK has not been received for message.
View xml acknowledgement	Displays business level acknowledgement.
View Reports	Opens the Bulk Transmit ICSR in the report view for all the reports in the message.
View Report Details (read -only)	Opens the existing Report Details dialog box in read-only mode.
View ICSR Report (ICSR Viewer for the report)	Opens the existing ICSR Viewer report.
ICSR Transmission History (Transmission History for the selected report)	Opens the new Transmission History screen.

ICSR Pending screen icons

After you accept, authenticate and queue an ICSR report, the report is then processed by background AG services. On the ICSR Pending screen, you can view the processing status of your report. Each status is depicted by an icon and a status legend is displayed at the bottom of the screen, as seen below:

To see the status changes, you can refresh your screen by using the search option.

Table 6-3   Status icons descriptions

Icon	Status	Description
	Queued	This icon is displayed when you accepted, authenticated and queued the report for the AG service to process it. When in this status, the actual processing has not started. In addition, the check box next to the report is disabled and you can not perform any actions on this report.
	Processing	This icon is displayed when the AG service has started processing the report. **Note:** Once processing is successful, the report will move to the ICSR Processed screen. When in this status, the check box next to the report is disabled and you can not perform any actions on this report.

Table 6-3   (Cont.) Status icons descriptions

Icon	Status	Description
	Retry in progress	If a report was not processed successfully, the system will retry before it marks the report as a failure. b. The default number of retries is 3. In addition, the number of retries that can be attempted is determined by the following new profile switch in Argus Console > Common profile Switch > Background Services: **Number of retries to be done for an unsuccessful report to be picked for reprocessing by Auto Accept AG Process**. This profile switch allows values from 1-999.
		The time interval for re-processing is determined by the below new profile switch in Argus: **Number of minutes to wait for a unsuccessful report to be picked for reprocessing by Auto Accept AG Process** The default value for this switch is set at 60.
		For the above two Console profile switches: • You can enter a 3 digits number, however if zero is used, the following warning message is displayed: *Please enter numeric value greater than zero.* • If you enter non-numeric and negative values, the following warning message is displayed: *This field can not contain non - numeric value!* • If a save is successful, the following message is displayed: *Common profile has been saved'*
		You can see the error link with the reason for the report to fail processing in the Details pop-up window.
		When in this status, the check box next to the report is disabled and you can not perform any actions on this report.
	Failed	If the report could not be processed by the background service after three retries, then it is marked as **Failed**.
		You can see the error link with the reason why the report failed processing in the Details pop-up window.
		When a report is in this status and the actual processing is completed, you can attempt to accept or reject the report again.
		The check box for these reports is enabled, thus you can select for Bulk accept or Reject.
		Note: These reports can be selected along with pending reports for Bulk Accept or Reject.

Track your failed ICSR imports

The ICSR Failed Imports screen displays the list of failed reports and it is accessible from Utilities > ICSR > ICSR Failed Imports.

You can view only the reports that failed during the import process. The reports appear in a descending order based on the processed date, with the latest on top. The processed date column also has a sorting option.

You can download these failed files for review by clicking the file name. To view details of the failure, an error link is provided.

This screen is available to the users with access to the User group menu. The screen is dependent on the enterprise that the user has logged in, and displays the reports that belong to the same enterprise only.

> **Note:**
>
> All files that are processed from the IN folder, whether failed or not, are moved to the Archive folder on the Interchange server.

You can use the **Archive** button to remove/ archive the report rows that you corrected and processed.

The **Print** button is available to print your ICSR failed imports list. The print output contains the filter criteria details in the header, such as the message type, file name and path, error details and interchange processed date.

You can search the screen based on the following:

- File Name
- Message Type (All, MSG, ACK, Unknown)
- File Name Message Type (All, MSG, ACK, Unknown)
- Date (From and To, Date Range)

The following details are available for your failed reports:

- **Message Type**: This field indicates if the file is an incoming Report MSG, ACK or an Unknown file.

- **File Name**: the XML report file name is displayed alongside the complete path location and the error link so you can view the error details.
- **Processed Date**: The processed date and time in the format Local Time / User Timezone.

Manage your Incoming ICSRs

To view the Incoming ICSR Reports screen, select **Reports**, and then click **ICSR Pending Reports**. You can:

- View the ICSR reports sent by the agency or the trading partner.
- Process an incoming ICSR report.
- Check all the ICSR values of the reports sent and determine whether to accept or reject the reports.
- Provide a user password and acceptance notes/rejection reason and accept or reject an incoming ICSR report.

For more information, see:

- Track incoming ICSR reports
- Track bulk incoming ICSR reports
- Search for duplicate reports
- View processed ICSR reports
- Track ICSR incoming status
- Find overdue reports

Track incoming ICSR reports

Field	Description
Message Type	Allows selection of ICSR based on the message type for all allowed values for the N.1.1 tag. By default, the drop-down is populated as **ichicsr**.
Trading Partner	1. To view report by a Trading Name, click **Filter** and select an agency. 2. To select multiple agencies, click **Add** in the Select Reporting Destinations dialog box.
Product Name/Generic Name	Click the **Select** button next to this text box. A pop-up screen appears with a text box (2000 characters), a **Search** button, an **OK** button, and a **Cancel** button. This pop-up screen is called Generic Name or Product Name as per the radio button selected in the Incoming ICSR Reports for which this popup was being invoked. This pop-up screen is titled Product Name when invoked from the Processed ICSR Reports screen. The text box in the pop-up screen is auto-populated with text entered in product name or generic name field on the corresponding screen but can be the user updated. Besides, when the user switches tabs between the Pending and Processed Sub Tabs, the default processing page icon appears which information that it is still processing and switching is not completed.

Field	Description
Report Type	The supported report types for the case received are: • Initial • F-U • Nullification • Amendment • Downgrade
Country of Incidence/ Primary Source Country	Displays the country where the incident occurred.
Is/Will be assigned to this site	Displays the site membership of the case. This field appears in the search result.
Accept ICSR	Imports ICSRs in a batch from ICSR Pending screen after selecting one or more reports (E2B(R2) and/or E2B(R3)).
Reject ICSR	Reject an ICSR file of a batch.

For more information, see:

• [Button and right-click options](#)

Button and right-click options

Button	Description
ICSR Viewer	Select this right-click option to launch the ICSR viewer. **✎ Note:** At the time of generating an ICSR report, some characters entered in the case form may not be displayed the same in the ICSR report. For the example: `The ICSR report equivalent of the "&" character entered in the case form is &. Similarly, there are other such characters that are represented differently in the ICSR report.`
View Error/Warning Message	Select this right-click option to view all warning messages including M2 validation errors and Multiple ICSR Codes log.

Button	Description
Accept ICSR	Selects the incoming ICSR report for both single and multiple acceptance.
	Execute these steps to accept an ICSR Case:
	1. Click the **Accept ICSR Case** button. The Acceptance of Initial Report Confirmation dialog opens.
	2. Enter your user password, date, and select a justification from the pre-defined list of justifications.
	3. Click **OK**.
	After you click **OK**, the report is queued and then it moves through the following stages: Queued, Proccessing, Failed and Retry in Progress.
	Accepting Amendment report is the same accepting a Follow-up report. The application supports importing attachments for the file types as configured in the profile switch `Case Processing > Valid attachment file type`.
Reject	
View Validation Failure	Opens the ICSR validation report (pdf) in the same format as it does at the time of export. This validation report prints all the validations that are categorized as soft validations for the import. Applicable for (R3) based ICSR reports only.
Duplicate Search	Select this right-click option to perform Duplicate Search for the case being imported with the case present in the system.

Track bulk incoming ICSR reports

The Bulk Incoming ICR Reports enable you to import multiple ICSR reports that are sent by the agency or trading partner.

During Bulk import, you can use the **Message / Batch Number** field option to retrieve reports belonging to the same batch number. If no value is specified in this field, then all batch numbers are selected.

You can retrieve reports belonging to a particular WWID with the **World Wide Unique #** field. This field also supports wildcard search.

To view the Bulk Incoming Reports:

1. Select multiple reports from the Incoming ICSR Reports screen.

2. Click **Accept ICSRs**.

Note that:

• The reports that are imported can be a combination of Initial, Follow-up, and Nullification reports.

• The only pre-requisite for this dialog box is that Case numbering should be set to auto-numbering and not manually.

• Bulk Incoming Reports does not prevent the duplicate cases to be loaded into the system.
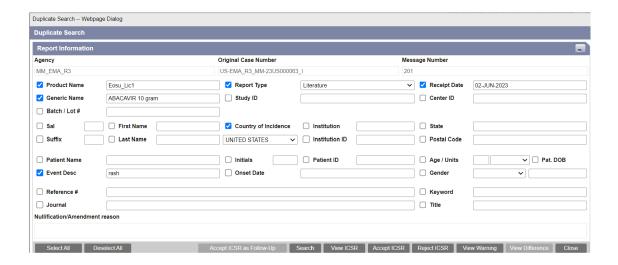
Search for duplicate reports

The Duplicate Search dialog box for an ICSR report enables you to search for possible duplicate cases in the Oracle Argus Safety system. You can select different combinations of search criteria. When you click **Search**, a list of cases that match the criteria you entered in

Duplicate Search is displayed along with their duplicate search score. Review the search results for a duplicate case. By default, the fields that are present in the ICSR Report are checked for the Duplicate Search.

If the **Enable Smart Duplicate Search** switch is enabled in `Argus Console > System Configuration > Common Profile Switches > Case Processing > Duplicate Search`, then the application search records based on the Smart Duplicate Search algorithm, otherwise the existing duplicate search algorithm is used.

Besides, the **Score** field appears in the result only when this switch is enabled.

For more information, see:

- Smart duplicate search
- View duplicate search options and actions
- Search duplicates for incoming review
- View differences report
- Accept initial E2B cases as follow-up

View duplicate search options and actions

Field	Description
View ICSR	Enables you to view the E2B report.
Reporter	Displays the reporter involved with the case matching the search criteria. This field appears in the search results.
Reference ID	Searches on the following fields in the Oracle Argus Safety case: • Additional Info > Case Reference ID • Reporters > Reporter's Reference # • Argus Case Number
Keyword	By default, the first value from the incoming affiliate event appears.

Action	Description
Onset Date	The date from when the first reaction or adverse event occurred.
Reference #	National Regulatory Authority's Report Number, used as a Reference Number.

You can view differences between the current XML to be imported (a message that is not yet imported into the database), the current case data in the database, and if a case has been imported before, and the last imported case.

> **Note:**
>
> This button is available only for follow-up and nullification reports.

Search duplicates for incoming review

You can right-click the Case Number for a listed case and use the following options:

Right-click Option	Description
Case Form Print	This option is displayed for only those users who belong to the group with access to `Argus Console > Access Management > Groups > Menu > File > Print`. This option allows you to print the case form report.
Case Summary	This option is displayed for only those users who belong to the group with access to `Argus Console > Access Management > Groups > Menu > File > Open Case Summary`. This option allows you to open the summary report of the case.
Medical Summary	This option is displayed for only those users who belong to the group with access to `Argus Console > Access Management > Groups > Menu > File > Print`. It displays the medical summary of the case.
Unlock/UnArchive Case	This option is displayed to allow users to re-open the archived and locked cases. On clicking this option, a Locked Case/Archived Case screen (as applicable) is displayed. You need to enter your password along with any remarks/notes and select a reason for your action to complete the unlocking/unarchiving of the case. > **Note:** > This option is available only when the case is in locked/archived status, and if the user has privileges to lock/close the case, as per `Argus Console User Configuration > Case Form` settings.

View differences report

You can view differences between the current XML to be imported (a message that is not yet imported into the database), the current case data in the database, and if a case has been imported before, the last imported case.

> **Note:**
>
> View Differences is available for follow-up reports only. This option is enabled only when an initial case or case number is selected in the duplicate search output section.

To view the View Difference report:

- From the Duplicate Search screen, click **View Differences**.
  The ICSR Difference Report screen appears.

  The differences in the ICSR reports appears as:

  - Addition—New elements are highlighted in grey.

  - Deletion—Deleted elements are highlighted in red.

  - Modification—Modified elements are highlighted in yellow.

The following table describes the fields in the report.

Field	Description
Trading Partner	Allows you to view the Trading Partner name from whom the ICSR report is received. > **Note:** > > The **Lock/Archive** icon displayed with this field denotes the status of the case.
DTD Version	Allows you to view the DTD version of the follow-up ICSR report.
Case Number	Displays the original case number of the ICSR report.
Follow Up #	Displays the sequence number of the follow-up for the E2B report.
Total Number of Rows	Allows you to select the type of ICSR Difference to view from: Current ICSR vs. Current Case in Database - Current ICSR vs. Last Imported ICSR - Current Case in Database vs. Last Imported ICSR
Import	Highlights the import differences.
ICSR Element	Highlights the ICSR differences.
Current ICSR	Highlights the differences in the current ICSR.
Current Case in Database	Highlights the differences in the current case in the database.
Last Imported ICSR	Highlights the differences in the last imported ICSR.

Field	Description
Accept Follow-up	Allows you to update the corresponding fields for the selected ICSR elements in the Oracle Argus Safety case.
Reject Follow-up	Does not update the corresponding fields for the selected ICSR elements in the Oracle Argus Safety case.
Print List	Provides the difference report in a PDF format.

Accept initial E2B cases as follow-up

This option is enabled **only** when an initial case or case number is selected in the duplicate search output section.

1. To add an ICSR as a follow up to the Case Number (that is highlighted in the duplicate search output section), click **Accept Initial E2B Cases As Follow-Up**.

2. Click **OK** when the following pop-up dialog box appears:

   ```
   Do you want to add this ICSR as a Follow-up to the Case
   Number<Num>?
   ```

The application attaches the incoming ICSR as a follow-up, to the selected case number highlighted in the duplicate search screen.

View processed ICSR reports

The Processed ICSR Reports page contains a list of ICSR that are processed successfully or processed with Errors/Warnings.

For more information, see:

- Search for reports
- View search results

Search for reports

Field	Description
Trading Partner	• To filter based on the Trading Partner, click **Filter**, and select an agency. • To select multiple agencies, click **Add** from the Select Reporting Destinations dialog box.
Product Name	Enables you to select a Product Name as a search criterion. For Product Name from Processed E2B Reports—searches all the Product Names for all the processed cases. The result set is limited to 1000 rows. To update the Product or Generic Name, selects a value from the search result, and click **OK**.

View search results

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

Field	Description
Interchange Date	Displays the Case Number with which the case has been imported on the specified interchange date.
ACK GEN Sent	Displays the status of the ACK GEN. • Yellow—Import is pending • Orange—Import is accepted but with warnings or errors • Red—Import is rejected • Green—Successful import
EDI Out	Displays the EDI Out status. • Yellow—Pending to send the report out of the EDI / XML or PHY out folders • Green—Already sent out of the EDI / XML or PHY out folders • Red—EDI gateway failed to send the report out of the EDI / XML or PHY out folders
Warnings / Errors	Click the **binoculars** icon to view warnings/errors associated, if any.

Track ICSR incoming status

To monitor incoming ICSR:

1. From **Utilities**, go to **ICSR**, and select **ICSR Receive Status**.

2. In the Search Reports section, enter the search criteria, and click **Search**.

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

   If the Agency is selected as **Any**, the search results display all ICSR messages and acknowledgements for all receivers.

3. Click the **Type Icon** link to view message options.

Find overdue reports

1. On the Home page, hover over the **Worklist** menu and click **Reports**.

2. Click on the **Days Past Due** field on the right of the Total Number of Rows and if needed click again to show Days Past Due in descending order (arrow pointing downwards).

3. To view all reports select **ALL** at top right of the screen.

For details on entering data in each section of the Total Number of Rows tab, see Total Number of Rows link.

FAQs

- [What is a scheduled report?](#)
- [What is a generated report?](#)

- What happens when a report is approved?
- What is the difference between submitting and transmitting a report?
- What happens when manually scheduling a Local Japan report?
- What happens when auto-scheduling a Local Japan report?
- What components are affected by the expedited reporting rules algorithm?
- When are follow-up reports created?
- When are the amendments created?
- Why can't I view a draft report?
- Why doesn't my draft report print a follow-up number?
- How does the Lock State Column under Reports > Compliance > Expedited allow me to sort my cases?
- How do I view the status of my Expedited Report?
- How do I know if an unscheduled report is due soon or needs to be submitted?
- Where can I view single reports which have been generated as part of a periodic report?

What is a scheduled report?

A scheduled report allows the system to calculate a report based on the date received, seriousness criteria, and reporting rule configuration if any. You can schedule any report. The case data within the reports continues to be updated as the case is updated.

What is a generated report?

A generated report creates a draft report for review. The case needs to be locked for the system to generate a report.

What happens when a report is approved?

Approving the report allows the User to sign off the report.

What is the difference between submitting and transmitting a report?

A report can be submitted to a regulatory authority either by printing it off and marking it as submitted, or sending it electronically from within Oracle Argus Safety via fax, email or E2B. Transmission is the electronic form of submitting a report.

What happens when manually scheduling a Local Japan report?

On Manual Scheduling of a report by a user, the application identifies if the report is a Local Japan report by matching the Country of the License#, Destination and Report Form chosen by the user in the Schedule New Report manual report scheduling dialog box with the Local Reports Configuration.

If DLP is not enabled for Expedited Report Generation:

1. On the Global lock of a case by a user, the application generates the global reports but does not generate any Local Japan reports.

2. The Local Japan reports shall be generated on subsequent local lock for Japan.

If DLP is enabled for Expedited Report Generation, refer to the chapter in *Oracle Argus Safety Japan User's Guide > 4 Reports* .

For a Study-based WHO Drug Report, the application identifies if the report is a Local Japan report by matching only the Destination and Report Form chosen by the user.

For a Study-based WHO Drug Report, the application identifies if the report is a Local Japan report by `ignoring the country`, matching only the Destination and Report Form chosen by the user and if the Truly Local Case switch returns value > 0.

Note that if AUTO_FOLLOWUP_MANUAL switch is ON, the existing functionality of scheduling a follow-up report for a manual report is retained as is and if the manual report was a local report, the follow-up is treated as a local report.

What happens when auto-scheduling a Local Japan report?

On the Global lock of a case by a user, the application triggers the qualifying reporting rules including the Japan reporting rules and schedule the relevant global and local reports. There are modifications to the Report Generation functionality however, and is explained under section *Changes to Report Generation*.

On the Local Lock of a case by a user, the Local Reporting Rules for Japan are triggered again as follows, depending on the value in the configuration switch `Case Form Configuration | Auto Regulatory Scheduling`:

- If the value is set to **Always**: The Local Japan reporting rules are triggered on case save during the follow-up cycles of case processing when any of the local fields caused the "Significant" data change. If any of the other fields caused the "Significant" data change, then all the reporting rules are triggered as with the existing algorithm. Also, for the initial case cycle, only local reporting rules are triggered on Local lock.

- If the value is set to **Significant**: The Local Japan reporting rules are triggered on Local Lock but respecting the existing algorithm to check that Significant Follow-up was added during the prior global lock cycle during the follow-up cycles. For the initial case cycle, as with the existing algorithm, they trigger on Local lock.

- If the value is set to any value other than **None**, including **Manual**: A new checkbox called **Schedule Local Reports Only** will be added under the Total Number of Rows section in the Regulatory Reports tab of the Case Form. This checkbox is visible only when the configuration switch `Case Form Configuration > Auto Regulatory Scheduling` is not set to **None**. After the rules are successfully triggered, the application unchecks the checkbox. If the checkbox is unchecked, the application triggers all the qualifying reporting rules keeping the current functionality.

> **Note:**
>
> As a result of triggering of local reporting rules again, the Local reports that were already scheduled during Global Lock may result in being overwritten or being removed.

Force Distribution: If force distribute is checked for a reporting rule, the application triggers that reporting rule as per the existing functionality. However, the generation and force distribution of the Local Reports have the following modifications:

1. When a Local reporting rule marked for "Force Distribute" has a local report that has become due, the report is scheduled, generated and force distributed by performing the global and local lock on the case using the existing AG Service Force Reporting process. When a Local report that was already scheduled outside of the force distribution process from a local reporting rule marked for "Force Distribute" has become due, the application does not force generate this report keeping it consistent with the existing functionality.

2. For the above scenario, AG Service uses the one step global/local lock comment "Case Globally and Locally locked for JP." (refer section *Routing Comments Log and Case Print*) followed by the configured comments under `Argus Console > Reporting > Expedited screen > Forced Distribution comments.`
Case Globally and Locally locked for JP. << Forced Distribution comments>>

3. After the report generation is complete, the case gets unlocked globally. AG Service uses the one step global/local unlock comment `Case Globally and Locally unlocked for JP.` (refer section *Routing Comments Log and Case Print*) followed by the configured comments under `Argus Console > Reporting > Expedited screen > Forced Distribution comments.`
Case Globally and Locally unlocked for JP. << Forced Distribution comments>>

What components are affected by the expedited reporting rules algorithm?

The expedited reporting rules algorithm affects the following:

- Suppression of duplicate reports
- Blinded or forced distribution

Suppression of duplicate reports

You can suppress duplicate expedited reports to be scheduled at the reporting destination level, according to the following criteria:

- The Suppress Duplicate Reports option **only** applies to drug reports. It **does not** apply to device reports.

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

- When you select **Suppress Duplicate Reports**, the system uses the following attributes to determine whether the reports are duplicates of other reports:

  – Report Form

  – Reporting Destination

  – Aware Date

- If two or more duplicate reports have different due dates (regardless of license type), the system schedules the report with the earliest due date.

Blinded or forced distribution

The system enables you to configure the Blinding Study option for products in the case.

- When you check this checkbox, the system blinds the study products for the report being sent to the reporting destination in a manner similar to the Bulk Reporting dialog box option.

- If you select either of the **Blind Study** product options (**Reporting Rules** or **Bulk Reporting**), the system blinds the study product information on the report form.

- The system blinds **only** active blinded studies. It **does not** blind the following case reports even if the **Blind Study** product is selected.

  – Open Label Studies

  – Study is eligible for unblinding - 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 due report 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 box.

- 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; the system is the user.

When are follow-up reports created?

Follow-up reports are created depending on the following parameters:

- Data for a case changes.

- Update information for a case has been entered by entering follow-up information in the General Information section of the General tab.

- Depending on the configuration set up by the Administrator, the system analyzes the scheduled reports prior to the data changes to see if they are still required.

- If the system determines that they are not required, the report status is marked as **Downgrade**. New reports are automatically scheduled, if required.

- If the system determines the report is still needed and needs to be updated, one of two functions can take place depending on the configuration done by the Administrator:

  – The system overwrites the report

  – The system schedules a new report in addition to the old report

- If the system has been configured to overwrite the existing report, the report status becomes **New Data Available**.

- In the Worklist, the status for this report shows **New Data Available** for this report. When you re-generate the report, you can select whether or not you would like to re-generate the report with the new data.
- If the system is configured to create a Follow-up report, the previous report remains in its current state and a new report is scheduled with the status of **Scheduled**.
- If a report has been previously submitted, this report is never deleted under any configuration.

When are the amendments created?

If the initial or follow-up E2B(R3) reports are submitted to a Reporting Destination or Agency, and the agency requests to send attachments, create the amendments by unlocking the case as significant follow-up and check the **Amendment** check box in the `Case Form > General Tab > Follow-up` section. Besides, enter the reason as well to create the amendments.

You can include attachments and provide details of the attachments in the Case Summary.

Amendment reports are auto-scheduled for the cases with Significant Amendments only, where the reporting destination is configured with an E2B(R3) profile.

Follow-up reports are auto-scheduled for the cases with Significant Amendments, where the reporting destination is configured other than E2B and E2B(R2) reports.

To manually schedule the Amendment reports for E2B(R3) for Significant Amendments or Non Significant Amendments, use the Scheduling New Expedited Report dialog. Select the Aware date pertaining to the amendment and schedule an E2B(R3) report. Aware date pertaining to an amendment can be identified by text (A) appended to the Aware date.

> **Note:**
> Oracle recommends that you have only one amendment for an Aware date, else it may be difficult to identify the latest amendment from the Aware date drop-down in the Scheduling New Expedited Report dialog.

When you manually schedule a report other than E2B or E2B(R2) for an Amendment Aware date, then the follow-up report is scheduled if there is a previously submitted report of the same report type to the same agency, else an initial report is scheduled.

> **Note:**
> You can create amendments only when a previously submitted E2B(R3) report exists.

Why can't I view a draft report?

You can only view a Draft report if the relevant case is unlocked.

Why doesn't my draft report print a follow-up number?

The following expedited report forms **do not** print a follow-up number when the user selects **DRAFT** on the Regulatory Reports tab or when they select the **Quick Launch Draft** option:

- US FDA MedWatch Drug/Device
- US FDA VAERS
- CIOMS I/CIOMS I (Local)
- French CERFA
- Spanish Spontaneous/Clinical

How does the Lock State Column under Reports > Compliance > Expedited allow me to sort my cases?

Click the **Lock State** header row to sort on the following category of cases. A pop-up window appears, with the following sorting options:

- Lock State
- SUSAR
- Exp/Per

Click the required option to sort cases based on the selected case categorization.

Lock icons

Icon...	Identifies...
	A case marked for a Periodic ICSR submission.
	A locked case.
	An unlocked case
	A SUSAR (Suspected Unexpected Serious Adverse Reaction) case.

Lock icon options

Field	Description
Report Details	Displays specific information about the report as entered in the **Regulatory Reports** section.
	The information displayed in the fields of the Report Details dialog box is fetched from the data entered in the Regulatory Reports section of Case Form.

How do I view the status of my Expedited Report?

To...	Do...
View the regulatory reports for a particular case (scheduled, generated and submitted)	Open the Regulatory Reports tab of the Case Form.
View all scheduled, generated, and approved reports, as well as other outstanding action items	Select **Reports** from the **Worklist** menu.
View a list of all scheduled, generated, and approved reports	Select `Compliance > Expedited` from the Reports menu.
View all the submitted reports in the system	Select `Compliance > Submitted` from the Reports menu.

How do I know if an unscheduled report is due soon or needs to be submitted?

As report scheduling is commonly configured to be executed when significant changes are made to a case, the expedited reports may be delayed if a case never gets locked. You cannot know that a report is late if it has never been scheduled. To address this potential compliance issue Oracle Argus Safety assesses case reportability prior to formal report scheduling. Workflow and Expedited Status monitoring screens identify unlocked cases due soon.

*   To view a list of unlocked cases with reports due, select **Dashboards**, and then click **Reports Due Soon**.
    The Unlocked Cases with Possible Reports Due Soon screen appears.

*   The Workflow and Expedited status include another report with cases that have not had reports scheduled but that may generate a report with a due date in the near future. This graph is displayed below the graph detailing the actual case status. The reports included in this sub-dashboard are limited to the filter criteria specified for the main dashboard.
    To view a Worklist with cases of the selected state (red or yellow), click the graphical bar.

Where can I view single reports which have been generated as part of a periodic report?

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

*   Pending Reports by Destination

*   Submitted Reports by Destination

*   Non-submitted Reports by Destination

7

Manage your periodic report submissions

Periodic reporting plays a key role in the safety assessment of drugs. It involves the compilation of safety data for a drug over a prolonged period of time (months or years), as opposed to single-case reporting which, by definition, involves only individual AE reports. The advantage of Periodic reporting is that it provides a broader view of the safety profile of a drug.

For more information, see:

- Prepare content for periodic reports
- View scheduled periodic report information
- Submit a periodic report
- Track your periodic report submission

Prepare content for periodic reports

In this section:

- Prepare your aggregate reports
- Periodic report types
- Prepare content for a Clinical Trial Periodic Report
- Prepare content for an ICH PSUR
- Prepare content for a US IND periodic report
- Prepare content for an NDA periodic report

Prepare your aggregate reports

These reports are executed in the background through the AG Services. A new Oracle Argus Safety service named Batch Aggregate Report Generation is available for this purpose.

For more information, see:

- Understand aggregate reports
- View saved aggregate reports
- Create a Case Data Analysis report
- Create a CIOMS II Line Listing report
- Create a case listing report
- Check aggregate report execution status

Understand aggregate reports

- The date and time printed on the following reports are the date and time the query is executed for case qualification. They **are not** the date/time the query was completed and the report obtained Web Server.

- – Case Listing Report

- – Case Data Analysis Report

- The system converts the following elements that display in the case form as actual text on the Case Listing and CIOMS II Line Listing reports:

  - – Duration of Administration

  - – Time Between First Dose/Primary Event

  - – Time between Last Dose/Primary Event

- Capture the report follow up number in the Regulatory Reports section. The system prints the report follow-up number on the expedited reports in the following format:
  F/U# X

  where:

  X is the report follow-up number.

- For an initial report, the system prints **initial** in the column.

- If there are no reports for the case in the Case Listing/CIOMS II Line Listing, the column is left blank.

- This option is available on the CIOMS II Line Listing/Case Listing reports.

- The system uses the IE offset of the client workstation to print the date and time component for **all** system-calculated fields on the Case Listing/CIOMS II Line Listing reports.

- You can filter cases in the following aggregate reports based on the lock/archived date.

- When you select **Case Locked/Archived** date, the system limits the cases based on whether the case is locked/archived within the specified time frame.

- The lock date is considered the locked date.

- If you select the **Case Patient** or **Reporter Information** in the Case Listing or CIOMS II Line Listing reports and the **Protect Confidentiality** field is checked for the Patient or Reporter Information, the application does not print the following information in Case Listing or in the CIOMS II Line Listing report:

  - – Data from the Patient information and Patient details section, excluding Race information

  - – Data from Reporter information

- If you **do not** have permission to view the reporter or patient information, the corresponding reporter or patient elements selected on the Case Listing or CIOMS II Line Listing report are blank.

View saved aggregate reports

The System Reports Library displays the list of the saved aggregate reports including Case Data Analysis, Case Listing and CIOMS II Line listing reports. This screen displays only the reports either created by the logged in user or the reports that are shared for your user group during report creation.

- The Aggregate report supports only PDF or CSV formats.

- The system report library screen, provides the way to filter the reports through:

  - – Report Name

  - – Description

- – Report Type

- – Output Type

- – Author

- – Last Modified

- – Available for Periodic

- – Shared

- • The reports can be executed through the Print option. When you click **Print**, the application opens the Report Batch Printing dialog box, where you can run or schedule the report for the desired format (PDF/CSV). You can send an email for the completion status.

- • The open option allows to open and edit the memorized reports.

- • If the user clicks **Transmit**, the system generates the selected report and starts the transmit process. The system displays the Recipient pop-up.

> **✎ Note:**
>
> A shared report can only be deleted by the Administrator or the user who created it.

Create a Case Data Analysis report

The Case Data Analysis Report enables you to view quantities of cases over time in a Cross-Tabular Fashion.

1. Select **Reports**, then select **Aggregate Reports**, and click **Case Data Analysis**.

2. In the Case Data Analysis Report view, select the information that must appear in the report.

3. In Row1, select the field the system uses to group cases by row.

4. In Column1, select the data the system uses to group cases by column.

5. In Row2, select the field by which each Row1 item will be categorized.

6. In Column2, select the field by which each Column1 item will be categorized.

7. Select a product family to which the report applies, if appropriate.

8. In Selection for Row1, select the value for Row 1 by which the report must be restricted.

9. Specify an advanced condition, as appropriate.

10. Select **Report Number of Cases** or **Report Number of Events**, depending on the number of cases or the number of events to be entered in the report.

11. If you select **Report Number of Events**, you can specify the kind of events (**Serious Listed**, **Non-Serious Listed**, **Serious Unlisted**, or **Non-Serious Unlisted**) that will appear in the report.

12. Select whether only the top few items should be displayed and enter the number of items that should be displayed.

13. Check the **Show% of Total** checkbox to specify the percentage in each cell in the report.

14. Check the **Blinded** checkbox to hide blinded information in the report. This field is unchecked and disabled for a restricted user.

15. Check the **Use Case Search Results** checkbox to limit the Case Data Analysis only to the cases present in the Case Search dialog box.

16. Specify a date range for the cases that will appear in the report.

17. Enter a title for the report.

18. Click the **Share this report with other users** if there is a need to share the report/report output to other users. Note that the report may contain sensitive data. By default, the report is shared with all users. You can restrict it through Group, where the allowed user groups can be selected. When a report is shared for a user group, only members of that group and the report creator can access the report further.

19. The report can be used in the periodic report using **Make available for use in Periodic Reports**.

20. Click **Print** to execute the report in background. This report can later be viewed under system reports library.

21. The **memorize** button saves the report in the application. It does not execute the report.

Create a CIOMS II Line Listing report

The CIOMS II line listing report is a common format desired by Drug Safety professionals for reviewing cases. Create this report from the CIOMS II Line Listing dialog box.

1. Select **Reports**, then select **Aggregate Reports**, and click **CIOMS II Line Listing**.

2. On the CIOMS II Line Listing Criteria tab, select information for the header, footer, product family, advanced condition (if any), cases to include, and date.

3. Select either the **Case Creation Date** or **Case Receipt Date** radio button and specify a date range to run the report.

> **✎ Note:**
>
> If you perform a search and return a list of cases to the Case Search screen, the **Use Case Search Results** is visible. Checking this box will disable all selection criteria with the exception of **Include Unlocked Cases**. For example, the Advanced Condition and Date Range will be disabled.

4. In the Line Listing tab, add or remove the appropriate fields.

5. In the Grouping tab, add or remove elements, insert a page break and change the sort order (if desired).

6. Click **Memorize** to open the Memorized Report dialog box.

   The **Memorize** button saves the report in the application. It does not execute the report.

7. Click **Print** to execute the report in background. This report can later be viewed under system reports library.

   This report can be shared with other users of Argus and the sharing can be restricted through the User Group selection.

Create a case listing report

The Case Listing Report enables you to filter cases based on Case Initial Receipt Date and Case Creation Date. You can select multiple entities from the List of available fields using the CTRL+CLICK functionality.

1. Select **Reports**, then select **Aggregate Reports**, and click **Case Listing**.

2. When the system opens the Case Listing Reports view select the information to appear on the report.

3. Select the fields that are to appear in the report from the **Available Fields** list.

4. Click **Add**. Repeat this process for each field that must appear in the report.

5. Use **Move Up** and **Move Down** to arrange the fields in the **Selected Fields** list.

6. Check the **Blinded** checkbox to hide blinded information in the report.

7. Specify an Advanced Condition, if appropriate.

8. Specify a date range for the cases to be displayed in the report.

9. If you check the Include in Header checkbox, the selected date range is displayed on the report.

10. Under Sorting Order, select the fields by which the cases will be sorted. You cannot sort the cases by fields that do not appear on the report.

11. Enter the title of the report.

12. Click **Memorize** to memorize the criteria specified for a particular report.

    The Memorized Report dialog box appears.

13. **Save**, **Delete** or **Cancel** the report, as applicable.

14. Click **OK** in the Case Listing Reports screen to generate the report. The report will be generated in PDF format.

Check aggregate report execution status

Go to **Reports**, then select **Compliance**, and click **Report Generation Status**.

This screen displays the status of report generation for both Periodic and Aggregate reports. The Aggregate Reports can be filtered using the report type filter.

Periodic report types

On the Reports menu, hover over the **Periodic Reports** option, to go to any of the Periodic Reports.

You can create the following periodic reports:

- Clinical Trial Periodic Reports
- ICH PSUR Reports
- US IND Periodic Reports
- US NDA Periodic Reports

For more information, see:

- Store periodic reports in Documentum
- View a summary of periodic regulatory reports
- Use the library page

Store periodic reports in Documentum

When you approve an expedited report from within Oracle Argus Safety, the system exports the report as a PDF file and saves it in the Documentum database by Oracle Argus Safety Service. From this point, you can perform document reviews within the Documentum system.

When the report is ready to be submitted, mark the report as Submitted from within Oracle Argus. Oracle Argus Safety Service updates the status of the report within Documentum to **Submitted**.

If the report is to be transmitted via fax or email, Oracle Argus Safety Service marks the report as a successful submission in Documentum only **after** the fax or email transmission has succeeded.

View a summary of periodic regulatory reports

You can select any of the following options in viewing the summary of a periodic regulatory report:

- To view the regulatory reports for a particular case (scheduled, generated, and submitted), open the Regulatory Reports tab of the Case Form.
- To view all scheduled, generated, and approved reports, as well as other outstanding action items assigned to you or your user group, select **Reports** in the **Worklist** menu.
- To view a list of all scheduled, generated, and approved periodic reports, select **Periodic Reports** from the `Reports > Compliance` menu.

Use the library page

The Periodic report has a library page from where you can create a new report, execute an already created report, view the output and so on.

- PSUR (legacy PBRER, PSUR and Flexible PBRER, PMAR reports)
- CTPR (legacy CTPR and Flexible DSUR reports)
  All fields that are used by the Flexible DSUR is highlighted with blue BIP icon.
- IND
- NDA

While a report is running, it can be modified or run again until the previous run is complete.

Prepare content for a Clinical Trial Periodic Report

The Clinical Trial Periodic Reports (CTPR) are created to report the IND Annual reports and EU Clinical Trial Directive line listing reports to FDA.

For more information, see:

- Create a Clinical Trial Periodic Report
- Enter common fields information
- Configure subject in the report header
- Select products to include in CTPR
- Configure license or study in the report header

- • Select inclusion criteria
- • Use the Data Lock Point (DLP) version
- • Use DLP queries for dates
- • Use As of Reporting function
- • Find DLP and As of Query functionality
- • Include line listing
- • Add data elements
- • View selected data elements
- • Group cases
- • Specify summary tabulations for line listing
- • Generate single case submission report
- • Select summary listing
- • Schedule the report
- • Setup frequency of the scheduled reports
- • Configure security level of the report
- • Use report templates

Create a Clinical Trial Periodic Report

1. Select **Reports**, then select **Periodic**, and click **CTPR (Clinical Trial Periodic Reports)** to open a list of CTPR Reports.

2. To create a new report from an existing report in the list, click **Copy** or **Modify**.

3. Click **New Report** to create an entirely new report. The Clinical Trial Periodic Reports pop-up window opens.

4. Enter an appropriate name for the report under Report Name.

   Use the tabs in this pop-up window to configure the CTPR.

Enter common fields information

The Report Name, Report Category and Report Sub-Category fields are common to all tabs of the Reports.

Field	Description
Report Name	Enter a name for the Report. The name entered here is displayed in the Reports menu.
Report Category	1. Select a category for the Report. This is displayed in the Reports menu. 2. Select **New** to define a subcategory within the report category. The Periodic Report Category dialog box is displayed. 3. Enter a category name in **Category** and click **OK**. 4. The category is entered in the **Report Category** drop-down list.

Field	Description
Report Sub Category	1. Select a subcategory for the report. 2. Select **New** to define a subcategory within the report sub-category. The Periodic Report Category dialog box is displayed. 3. Enter a category name in **Category** and click **OK**. 4. The category is entered in the **Report Sub-Category** drop-down list.

Configure subject in the report header

The Subject of Report tab is used to configure the report header and to specify the agency, products, etc. for which the CTPR is applicable.

Field	Description
Available Reporting Destination	Displays the list of configured Regulatory Agencies. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. Select multiple agencies by holding the CTRL key when you click them. Likewise, select an agency from the **Selected Destination** list and click **Remove** to remove it from the selected destination.
Primary Agency	Select the primary agency for the report. When you submit a Periodic report, it goes to the selected Primary Agency.
Selected Reporting Destination	Displays the list of agencies where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list. Select multiple agencies by holding the CTRL key when you click them. Likewise, select an agency from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.
Ingredient	Automatically displays the **Ingredient** as provided in the Subject of Report dialog box. You can choose whether to view this field or not. Click the checkbox displayed with this field to hide or view it.
Trade Name	Automatically displays the **Trade Name(s)**. Multiple trade names are also displayed together, separated by commas. You can choose whether to view this field or not. Check the checkbox displayed with this field to hide or view it.
International Birth Date	Automatically displays the earliest license awarded date, when a user selects an Ingredient and a Product. You can choose whether to view this field or not. Check the checkbox displayed with this field to hide or view it.
Print all configuration criteria on separate cover page	Mark this box to print out the configuration of this report when the report is printed. This is only available when PDF option is selected during printing.

Field	Description
Print page numbers on reports	When checked, this option enables the user to print page numbers on a periodic report. This is the default for all report configurations.
	If this checkbox **is not checked**, the following occur.
	• The **Include Periodic Page Numbering** option in the CTPR Summary Tabulations CIOMS Report section is inactive and grayed out.
	• The **User Periodic Numbering on the report** option on CTPR Summary Tabulations FDA CTPR support section is grayed out and inactive.
	• The **Additional Separate Page Numbering for UD Summaries** option on the CTPR UD Summaries tab is grayed out and inactive.
	• The system removes all existing report page numbering and the option to check page number checkboxes on the report configuration tabs are grayed out and inactive.
Allow access to report cases through Case Series	When the report is run as final, it creates a Hit List, which can be retrieved from other areas of the application where advanced conditions can be selected. Click this checkbox to report cases through the Hit List.

Select products to include in CTPR

The Product Selection tab enables you to select the products included in the CTPR report.

Field	Description
Available Ingredients	Displays the list containing the Ingredients used for the product configuration. Select an ingredient from the list displayed in **Available Ingredients** and click **Add/Remove** to add or remove the ingredient.
	You can select multiple ingredients at a time.
Filter	Enter an Ingredient name and click **Filter** to search for the entered ingredient within the Available list of Ingredients.
Selected Ingredients	Displays the list of ingredients selected from the **Available Ingredients** list.
Available Countries	This list is auto-populated and displays only the countries with a license containing the ingredient selected from the **Available Ingredients** list.
Selected Countries	Displays the countries selected from the **Available Countries** list.
Indication	This list contains the Indication configured for the product containing the ingredients in the **Available Ingredients** section. The selections made from this list get displayed in the **Available Products** section.
	You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Formulation	This list contains the Formulation configured for the product containing the ingredients in the **Available Ingredients** section. The selections made from this list get displayed in the **Selected Products** section.
	You can select multiple Formulations from the list at a time by pressing the `CTRL` key and clicking the different Indication entities.

Configure license or study in the report header

The License or Study tab is used to configure the report header and to specify the agency, products, etc. for which the CTPR will be applicable.

Field	Description
Available Licenses	Contains licenses that use the ingredient selected in the **Ingredient** field. This field is automatically populated when an ingredient has been selected.
Selected Licenses	Displays the licenses selected from the **Available Licenses** list by clicking **Add/Add All**. You can select Licenses that are related to different ingredients for a report.
Available Studies	Contains studies that use the ingredient selected in the **Ingredient** field. This field is automatically populated when an ingredient has been selected.
Selected Studies	Displays the studies selected in the **Available Studies** list by clicking **Add/Add All**. You can select studies that are related to different ingredients for a report.

Select inclusion criteria

The Inclusion Criteria tab allows you to select search parameters for inclusion of cases in a periodic report.

The top section of the dialog box allows you to specify the type of cases that will be included in the periodic report.

Inclusion criteria of the reports considers listedness of all blinded products configured in the study and present in the case while still being in the blinded state. Such blinded products are included in the periodic report when event-level listedness is considered.

Field	Description
Case Creation Date	Allows you to specify a range of cases by the date when the case was created.
Case Receipt Date	Allows you to specify a range of cases by the initial receipt date.

> **✎ Note:**
>
> The **Date Range** is only available when an unscheduled CTPR is being created. You must specify only one date range out of **Case Creation Date** and **Case Receipt Date**.

Case Locked/Archived Date	Allows you to specify the date when the case was locked/archived.
Use Current Version	Allows you to use the latest revision to populate the data within the selected reports.
Use DLP Version	Allows you to use the case data of the version as of the specified DLP Version.
Age Groups	Allows you to include or exclude cases based on the patient's age group. Select all the age group categories that apply.

Field	Description
Restrict Cases to countries where studies are active	References study configuration to determine if the case was submitted during the dates the study was active. **Note:** This option is available only if a study is selected from the **Available Studies** section in the License/Study tab. It should not be used for Centrally approved products (CAP), which only have an EU license.
Advanced Condition	Allows you to specify an advanced condition that must be satisfied by each case that is included in the report. Ensure that the advanced condition or the advanced condition query set that is specified here does not contradict any other criteria specified in the dialog box.
Datasheet for Listedness	Select the Datasheet to look against for Listedness when running the report. **Note:** Select the **ALL** datasheet to use the most conservative listedness for the primary event, or the Case Listedness for the tabulation.
Use Assessment in Cases	When selected, the CTPR Report will use the Case Event Assessment when performing datasheet listedness calculations.
Re-assess cases against datasheet in effect at the beginning	When selected, the CTPR will re-assess the cases in the line listing based on the Active Datasheet on or before the Start Date of the Reporting period.
Re-assess cases against datasheet in effect at end	When selected, the CTPR will re-assess the case in the line listing based on the Active Datasheets on or closest to the end date of the CTPR Reporting end date range without exceeding that date.
Reference Type (Clinical Reference Data Element)	Select the reference type to be displayed on the Main Listing if **Clinical Study Reference** is selected as a **Data Element** in the **Available Data Elements** section of the Line Listing tab.
Expeditable Only	This option is enabled only when an agency has been specified on the Subject of Report tab. Check this option to include only those cases that have submitted expedited reports to the specified Primary Agency.
Exclude Follow-up cases	Follow-up cases are cases with a significant follow-up in the Clinical Trial reporting period where the initial receipt date is in a prior period. Check this option to exclude follow-up cases from appearing on the Clinical Trial report.
Include Unlocked Cases	Check this option to allow cases that have not been locked for reporting to appear on the report.
Use Datasheet Assessment for UDF Tabulations	Allows you to select datasheet for a report to make UDF tabulations. If no datasheet is selected, the most conservative listedness is chosen, such as Unlisted followed by Listed.
Add Cases not included in previous reporting period	Allows you to add cases which were not included in the previous reporting period. You can enter the start date of the period in the Start Date field.

Use the Data Lock Point (DLP) version

DLP primarily uses two processes:

- Last Completed Version—This option always uses the case version with the last lock that existed prior to the DLP or **As of Reporting** date. This option does not enable data cleaning
DLP saves only the last revision when multiple saves are performed in the same job session.

- Next Completed Version—This option uses the current case lock or the next following case lock if the case version was initiated prior to the DLP or the **As of Reporting** date with two exceptions:

    - If there is no case lock for the current version that was received prior to the DLP, the last (current) case revision is used.

    - If there is a case version after the case lock that was created for the purpose of data cleaning, it is to be used instead of the first locked case revision.

    - If there are multiple contiguous case versions following the first case lock for the purpose of data cleaning, the last case data cleaning version is used.

> ✏️ **Note:**
>
> The Data Cleaning option is available only with the DLP option **Use Next Completed Version (Includes Data Cleaning)**.

Use DLP queries for dates

You can perform DLP queries for the following:

- Receipt Date - date entered by the user during case creation.

- Initial/Follow up Receipt Date

- Safety/Safety Follow up Receipt Date

- System Date (Case Creation Date) - date the case was physically entered.

Use As of Reporting function

The **As of Reporting** function returns the same case version results as the DLP Options, with the only difference that the date depends on the **As of date** instead of a DLP date.

Find DLP and As of Query functionality

The DLP and **As of Query** functionality is available in the following application modules:

- Periodic Reports

    - PSUR including all User defined Tabulations and expedited reports within the Periodic Report

    - CTPR including all User defined Tabulations and expedited reports within the Periodic Report

    - IND including all User defined Tabulations

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- NDA including all User defined Tabulations and expedited reports within the Periodic Report
- System Reports
  - CIOMS II Line Listing
  - CDA Reports
  - Case Listing Reports

Include line listing

Field	Description
Include Line Listing	Allows you to select whether you want the Line Listing Data Elements printed with the CTPR Report.
	From the Available Data Elements, select **As determined listedness** to print listedness.
	For Blinded clinical trial cases, when the **Include datasheet/licenses for all the blinded study products** common profile switch is checked, then listedness is printed against the default study product.
Blind Line Listing and Summary Tabulations	Hides the selected listings from being displayed

Add data elements

Select the checkbox associated with a data element (field) to add that field to the report.

- By default, the system prints unavailable fields on the report, and they cannot be changed.
- Required data elements are printed as columns in the report. The optional data elements are printed as separate rows below the column data for each case.

View selected data elements

This section lists the selected elements and enables you to arrange the order in which these are to be printed. Click the **Up** or **Down** buttons to arrange the listed elements above or below in order of priority.

Field	Description
MedDRA Hierarchy from Cases/Dictionary	Select Cases to populate the data from the case data. Select **Dictionary** to populate the data from the MedDRA dictionary.
Print Only the Term (Preferred Term or Lower Level Term)	Prints only the event Preferred Term (PT) or event Lower Level Term (LLT) as per the selected radio button. Select the PT option to print only the preferred term and not the verbatim description.
Print Dose Text in place of regimen dose	Prints the dosage and frequency information from **Dose Description** field instead of **Regimen Dose**.
Indicate if case was expedited previously	This checkbox is selected if a primary agency has been selected in the Subject of Report tab. Cases for which an expedited report was previously submitted to the selected authority are marked with an asterisk.
Local Language	Allows a user to specify which Local language for a multi-language field is to be printed. Namely, the Abbreviated Narrative field.

Field	Description
Print event info (Serious, Un-listed, Causal) as Column	Select this checkbox to print the **Seriousness**, **Listedness** and **Causality** under the **Event Verbatim** column.
	Note: Events having listedness of *Unknown* are considered **Unlisted**. If only diagnoses are assessed for event assessment, the events which are associated with a **Diagnosis** but have been marked with **Diagnosis** as *Np* display **'-'** for both listedness and causality.
List cases only once, under the primary event	Select this option to view the details of cases in the **Main Line Listing** only once under the **Primary Event**.
List cases under all events, details under the primary event	Select this option to view the details of cases in the **Main Line Listing** only once under the **Primary Event**, while non-primary events are listed under their respective event hierarchy with a reference to the primary event body system. Therefore, use this option when grouping on **Main Line Listing** is by the **Event Body System**.
Print Product Indication for the product selected in the report	Select this option to print **Product Indication** for the product selected in the report.

Group cases

Field	Description
Available Groupings	Allows a user to group cases together from the given list. Select the desired groupings from the list and click **Add** to move the grouping to the **Selected Groupings** list. Up to 10 grouping options can be selected.
Selected Groupings	Lists the added groupings made available from the **Available Groupings** list, and reports the groups in the order they were selected.
Ascending	Select this checkbox to sort the selected entities in ascending order.
Page Break	Select this checkbox to start the cases from a new page, while also keeping the sorting together for every selected page break.
Available Sortings	Allows a user to sort cases together from the given list. Select the desired sortings from the list and click **Add** to move the sorting to the Selected Sortings list.
Selected Sortings	Allows a user to further sort cases without a total count for each sorted item. Up to 3 levels of sorting can be selected from the **Available Sortings** list.

Specify summary tabulations for line listing

The Summary Tabulations tab enables you to specify which summary tabulations/Listings will appear along with the line listing.

Field	Description
Include Index of Cases in Line Listing	Create an index page of case numbers, for all cases included in the CTPR.

Field	Description
Include Summary of Cases Missing Assessments	This option creates a sub-report of cases missing one of the following items: • Seriousness • Case Causality • Case Listedness • Case Outcome • Event Causality • Event Listedness Click this checkbox to create one or both of the following sub reports: **Cases Missing Assessments** - This sub-report displays cases that have been included in the CTPR line listing, but one or more of the following have not been assessed: • Case Seriousness • Case Causality • Case Listedness • Case Outcome • Event Causality • Event Listedness **Cases Not Included in Report** - This sub-report displays cases that have not been included in the CTPR line listing as a result of missing one or more of the following items: • Lock Status • Safety Date • Uncoded Event • Causality
Count of Cases per Report Type	This option prints a Sub Report that counts the number of cases versus the Report Type, based on the cases within the CTPR. The Cases per Report Type can be either of the following: **Count Cases with Initial Expedited Reports:** Counts cases with initial Expedited report. Count of cases with **Follow-up** Expedited report: Counts cases with Follow-up Expedited report. **Total Count of Initial Cases in the Report**: Counts any (serious - non-serious) cases received during the reporting period. **Total Count of Follow-up Cases in the Report**: Counts any (serious - non-serious) follow-up cases entered during the reporting period. **Cumulative Count**: Count of cases received from the start of the trial.
Event Count per Study Drug	Creates a sub-report with Event count per Study Drug based on the selected causality. 2 configurations are possible as to allow for a count of related events vs. non-related events.
All Drugs in Single Table	Suppresses *0* current columns (with their cumulative) and print everything in a single cross tab.
Grouped by Drug	Prints a cross tab report for every product. Prints the cumulative totals even if the current period has no events.

Field	Description
Event Type to Include	Prints SUSAR events on the CTPR Report based on the option selected from the drop-down list: • Separate counts of SUSAR and non-SUSAR events Prints SUSAR and non-SUSAR events listed separately. SUSAR events are marked with an asterisk • Combined count of SUSAR and non-SUSAR event Prints SUSARs. Normal events are grouped into one (current functionality) • Only count SUSAR events Prints Only SUSARs. Namely, non-SUSARs would not be printed.
Include Line Listing Tabulation	Select this checkbox to view a pre-defined summary tabulation of Report type, Seriousness and Listedness of all cases in the CTPR.
Include Initial Cases	Select this checkbox to include initial cases in the CTPR tabulation.
Additional Expedited Report Forms (CIOMS/ MedWatch/VAERS)	Allows you to print CIOMS/MedWatch/AERS forms (as per selection) for its respective regulatory agency (as selection), for all cases in the report. It also provides an option to have (or not have) a watermark in the forms. When MedWatch is selected for PSUR, CTPR, and NDA, then the Reporting Destination drop-down displays only those agencies that has MedWatch profile (standard or custom) configured in the `Reports > Periodic Reports > ICH PSUR or CTPR > Summary Tabulations > Additional Expedited Report Forms (CIOMS/ MedWatch/ VAERS)> Print MedWatch > Forms of Agency` section.

CIOMS reports—fields descriptions

Field	Description
Print CIOMS reports for serious/unlisted cases	Allows a user to print CIOMS I forms for all Serious or Unlisted (Case Level) cases appearing in the CTPR. CIOMS contain Internal or Other text printed on them when the CTPR is printed using the Internal or Other option.
Include Periodic Numbering on the CIOMS reports	Numbers the requested CIOMS I with a periodic format. (Namely, A-1-1 of 2, A-1-2 of 2, A-2-1 of 1, A-3-1 of 1 etc.). The index is modified to also contain the Periodic paging of each CIOMS report.

Cumulative summary—fields descriptions

Field	Description
Include Cumulative Summary	Select the checkbox to create a sub-report count of events, grouped by Product and Body System (SOC) and sorted by Preferred Term. The sub-report contains a previous date range count of events (comparative date range), a current date range count (current CTPR date range) and a cumulative count (all dates) of events assessed against the product(s) of the CTPR and matching the inclusion criteria.
Comparative Date Range	Allows a user to specify the previous date range as a comparison date for the events counted, and therefore should not overlap with the current date range specified on the CTPR inclusion criteria tab.

FDA CTPR support—fields descriptions

Field	Description
Include Adverse Event Summary	Select this option to generate a sub-report of events from the line listing. This sub report is grouped by Body System and Preferred Term.

> **✎ Note:**
>
> This section can be used if the company has obtained an FDA waiver to submit a CTPR instead of an NDA report.

Field	Description
Causality	Select the desired causality from the list. **Ignore** - Counts events regardless of causality assessment. **Causal** - Counts events where the causality is considered reportable in the Causality Category configuration in List Maintenance. **Not Causal** - Counts events where the causality is considered non-reportable in the Causality Category configuration in List Maintenance. **As Determined** - Counts events where **As Determined** causality meets the above selected causality criteria. **As Reported** - Counts events where **As Reported** causality meets the above selected causality criteria. **Both** - Counts events where both **As Reported** and **As Determined** causality meet the above causality criteria. **Either** - Counts events where either the **As Reported** or **As Determined** causality meets the causality criteria.
Only Cases with HCP Reporter	Select this checkbox to include events for only those cases that feature an HCP reporter.
Diagnosis	Select this radio button to ensure that only events marked as diagnosis are counted.
Diagnosis & Symptoms	Select this option to ensure that all events are counted in the sub-report.
Separate Diagnosis & Symptoms	Select this option to include all SUSAR events in the CTR Report.
Print Unsubmitted	This option allows a user to print MedWatch or VAERS forms for U.S. cases. The following types of cases will be excluded: • Foreign Cases (Country of Incidence not equal to U.S.) • Clinical Trial Cases (Case Report type in list maintenance has **this type includes cases from clinical trials** checked.) • Literature Cases (Case Report type in list maintenance has **this type include case from literature** checked.) • Cases with submitted expedited reports to the Agency selected in the CTPR. When MedWatch is selected for PSUR, CTPR, and NDA, then the Reporting Destination drop-down displays only those agencies that has MedWatch profile (standard or custom) configured in the `Reports > Periodic Reports > NDA > Line Listing > Print MedWatch > Forms of Agency` section.

Field	Description
Exclude Reports that are Non-Serious and Listed	Allows a user to suppress MedWatch or VAERS forms from printing for Non-Serious listed cases where all events are non-serious and listed for the datasheet specified.
Use Periodic numbering on the Reports	Numbers the requested forms with a periodic format. (Namely, Periodic Page 1 - 1, Periodic Page 1 - 2, Periodic Page 2 - 1, Periodic Page 2 - 2, etc.) An index with the Case Number is also included.

Generate single case submission report

Use the following fields in the Single Case Submission Support section to generate the report.

Field	Description
Generate Periodic ICSR submissions for cases that do not have at least one ICSR report scheduled during the reporting period to any of the following Reporting Destination(s)	Select this checkbox to generate the ICSR Reports only for the cases, where a Periodic ICSR Report for the message type chosen, does not exist. Select one or more trading partners from the list box. **Important**: Any case that does not have an expedited or single case periodic submission to a trading partner, must have an ICSR report scheduled as a part of the Periodic submission.
Modify	Click **Modify** to select a different Reporting Destination.
Generate Periodic ICSR submissions to the following Reporting Destination	Select a single-destination trading partner for Periodic Reports from the drop-down list box.
Using the Message Type	Select the required message type from the drop-down list box

Select summary listing

The UD Summaries tab allows you to specify which summary listings will appear along with the line listing.

Field	Description
Include these summary tabulations/listings based on the set of cases presented in the line listing	Allows you to select from pre-configured summary tabulations/listings based on Case Data Analysis, Case listing or CIOMS II line listing reports. These tabulations are based only on the data included in the line listing. Select the **Exclude Follow-up Cases** checkbox to filter out follow-up cases from the attached report. If the Exclude Follow-up Cases option is selected on the Inclusion criteria tab, this option is ignored and follow-up cases are always filtered out.
Include these summary tabulations based on all cases	Allows for additional sub-reports based on the **Case Data Analysis** template, to be included as an output for the all cases in the database that meet the CTPR inclusion criterion for all dates.

Field	Description
Include these summary tabulations/ listings based on the Date Range	This option allows for additional sub-reports based on Case Data Analysis, Case listing or CIOMS II line listing reports to be included as an output for the cases meeting the CTPR inclusion criterion for the Date Range specified when adding the sub-report.
	The dates are based on either the **Case Creation Date** or the **Initial Receipt Date** as entered on the CTPR Inclusion Criteria tab. Check the checkbox to the right of the sub-report to ignore considering follow-up cases for the sub-report.

Schedule the report

The Scheduling tab enables you to specify details of how often the periodic report will be scheduled.

Field	Description
Start Date	This is the International Birth Date for the PSUR product. This date is computed as the earliest Awarded date for any license of any type.
Recalculate	Allows a user to recompute the International Birth Date of the PSUR Product. This date can be overwritten/manually entered, if needed.
Report is due xx days after specified end date	Enter the number of days when the report will be due after the end date specified for the scheduling period.
Automatically generate report xx days before/ after selected end date at xx:xx	Allows a user to specify the timing of the automatic report generation, by specifying the number of days before/after the selected end date of the report.
Group	Allows the user to select the group to which the automatically generated report is to be assigned.

Setup frequency of the scheduled reports

Field	Description
Frequency	Allows a user to specify the interval required for this scheduling period.

Configure security level of the report

The Security tab is used to configure the security level for the PSUR.

Field	Description
Share this Report with Other Users	Click this checkbox to share this report with other users. Specify the privileges to be granted to groups by adding the group name from the Users Groups list to either the **Execute** or **Modify and Execute** list. A user group can exist in only one of these access lists.
User Groups	The groups listed here have no access to the PSUR report template. Click **Add** or **Remove** to move them to another access list.
Execute	The groups listed here have read and execute access to the shared PSUR report template.

Field	Description
Modify & Execute	The groups listed here have read, execute and modify access to the shared PSUR report template.

Use report templates

Refer to the *Oracle Argus Dossier User's Guide* for description of fields in the Templates tab.

Prepare content for an ICH PSUR

The Periodic Safety Update Reports (PSURs) are created on a periodic basis to enable regulatory authorities to monitor the safety of a marketed product. This information is used to view new data about the product acquired from appropriate sources. It helps relate this data to the patient exposure and also indicates whether changes should be made to the product information in order to optimize the use of the product. Requirements on the due date of periodic reports may differ for different regulatory authorities.

For more information, see:

*   Create Periodic Safety Update Reports (PSURs)
*   Enter common fields information
*   Configure subject in the report header
*   Select products to include in ICH PSUR
*   Select inclusion criteria
*   Include line listing
*   Add data elements
*   View selected data elements
*   Group cases
*   Specify summary tabulations for line listing
*   Include CIOMS reports
*   Add PBRER Section 6.2 - Cumulative Summary Tabulations of SAEs from clinical trials
*   Add PBRER Section 6.3 - Cumulative and Interval Summary Tabulations from Post-Marketing Data Sources
*   Add cumulative summary
*   Add FDA PSUR support information
*   Generate single case submission report
*   Select summary listing
*   Schedule the report
*   Setup frequency of the scheduled reports
*   Configure security level of the report
*   Use report templates

Create Periodic Safety Update Reports (PSURs)

1. Select **Reports**, then select **Periodic**, and click **ICH PSUR Reports**. A list of PSUR Reports opens in the right frame.

2. Click **Copy** or **Modify** to create a new report from an existing report.

   OR

   Click **New Report** to create an entirely new report.

3. When the system opens the ICH PSUR Line Listing Reports dialog box, enter an appropriate report name in the Report Name field.

   Use the tabs to configure the PSUR.

Enter common fields information

See Enter common fields information.

Configure subject in the report header

The Subject of Report tab is used to configure the report header and to specify the agency, products, etc. for which the PSUR will be applicable.

Field	Description
Primary Agency	Select the Primary Agency.
Reporting Destination	Displays the list of agencies from where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list.
	You can select multiple agencies from the list of agencies such that the report can be submitted to multiple agencies at the same time.
	Likewise, select a report from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.
Selected Destination	Displays the list of agencies where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list.
	You can select multiple agencies from the list of agencies such that the report can be submitted to multiple agencies at the same time.
	Likewise, select a report from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.
Ingredient	Automatically displays the **Ingredient** as provided in the Subject of Report dialog box.
	You can choose whether to view these field or not. Check the checkbox displayed with this field to hide or view it.
Trade Name	Automatically displays the **Trade Name(s)** as provided in the Subject of Report dialog box. Multiple trade names are also displayed together, separated by commas.
	You can choose whether to view this field or not. Check the checkbox displayed with this field to hide or view it.
International Birth Date	Automatically displays the earliest license awarded date, when a user selects an Ingredient and a Product.
	You can choose whether to view this field or not. Check the checkbox displayed with this field to hide or view it.

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Field	Description
Print all configuration criteria on separate cover page	Mark this box to print out the configuration of this report when the report is printed. This is only available when PDF option is selected during printing.
Print page numbers on reports	When checked, this option enables the user to print page numbers on a periodic report. This is the default for all report configurations. If this checkbox **is not checked**, the following occur. • The **Include Periodic Page Numbering on CIOMS reports** option on the PSUR Summary Tabulations CIOMS Reports section is grayed out and inactive. • The **Use Periodic Numbering on the reports** option in PSUR Summary Tabulations FDA PSUR section is grayed out and inactive. • The **Additional Separate Page Numbering for UD Summaries** in the PSUR UD Summaries tab is grayed out and inactive. • The system removes all existing report page numbering and the option to check page number checkboxes on the report configuration tabs are grayed out and inactive.
Allow access to report cases through Hit List	When the report is run as final, it creates a Hit List, which can be retrieved from other areas of the application where advanced conditions can be selected. Click this checkbox to report cases through the Hit List.

Select products to include in ICH PSUR

Field	Description
Available Ingredients	Displays the list containing the Ingredients used for the product configuration. Select an ingredient from the list displayed in **Available Ingredients** and click **Add/Remove** to add or remove the ingredient. You can select multiple ingredients at a time.
Indication	This list contains the Indication configured for the product containing the ingredients in the **Available Ingredients** section. The selections made from this list get displayed in the **Available Products** section. You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Formulation	This list contains the Formulation configured for the product containing the ingredients in the **Available Ingredients** section. The selections made from this list get displayed in the **Selected Products** section. You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Available Products	This list is automatically populated with the selections made in the **Indication** section.
Selected Products	This list contains products selected by the user from the **Available Products** list. When a product is selected, the **Trade Name** field and International Birth Date fields are auto-populated with the license trade name (*formulation*, *concentration*) and earliest License Award Date for the product.

Select inclusion criteria

The Inclusion Criteria tab allows you to select search parameters for inclusion of cases in a periodic report. The top section of the dialog box allows you to specify the type of cases that are to be included in the periodic report.

Inclusion criteria of the reports considers listedness of all blinded products configured in the study and present in the case while still being in the blinded state. Such blinded products are included in the periodic report when event-level listedness is considered.

Click **Add** to add a criterion. Select appropriate items from the list of items that appear.

Field	Description
Use Assessments in Cases	When selected, the PSUR Report will use the Case Event Assessment when performing datasheet listedness calculations.
Re-assess cases against datasheet in effect at the beginning	When selected, the PSUR will re-assess the cases in the line listing based on the Active Datasheet on or before the Start Date of the Reporting period.
Re-assess cases against datasheet in effect at end	When selected, the PSUR will re-assess the case in the line listing based on the Active Datasheets on or closest to the end date of the PSUR Reporting end date range without exceeding that date.
Expeditable Only	This checkbox is available only when an agency is selected in the Subject of Report tab. If you check this checkbox, only the cases classified as submitted expedited reports to the specified agency are used.
Exclude Follow-up Cases	Filters out follow-up Reports from the PSUR Line Listing Report.
Include Unlocked Cases	Allows you to include unlocked cases in the periodic report.
Advanced Condition	Allows you to specify an advanced condition that must be satisfied by each case that is included in the report. Ensure that the advanced condition or the advanced condition query set that is specified here does not contradict any other criteria specified in the dialog box.
Use Datasheet Assessment for UDF Tabulations	Allows you to select datasheet for a report to make UDF tabulations. If no datasheet is selected, the most conservative listedness is chosen. Namely, Unlisted followed by Listed.
Add Cases not included in previous reporting period	Allows you to add cases which were not included in the previous reporting period. You can enter the start date of the period in the Start Date field.
Dropdown list	Select the appropriate report type from the drop-down list.
Datasheet	This list allows you to specify which datasheet is to be checked to determine the listedness (listed or unlisted) of the case.
Serious/Non-Serious	If you select **Serious** and clear **Non-serious**, only cases having a **serious** event are included and vice-versa. If you select both **Serious** and **Non-Serious** the seriousness criteria is ignored.
Fatal/Non-Fatal	Select **Fatal** when at least one event has an event outcome of **Fatal**. If not, select **Non-Fatal**. If you select both **Fatal** and **Non-Fatal**, both types of cases are included.
Listed/Unlisted	Select Listed to view only Listedness values. If you select both **Listed** and **Unlisted**, all Listedness values (including Unknown) are included.
Related/Non-Related	Relatedness refers to the more conservative of reported or company causality. Select **Related** for any reportable causality type, and **Non-Related** for any non-reportable causality type.
HCP/Non-HCP	**HCP** refers to cases that identify a Health Care Professional in the **Reporter** section within the General tab of the Case Form.
Primary Reporter Only	This checkbox displays whether the Primary Reporter has been selected to determine the HCP status.

Include line listing

Field	Description
Include Line Listing	Allows you to select whether you want the Line Listing Data Elements printed with the PSUR Report.
	From the Available Data Elements, select **As determined listedness** to print listedness.
	For Blinded clinical trial cases, when the **Include datasheet/licenses for all the blinded study products** common profile switch is checked, then listedness is printed against the default study product.

Add data elements

- Select the checkbox displayed against each data element to add it to the report.
- The unavailable fields are printed on the report by default and cannot be changed.

View selected data elements

This section lists the selected elements and enables you to arrange the order in which these are to be printed.

Field	Description
MedDRA Hierarchy from Cases/Dictionary	Select cases to populate the data from the case data. Select **Dictionary** to populate the data from the MedDRA dictionary.
Print Only the Term (Preferred Term or Lower Level Term)	Prints only the event Preferred Term (PT) or event Lower Level Term (LLT) as per the selected radio button. Select the PT option to print only the preferred term and not the verbatim description.
Print Dose Text in place of regimen dose	Prints the dosage and frequency information from **Dose Description** field instead of **Regimen Dose**.
Indicate if case was expedited previously	This checkbox is selected if an agency has been selected in the Subject of Report tab. Cases for which an expedited report was previously submitted to the selected authority are marked with an asterisk and the date of submission appears in the line listing.
	Any case that has been previously expedited to a selected agency, is listed in the list of Agencies in the Subject of Reports tab.
English Language	Provides the option to print the descriptions in English.
Local Language	Allows a user to specify which local language for a multi-language field is to be printed - namely, the **Abbreviated Narrative** field.
Print event info (Serious, Un-listed, Related) as Column	Check this checkbox to print the **Seriousness**, **Listedness** and **Causality** under the **Event Verbatim** column.
	Events having listedness of 'Unknown' are considered **Unlisted**. If only diagnoses are assessed for event assessment, the events which are associated with a diagnosis but have been marked with **Diagnosis** as 'No' display **'-'** for both listedness and causality.
List cases only once, under the primary event	Select this option to view the details of cases in the **Main Line Listing** only once under the **Primary Event**.

Field	Description
List cases under all events, details under the primary event	Select this option to view the details of cases in the **Main Line Listing** only once under the **Primary Event**, while non-primary events are listed under their respective event hierarchy with a reference to the primary event body system. Therefore, use this option when grouping on **Main Line Listing** is by the Event Body System.
Print Product Indication for the Product selected in the Report	Enables you to print the product indication for the product selected in the report.

Group cases

Field	Description
Available Groupings	Allows a user to group cases together from the given list. Select the desired groupings from the list and click **Add** to move the grouping to the **Selected Groupings** list.
Selected Groupings	Lists the added groupings, and reports the groups in the order they were selected. Up to 5 grouping options can be selected from the **Available Groupings** list.
Available Sortings	Allows a user to sort cases together from the given list. Select the desired sortings from the list and click **Add** to move the sorting to the **Selected Sortings** list.
Selected Sortings	Allows a user to further sort cases without a total count for each sorted item. Up to 3 sorting options can be selected from the **Available Sortings** list. This list is populated with the Mandatory Line Listing entities plus any optional data elements chosen for this configuration.

Specify summary tabulations for line listing

The Summary Tabulations tab enables you to specify which summary tabulations/listings will appear along with the line listing. The system enables you to separate the cumulative summary by seriousness, relatedness, and listedness. If you choose this option, the system separates the product event detail into the following categories: Serious/Non-Serious, Related/Non-Related, and Unlisted/Listed events.

Field	Description
Include Index of Cases in PSUR	Create an index page of case numbers, for all cases included in the PSUR.

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Prepare content for periodic reports

Field	Description
Include Summary of Cases Missing Assessments	This option creates a sub-report of cases missing one of the following items: • Seriousness • Case Causality • Case Listedness • Case Outcome • Event Causality • Event Listedness Click this checkbox to create one or both of the following sub reports: **Cases Missing Assessments** - This sub-report displays cases that have been included in the PSUR line listing, but one or more of the following have not been assessed: • Case Seriousness • Case Causality • Case Listedness • Case Outcome • Event Causality • Event Listedness **Cases Not Included in Report** - This sub-report displays cases that have not been included in the PSUR line listing as a result of missing one or more of the following items: • Lock Status • Safety Date • Uncoded Event • Causality
Include Line Listing Tabulation	Check this checkbox to view a pre-defined summary tabulation of Report type, Seriousness and Listedness of all cases in the PSUR.
Additional Expedited Report Forms (CIOMS/ MedWatch/VAERS)	Allows you to print CIOMS/MedWatch/AERS forms (as per selection) for its respective regulatory agency (as selection), for all cases in the report. It also provides an option to have (or not have) a watermark in the forms.

Include CIOMS reports

Field	Description
Print CIOMS reports for serious/unlisted cases	Allows a user to print CIOMS I forms for all Serious/Unlisted (Case Level) cases appearing in the PSUR. CIOMS contain Internal or Other text printed on them when the PSUR is printed using the Internal or Other option.
Include Periodic Numbering on the CIOMS reports	Numbers the requested CIOMS I with a periodic format. (Namely, A-1-1 of 2, A-1-2 of 2, A-2-1 of 1, A-3-1 of 1 etc.). The index is modified to also contain the Periodic paging of each CIOMS report.

Add PBRER Section 6.2 - Cumulative Summary Tabulations of SAEs from clinical trials

Field	Description
Include Section 6.2	Check this checkbox to include Section 6.2. By default, this is unchecked.

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Field	Description
Cumulative Start Date	Enter the cumulative start date in this field. This field specifies the Start Date of the Cumulative date range. If not specified, the start date is picked from the date specified in the Inclusion Criteria. If specified, the application ensures that the date entered is a valid date, and is before the Start Date specified in the Inclusion Criteria.
Identify Study Cases using Report Type	Allows you to select the study cases that use report type from the multi-select list box. The values that are populated here, come from the Report Type codelist where the values display the **This type includes cases from clinical trials** as checked.
Group by Comparator	If the Product Type attribute is present in the Study Configuration for the Product being evaluated, this option is displayed. By default, this is unchecked. If this checkbox is selected, it displays sub columns based on Active Comparator names if **Group by Comparator** is selected. If **Group by Comparator** is not selected, the count is displayed under the name of the respective active comparator.

PBRER 6.2 Output for the non-company or non-configured study cases is fetched based on the following:

- When the case being evaluated is a non-company or non-configured study case, the suspect company products are printed with the product type as Medicinal Product. The name of the medicinal product(s) is printed along with the counts:

  – If the case and the study are not blinded, and the product type is identified as **Investigational Product**.

  – If the case is unblinded (but the study is blinded), and the user has privilege to view the unblinded data.

  – If the study is blinded but the case is unblinded, and you do not have privilege to view the unblinded data, the count is printed under **Blinded**.

- Counts for Active Comparator and Placebo are not expected for a non-company study cases as the comparator or placebo information cannot be determined for the non-company studies.Non-company study cases that do not have any company suspect products are not included in the case series and cumulative tabulations.

- If counts for Blinded, Active Compactor and Placebo are Zero, these columns are still displayed in the report with zero counts as the value.

- The report also prints SOCs with zero counts if there are no events reported.

Add PBRER Section 6.3 - Cumulative and Interval Summary Tabulations from Post-Marketing Data Sources

Field	Description
Include Section 6.3	Check this checkbox to include Section 6.3. By default, this is unchecked.
Cumulative Start Date	Enter the cumulative start date in this field. This field users to specify the Start Date of the Cumulative date range. If not specified, the start date is picked from the date specified in the Inclusion Criteria. If specified, the application ensures that the date entered is a valid date, and is before the Start Date specified in the Inclusion Criteria.

Field	Description
Identify Spontaneous Cases using Report Type	Allows you to select the study cases that use report type from the multi-select list box. The values that are populated here, come from the Report Type codelist where the values display the **This type includes cases from clinical trials** as NOT checked. Only those values are included, where Display is set to Yes, in order to be consistent with the Report.
Identify Non-interventional Studies (UNION of rules below)	This is a mandatory field, comprising three new rules to identify Non-Interventional Studies: (Case Classification, Report Type, and Observe Study Type). These three new rules are displayed as checkboxes and have a section label called **Identify Non-interventional Studies (UNION of the rules below**). This field is mandatory, which means that at least one of the options must be selected if Include Section 6.3 is selected. Along with the three options, there is a multi-select list box for each that is populated with values from the respective codelist (given below) for the corresponding option that the user selected: • Case Classification is populated with values from **Case Classification** codelist. • Report Type is populated with values from **Report Type** codelist • Observe Study Type is populated with values from **Case Classification** codelist with ICSR code values that are not-null All values are included in this list, irrespective of the Display field for Case Classification and Observe Study Type codelists. Those values where Display for Report Type codelist is set to Yes, are also included. A **+** sign is displayed as a label, next to these options to indicate that it is a UNION of selections.

Add cumulative summary

Field	Description
Include Cumulative Summary	Select the checkbox to create a sub-report count of events, grouped by Product and Body System (SOC) and sorted by Preferred Term. The sub-report contains a previous date range count of events (comparative date range), a current date range count (current PSUR date range) and a cumulative count (all dates) of events assessed against the product(s) of the PSUR and matching the inclusion criteria.
Comparative Date Range	Allows a user to specify the previous date range as a comparison date for the events counted, and therefore should not overlap with the current date range specified on the PSUR inclusion criteria tab.

Add FDA PSUR support information

The FDA PSUR Support section can be used if the company has obtained an FDA waiver to submit a PSUR instead of an NDA report.

Field	Description
Include Adverse Event Summary	Select this option to generate a sub-report of events from the line listing. This sub report is grouped by Body System and Preferred Term.

Field	Description
Causality	Select the desired causality from the list.
	Ignore - Counts events regardless of causality assessment.
	Causal - Counts events where the causality is considered reportable in the Causality Category configuration in List Maintenance.
	Not Causal - Counts events where the causality is considered non-reportable in the Causality Category configuration in List Maintenance.
	As Determined - Counts events where 'As Determined' causality meets the above selected causality criteria.
	As Reported - Counts events where 'As Reported' causality meets the above selected causality criteria.
	Both - Counts events where both 'As Reported' and 'As Determined' causality meet the above causality criteria.
	Either - Counts events where either the 'As Reported' or 'As Determined' causality meets the causality criteria.
Only Cases with HCP Reporter	Check this checkbox to include events for only those cases that feature an HCP reporter.
Diagnosis	Select this option to ensure that only events marked as diagnosis are counted.
Diagnosis & Symptoms	Select this option to ensure that all events are counted in the sub-report.
Separate Diagnosis & Symptoms	Select this option to include diagnosis and symptoms separately in the sub-report. Selecting this option means that the case numbers are separated by Diagnosis and Symptoms respectively.
Domestic Consumer Support	Select this option to enable domestic consumer support.
Print Unsubmitted	This option allows a user to print MedWatch or VAERS forms for U.S. cases.
Exclude Reports that are Non-Serious and Listed	Allows a user to suppress MedWatch or VAERS forms from printing for Non-Serious listed cases where all events are non-serious and listed for the datasheet specified.
Use Periodic numbering on the Reports	Numbers the requested forms with a periodic format. (Namely, Periodic Page 1 - 1, Periodic Page 1 - 2, Periodic Page 2 - 1, Periodic Page 2 - 2, etc.) An index with the Case Number is also included.

Generate single case submission report

Use the following fields in the **Single Case Submission Support** section to generate the report.

Field	Description
Generate Periodic ICSR submissions for cases that do not have at least one ICSR report scheduled during the reporting period to any of the following Reporting Destination(s)	Check this checkbox to generate the ICSR Reports only for the cases, where a Periodic ICSR Report for the message type chosen, does not exist.
	Select one or more trading partners from the list box.
	Important: Any case that does not have an expedited or single case periodic submission to a trading partner, must have an ICSR report scheduled as a part of the Periodic submission.

Field	Description
Modify	Click **Modify** to select a different Reporting Destination.
Generate Periodic ICSR submissions to the following Reporting Destination	Select a single-destination trading partner for Periodic Reports from the drop-down list box.
Using the Message Type	Select the required message type from the drop-down list box

Select summary listing

The UD Summaries tab allows you to specify which summary listings will appear along with the line listing.

Field	Description
Include these summary tabulations/listings based on the set of cases presented in the line listing	Allows you to select from pre-configured summary tabulations/listings. These tabulations are based only on the data included in the line listing. Selecting the **Exclude Follow-up Cases** checkbox filters out follow-up cases from the attached report.
	If the Exclude Follow-up Cases option is selected on the Inclusion criteria tab, this option is ignored and follow-up cases are always filtered out.
Include these summary tabulations based on all cases	Allows for additional sub-reports based on the **Case Data Analysis** template, to be included as an output for the all cases in the database that meet the PSUR inclusion criterion for all dates.
Include these summary tabulations/listings based on the Date Range	This option allows for additional sub-reports based on Case Data Analysis, Case listing or CIOMS II line listing reports to be included as an output for the cases meeting the PSUR inclusion criterion for the Date Range specified when adding the sub-report.
	The dates are based on either the **Case Creation Date** or the **Initial Receipt Date** as entered on the PSUR Inclusion Criteria tab. Check the checkbox to the right of the sub-report to ignore considering follow-up cases for the sub-report.
Identify SUSAR and Special Interest Events	Enables you to identify any SUSAR and special interest events.
Additional Separate Page Numbering for UD Summaries (PDF only)	Enables you to include additional separate page numbering for summaries.

Schedule the report

See Schedule the report.

Setup frequency of the scheduled reports

See Setup frequency of the scheduled reports.

Configure security level of the report

See Configure security level of the report.

Use report templates

Refer to the *Oracle Argus Dossier User's Guide* for a description of fields in the Templates tab.

Prepare content for a US IND periodic report

The system enables you to define an IND summary report. You can add a new report as well as copy, modify and delete existing reports.

For more information, see:

- Create new IND report
- Enter common fields information
- Configure subject in the report header
- Select products to generate the report
- Select inclusion criteria
- Include line listing
- Specify summary tabulations for line listing
- Schedule the report
- Configure security level of the report

Create new IND report

1. Select **Reports**, then **Periodic Reports**, and click **IND** to open IND Subject of Report view.

2. Click **New Report**.

   OR

   Select an existing report from the list and click **Copy** or **Modify**.

3. When you click **New Report**, the IND Line Listing Reports dialog box opens.

4. Enter an appropriate name for the report under Report Name.

5. Use the tabs in this dialog box to configure the IND Report.

6. From each tab in the IND Summary Report, you can choose to Print all configuration criteria on separate cover pages (PDF Only).

Enter common fields information

See Enter common fields information.

Configure subject in the report header

The Subject of Report tab is used to configure the report header and to specify the agency, products, and other elements. Select multiple ingredients for a configured IND Report to view the multiple licenses to be selected for the report.

Field	Description
Primary Agency	Select the Primary Agency.
Available Reporting Destinations	Displays the list of configured Regulatory Agencies. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list.
	Select multiple agencies by holding the CTRL key when you click them.

Field	Description
Selected Reporting Destinations	Displays the list of agencies where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list.
	Select multiple agencies by holding the CTRL key when you click them.
	Likewise, select an agency from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.
Company Name	If a regulatory agency is selected in the Subject of Report tab, then the company name associated with the regulatory agency (this association is created by the Administrator) is automatically entered in this field.
Product Name	This field is automatically filled as per the **Ingredient** field.
	Check the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Approval	This field is automatically filled with License numbers, separated by commas. This is an editable field.
Award Date	This field is populated with the earliest awarded Investigational License for US amongst the licenses selected. This field cannot be edited.
	Check the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Print all configuration criteria on separate cover page	Click this checkbox to print out the configuration of this report when the report is printed. This is only available when the PDF option is selected during printing.
Print page numbers on reports	When checked, this option enables the user to print page numbers on a periodic report. This is the default for all report configurations.
	If this checkbox **is not checked**, the following occur.
	• The **Additional Separate Page Numbering for UD Summaries** option on the IND Summaries Tabulation tab is grayed out and inactive.
	• The system removes all existing report page numbering.
Allow access to report cases through Hit List	When the report is run as final, it creates a Hit List, which can be retrieved from other areas of the application where advanced conditions can be selected. Click this checkbox to report cases through the Hit List.

Select products to generate the report

Use the Product Selection tab to select product information to include in the report.

Field	Description
Available Ingredients	Displays the list containing the Ingredients used for the product configuration. Select an ingredient from the list displayed in **Available Ingredients** and click **Add/Remove** to add/remove the ingredient.
	You can select multiple ingredients at a time.
Filter	Enter an Ingredient name and click **Filter** to search for the entered ingredient within the Available list of Ingredients.
Selected Ingredients	Displays the list of ingredients selected from the **Available Ingredients** list.

Field	Description
Indication	This list contains a list of all the indications for the products containing the selected ingredient. The selections made from this list are displayed in the **Available Products** section.
	You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Formulation	This list contains the Formulations configured for the product containing the selected ingredient and indication. The selections made from this list get displayed in the **Selected Products** section.
	You can select multiple Formulations from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Available Licenses	This list is automatically populated with the licenses from the **Indication** section.
Selected Licenses	This list contains licenses selected by the user from the **Available Licenses** list. When a product is selected, the **Trade Name** and **International Birth Date** fields are auto-populated with the license trade name (*formulation*, *concentration*) and earliest License Award Date for the product.

Select inclusion criteria

The Inclusion Criteria tab allows you to select search parameters for inclusion of cases in a periodic report.

Field	Description
Case Creation Date	Allows you to specify a range of cases by the date when the case was created.
Case Receipt Date	Allows you to specify a range of cases by the initial receipt date.
Use Current Version	Allows you to use the latest revision to populate the data within the selected reports.
Use DLP Version	Allows you to use the case data of the version as of the specified DLP Version.
Age Groups	Allows you to include or exclude cases based on the patient's age group. Select the **Age Groups** checkbox to activate the age groups and select all the age group categories that apply.
Options - Domestic/ Foreign Cases	This option allows the user to include domestic and foreign cases within the periodic report. Select **Domestic** if **Country of Incidence** is USA and **Foreign** if **Country of Incidence** is not USA.
Expeditable Only	This checkbox is available only when an agency is selected in the Subject of Report tab. If you check this checkbox, only the cases classified as submitted expedited reports to the primary agency are used.
Include Unlocked Cases	Allows you to include unlocked cases in the periodic report.
Advanced Condition	Allows you to specify an advanced condition that must be satisfied by each case that is included in the report. Ensure that the advanced condition or the advanced condition query set that is specified here does not contradict any other criteria specified in the dialog box.

Include line listing

Field	Description
Report All Events	Select this option to report all events.

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Field	Description
Report only Diagnosis Events	Select this option to report only diagnosis events (only the diagnosis events that are either explicitly marked as diagnosis or are non-related symptoms).
List cases only once, under the primary event System Organ Class(SOC)	Select this option to view the details of cases in the Main Line Listing only once under the Primary Event.
List cases under all event System Organ Class (SOC)	Select this option to view the details of cases in the Main Line Listing only once under the Primary Event, while non-primary events are listed under their respective event hierarchy with a reference to the primary event body system. Therefore, use this option when grouping on Main Line Listing is by the Event Body System.
Create a Sub Report for Death Cases	Check this checkbox to separate death cases from the main IND listing. If the checkbox is checked, all death cases (Identified by any event marked as death in Seriousness Criteria or any event having an Event Outcome as Death) are filtered out from the IND Line Listing. All death case show up in a sub report, called **IND Line Listing (Death Cases)**.

Specify summary tabulations for line listing

The Summary Tabulations tab enables you to specify which summary tabulations will appear along with the line listing.

Field	Description
Include these summary tabulations/listings based on the set of cases presented in the line listing	Allows you to select from pre-configured summary tabulations/listings. These tabulations are based only on the data included in the line listing. Select the **Exclude Follow-up Cases** checkbox to filter out follow-up cases from the attached report. If the Exclude Follow-up Cases option is selected on the Inclusion criteria tab, this option is ignored and follow-up cases are always filtered out.
Include these summary tabulations based on all cases	Allows for additional sub-reports based on the **Case Data Analysis** template, to be included as an output for the all cases in the database that meet the IND Report inclusion criterion for all dates.
Add	Displays a list of memorized Case Data Analysis Reports that have been marked for availability in a periodic report.
Remove	Click this button to remove a selected report.
Additional Separate Page Numbering for UD Summaries	Enables you to include additional separate page numbering for summaries.
Include Summary of Unlocked Cases	Enables you to print the list of Case Numbers that are included in the Periodic Reports but are not locked.

Schedule the report

See Schedule the report.

Configure security level of the report

See Configure security level of the report.

Prepare content for an NDA periodic report

The NDA Periodic Reports enable you to define an NDA Periodic report. You can add a new report as well as copy, modify and delete existing reports.

- You can print an Index of Cases included in the NDA report.

- If you select this option, the system lists the cases from the following sections **once** at the end of the configuration pages:

  - Sequential List of cases

  - Serious Listed Initial/Follow up

  - Non Serious Listed Initial/Follow up

  - Non Serious Unlisted Initial/Follow up

  - 15 Day Submission

- The page numbering for this sub-report continues from the configuration pages.

- You can separate initial case events from follow-up case events in the Summary Tabulation tab of the NDA Report.

  - If you select this option, the system counts events in the Initial section if the case is in the Serious Listed, Non-Serious Listed, or Non-Serious Listed/Unlisted sections.

  - If you select this option, the system counts events in the Follow-up section if the case is in the Serious Listed or Non-Serious Listed/Unlisted follow-up sections of the NDA report.

  - For the **15 Day** events, if the case has not been previously reported in a NDA, the system counts it in the **Initial** section then the Follow-up section.

  - If you select List cases once under the Primary Event System Organ Class (SOC), the system displays a footnote with an asterisk (*) printed across all the System Organ Classes on the report and the following statement: `Primary Event System Organ Class.`

- If you select the **Print FDA-3500A/VAERS form at the end** option, the system prints the report sections in the following order:

  - Configuration (Including Case Indices (e.g. Sequential Case Listing, Listing by Seriousness/Listedness, Listing of Cases Missing Analysis)):

    * Line Listing

    * Summary Tabulations

    * MedWatch/VAERS reports at the end of the report

  - Page numbering for the MedWatch reports continue from the last page of the NDA report.

  - The configuration pages have been updated to reflect the updates made to the NDA Reports.

  - The configuration pages are printed at the beginning of the NDA report.

  - By default, these are unchecked on all the existing configured reports.

- Create NDA summary report

- Enter common fields information

- Configure subject in the report header

Prepare content for periodic reports

- Select products to generate the report
- Select inclusion criteria
- Include line listing
- Specify summary tabulations for line listing
- Schedule the report
- Configure security level of the report

Create NDA summary report

1. Go to **Reports**, then select **Periodic Reports**, and click **NDA Reports** to open the NDA Subject of Report view.

2. Click **New Report** to create an entirely new report,

   OR

   Select an existing report from the list and click **Copy** or **Modify**.

3. When you click **New Report**, the NDA Line Listing Reports dialog box opens.

4. Enter an appropriate report name in the Report Name field.

5. Use the tabs in this dialog box to configure the NDA Report.

6. From each tab in the NDA Report, you can choose to Print all configuration criteria on separate cover pages (PDF Only).

Enter common fields information

See Enter common fields information.

Configure subject in the report header

On the Subject of Report tab you can select multiple Ingredients for a configured NDA Report per allowable variations of product and license configuration and periodic reporting requirements for the FDA. Select multiple ingredients to view the multiple licenses to be selected for the report.

Field	Description
Available Reporting Destinations	Displays the list of configured Regulatory Agencies. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list.
	Select multiple agencies by holding the CTRL key when you click them.
Selected Reporting Destinations	Displays the list of agencies where the report is being sent. Select an agency from the list displayed in **Reporting Destination** and click **Add** to add the report to the **Selected Destination** list.
	Select multiple agencies by holding the CTRL key when you click them.
	Likewise, select an agency from the **Selected Destination** list and click **Remove** to prevent it from being sent to the selected destination.
Company Name	If a regulatory agency is selected, the company name associated with the regulatory agency (this association is created by the Administrator) is automatically entered in this field.

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Field	Description
Ingredient	This field is populated with ingredient selected in the Subject of Report tab. Check the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Approval	This field is automatically filled with License numbers, separated by commas. This is an editable field.
Trade Name	Automatically displays the Trade Name. Multiple trade names are also populated from license trade name (formulation, concentration) of selected licenses, separated by commas. Check the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Award Date	Automatically displays the earliest license awarded date, when a user selects an Ingredient and a Product. Check the checkbox corresponding to this field to choose whether you want this field to appear on the report.
Print all configuration criteria on separate cover page	Click this checkbox to print out the configuration of this report when the report is printed. This is only available when the PDF option is selected during printing.
Print page numbers on reports	When checked, this option enables the user to print page numbers on a periodic report. This is the default for all report configurations. If this checkbox **is not checked**, the following occur. • The **Use Periodic Numbering on the reports** option in the NDA Line Listing tab is grayed out and inactive. • The **Additional Separate Page Numbering for UD Summaries** in the NDA Summary Tabulations tab is grayed out and inactive. • The system removes all existing report page numbering and the option to check page number checkboxes on the report configuration tabs are grayed out and inactive.
Allow access to report cases through Hit List	When the report is run as final, it creates a Hit List, which can be retrieved from other areas of the application where advanced conditions can be selected. Click this checkbox to report cases through the Hit List.

Select products to generate the report

The Product Selection tab enables you to select product information to include on the report.

Field	Description
Available Ingredients	Displays the list containing the Ingredients used for the product configuration. Select an ingredient from the list displayed in **Available Ingredients** and click **Add/Remove** to add or remove the ingredient. You can select multiple ingredients at a time.
Filter	Enter an Ingredient name and click **Filter** to search for the entered ingredient within the Available list of Ingredients.
Selected Ingredients	Displays the list of ingredients selected from the **Available Ingredients** list.
Indication	This list contains a list of all the indications for the products containing the selected ingredient. The selections made from this list are displayed in the **Available Products** section. You can select multiple Indications from the list at a time by pressing the CTRL key and clicking the different Indication entities.

Field	Description
Formulation	This list contains the Formulations configured for the product containing the selected ingredient and indication. The selections made from this list get displayed in the **Selected Products** section. You can select multiple Formulations from the list at a time by pressing the CTRL key and clicking the different Indication entities.
Available Licenses	This list is automatically populated with the licenses from the **Indication** section.
Selected Licenses	This list contains licenses selected by the user from the **Available Licenses** list. When a product is selected, the **Trade Name** and **Award Date** fields are auto-populated with the license trade name (*formulation*, *concentration*) and earliest License Award Date for the product.

Select inclusion criteria

Field	Description
Case Creation Date	Allows you to specify a range of cases by the date when the case was created.
Case Receipt Date	Allows you to specify a range of cases by the initial receipt date.
Use Current Version	Allows you to use the latest revision to populate the data within the selected reports.
Use DLP Version	Allows you to use the case data of the version as of the specified DLP Version.
Age Groups	Allows you to include or exclude cases based on the patient's age group. Select the **Age Groups** checkbox to activate the age groups and select all the age group categories that apply.
Option (Applicable to Non-15-Day Selection Only)- Domestic/ Foreign Cases	This option allows the user to include domestic and foreign cases within the periodic report. Select Domestic if Country of Incidence is USA and Foreign if Country of Incidence is not USA.
Option (Applicable to Non-15-Day Selection Only)- Exclude Literature Cases/Study Cases	This option allows the user to exclude Literature and Study Cases from being considered for the NDA Report. Select **Exclude Literature Cases** to exclude literature cases and select **Exclude Study Cases** to exclude study cases.
Advanced Condition	Allows you to specify an advanced condition that must be satisfied by each case that is included in the report. Ensure that the advanced condition or the advanced condition query set that is specified here does not contradict any other criteria specified in the dialog box.
Add Cases not Included in a previous reporting period Start Date	Enter the start date. This adds cases not included in a previous reporting period with the specified start date.
Include Unlocked Cases	Allows you to include unlocked cases in the periodic report.
Evaluate Primary Suspect Drug Only	Allows you to select only the **Primary Suspect Drug**.

Include line listing

The NDA report comprises of three tabs. The options for these tabs can be configured in the Line Listing tab.

Field	Description
Tab 1: FDA - 3500/VAERS Forms	Check this checkbox to generate the MedWatch 3500A (Drug) or VAERS reports which are serious listed or non-serious.
Suppress printing of non-serious listed reports	Check this checkbox to prevent printing the non-serious listed reports but print their case numbers in the main NDA report indices.
	Tab 1 of the NDA Line Listing report cannot be generated without Tab 2. However, Tab 2 can be generated without Tab 1.
Tab 2: Index of Submitted Forms in Tab 1	Check this checkbox to generate an index of the forms from Tab 1. It prints all MedWatch/VAERS forms for the following cases:
	• Serious Listed
	• Non-Serious Unlisted
	• Non-Serious Listed
	Previously expedited 15-day reports that are Serious and Unlisted that have already been submitted to the FDA do not need to be re-submitted with this periodic report.
Tab 3 Part 1: NDA Line Listing of 15 Day Reports Submitted	Check this checkbox to generate a list of all serious unlisted expedited reports within the specified time period.
	The dates in these reports are in GMT.
TAB 3 Part 2: Tabulation by System Organ Class (SOC) of All Event Reports Submitted	Check this checkbox to generate a tabulation by System Organ Class (SOC) of all events reported during the specified time period. This includes the cases for which expedited reports were previously generated, as well as the cases that are submitted as part of the current report.
TAB 3 Part 3: Cases sent to FDA under another NDA	Check this checkbox to print a list of all the serious unlisted events for which reports were submitted to the FDA previously.

> **Note:**
>
> If you select to print out the Tab 3 Part 3 section, the NDA report looks for other submissions (E2B, MW, MW Drug, VAERS, eVAERS, eMDR) to the same agency for the same case against other (not included in selection criteria for this report) marketed licenses. Any submission matching this criterion is listed on the Tab 3 Part 3 section of the NDA report. If there are multiple submissions against different licenses, then each one is listed. Each license is listed only once.

Field	Description
Include Periodic Submissions	Check this checkbox to include all cases that have been sent under another NDA.
Start Page Number	Select the page number for the first page of the report.
Listing Options	These options for **List cases only once, under the primary event body system** and **List cases under all events body systems** only apply to the NDA Line Listing of Expedited Reports Submitted report.
List cases only once, under the primary event System Organ Class	Select this option to list cases only once.
List cases under all events System Organ Classes	Select this option to list cases under each SOC for each event.

Field	Description
Include Summary of Cases Missing Assessments	Check this checkbox to include a Summary of Cases missing Assessments at the end of the report.
Include Summary of Unlocked Cases	Select this option to include a summary of unlocked cases.
Include Listing of Nullified 15-day Alert Cases Submitted During the Reporting Period	Any case that was deleted which has submitted report within the reporting period after an expedited submission was made to the FDA (primary agency) for the license specified in the NDA Periodic report, regardless of the report form used, e.g., it could be MedWatch or Expedited E2B (E2Bs with MESSAGETYPE tag value configured as **Expedited** in Message Type Code List) or eVAERS.
Use Periodic numbering on the Reports	Select this option to use periodic numbering on reports.
Custom Case Summary Tabulation	Enter the Summary Report Title.
Advanced Condition	Select the Advanced Condition from the drop-down list.

Specify summary tabulations for line listing

The Summary Tabulations tab allows you to specify which summary tabulations will appear along with the line listing.

Field	Description
Include these summary tabulations/listings based on the set of cases presented in the line listing	Allows you to select from pre-configured summary tabulations/listings. These tabulations are based only on the data included in the line listing. Select the **Exclude Follow-up Cases** checkbox to filter out follow-up cases from the attached report.

> **Note:**
>
> If the Exclude Follow-up Cases option is selected on the Inclusion criteria tab, this option is ignored and follow-up cases are always filtered out.

Field	Description
Include these summary tabulations based on all cases	Allows for additional sub-reports based on the **Case Data Analysis** template, to be included as an output for the all cases in the database that meet the NDA Report inclusion criterion for all dates.
Add	Displays a list of memorized Case Data Analysis Reports that have been marked for availability in a periodic report.
Remove	Click this button to remove a selected report.
Additional Separate Page Numbering for UD Summaries	Enables you to include additional separate page numbering for summaries.
Case Count Summary Report	Enables you to print the list of Case Numbers that are included in the Periodic Reports but are not locked.

Schedule the report

See Schedule the report.

Configure security level of the report

See Configure security level of the report.

View scheduled periodic report information

In this section:

- Available user options
- View report details
- View report schedule details
- View report routing history

Available user options

Common features on the Period Reports page. Click the icon associated with each report to view the following options:

Option	Description
Description	Displays the report name. Click this to open the selected report in PDF format.
Status	Opens the Report Details dialog box for the selected report.
Print List	Allows the user to print the current Periodic Reporting for referencing the current view of the Periodic Reporting.
View Report	Opens the Individual Periodic Report selected by the user.
Report Details	Displays specific information about the report as entered in the Regulatory Reports section.
	The information displayed in the fields of the Report Details dialog box is fetched from the data entered in the Regulatory Reports section of Case Form.

View report details

The Report Details > General tab displays the general information about the report. The information on this tab cannot be modified.

Field	Description
Agency	Displays the **Reporting Destination** for which the report is scheduled.
Responsibility	Displays the **User Group** to which the report is assigned.
Case Nullification Date	Displays the date when the case was nullified.
Case Nullification Reason	Displays the reason entered when a case is logically deleted in Oracle Argus Safety.

View report schedule details

The Scheduling tab displays a reason for scheduling this report. It also shows the date on which the report was scheduled.

All fields in this tab are auto-populated as per records entered in Oracle Argus Safety.

View report routing history

The Routing tab displays the routing history of the report. To route the report, click **Route**.

Field	Description
Group	Displays the group of the report. This button is enabled when you click the **Route** button.
User	Displays the state of the report. This button is enabled when you click the **Route** button.
Comments	Displays routing comments entered before routing the report.

Submit a periodic report

In this section:

- Specify submission details
- Add comments
- Transmit a report
- View report generation status
- Create unscheduled periodic reports
- Approve and submit a report
- View submitted reports
- Use bulk report

Specify submission details

The Submission tab enables you to specify whether submission is required and enter a reason for not submitting the report.

Field	Description
Submission Required	Enables you to select if this report is not required to be submitted to the regulatory authority.
Reason for Non-Submission	Click **Select** to select the reason for non-submission.

Add comments

The Comment tab enables you to enter a local comment that prints out on that specific report when generated. Each report has its own Local Comment section.

Transmit a report

1. Click the icon associated with a report and select the Transmission tab from Report Details. The Report Details dialog box opens.

2. Click **OK** or **Cancel** to approve the transmission or discard any changes, respectively.

3. Click the **Transmit** button to transmit a report. The Transmit to Recipients dialog box is displayed.

4. Select the recipients of the report, as applicable from the **Available Recipients** list.

5. Select the method of transmission from **Method**, as applicable.

6. Enter remarks in Comments.

7. Click **Transmit**.

8. The selected report is transmitted to the specified recipients.

View report generation status

The Report Generation Status tab is displayed for users who have been configured by the Oracle Argus Safety administrator in Argus Console, under `Access Management > Groups > Menu > Reports > Periodic Reports` and for users who have access to the System Library.

Field	Description
Run At Date	Displays the date and time when the report generation started.
	For English users, it is displayed in DD-MMM-YYYY HH:MM:SS (GMT offset) format.
	For Japanese users, it is displayed in YYYY/MM/DD 00:00 (GMT offset) format

Field	Description
Status	Displays the current status of report generation in the form of hyperlinks, with the options listed below: • Executing • Error • Pending • Generated On clicking the Generated status, the Periodic Report is displayed. On selecting any status other than Generated, the Background Periodic Report Execution Status dialog box is displayed, as shown below: This dialog box displays the different stages of Periodic Report status. A grey tick mark is denotes Pending state, a Green tick mark denotes Completed State, and a Red cross mark denotes an Error.
Context Menu > View Report	This option is displayed in the context menu only when **PDF/CSV/DOCX Report Creation** is *Generated*. On clicking View Report, the selected report is displayed. Applicable only for Periodic reports.
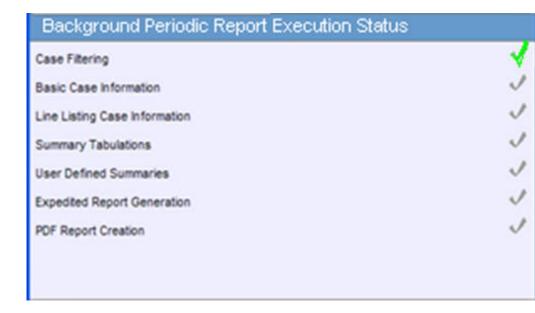
The Report Status screen displays the report outputs for the logged in user with the last report run as the first report. The reports can be filtered using:

• Report Name

• Draft/Final

• Report Type

• Scheduled By

• Scheduled On

• Run At Date

• Status

Create unscheduled periodic reports

1. Go to **Reports**, and select **Compliance**, then select **Periodic**, and click **Create Unscheduled Report**.

2. The system opens Periodic Reports dialog box that provides a list of configured reports of the following types:

   - PSUR - Containing ICH PSUR Line Listing Reports
   - IND - Containing US IND Periodic Reports
   - NDA - Containing US NDA Periodic Reports
   - CTPR - Containing CT Periodic Reports

3. Click the **(+) icon** against the desired category to view all the reports within that category.

4. Select the report you wish to create from this list and click **Select**.

5. When the system opens the Report Batch Printing dialog box, select **Run Now** or **Run at**, as appropriate.

   > **Note:**
   >
   > If you select **Run Now**, specify PDF, DOCX, or CSV from the drop-down list for the report output option to generate the PSUR or CTPR report in the selected format.
   > If you select **Run at**, specify the date/time to schedule the PSUR report to be generated by Argus Safety Service. This enables only **Final** and disables all other **Print As** options.

6. In the **Email** field, enter the email ID of the user to whom the periodic report should be emailed, once completed. By default, this field lists the email address (if configured) of the current user.

7. Select what you want printed on the report: **Final**, **Draft**, **Internal**, or enter Other information.

8. **Run Using** allows users to select between Argus Native Periodic report and BI Publisher.

9. **Report Form Type** allows users to select the Report Templates and these options are dependent on the value selected in **Run Using**. If **Run Using** is selected as Argus Native, the Report Form Type drop-down list displays PBRER and PSUR. The option selected from this drop-down list is used as Report Form Type for follow-up algorithm.

10. The options displayed in the Report Form Type are configurable through the flexible codelist Report Template.

11. Click **OK**.

12. The system generates the periodic report.

Approve and submit a report

Before you can mark a report as submitted, the report must first be approved.

1. Open the case for which the report has to be approved.

2. Open the Regulatory Reports tab in the Case Form.

3. When the system opens the Regulatory Reports details for the selected case, click the icon associated with the report you wish to approve.

4. Select View Report Details.

> **Note:**
>
> The Case Nullification Date is the date when the case is deleted, the Case Nullification Reason is the comment entered when the case is logically deleted in Argus.

5. Select **Submitted** from the **State** list in the Routing tab and click **Route**.

6. When the system opens a dialog box, enter the required details and click **OK**.

7. The report is approved.

> **Note:**
>
> A user who has *Workflow Manager* rights can undo the submission of a report, if necessary.

View submitted reports

1. Go to **Reports**, then select **Compliance**, and click **Submitted Reports**.

2. When the system opens the Submitted Reports page, enter the appropriate search criteria and click **Search**. The system displays the Search Results.

Submitted reports—fields and field descriptions

Field	Description
Case ID	Enter the specific case number.
	Tip: Use wild cards such as `2007%` to search for cases starting with 2007.
Include these Reports	Select the required report type or case status to be displayed.
Product	Select the product as required. The reports scheduled for these products will be displayed.

Use bulk report

Bulk Reporting enables you to print, transmit or submit reports in bulk. Go to **Reports**, and then select **Bulk Reporting** to view the Bulk Report screen.

The system displays the screen.

For more information, see:

- Filter bulk reports
- View bulk report filter results
- Print reports in bulk

- Sort cases
- Lock state icon options

Filter bulk reports

The Bulk Reporting Filter section enables you to filter reports.

Field	Description
Destination	1. To filter reports by agency, select an Agency. The agencies that have reports in the Scheduled, Approved and Generated states are displayed. 2. Click **Filter** to select multiple agencies from the Reporting Destinations dialog box. The previous filtering criteria is saved and retained when the user invokes this dialog box. By default, all agencies are displayed.
Report Status	From the drop-down list, select one of the options: • Generated Only—Displays the reports that have been generated (Generated, Approved, Disapproved and New Data Available states) • Scheduled/Generated—Retains the existing behavior as it does today when this value is selected • Pending • Failed • Printed/Transmitted Note that to display Generated Only or both Scheduled and Generated reports, configure the common profile switch **Allows Bulk Reporting screen to show Generated Reports Only** as follows: • For Generated Only reports, set the profile switch as **Bulk Reporting will allow filtering on generated reports only**. • For Scheduled/Generated reports, set the profile switch as **Bulk Reporting will allow filtering on both scheduled and generated reports**.
Report Status	Choose either Scheduled/Generated, Pending, Failed, or Printed/Transmitted from the drop-down list.
Print Regulatory Report	Prints the report as Draft or Final. The Draft option is disabled when the printing option is set to **Transmit**. Select **Medical Summary** to view the list of only medical summaries of distinct cases in a PDF.
Approved Reports Only	Filters reports for only approved reports.
View All	Displays the bulk reports applicable to your filter selections.
Product Family	Enter a Product family to view all cases where the scheduled reports belong to the searched Product family.
Study ID	Filters reports on the basis of the Study ID.
Product Group	Filters reports on the basis of the Product Group. If a value is selected in the Product Group filter, the **Product Family** drop-down list's values automatically narrow down to the product families which belong to the selected Product Group filter.
Specific Case #	To search a case, enter the Case Number, and click **Retrieve**.

View bulk report filter results

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

Field	Description
Suspect Product	Displays the Trade Name for which the report has been scheduled. If more than one Suspect Company Product exists for the case, an (+) is placed at the end of the product name. For Reports which were scheduled for the Device, the Device name is displayed.
Diagnosis	Displays the Primary Event Diagnoses PT.
(Event Verbatim)	Displays the (Verbatim as reported) of the Primary Event.
S/U/R	• Displays the Case Level Assessments: – Serious (Y/N) – Unlisted (Y/N) – Causality (Y/N) • Unknown is treated as a "?" • The SUR link displays the Case Summary for the selected case.
F or LT	Fatal / Life Threatening • If any of the events in the case are Fatal (F) or Life Threatening (LT) is displayed. • If the case is both **F** and **LT**, only **F** is displayed. • If the case is neither **F** nor **LT**, only **No** is displayed.
7/15	Number of days for which the report is due: • 7—if the report is within 7 days • 15—if the report is due for more than 7 days
⬚	Indicates that the labeling was not assessed for the license for which the report was scheduled. When you click the icon, the Local Labeling screen opens. A license is considered assessed: • if it has been done through local labeling (marked as assessed); • if there is a justification associated with the listedness, i.e., the value was changed from **Unknown** to **Listed** or **Labeled**, or the datasheet computed value was modified by the user.
Blind Study Product	Transmits and prints study cases with blinded information.
Mark as Submitted	1. Select this option to mark reports as **Submitted** when the transmission or e-mail has been sent. A confirmation dialog box appears if this option is not selected. 2. Select **Yes** or **No**. This selection is remembered for the next time when you print a report.
Report Form	Displays the Description of the report. Click the Report form link to view the **DRAFT** Report as a PDF.
Destination	Displays the report destination (agency) for which the report is scheduled.
Downgrade	Allows the user to view if the report is downgrade. Displays **Yes** if the report is a downgrade report else **No**.
View All	Allows administrator and workflow manager to see all items in the system.

> 💡 **Tip:**
>
> The icon (displayed in the lock state) in the `Reports > Bulk Reporting` screen denotes a SUSAR (Suspected Unexpected Serious Adverse Reaction) case.

Print reports in bulk

Field	Description
Blind Study Product	Check this checkbox to print study cases with blinded information.
Mark as Submitted	Check this checkbox to mark reports as **Submitted** when the transmission/ email has been sent.
	A dialog box is displayed if this checkbox is not selected. This dialog box prompts you to confirm if the report is marked as submitted or not.
	Select **Yes** or **No**, as required. This selection is remembered for the next time when you print a report.
Print Medical Summary	Allows the user to print the Medical Summaries.
Print	Allows you to choose the printer for the selected report from the Select Site Printer dialog box.
	Select the **Site** and **Printer Name** where you wish to print the report and click **OK**.
Print List	Allows the user to print the current view of the Bulk Reporting.

Sort cases

To sort the cases based on the case status, click the **Lock State** header row.

- Lock State
- SUSAR
- Exp/Per

These options enable you to sort cases based on the case categorization.

> ⚡ **Tip:**
>
> The icon (displayed in the lock state) in the `Reports > Bulk Reporting` screen denotes a SUSAR (Suspected Unexpected Serious Adverse Reaction) case.

Lock state icon options

Click the **Lock State** icon to view the list of available options.

Field	Description
View Report	Displays the Draft report.
Report Details	Displays specific information about the report as entered in the Regulatory Reports section.
Case Summary	Displays the Case Summary dialog box.
Remove Report	Deletes the report from the case on being asked for a justification.
Mark for Non-Submission	Displays the Submission tab in the Report Details dialog box.
	Select **No** for **Mark for Non-Submission** and enter the reason for the non-submission.

Track your periodic report submission

In this section:

- Use submitted reports search results
- Reopen submitted reports
- About initial and follow-up cases in periodic reports
- View batch reports scheduled for generation

Use submitted reports search results

Field	Description
Time Frame (I/F-u)	Displays whether the report was initial or follow-up.
Product	Displays the first suspect product for the case on which the report is based (expedited reports).
License Type	Displays the license type of the report.
Primary Event	Displays the first event term for the case on which the report is based (expedited reports).
Reason for Scheduling	Displays the reason provided for scheduling the report.
Report Form	Displays the type of report scheduled (form) and initial/follow-up status (e.g. "Initial Report" or "Follow-up #3").
Submitted Date	Displays the report's submission date.
Case Del. Date	Displays the date when the case was deleted.
Blind Study Product	Enables you to mark the study product as blinded. When you manually schedule a report, the system enables you to check **Blind Product Study** on the Schedule New Expedited Report dialog box to blind the study products if they are in the case.
Print All Submitted Reports	Enables you to print all the submitted reports.

Reopen submitted reports

Cases that are archived while unsubmitting reports can be reopened from the Archived Case dialog box.

1. Enter the password and notes required in the Archived Case dialog box.
2. When the system opens the Report Unsubmit dialog box, enter the reason for unsubmitting the report and click **OK**.
3. The system unsubmits the report.

> 💡 **Tip:**
>
> The icon (displayed in the lock state column) in the `Reports > Compliance - Expedited` and `Reports > Compliance - Submitted` screens denotes a SUSAR case.

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About initial and follow-up cases in periodic reports

A case is categorized as follow-up only if it has been previously submitted to the same regulatory agency, report form type and configured product/licenses or study. Otherwise, it is considered initial.

View batch reports scheduled for generation

- To view this list of System, Expedited, and Periodic reports that scheduled for generation, from the **Utilities** drop-down menu, select **Batch Reports**.
- To delete a batch report, select the corresponding checkbox, and click **Delete**.

8

Work in a multi-tenant Oracle Argus environment

In this chapter:

Access your global worklist items

1. Enter the URL address for the Global Portal homepage in a browser window.

2. In the Application Access Portlet, select a tenant from the **Enterprise** drop-down list, and an Oracle Argus application to launch from the **Application** drop-down list.

3. Select the **Global Worklists** tab.

> ✎ **Note:**
>
> The data from Global Worklists is not exclusively Oracle Argus Safety data. In addition to Oracle Argus Safety, you can also access data from Oracle Argus Insight and Oracle Argus Affiliate for the selected tenant.

4. To view global worklist items based on user assignment, from the top right of the screen, select one of the following:

   - **Individual**—For worklist items assigned to you across the tenants you are authorized for.

   - **Group**—For worklist items assigned to any other member of your user group across tenants you are authorized for.

   - **All** — For worklist items across all user groups across tenants you are authorized for.

   > ✎ **Note:**
   >
   > This option is available only if you have the Workflow Manager right.

5. To further narrow the search results based on specific work item details, enter search criteria in the relevant fields in the grey area at the center of the page.

   > 💡 **Tip:**
   >
   > You can use predictive text to complete these fields.

6. Click the link for a case number.

FAQs

- [What is a tenant?](#)
- [What is multi-tenancy?](#)
- [Can I open both the Global Portal homepage and the Oracle Argus Safety application in my browser?](#)
- [Can I open the Oracle Argus Safety application a second time for the same or a different tenant?](#)
- [Can I open the Oracle Argus Safety application for different tenants?](#)
- [Can I launch different Oracle Argus applications in separate browser windows?](#)
- [Is there a Japanese version of the Global Portal homepage?](#)
- [Which actions can I perform from my global worklist?](#)
- [Can I perform actions on multiple cases from my global worklist?](#)
- [Can I open Oracle Argus Safety cases for multiple tenants from my global worklist?](#)
- [How can I close or exit from the Global Portal homepage?](#)

What is a tenant?

A tenant is a client to which a CRO assigned a logical section of the Oracle Argus Safety environment within multi-tenancy. Depending on business needs, tenants can use specific data configurations and access distinct Oracle Argus Safety modules. However, they cannot access data that belongs to other tenants. Each tenant has a unique identifier in multi-tenancy called **enterprise ID**.

What is multi-tenancy?

Multi-tenancy is an Oracle Argus Safety feature that can be enabled with Single Sign-On to allow CROs to share their environment between multiple independent clients called **tenants**. The environment is partitioned so that the tenants can access specific Oracle Argus Safety modules and use customized data configurations as needed.

In multi-tenant environments, authorized SSO users can review cases and case actions, and manage worklist items that they are responsible for across any number of tenants.

Can I open both the Global Portal homepage and the Oracle Argus Safety application in my browser?

Yes, you can open both sites by entering their URL addresses in different tabs in your browser.

Can I open the Oracle Argus Safety application a second time for the same or a different tenant?

Yes, you can open Oracle Argus Safety a second time for the same or a different tenant. However, the application will open in the same browser window in which the application is already open.

Can I open the Oracle Argus Safety application for different tenants?

Yes, you can open the Oracle Argus Safety application for different tenants, provided you close the Oracle Argus Safety application for the existing tenant before you open it for a new one.

Can I launch different Oracle Argus applications in separate browser windows?

Yes, you can launch different Oracle Argus applications in separate browser windows. However, if you attempt to open the same Oracle Argus application for the same or a different tenant, the application will open in the same browser window in which the application is already opened.

Is there a Japanese version of the Global Portal homepage?

The Japanese version of the Global Portal homepage and related screens is not supported yet. However, the features and functionalities that are specific to Oracle Argus Safety Japan and Argus J users apply also to multi-tenancy environments.

Which actions can I perform from my global worklist?

Depending on your role and access rights, you can use your global worklist to:

- Search for a case. Perform case actions on a case, for example:
  - Open as Read-only
  - Accept Case
  - Adjust Priority
  - Adjust Assignment
  - Adjust Case Owner
  - Close Case
  - Perform Coding Review or Medical Review
  - View a Case Summary
- Manage your worklist items, for example:
  - Close Action Item
  - Print Worklist
  - Generate Letter

Can I perform actions on multiple cases from my global worklist?

Global Worklist pages do not support simultaneous actions on multiple cases, such as Close Multiple Cases, Route Multiple Cases, Print Multiple Cases, and Assign Multiple Cases. These options are only available on the Oracle Argus Safety Worklist Open page. If you use the **Route multiple cases** option in `Case Action > Open and Worklist > New/Open,` then the cases would not get locked even if the workflow rule is configured for locking the case on route.

Can I open Oracle Argus Safety cases for multiple tenants from my global worklist?

No. If you have an open Oracle Argus Safety case for a tenant, you must save and close the case before you open a case for another tenant.

How can I close or exit from the Global Portal homepage?

To close or exit from the Global Portal homepage (GHP), use the **X** button from the top-right corner of the screen.

What If

- There are no items in my global worklist
- I can't see cases for a tenant even though I used its Enterprise ID as search criteria for my global worklist
- The results list from my global worklist includes case data items that are not referred to by worklist menu actions
- A case data item appears in my Oracle Argus Safety worklist, but does not appear in the results list from my global worklist

There are no items in my global worklist

If no work items appear in your global worklist, then you are not authorized for any tenant.

I can't see cases for a tenant even though I used its Enterprise ID as search criteria for my global worklist

The results list from your global worklist shows cases only for tenants you are authorized for.

The results list from my global worklist includes case data items that are not referred to by worklist menu actions

The fields and columns from your global worklist results list are configurable by Administrators. If the respective field or column is not relevant for your work actions from your global worklist, contact your Administrator to configure it as hidden.

A case data item appears in my Oracle Argus Safety worklist, but does not appear in the results list from my global worklist

The respective case data item may be configured as hidden in your global worklist. Contact your Administrator to change the setting for the item to visible.

9

Argus Unblinding Advanced

End-of-Study Unblinding (EOSU) is the process in which a blinded study is unblinded after the study ends and investigators and/or participants are informed which treatment the participant is receiving. When the study is unblinded in the clinical system, the safety cases for same must be unblinded in Argus Safety. This activity is usually performed in bulk for all the cases belonging to the study.

Oracle Argus supports the functionality of End-of-Study Unblinding via Argus Safety user interface, which can be accessed from `Argus > Utilities > Argus Unblinding > Unblinding Advanced`. This interface is available only if you belong to a user group with menu access to Argus Unblinding.

Unblinding Advanced allows you to create, maintain, execute, and track End-of- Study Unblinding profiles and status. It also enables you to generate a Study Case Report for a profile/study ID, which details the cases present in Argus Safety for that study.

> ✎ **Note:**
>
> The profiles available in the Argus Unblinding Client Server module are also reflected in the Unblinding Advanced screen.
> Oracle recommends to use Unblinding Advanced for new profile creation and execution.

> ⚠ **WARNING:**
>
> The Argus Unblinding Client Server module will be deprecated in the future release.

For more information, see:

- Unblinding Advanced - Options
- Configure an unblinding profile
- Execute an unblinding profile
- View Argus Unblinding log

Unblinding Advanced - Options

Field Name	Description
New Profile	Launches the EOSU Profile page where you can configure a new EOSU profile and save.

Field Name	Description
View/Modify Profile	Launches the selected EOSU Profile page with all the existing saved data. You can update this data, if required. If the status of the unblinding process is In Progress, then the profile page opens as read-only with the options to download template, logs, and loading report. Use this screen to execute the profile to initiate unblinding of the cases.
Delete	Enables you to delete a profile. You cannot delete a profile, if the profile has completed execution in the Update mode and has unblinded cases . This button is disabled when the profile execution is in progress.
Study Case Report	This button is enabled when an existing profile is selected and generates a report on the cases belonging to the Study ID for that profile. You can generate a report even during execution of a profile. The study case report generates a report in .TXT format containing all of the non-deleted cases belonging to the specified study ID in the profile. The report displays a list of cases divided into the following sections: • Locked or Closed Blinded Suspected cases • Not Locked and Not Closed Blinded Suspected cases • Locked or Closed Blinded Not-Suspected cases • Not Locked or Not Closed Blinded Not-Suspected cases • Locked or Closed Cases Un-blinded (during study) cases • Not Locked or Not Closed Cases Un-blinded (during study) cases • Suspected Cases which were Un-blinded following the study end • Non-Suspected Cases that were Un-blinded following the study end • Pending Report Submission Blinded Suspected cases • Pending Report Submission Blinded Not-Suspected cases • Pending Report Submission Un-blinded (during trial) cases • Suspected Cases Unblinded AT END OF Specified Trial and need manual local data entry and local Lock • Not Suspected Cases Unblinded AT END OF Specified Trial and need manual local data entry and local Lock Note: The sections mentioned above as Closed implies that the case is archived.
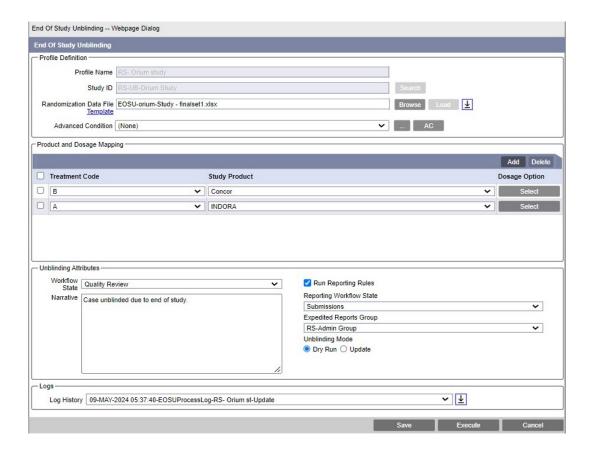
Field Name	Description
Print List	Prints all the configured profile names along with details in the Unblinding Advanced screen.

Configure an unblinding profile

You can create a new unblinding profile, view or modify an existing unblinding profile.

To create a new profile:

1. Go to `Argus > Utilities > Argus Unblinding > Unblinding Advanced`.

2. Click **New Profile**.

3. Enter the information in the following sections:

   - Profile Definition

   - Product and Dosage Mapping

   - Unblinding Attributes

   - Logs

4. Click **Save**.

Profile Definition

1. In **Profile Name**, enter a unique name for the profile.

2. To select a Study ID, click **Search** adjacent to this field.

   a. In the Study Search dialog, search by study ID or project ID.
      The result list for the search for study ID displays studies that are marked as **Eligible for unblinding** belonging to the same enterprise as your log-in.

   b. From the search result, select the Study ID.

   There can only be one profile for one Study ID. Same Study ID cannot be associated with different profile names.

   Once a profile has been saved at the first entry, the selected study ID and profile name cannot be changed.

3. In **Randomization Data File**, browse to a Patient Randomization data file (PRD) file, and click **Load**.

   > **Note:**
   >
   > Make sure you have obtained the complete set of PRD data from the external official source. Also, the PRD file must be an Excel file (.xls or .xlsx) in a fixed template (columns must contain data in the prescribed order and column names). (Optional) Click **Template** to download the randomization file template. The default name of this file is EOSU PRD Template. The certified file size if upto 2MB.

   The PRD file can contain multiple rows of patient data in the following order without altering the header names:

   a. Study ID

   b. Country

   c. Centre

   d. Patient Randomization Number

   e. Treatment Code

   f. Patient ID

   > **Note:**
   >
   > Leading zeros and spaces in the PRD file are trimmed by the Argus Unblinding system during validation.

   When loading is complete, the PRD loading report can be downloaded to view the valid and invalid rows with relevant messages. In case of discrepancies in the PRD file, relevant error message appears when you click Load.

   The profile is automatically saved on the first successful load, and the Load button is disabled. The Load button is enabled only when you select a new PRD file for loading, and overwrites the existing file.

   Without a successfully valid loaded randomization data, product mapping and execution of profile is not possible. If the loading report has all invalid rows, you will not be able to execute the profile.

Table 9-1   PRD file validation logic

Field name	Validation logic	Mandatory/Optional
Study ID	Match to data in LM_STUDIES. STUDY_NUM	Mandatory
Country	Match to data in LM_COUNTRIES. COUNTRY	Optional
Centre	Match to data in LM_CENTERS. CENTER_NO	Optional
PRN [Patient Randomization Number]	Match to data in CASE_PAT_INFO.PAT_SUBJ_NUM.	The PRD file must have either PRN or Patient ID.
Patient ID	Match to data in CASE_PAT_INFO.PAT_ID.	The PRD file must have either PRN or Patient ID.
Treatment Code	This value is mapped to study drugs in the unblinding profile. Maximum size allowed is 10 characters.	Mandatory

Advanced Condition (Optional)

Select a standard advanced condition to restrict cases that are executed for unblinding. You can select an existing advanced condition or create a new one and attach the same.

You can apply only those advanced condition for which you have permissions.

Product and Dosage Mapping

This section is enabled only when a PRD file is successfully loaded for this unblinding profile.

- **Treatment Code** - The data on this tab is arranged into records, the number of records being derived from PRD for every treatment code belonging to the study ID.

> **Note:**
>
> Treatment codes are provided by the clinical source data and need not be same as study names in Argus.

  One record per distinct treatment code from the PRD is displayed and must have a treatment code - product pair along with Dosage options.

  For example, if the randomization data contains two treatment codes DIASTUDY and DIASTUDY1, then this section allows you to define the study drug for those two treatment codes.

- **Study Product** - This drop-down contains a list of all blinded products (Drugs, Devices, Vaccines) defined for Study ID (all study names/arms) specified in the `Argus Console > Business Configuration > Study Definition (Blinded company and non-company Products)`.

- To map multiple products for the same treatment code to enable unblinding of comparator products, click **ADD** in the product mapping section. This creates a new blank record with first available treatment code as default.

- Select a treatment code from the **Treatment Code** drop-down that list all the valid treatment codes from PRD.

- Select the study product from the **Study Product** drop-down which is populated as described in the above point.

- Select **Dosage** for the newly added row after selection of the study product. The available options are:

  * Add to Existing Dosages - Allows you to define values for a set of dosage regimen fields. When the unblinding profile is executed, a record is created in the Dosage Regimen section of the case in addition to any existing dosage regimen records for the relevant study drug.

  * Replace All by Following Dosages - Allows you to define values for a set of dosage regimen fields. When the unblinding profile is executed, dosage records are created in the Dosage Regimen section of the case, and replaces any and all existing dosage regimen records for the relevant study drug.

  * Remove All Existing Dosages - The Dosage fields are disabled and cannot be edited. You cannot edit or add any new dosage information. When the unblinding profile is executed, all dosage regimen records belonging to the relevant drug are deleted.

  * No Changes to Dosages (default) - The Dosage fields are disabled and cannot be edited. You cannot edit or add any new dosage information. When the unblinding profile is executed, all dosage information in the Case Form is retained without any changes.

  If you update an existing Dosage option from **No Changes to Dosages** to any other option or add new dosage rows, the Select button changes to **Update**.

  Select the **Dosage Regimen** for the treatment code based on the dosage rules defined at treatment-study drug level. You may define one or more dosage for each treatment code-study drug in this section.

- Click **OK** to save changes.

Unblinding Attributes and Mode

- Narrative (Optional) - Enter a standard piece of narrative that is appended to the existing Case Narrative upon successful completion of the cases unblinding.
  By default, this field displays the text `Case unblinded due to end of study`. You can edit as per your requirement.

- Workflow State - Select a workflow state in which a case is placed when unblinding is successfully completed, and no expedited report has been scheduled by the unblinding procedure. By default, the state is Closed.

- Reporting - Check the **Run Reporting Rules** check box to run all reporting rules configured in Argus, and schedule reports against the cases that are unblinded by the unblinding process. By default, this check box is unchecked.
  When checked, the **Reporting workflow state** and **Expedited reports group** fields are enabled. These are mandatory fields for execution.

  Reporting workflow state lists all the available workflow states. This field takes precedence over **Workflow State** when the report is scheduled for the case.

  Expedited reports group lists all the available user groups. Select a group to which the report is assigned when scheduled.

- Unblinding Mode - Select a mode to execute the unblinding process. The availble modes are:

– Dry Run mode (default) - Acts as a preview of the unblinding execution after unblinding and closing of case is successfully completed. It produces the execution log files and exception log files without actually unblinding the cases and saving the changes to the database.

– Update Mode - Commits all the changes done during the unblinding processing to the database. The execution and exception logs are generated with details.

Execute an unblinding profile

This section describes the functional behavior of the Advanced Unblinding module.

1. Go to `Argus > Utilities > Argus Unblinding > Unblinding Advanced`.

2. Select a profile, click **View/Modify**, and then click **Execute**.
The application validates the following, before beginning the unblinding execution process.

   • User privileges - You must have the following privileges to execute an unblinding profile:

     – Allow unblinding of cases

     – Allow locking of cases

     – Allow closing of cases

     If you do not have any of these privileges, a relevant message appears.

   • Each product mapping must be unique. Each treatment must be mapped to a different study in the product mapping.

   • A study drug mapping for every treatment code is added.

   • Reporting workflow and Reports Group are provided, if **Run Reporting Rules** is checked.

   • If Dosage Options is selected as **Add to Existing Dosage** or **Replace all by following Dosage**, then dosage regimen values are provided.

3. When successfully validated, the execution process runs in the background through AG service with the following details:

   • Task Name: End Of Study Unblinding

   • Default User ID: oagsvc_end_of_study_unblinding_1

   • Multiple Instances Allowed: Yes

You can execute multiple different unblinding profiles at the same time by one or multiple users.

However, when the execution process starts for a profile, for all users, Configuration screen becomes un-editable and in the read-only mode until the unblinding process completes for that profile. Besides, you cannot cancel the execution process.

Criteria for a case to qualify for unblinding

A qualifying case must meet one of the following criteria:

• Case belongs to the specified clinical study ID (including archived cases).

• Case has not had the blind broken previously. That is, the Blinding Status field is not equal to **Broken by Sponsor** or **Broken by Investigator**.

• Case has not previously been successfully processed by the **End of Study Unblinding** program.

- Case satisfies the advanced condition, if specified.

- Case is not deleted.

> **Note:**
>
> The case status (whether it is open, closed, locked etc.) is irrelevant at the start of the process. Unlocked and open cases fail during the unblinding process.

Process the qualifying case

For each qualifying case the following processing is performed:

1. If the case is not locked or case is not closed (open by a user), then the case ID is added to the exception tables, with the failure reason `Case is unlocked (globally and/or locally) or open`.

2. If the case is currently closed, add the re-open information to record that the case has been re-opened by EOSU.

3. If the case is locked (both Global and Local), then add the unlock information to record that the case has been unlocked by EOSU.

Inspect the Patient Randomization tables

Inspect the Patient Randomization tables to map the patient for the current case with a specific study product based on the following algorithm:

1. Select the Country of Incidence, Study ID and Patient Randomization Number (or) Patient ID for the current case.

2. If any of the data is NULL for the case being processed, then write an exception `Case is missing Country or Study or Center or PRD#. Blind cannot be broken without these fields.` and move to the next case.

3. Attempt to find a matching record in the randomization data using the Country, Study ID, Centre Number and Randomization number (or) Patient ID obtained from the current case.

4. During the above matching against the randomization data, all records with either of the columns (Study, Country, Center, Randomization Number, and Treatment Code) as invalid are not considered for a match.

5. If duplicate entries in the randomization data are obtained for this combination, then log the message `Duplicate entries in Randomization Data (Study+Rand#/ Patient ID) are matching the Case Data.` in the exception report and move to the next case.

6. If a match is found, then read the study drug treatment code for that randomization record. This is based on the Treatment Code to Study Product mapping table. That is, an attempt is made to match the Study Drug of the current case with the relevant randomization record via the Treatment to Study Product mapping table.

7. If no record can be found, then write the case ID to the exception list, along with the failure reason, and move onto the next case.

8. If the study drug mapped to the treatment code does not belong to the study name/study arm the patient belongs to in Argus Safety case, then an error message appears in the exception log as `The Patient Exposure drug could not be located in LM_STUDIES.`

Dosage regimen

If the derived Study Drug is configured with dosage regime, then dosage regimen in case is marked as updated/added/no updates made based on the profile configuration settings. The case's Un-Blinding Status field is set to Broken After Study, Un-blinding date is set to System (Database) date and time, and set the Product Administered Drug for the Study Drug.

Unblinding of other drugs

Unblinding of Investigational, Comparator, Additional or Placebo Drugs also follow the same logic. Unblinding must be performed using the company product or WHO Drug products.

If any new expedited reports are scheduled, then set the Case Workflow State to the Reporting Workflow State and assign the report to the configured reporting group.

When Unblinding is complete

*   Event Assessment is recalculated after the case is unblinded.

*   If the case was locked at the start of the process, then re-lock it.

*   If the case was closed at the start of the process, and the case does not have regulatory report scheduling due, then re-close it.

*   If any expedited reports are scheduled, then lock the case, irrespective of the state of the case prior to processing.

*   Create a significant follow-up entry for the current case – giving the current date as the date of follow up and the central receipt date.

*   Save the changes to the case (i.e., commit the changes to the database; set the Last Saved Date to the current date and time; set the Last Update user to the value of the current Argus Safety username).

View Argus Unblinding log

Log files for the execution of the unblinding process are available in the profile screen as a list down for download. The latest log is available at the top.

Two log files are generated for every execution of a profile. One file for the unblinding process execution and other for the exception. Both Dry Run and Update modes produce Logs.

The log files are named as *Date time stamp-Type-12 characters of profile name- Mode*. The timestamp reflects GMT.

For example:

```
05 JAN 2024 06:51:30-EOSUProcessLog-Study14USA-Update
05 JAN 2024 06:51:30-ExceptionLog-Study14USA-Update
05 JAN 2024 06:50:30-EOSUProcessLog-Study14USA-DryRun
05 JAN 2024 06:50:30-ExceptionLog-Study14USA- DryRun
```

The execution log file has a header with all the details of the unblinding profile and selected parameters, randomization data summary, unblinding attributes, and unblinding procedure log case by case.

The exception log file has a header with all details of the unblinding profile and an exception report: list of cases with exception message