Oracle Argus Affiliate

User's Guide

Release 8.4.1
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Oracle Argus Affiliate User's Guide, Release 8.4.1

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Preface

This preface contains the following sections:

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.

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Product Overview

The Oracle Argus Affiliate Module enables users from a company's local affiliates to manage and track cases that are specific to their workflow. It is the complete and seamless solution that allows for case data from affiliates to be entered at the source, a complete case review, acceptance of the case into the central database, and determination if a case is reportable at the local level.

For more information, see:

- Oracle Argus Affiliate Process Overview
- User Types

Oracle Argus Affiliate Process Overview

The following table lists some of the main tasks that users perform when using Oracle Argus Affiliate.

Task	Description
Log on to Oracle Argus Affiliate	Log on to the Local Affiliate Module using a Local Oracle Argus Affiliate account.
Enter Local Event Information	Enter information about local events.
Route Events to Central	Send the events to Central Safety for review.
Log on to Oracle Argus Safety Web	Log on to Oracle Argus Safety Web as a regular Oracle Argus Safety user.
Review and Accept Local Events	View events sent by local affiliates around the world and accept these events.
Encode Events	Encode the events sent in by Local Affiliates.
Perform Local Labeling	Label events for cases that are pending labeling.
Submit Reports	Submit reports according to the requirements of local regulatory authorities.

User Types

The following two broad categories of Oracle Argus Affiliate users can exist:

- **Central Users** - These are users that belong to the Central Safety site of a pharmaceutical company.
- **Affiliate Users** - These are users that belong to other global sites of the company or its local affiliates. Oracle Argus Affiliate sites may fall under different regulatory reporting requirements compared to the Central Safety site and other affiliate sites.

For more information, see:

- Getting Started

Getting Started

For information about required fields and standard buttons used in Oracle Argus Affiliate, see:

- Required Fields
- Standard Buttons

Required Fields

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

Standard Buttons

The standard buttons used in Oracle Argus Safety are described in the table below:

Button	Purpose
Save	Use this button to save changes associated with an event.
Cancel	Use this button to cancel changes associated with a section.
Print	Use this button to print information associated with an event, in PDF format.
Add	Use this button to add an item associated with a section.
Delete	Use this button to delete an item associated with a section.
Copy	Use this button to create a new editable copy of an item within a section.
OK	Use this button to confirm an action associated with a section.
Yes	Use this button to confirm an action associated with a section.
No	Use this button to cancel an action associated with a section.
Help	Use this button to launch the online manual.

2

Oracle Argus Affiliate Users

This chapter describes the tasks that can be performed by the Oracle Argus Affiliate Users of Oracle Argus Affiliate.

> **Note:**
>
> To access the LAM user interface, users must first log on to Oracle Argus Affiliate using the user name and password that have been provided to them.

For more information, see:

- Logging on to Oracle Argus Safety Web
- Viewing the Worklist
- Creating Local Events
- Entering Event Information
- Routing Events to Central
- Opening Local Events
- Performing Local Labeling
- Submitting Reports
- Bulk Reporting
- Viewing Report Details
- Viewing Report Submission History
- Changing Your Password

Logging on to Oracle Argus Safety Web

1. Open Microsoft Internet Explorer.
2. Under **Address**, enter the URL for Oracle Argus Safety and press **ENTER**.
3. When the log-on screen opens, enter your Oracle Argus Safety user name, password, and select the required database from the list.
4. Click **Login**.

Viewing the Worklist

In the Oracle Argus Safety User Interface, select **Worklist** from the **Local Affiliate Menu** to access the different options available through this screen.

The following table lists and describes the different views:

View	Description
Pending Central Actions	Displays actions on local events that are pending at central
Not Routed	Displays local events that have not yet been routed to central
Cases Pending Local Labeling	Displays pending action items that have been assigned to the Local Affiliate Users.
Action Item from Local/Central	Displays pending action items from Local/Central Users.

For more information, see:

- Pending Central Actions
- Not Routed
- Cases Pending Local Labeling

Pending Central Actions

The following tables lists and describes the fields on the **Pending Central Actions** tab.

Field	Description
Local Event Number	Displays the local event number. The link displayed in this field helps you in viewing event information.
Central Case Number	Displays the central case number.
Local Affiliate Number	Displays the name of the local affiliate.
Actions/Routing Comments	Displays any actions or routing comments for the case.
Print List	Prints the list displayed in the screen in a PDF.

Not Routed

The following table lists and describes the fields in the **Not Routed** tab.

Field	Description
Local Event Number	Displays the local event number. The link displayed in this field helps you in viewing event information.
Primary Suspect Product	Displays the name of the primary suspect product.
Primary Event	Displays the name of the primary event.
Country of Incidence	Displays the country where the adverse event occurred.
Local Affiliate Name	Displays the name of the local affiliate.
Print List	Prints the list displayed in the screen in a PDF.

Cases Pending Local Labeling

The following table describes the fields on **Cases Pending Local Labeling** tab.

Field	Description
Local Event Number	Displays the local event number. The link displayed in this field helps you in viewing event information.
Primary Suspect Product	Displays the name of the primary suspect product.
Central Case Number	Displays the case number with Central.
Primary Event	Displays the name of the primary event.
Country of Incidence	Displays the country where the adverse event occurred.
Local Affiliate Name	Displays the name of the local affiliate.
Print List	Prints the list displayed in the screen in a PDF.

Creating Local Events

1. In the **Local Affiliate** menu, select **Create Local Event** to open the Local Event Entry form.

2. When the system opens the Local Event Entry Form, enter the appropriate information in the fields.

   The following table lists and describes the fields on the **Local Event Entry** form.

Item	Description
Product Name	Enter the name of the product which is associated with the case. If the adverse event(s) is associated with more than one product, each of the additional product can be added from the Case Form. It is advisable to enter the most suspect product here. You can click **Select** to search for a product from the *Trade Name Product Lookup* dialog. Several items will be automatically entered on the Case Form based on the product selected here. **a.** Click on **Select**. The Product Browser window appears. **b.** Enter the *Ingredient* key word for the search. The ingredient is displayed in the first column. **c.** Select the **Ingredient** to obtain the **Family** it is associated with. **d.** Select the **Product Name** to view the associated Trade Names. **e.** Select the **Trade Name** required. **f.** **Select** is now enabled at the bottom of the window. Click **Select** to add the product details
Report Type	From the list, select the item that best describes the type of report. The report type chosen here will determine which fields will be available for entering case information. The report type will also impact the duplicate search. For example, selecting "Sponsored Trial" will make the **Study ID** and **Protocol ID** fields available. The Administrator can adjust the information in this list.
Receipt Date	Enter the date on which your company became aware of the case.
Study Number & Center ID	The **Study Number** and **Center Id** fields are enabled when the Product details are filled in this section. Enter the ID for the Center. You can click **Select** to search for a study from the *Study Name Lookup* dialog. Several items will be automatically entered on the Case Form based on the product selected here. Steps to select the Center Id: **a.** Click **Select** to open the Clinical Trial Selection dialog. **b.** Select the **Project** from the drop-down list and enter the Study details as applicable. **c.** A list of centers associated with the row that you select appear at the bottom of the dialog. **d.** Highlight the required clinical study and study center and click **Select**.
Reporter First Name Reporter Last Name	Enter the reporter's first and last name.

Item	Description
Country of Incidence	Enter the country where the adverse event occurred. In Oracle Argus Safety application, you can either type the complete country name, or enter a two letter country code that will automatically be decoded. In Oracle Argus Safety Web, you can select the appropriate country from the list. **Note:** This may or may not be the reporter's or the patient's country of residence.
Patient Initials	Enter the patient's initials.
Patient Date of Birth	Enter the patient's date of birth.
Patient Gender	Enter the patient's gender.
Event Description	Enter a brief verbatim description that describes the event that is most clinically important in the case.
Onset Date	Enter the date for the onset of adverse event symptoms.
Keyword	Enter a keyword when searching for duplicates. Keywords are only used for searching for cases.
Receipt Range Limits	Select this check box to search for cases that have been entered in the range of 60 days before the current date and 60 days after the current date.

Tip:

You can click **Search** to determine if this case has been entered before. A list of cases that match the search criteria appears. Inspect the list and determine if any case matches the event information that is to be entered.

3. Click **Create Local Event** to create a new local event. The Local Event- Initial Event Entry screen appears.
4. Enter the available event information in the AE Entry and Local Info tabs.

Refer to Entering Event Information for further instructions.

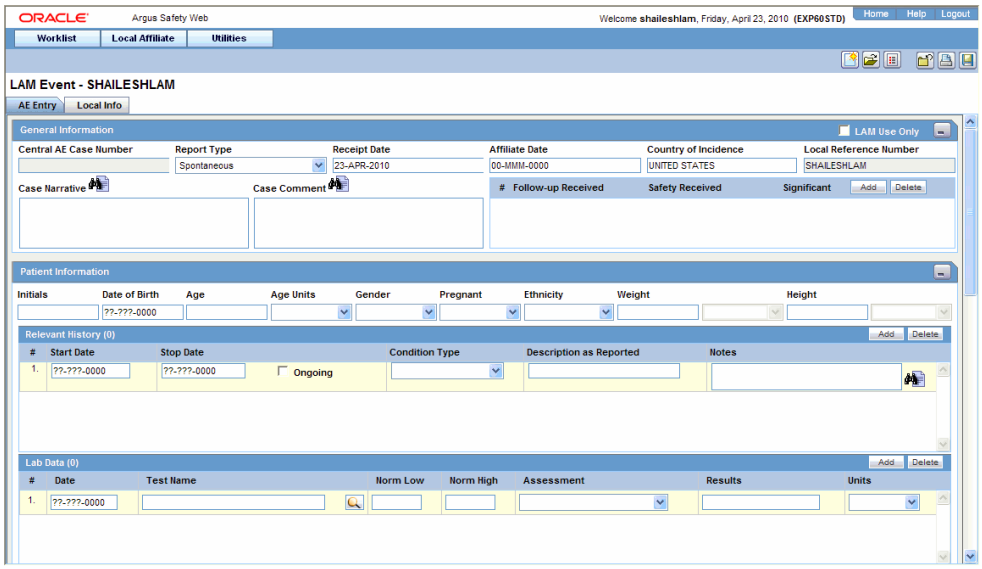
Entering Event Information

When entering event information in the **AE Entry** and **Local Info** tabs, be aware of the following:

- Click **Add** to add another row to the section.
- Click the **Zoom** icon to enter text or notes in a separate window. You can also check the spelling of the text in this separate window.

To enter text information:

1. Open the **AE Entry** tab.



2. Enter the available event information in each of the sections of the AE Entry tab as shown in the following tables.

General Section

Item	Description
LAM Use Only	Select this check box if this event is for local usage only and will not be routed to Central.
Central AE Case Number	The case number that is assigned to this event at Central will be entered here. No text can be entered in this field when initial event information is being entered.
Report Type	Select the type of report.
Receipt Date	Enter the Receipt Date. This date will be used at the Central end.
Affiliate Date	Enter the date received.
Country of Incidence	Select the country in which this event occurred.
Local Reference Number	The number by which the event is identified is entered here. This number will be automatically generated if the system has been configured to automatically number local events.
Case Narrative	Enables the user to enter a narrative description of the case.
Case Comment	Enables the user to enter relevant comments about the case.
Follow up Received	Enter the date on which follow up information was received at the local affiliate location.
Safety Received	Enter the date on which the follow-up information was received by the Central safety office.
Significant	Select this check box if significant follow-up information has been received.

Patient Information Section

Item	Description
Initials	Enter the initials of the patient.
Date of Birth	Enter the date of birth of the patient.
Age/Age Unit	Enter the patient's age and the age units used.
Gender	Enter the patient's sex.
Patient ID	Enter the patient's identification number. Note: This field is available only if the event is associated with a clinical trial or other study.
Study Number	Enter the study number. Note: This field is available only if the event is associated with a clinical trial or other study.

Other Relevant History Section

Item	Description
Start Date	Enter the start date of the condition. You can enter a partial date if the actual date is not available. You can also choose not to enter a date.
Stop Date	Enter the stop date of the condition. You can enter a partial date if the actual date is not available. You can also choose not to enter a date.
Ongoing	Indicates whether the condition is continuing. If it is set to Yes or Unknown, the Stop date is disabled.
Condition Type	Select a condition type from the list. The Administrator can adjust this list.
Description as Reported	Enter the verbatim term used by the reporter, or patient, to describe the adverse event or product name.
Notes	Enter any notes pertinent to relevant history.

Reporter Information Section

Item	Description
Address	The address of the institution.
City	The city where the institution is located.
Country	The Country where the institution is located.
Department	The name of the reporter's department
Email Address	The email address for the reporter.
FAX Number	The fax number for the reporter.
First Name	The first name of the reporter.
Health Authority Case Number	The Health Authority Case Number.
Health Care Professional	Indicates whether the reporter is a health care professional.
Institution	The name of the institution where the reporter is currently employed.
Intermediary	Identifies the intermediary for the case.
Last Name	The last name of the reporter.
Middle Name	The middle name of the reporter.

Item	Description
Occupation	Displays the occupation of the reporter.
Postal Code	The postal code where the institution is located.
Protect Confidentiality	Indicates that the reporter's identity is protected in expedited reports.
Dosage Regimen Dose Description	User this field to describe non-standard dosages that cannot be adequately described using the dose, route, and frequency fields. Note that the initial value for this field defaults to the dose, route, and frequency information and can be amended as appropriate.
Report Media	Displays the method used to report the case.
Reporter Type	Identifies the reporter type.
Sal.	Identifies the title of the reporter.
State	The state where the institution is located.
Suffix	Displays the reporter's suffix, if appropriate.

Event Information Section

Item	Description
Onset Date	Enter the date/time the event started. You can enter a partial date if the complete date is unavailable.
Stop Date	Enter the date/time the event stopped.
Event Description	Enter the verbatim term used by the reporter to describe the adverse event. As you type, the system automatically copies the term in to the Description to be Coded field.
Death	Click the appropriate box to select the Serious Criteria for the event.
Hospitalized	Click the appropriate box to select the Serious Criteria for the event.
Disability	Click the appropriate box to select the Serious Criteria for the event.
Other	Click the appropriate box to select the Serious Criteria for the event.
Other Text	Enter text to describe the other type of serious event.
Medically Significant	Click the appropriate box to select the Serious Criteria for the event.
Life Threatening	Click the appropriate box to select the Serious Criteria for the event.
Intervention Required	Click the appropriate box to select the Serious Criteria for the event.
Congenital Anomaly	Click the appropriate box to select the Serious Criteria for the event.
Symptoms	Enter the appropriate symptoms for the cases.
Outcome	Select the outcome of the event from the drop-down list (e.g., recovered, improved, fatal, etc.) The Administrator can adjust the information on this list. If Fatal is selected, Death is check in the list of seriousness criteria.

Item	Description
Duration	The system automatically calculates this field from the event start and stop dates. If duration is greater than five (5) days, the system only displays days. You can enter or modify the duration manually.
Diagnosis/Symptom	Click the appropriate radio button to indicate whether the event is a diagnosis. Clicking Yes marks this event as the primary event. In case of multiple diagnosis events, the event on the left is considered as the primary event. Click Relationships to display the Event-Relationships dialog. This enables you to group symptoms and signs with diagnoses.

3. Open the **Local Info** tab.
4. Enter the available case information in each of the sections of the Local Info tab as listed in the following tables.

Contact Log Section

Item	Description
Date	Enter the date associated with the letter.
Code	Enter the contact code associated with the letter.
Description	Enter the description associated with the letter.
User	Select the user to whom the letter is to be sent.
Date Sent	Enter the date on which the letter was sent.

Action Items Section

Item	Description
Date	Displays the date associated with the Action Item.
Code	Displays the code associated with the Action Item.
Description	Displays a description of the Action Item.
User	Displays the user to whom the Action Item is assigned.
Due Date	Displays the date on which the Action Item is due.
Date Completed	Displays the date on which the Action Item was completed.

Notes and Attachments Section

Item	Description
Attach Documentum Link	Displays the Documentum Lookup Dialog. Use this dialog to search for and select Documentum links.
Attach File	Click Attach File to add an attachment. Browse to the location of the file on your system.
Date	Enter the date associated with the note or attachment.
Classification	Select the type to which the attachment belongs.
Description	Enter the description of the attachment.
Item	Description

Item	Description
Keywords	Enter the keywords relevant to the attachment. To select a keyword from a list, click Select.
Select	Click Select to enter a new keyword or select a keyword from the list.

Routing Comments Section

Item	Description
Date	Displays the date on which the event information or follow-up information was routed to Central.
Route By	Displays the user who was responsible for the routing.
Comment	Displays the routing comments.

5. Add letters as necessary. Select **Save** in the **Local Affiliate** menu to save the case.

> **Note:**
>
> For follow-up information associated with an event, enter the follow-up information and then route the event to Central.

For more information, see:

- Adding a Letter

Adding a Letter

1. In the Contact Log section of the Local Info tab, click **Add**.
2. Click in the row to select it and click **New Letter**.
3. Select a letter template from the list and click **OK**.

   The letter will open in a separate Internet Explorer window.
4. If you make changes to the letter, save the letter on your system by selecting **Save As** in the File menu of Internet Explorer.
5. Close the Internet Explorer window.
6. In the Save Letter dialog, click **Yes** to save the modified letter or **No** to save the automatically generated letter without the changes you made.
   - If you click **No**, the letter will be inserted in the new contact log row.
   - If you click **Yes**, the Attach Letter for LAM dialog appears. Attach the letter that you saved on your system in step 4 by clicking Browse.
7. When a new letter is added, an action item corresponding to that letter is inserted in the Action Items section.

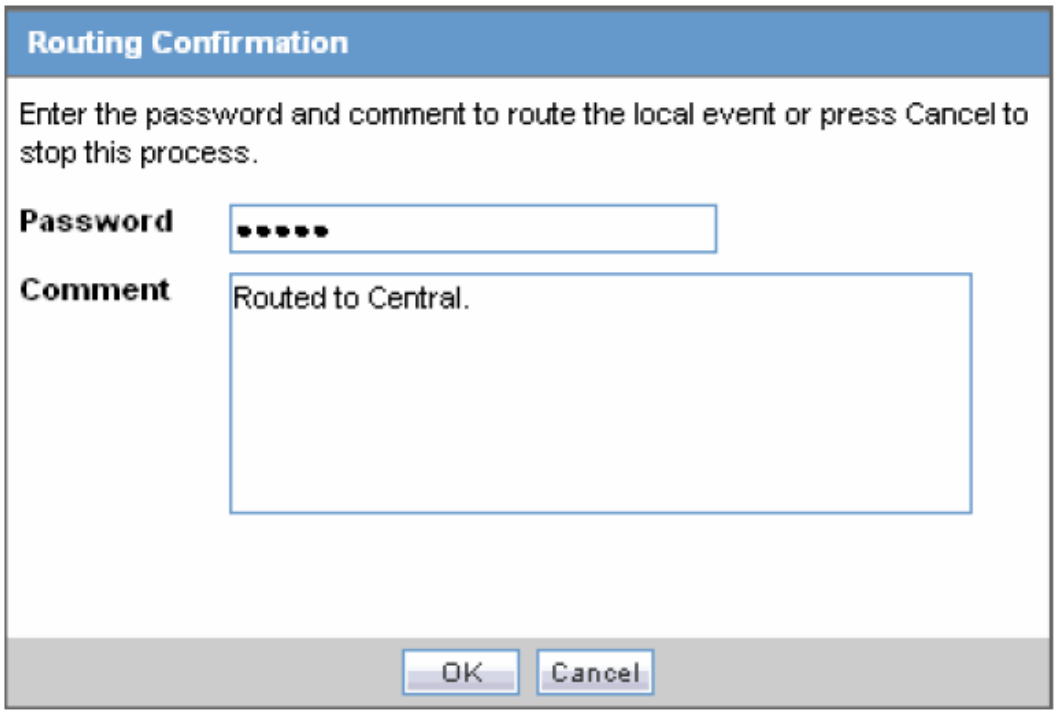
Routing Events to Central

When routing local events, be aware of the following:

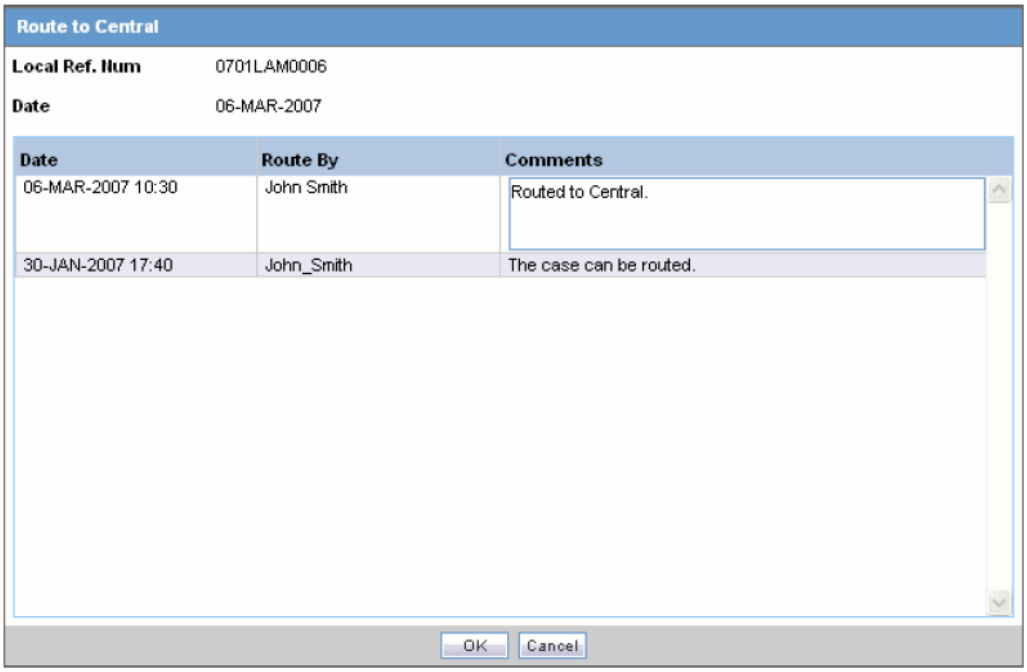
- The system disables the routing button after the event is routed and enables it again when Central accepts the event.
- You can route a local event for the first time even if there are multiple Oracle Argus Affiliate follow-up receipt dates entered.
- When you route a local event after the first time and all the Oracle Argus Affiliate Follow-up Receipt Dates are blank or grayed out (read-only), the system does not permit routing and presents a popup message.
- After successfully routing a local event, the system makes the following fields read-only:
  - Oracle Argus Affiliate Follow-up Receipt Dates
  - Oracle Argus Affiliate General Receipt Date
  - Oracle Argus Affiliate General Affiliate Date
  - Oracle Argus Affiliate Follow-up Safety Date
  - Significant Checkbox
- After successfully routing a local event, the system grays out all the existing follow-up date rows; you cannot delete the grayed out rows.

To route events to Central:

1. Open the event that is to be routed to Central.
2. The **AE Entry** tab opens when the event is opened.
3. Open the **Local Info** tab.
4. Scroll to the **Routing Comments** section and click **Route** to open the **Local Affiliate** dialog box.
5. Click **OK** to open the **Routing Confirmation** dialog box.



6. Enter your **Password** and **Comment** and click **OK**.
7. When the **Route to Central** dialog appears opens, click **OK**.



For more information, see:

- Searching for Local Events

Searching for Local Events

1. Select **Local Event Search** from the **Local Affiliate** menu to open Local Event Search form.
2. Under **Search for**, select the item by which the search is to be done.
3. Enter the relevant search text in the text box.

   For example: To search for local events by local tracking number, select **Local Tracking Number** in the list and then enter the tracking number which is to be searched.
4. Select the product family to which the event is related under **Product Family**.
5. Enter the text that describes the event under **Event**.
6. Select the date range in which the event was entered under **Date Range**.

> **Tip:**
>
> To specify your own date range, select **Custom Date Range**. Enter the dates in the Custom Date Range dialog and click **OK**.

7. Click **Search** to view the list of search results.

Opening Local Events

1. Select **Local Event Search** from the **Local Affiliate** menu to open the Local Event Search form.
2. Enter the search conditions to search for local events.
3. Find the required event in the search results.
4. Click the link associated with the **Local Tracking Number** of the required event to open it.

Performing Local Labeling

1. Select **Local Labeling** from the **Local Affiliate** menu to open the Local Labeling screen.
2. Select **Pending** to view cases that are waiting for labeling.

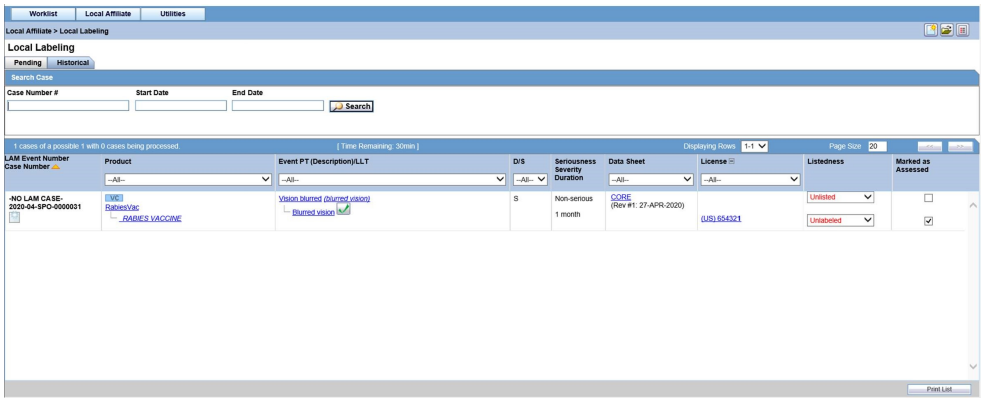
   Pending Tab Field Information

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

Field	Description
LAM Event Number	Displays the LAM event number. The link displayed in this field helps you in viewing event information.
Case Number	Displays the case number with Central.
Product	Displays the name of the primary suspect product.
Event PT (Description) / LLT	Displays the name of the primary event.
D/S	Displays if the event was diagnosis or symptom.
Seriousness	Displays all the seriousness criteria for the event.
Severity	Displays the severity for the event.
Duration	Displays the duration for the event.
Datasheet	Displays the datasheet(s) and its corresponding revision number and activation date that were used in assessment of the product and the event.
License	Displays the license(s) for the agent.
Listedness	Displays the listedness of the drug. Values may include Listed, Labeled, Unlisted, Unknown.

Field	Description
Marked as Assessed	Allows the user to mark whether local assessment is done against the licenses displayed for the product or not. It provided 3 methods to mark this status at 3 different levels. 1) Assessed checkbox at License Level: This checkbox allows users to specify the local assessment status at each license level. It shall be available in both Pending and Historical tabs. 2) Assessed checkbox at Database Level: This checkbox allows users to specify the local assessment status at each datasheet level. If user checks or un-checks this checkbox, it shall automatically update all the license level checkboxes under this datasheet accordingly. It shall be available in both Pending and Historical tabs. 3) "Assessed" button at Product Level: Clicking on this button shall mark all the licenses and datasheet level checkboxes as checked. It shall only be available on Pending tab.

3. Select **Historical** to view cases that have been assessed.



Historical Tab Field Information

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

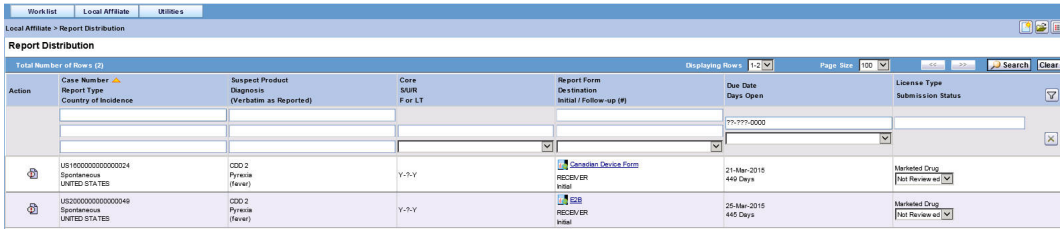
Field	Description
LAM Event Number	Displays the LAM event number. The link displayed in this field helps you in viewing event information.
Case Number	Displays the case number with Central.
Product	Displays the name of the primary suspect product.
Event PT (Description) / LLT	Displays the name of the primary event.
D/S	Displays if the event was diagnosis or symptom.
Seriousness	Displays all the seriousness criteria for the event.
Severity	Displays the severity for the event.
Duration	Displays the duration for the event.

Field	Description
Datasheet	Displays the datasheet(s) and its corresponding revision number and activation date that were used in assessment of the product and the event.
License	Displays the license(s) for the agent.
Listedness	Displays the listedness of the drug. Values may include Listed, Labeled, Unlisted, Unknown.
Marked as Assessed	Allows the user to mark whether local assessment is done against the licenses displayed for the product or not. It provided 3 methods to mark this status at 3 different levels. 1) Assessed checkbox at License Level: This checkbox allows users to specify the local assessment status at each license level. It shall be available in both Pending and Historical tabs. 2) Assessed checkbox at Database Level: This checkbox allows users to specify the local assessment status at each datasheet level. If user checks or un-checks this checkbox, it shall automatically update all the license level checkboxes under this datasheet accordingly. It shall be available in both Pending and Historical tabs. 3) "Assessed" button at Product Level: Clicking on this button shall mark all the licenses and datasheet level checkboxes as checked. It shall only be available on Pending tab.

4. Enter the **Case Number**, if it is known.
5. Click **Search** to view the list of events, grouped by the Local Event Number.
6. Under **Local Labeling**, select the appropriate labeling for each product associated with the event.
7. Select the **Assessed** checkbox for the labeled case and click **Mark as Assessed** to mark the selected case for a Preferred Term. The system enables the **Process** button.
8. Click **Process** to save the labeling changes.
9. The selected report is displayed in a PDF.

Submitting Reports

1. Select **Report Distribution** from the **Local Affiliate** menu to open the Report Distribution page.

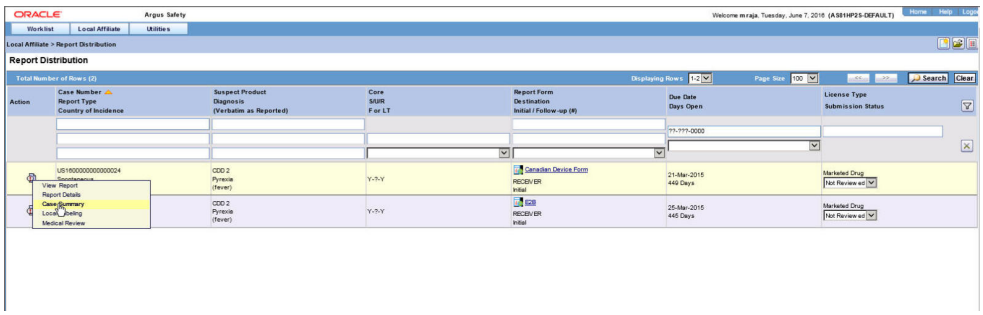


Report Distribution Fields

The following table lists and describes the fields on the **Report Distribution** page.

Field	Description
Action	Enables you to view and select the different options available as action items.
Case Number	Enables you to search for a case based on its case number.
Report Type	Displays the type of report.
Country of Incidence	Displays the name of the country where the adverse event occurred.
Suspect Product	Displays the name of the suspect product.
Diagnosis (Verbatim as reported)	Displays the diagnosis made for the event.
Core	Displays the core labeling made for the event.
S/U/R	Displays whether the case is serious unrelated or related.
F or LT	Displays if the event is Fatal or Life-Threatening.
Report Form	Displays the name of the report in a link. Click the link to view the report in a PDF.
Destination	Displays the destination name.
Initial/Follow-up (#)	Displays if the report is an initial report or a follow-up report.
Date Due	Displays the date when the report is due.
Days Open	Displays the days since when the report has been open.
License Type	Displays the license type of the report.
Submission Status	Displays the submission status for the report.

2. Use the standard filters provided for Case Number, Report Type, Country of Incidence, Suspect Product, Diagnosis, and so on to filter to locate the required report.
3. Locate the report to be submitted and click the icon associated with the report in order to view the available options.



Descriptions of the Action Items

The following table lists and describes the available action items.

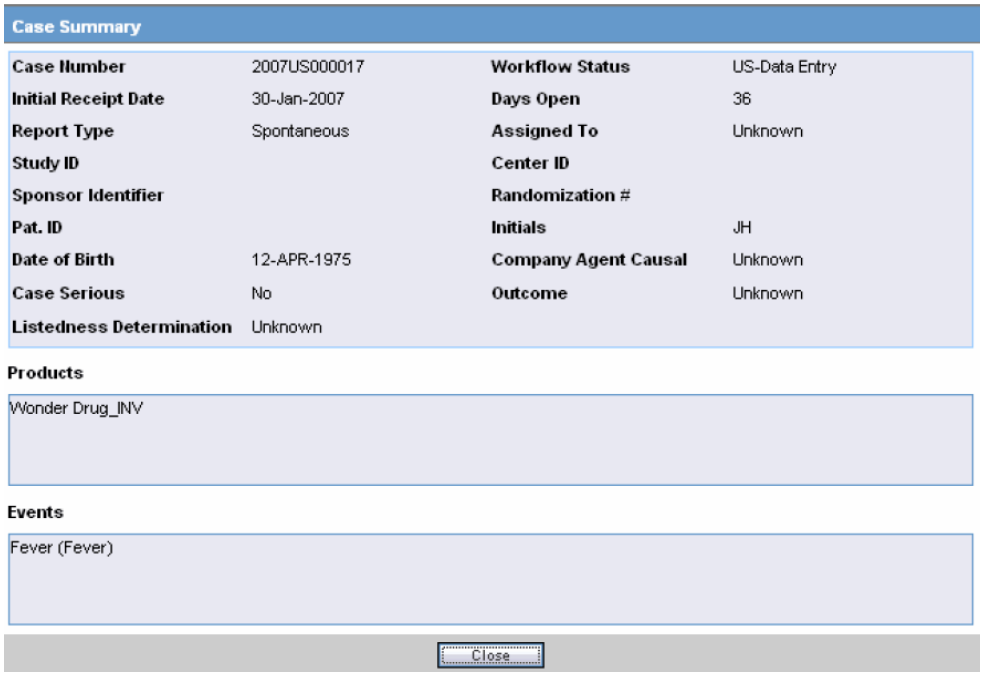
Field	Description
View Report	Displays the selected report in a PDF.
Report Details	Enables you to view the report details associated with the report.
Case Summary	Enables you to view a summary of the selected case as shown in the table below.
Local Labeling	Enables you to determine whether labeling has been assessed for the case.
Medical Review	Displays the Medical Review screen of Argus.

The following table describes the meaning of each action item.

Action Item	Description
	This report has been scheduled/generated and it is past its due date of submission.
	This report has been scheduled and saved.
	This report has been scheduled and generated.
	This report has been routed and approved by a user.

Case Summary Field Descriptions

The following is an illustration of the **Case Summary**:



The following table lists and describes the **Case Summary** fields.

Field	Description
Case Number	Displays the case number
Workflow Status	Displays the workflow status of the case
Initial Receipt Date	Displays the Initial Receipt Date of the case
Days Open	Displays the number of days the case has been opened. This is calculated by the difference between the Initial Receipt Date and the System Date (Current Date)
Report Type	Displays the Report Type.
Assigned To	Displays the individual that the case was assigned to.
Study ID	Displays the Study ID of the case
Center ID	Displays the Center ID of the case
Sponsor Identifier	Displays the Sponsor Identifier of the case
Randomization #	Displays the Randomization # of the case
Pat. ID	Displays the Patient ID
Initials	Displays the Initials of the patient
Date of Birth	Displays the Date of Birth of the patient
Company Agent Causal	Displays the whether the case was Company Agent Causal or not.
Case Serious	Displays whether the case was serious or not.
Outcome	Displays the outcome of the case.
Listedness Determination	Displays the Listedness status of the case

Field	Description
Products	Displays the Suspect Products associated with the case.
Events	Displays the Events associated with the case.

4. In the Submission Status list of the required report, select **Submit**.

   You can submit multiple reports at a time by selecting Submit for the required reports.
5. Click **Process** to open the Report Submission Information dialog box.
6. Enter any remarks in **Note** and click **OK**.
7. The report(s) opens and a list of submitted reports is generated.

Bulk Reporting

Bulk Reporting enables you to print, transmit and/or submit reports in bulk.

Select **Affiliate** > **Bulk Reporting** to view the **Bulk Report** screen shown in the following illustration.

For more information, see:

- Bulk Reporting Filter Section
- Total Number of Rows Section
- Printing Options
- User Options

Bulk Reporting Filter Section

The **Bulk Reporting Filter** sections enables you to filter reports.

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

Field	Description
Destination	Select an Agency to filter reports by that particular agency. Only the agencies that have reports in the Scheduled, Approved and Generated states are displayed. Click **Filter** to select multiple agencies from the **Reporting Destinations** dialog. The previous filtering criteria is saved and retained when the user invokes this dialog. By default, all agencies are assumed.
Report Form	Select any of the listed report forms to view reports belonging to the selected report form only.
Report Status	Choose either Scheduled/Generated, Pending, Failed, or Printed/Transmitted from the drop-down list.
Print Regulatory Report	Prints the report as Draft or Final. The Draft option is disabled when the printing option is set to **Transmit**. Select **Medical Summary** to view the list of only medical summaries of distinct cases in a PDF.
Approved Reports Only	Filters reports for only approved reports.
Product Family	Enter a Product family to view all cases where the scheduled reports belong to the searched Product family.

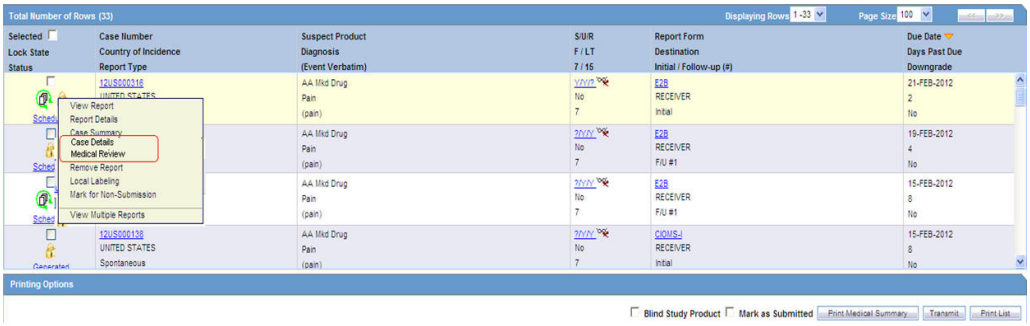
Field	Description
Specific Case #	Searches a specific case. To do so, enter the Case Number of the case you wish to search and click the **Retrieve** button. This stores the agency selections last made.

Total Number of Rows Section

The system displays the search results in the **Total Number of Rows** section.

It is worth noting that only those reports that are assigned to any LAM groups are listed in Affiliate > Bulk Reporting.

Reports that are unassigned or assigned to Central user group are not listed in Affiliate > Bulk Reporting.



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

Field	Description
Selected	Allows the user to select the report.
Lock State	Displays the Case status of the case to depict if the case is locked or un-locked.
Status	Displays the Report Status e.g. Scheduled or Generated etc. Click the status to view the report details.
Case Number	Displays the Case number. Click the Case Number link to open the case.
Country of Incidence	Displays the view Country of Incidence.
Report Type	Displays the Case Report Type
Suspect Product	Displays the Trade Name for which the report has been scheduled. If more than one Suspect Company Product exists for the case, an "(+)" is placed at the end of the product name. For Reports which were scheduled for the Device, the Device name is displayed.
Diagnosis	Displays the Primary Event Diagnoses PT
(Event Verbatim)	Displays the (Verbatim as reported) of the Primary Event.

Field	Description
S/U/R	• Displays the Case Level Assessments: – Serious (Y/N) – Unlisted (Y/N) – Causality (Y/N) • Unknown is treated as a "?" • The SUR link displays the Case Summary associated with the selected case.
F or LT	Fatal / Life Threatening If any of the events in the case are Fatal or Life Threatening F or LT is displayed. If the case is both **F** and **LT**, only **F** is displayed. If the case is neither **F** nor **LT**, only **No** is displayed.
7/15	Displays 7 if the report is due within 7 days Displays 15 if the report is due in more than 7 days
Report Form	Displays the Description of the report Click the Report form link to view the DRAFT Report as a PDF.
Destination	Displays the report destination (agency) for which the report is scheduled.
Initial / Follow-up (#)	Initial or Follow-up If Follow-up, the follow-up number is printed
Due Date	Displays the due date.
Days Past Due	Displays the number of days the report is past due date.
Downgrade	Allows the user to view if the report is downgrade. Displays Yes if the report is a downgrade report else.

Tip:

The icon (displayed in the lock state) in the Affiliate-> Bulk Reporting screen denotes a SUSAR (Suspected Unexpected Serious Adverse Reaction) case.

Printing Options

Several printing options are available to you.

The following table lists and describes the available printing options:

Field	Description
Blind Study Product	Select this check box to print study cases with blinded information.
Mark as Submitted	Select this check box to mark reports as **Submitted** when the transmission/e-mail has been sent. A dialog is displayed if this check box is not selected. This dialog prompts you to confirm if the report is to marked as submitted or not. Select **Yes** or **No**, as required. This selection is remembered for the next time when you print a report.

Field	Description
Print Medical Summary	Allows the user to print the Medical Summaries.
Print	Allows you to choose the printer for the selected report from the **Select Site Printer** dialog. Select the **Site** and **Printer Name** where you wish to print the report and click **OK**.
Print List	Allows the user to print the current view of the Bulk Reporting.

For more information, see:

- Suppress Default Printer option in Select Site Printer dialog

Suppress Default Printer option in Select Site Printer dialog

While printing reports from the **Reports** > **Bulk Reporting** option, if a Site is not selected or left blank, the **Default Printer** is selected by default under the **Printer Name** drop-down list.

If a particular Site is selected, the **Default Printer** option is not listed. By default, the **<Select Printer>** option is displayed as the first option.

To print Bulk Reports for a particular site, the user can select one of the printers listed for that site from the **Printer Name** drop-down list and can perform further actions.

User Options

The following options are available to you:

- Lock State Header Options
- Lock State Icon Options

Lock State Header Options

To sort the cases based on the following case status, click the **Lock State** header row. A pop-up appears listing the following sorting options:

- Lock State
- SUSAR
- Exp/Per

These options enable you to sort cases based on the case categorization.

> **Tip:**
>
> The icon (displayed in the lock state) in the Reports > Bulk Reporting screen denotes a SUSAR (Suspected Unexpected Serious Adverse Reaction) case.

Lock State Icon Options

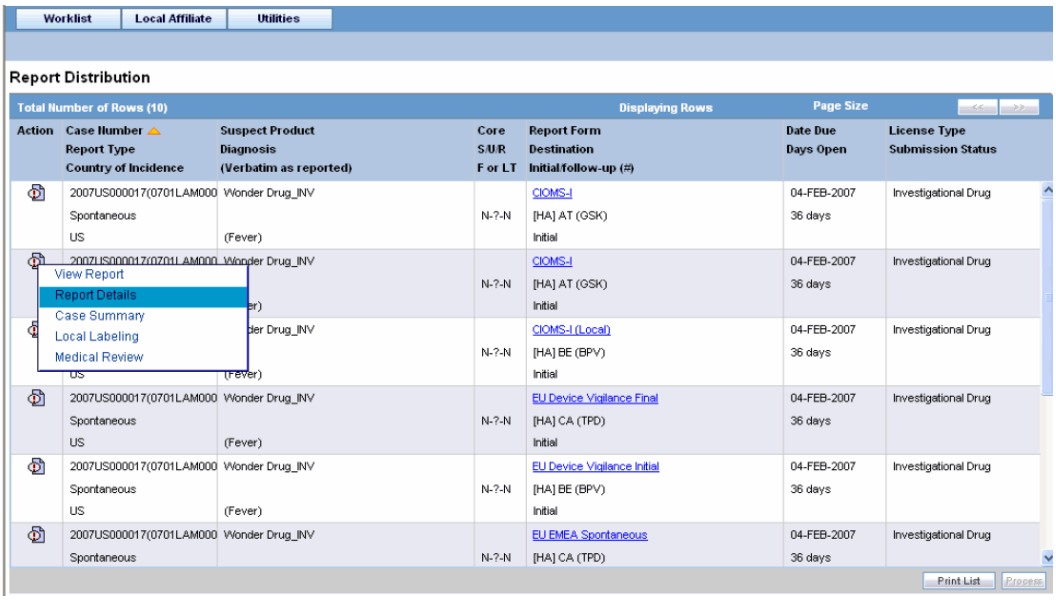
Click the **Lock State** icon to view the list of options.

The following table describes these options:

Field	Description
View Report	Displays the Draft report.
Report Details	Displays specific information about the report as entered in the **Regulatory Reports** section.
Case Summary	Displays the Case Summary dialog.
Case Details	Displays the Case Details screen. The tree structure of the case displays only the 'Reports' node, with its existing features.
Medical Review	Displays the Medical Review screen.
Remove Report	Deletes the report from the case on being asked for a justification
Local Labeling	Allows Local Labeling for the selected case.
Mark for Non-Submission	Displays the **Submission** tab in the Report Details dialog. Select **No** for **Mark for Non-Submission** and enter the reason for the non-submission.
Remove Multiple Reports	Deletes multiple reports from the case on being asked a justification.
View Multiple Reports	Allows you to view multiple reports.

Viewing Report Details

1. Select **Local Affiliate** > **Report Distribution** to open the Report Distribution page.
2. Click the icon associated with the report and select **Report Details** to open the Report Details dialog box.



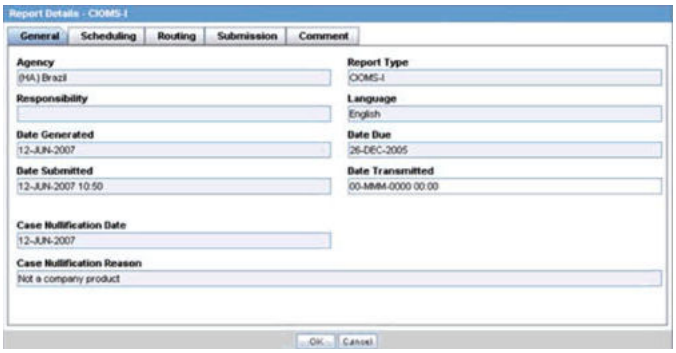
3. The Report Details dialog opens.

For more information, see:

- About the Report Details Dialog Box

About the Report Details Dialog Box

The **Report Details** dialog contains the following tabs:



For more information, see:

- General Tab
- Scheduling Tab
- Submission Tab
- Comments Tab

General Tab

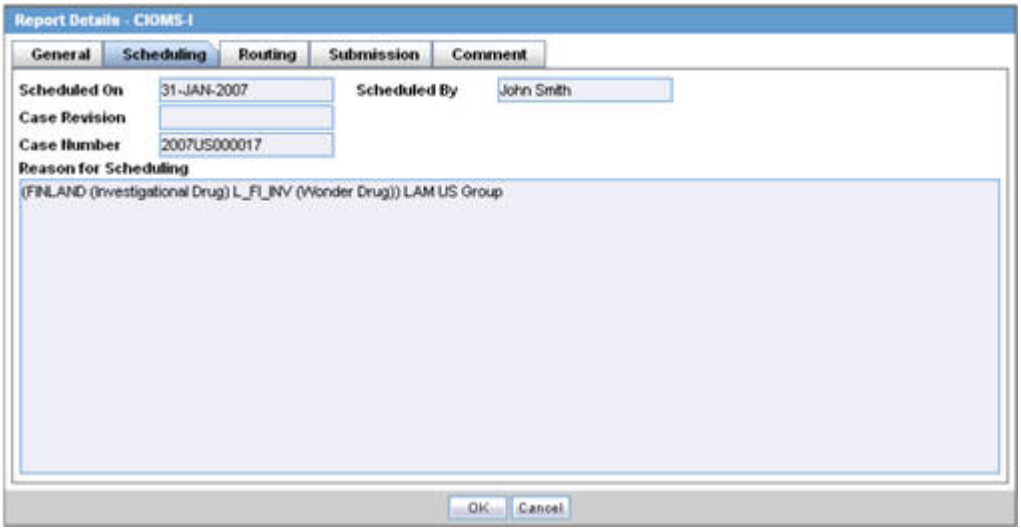
The **General** tab displays the general information about the report. The information on this tab cannot be modified. The following is an illustration of the **General** tab.

The following tables lists and describes the fields on the **General** tab.

Field	Description
Agency	Displays the Reporting Destination for which the report is scheduled.
Responsibility	Displays the User Group to which the report is assigned.
Date Generated	Displays the date when the report was generated.
Date Submitted	Displays the date when the report was submitted.
Report Type	Displays the Expedited Report Form of the report.
Language	Displays the language in which the report has been made.
Date Due	Displays the date when the report is due.
Date Transmitted	Displays the date when the report was transmitted.
Case Nullification Date	Displays the date when the case was nullified.
Case Nullification Reason	Displays the reason entered when a case is logically deleted in Argus.

Scheduling Tab

The **Scheduling** tab displays a reason for scheduling this report. It also shows the date on which the report was scheduled.



The following tables lists and describes the fields on the **Scheduling** tab.

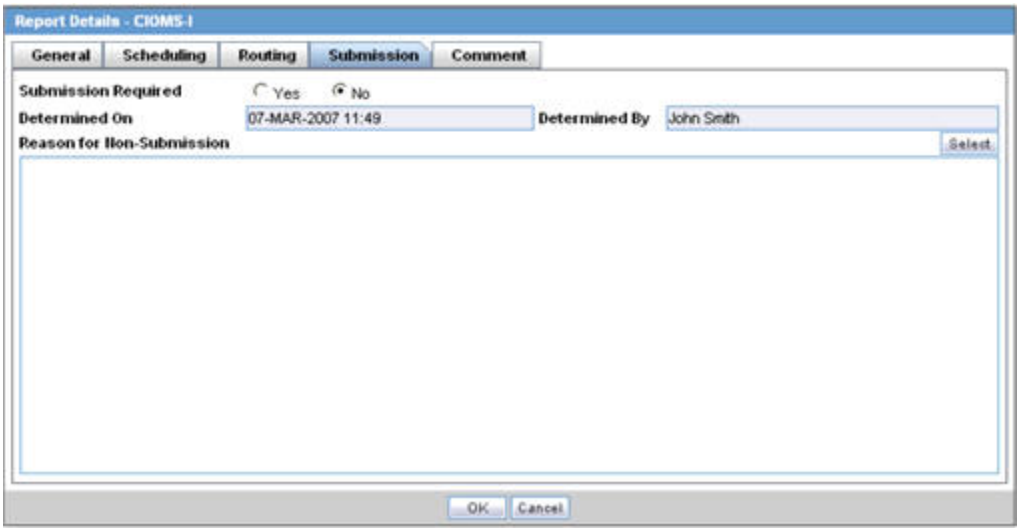
Field	Description
Scheduled On	Displays the date when the report was scheduled.
Scheduled By	Displays the name of the person who schedule the report.
Case Revision	Displays the case revision number.
Case Number	Displays the case number.
Reason for Scheduling	Displays the reason for scheduling the report.

Note:

All fields in this tab are auto-populated as per records entered in Oracle Argus Safety.

Submission Tab

The **Submission** tab allows you to specify whether submission is required and enter a reason for not submitting the report.

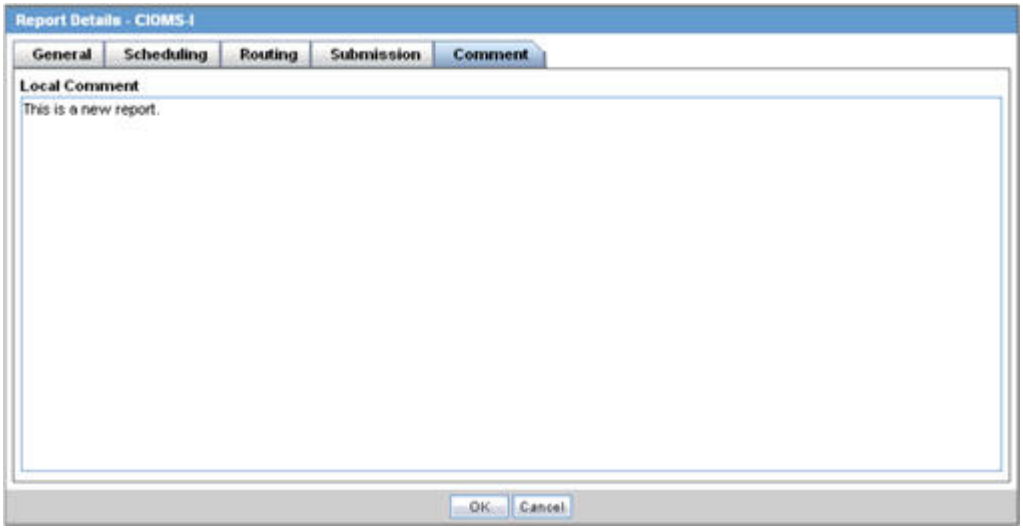


The following table lists and describes the fields on the **Submission** tab.

Field	Description
Submission Required	Enables you to select if this report is not required to be submitted to the regulatory authority.
Determined On	Displays the date when the report was considered not required to be submitted.
Determined By	Displays the name of the user who decided the report was not required to be submitted.
Reason for Non-Submission	Click **Select** to select the reason for non-submission.

Comments Tab

The **Comment** tab allows you to enter a local comment that prints out on that specific report when generated. Each report has its own respective Local Comment Section.

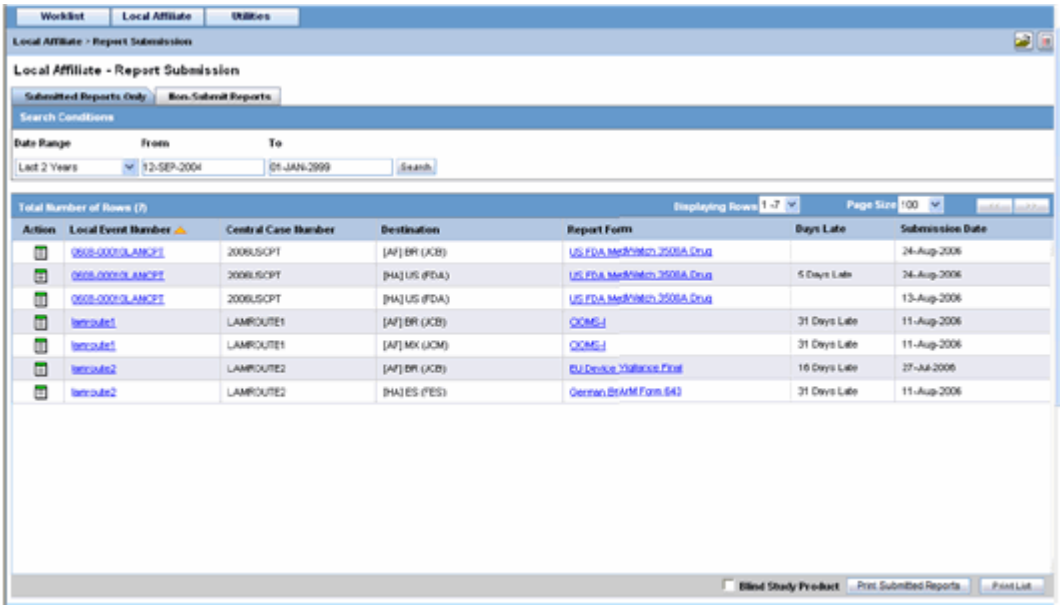


The following table lists and describes the fields on the **Comments** tab.

Field	Description
Local Comment	Enables you to enter any remarks about the report.

Viewing Report Submission History

You can view a history of the reports that have been sent from the **Report Submission** page as shown in the following illustration.



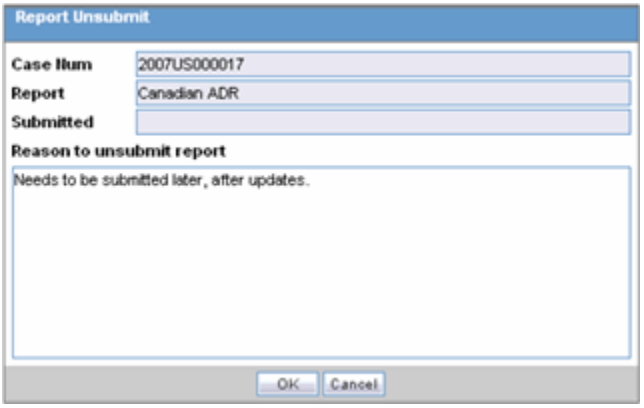
To view Report Submission history

1. Select **Local Affiliate** > **Report Submissions** to open the **Report Submissions page**.
2. Select whether you want to view **Submitted Reports only** or **Non-Submit Reports**.
3. Enter a custom date range or select an appropriate date range under **Range**.
4. Click **Search**. A list of submitted reports appears as per the option you selected.
5. To open a report, click the icon assicated with the report and select **View Reports**.
6. To view the report details, click the icon associated with the report and select **Report Deatils**.

The system submitse the report.

To un-submit a report

1. Click the icon assiciated with the report and select **Unsubmit Report** to open the **Report Unsubmit** dialog.



2. The dialog displays the **Case Number**, **Report Name**, and **Submitted** status of the selected report.
3. Enter the reason for non-submission of the report in the **Reason to unsubmit report** field and click **OK**.

For more information, see:

- Report Submission Tabs

Report Submission Tabs

The **Report Submission** page has the following tabs:

- Submitted Reports
- Non-submitted Reports

Submitted Reports Tab

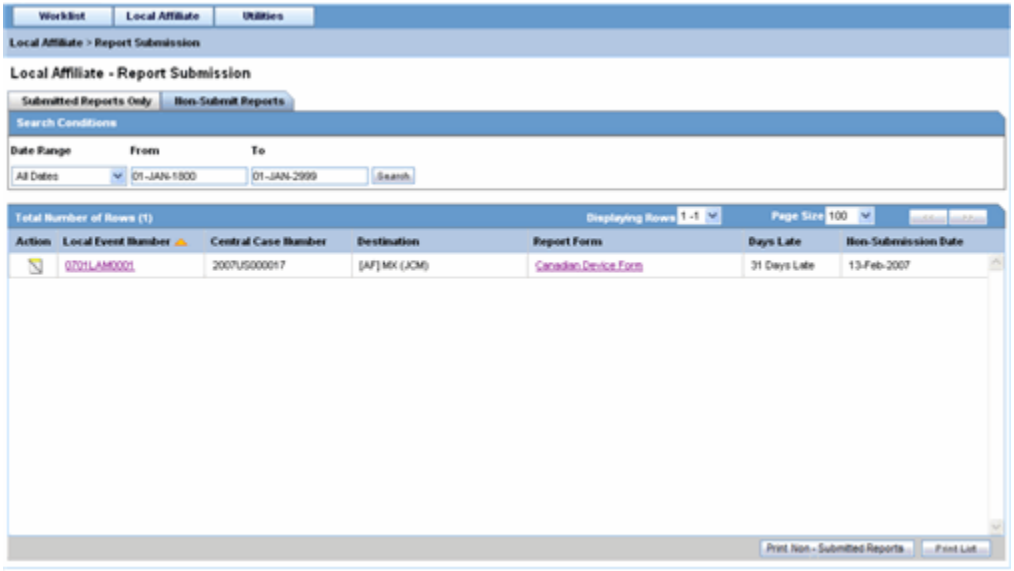
The following table lists and describes the fields on the **Submitted Reports Only** tab.

Field	Description
Date Range	Enables you to specify a date range for searching report during a period. **Note:** If a Date Range is selected, the From and To fields get populated automatically.
From	Enables you to manually enter the start date for the search period.
To	Enables you to manually enter the last date for a search period.
Action	View Report Report Details Unsubmit Report

Field	Description
Local Event Number	Displays the Local Event Number of submitted reports. Click this link to view the case details.
Central Case Number	Displays the Central Case Number of submitted reports.
Destination	Displays the destination of submitted reports.
Report Form	Displays the type of report form for the report. Click this link to view the report in a PDF.
Days Late	Displays the days by which the report had been delayed in its submission.
Submission Date	Displays the date when the report was submitted.
Blind Study Product	Enables you to blind the study product on the Submitted Expedited reports.
Print Submitted Reports	Allows you to print the submitted reports.

Non-Submit Reports tab

The following is an illustration of the **Non-Submit Reports** tab.



The following tables lists and describes the fields on the **Non-Submit Reports** tab.

Field	Description
Date Range	Enables you to specify a date range for searching report during a period. **Note:** If a Date Range is selected, the From and To fields get populated automatically.
From	Enables you to manually enter the start date for the search period.
To	Enables you to manually enter the last date for a search period.
Action	View Report
Report Details	Enables you with the option of viewing report details.
Local Event Number	Displays the Local Event Number of unsubmitted reports. Click this link to view the case details
Central Case Number	Displays the Central Case Number of unsubmitted reports.
Central Country of Incidence	Enter the country where the adverse event occurred. Enter the partial two-character code, the country name, or the three-character code. Oracle Argus Safety will decode the entry. The Administrator can adjust the information in this list.
Destination	Displays the destination of unsubmitted reports.
Report Form	Displays the type of report form for the report. Click this link to view the report in a PDF.
Days Late	Displays the days by which the report had been delayed in its non-submission.
Non-Submit Date	Displays the date when the report was not submitted.

Changing Your Password

The **Change Password** utility enables you to change your password as necessary. When you log on to the system for the first time, it is recommended that you change your password.

To change your password:

1. Select **Utilities** > **Change Password** from the Utilities menu.
2. When the system opens Change Password dialog box:
   a. Enter your current password in the **Old Password** field.
   b. Enter your new password in the **New Password** field.
   c. Enter your new password a second time in the **Confirm Password** field.
3. Click **OK**.

The system changes your password.

3
Central Users

In this chapter:

About Central Users

This chapter describes the tasks that can be performed by the Central Users of Oracle Argus Affiliate. Unless you are an Enterprise Workflow Manager, you are limited to events you can access from the following dialog boxes:

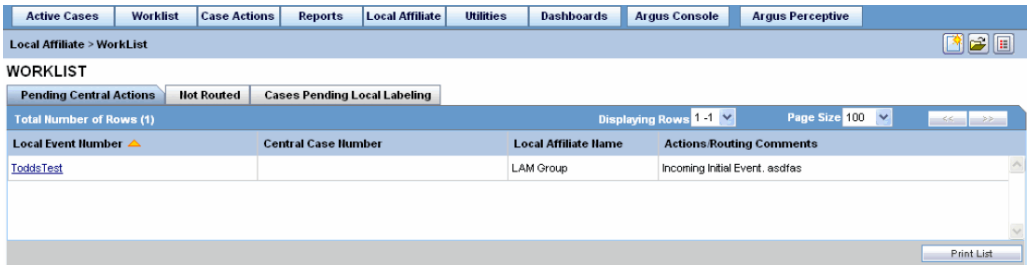
- Local Affiliate --> Worklist --> Pending Local Labeling
- Local Affiliate --> Worklist --> Cases in Pending Central Actions
- Local Affiliate --> Worklist --> Not Routed cases

If you are an Enterprise Workflow Manager, you can view **all** cases across multiple sites.

> **Note:**
>
> Central users must log on to Oracle Argus Safety Web in order to perform the activities that are related to local affiliates.

Viewing the Worklist

In the Oracle Argus Safety User Interface, select **Worklist** from the **Local Affiliate Menu** to access the different options available through this screen. The **Worklist** screen appears as shown:



The following table lists and describes each of the tabs on this screen.

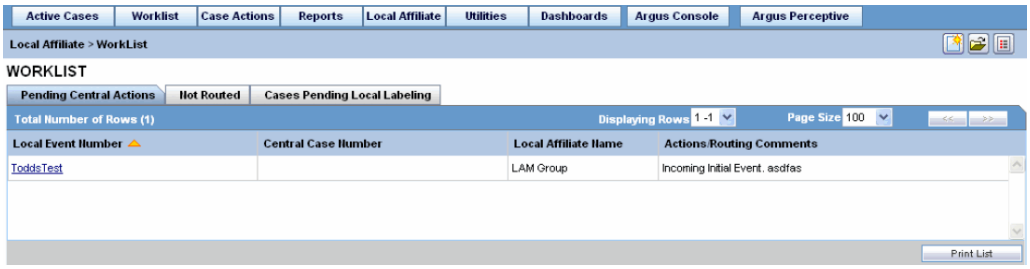
Field	Description
Pending Central Actions	Displays actions on local events that are pending at central
Not Routed	Displays local events that have not yet been routed to central
Cases Pending Local Labeling	Displays pending action items that have been assigned to the Local Affiliate Users.
Action Items from Local	Displays the list of action items pending from Local.
Action Items from Central	Displays the list of action items pending from Central.
Intake Worklist	Displays the list of cases present in the Intake queue.

For more information, see:

- Pending Central Actions Tab
- Not Routed Tab
- Action Items from Local
- Action Items from Central
- Cases Pending Local Labeling Tab
- Intake Worklist

Pending Central Actions Tab

The following is an illustration of the **Pending Central Actions** tab.

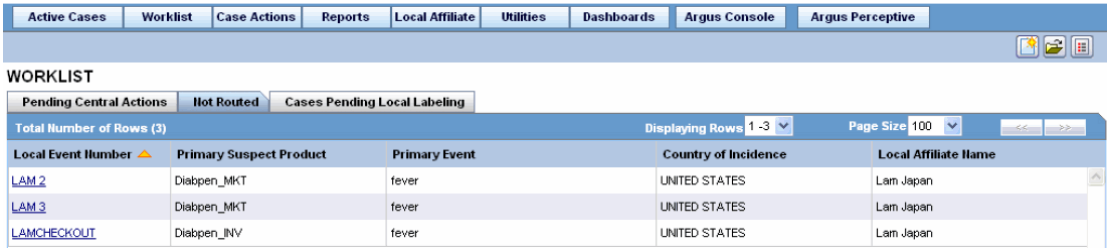


The following table lists and describes the fields on the **Pending Central Actions** tab.

Field	Description
Local Event Number	Displays the local event number. The link displayed in this field helps you in viewing event information.
Central Case Number	Displays the central case number.
Central Workflow State	Displays the current workflow state of the Central Case.
Actions/Routing Comments	Displays any actions or routing comments for the case.
Print List	Prints the list displayed in the screen in a PDF.

Not Routed Tab

The following is an illustration of the **Not Routed** tab.

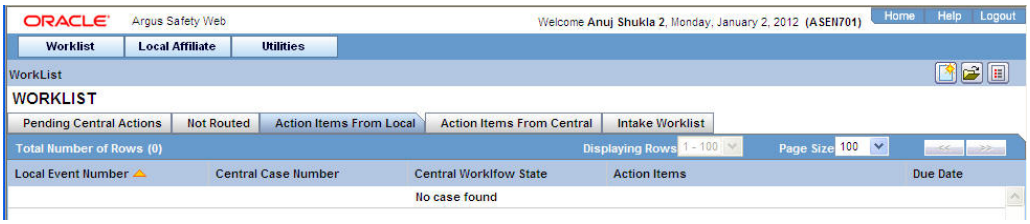


The following table lists and describes the fields on the **Not Routed** tab.

Field	Description
Local Event Number	Displays the local event number. The link displayed in this field helps you in viewing event information.
Primary Suspect Product	Displays the name of the primary suspect product.
Primary Event	Displays the name of the primary event.
Route to Central	On selecting LAM Event(s) and clicking the Route to Central button, the system displays the Routing Confirmation dialog followed by the Route to Central dialog to confirm the routing of LAM Events to Central.
Country of Incidence	Displays the country where the adverse event occurred.
Local Affiliate Name	Displays the name of the local affiliate.
Print List	Prints the list displayed in the screen in a PDF.

Action Items from Local

The following is an illustration of the **Action Items from Local** tab.

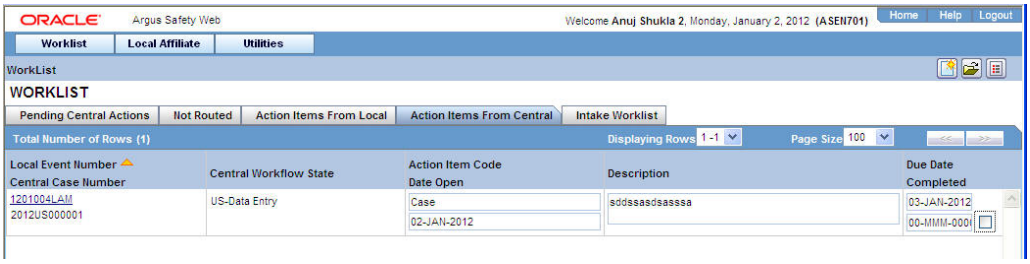


The following table lists and describes the fields on the **Action Items from Local** tab.

Field	Description
Local Event Number	Displays the local event number. The link displayed in this field helps you in viewing event information.
Central Case Number	Displays the case number with Central.
Central Workflow State	Displays the workflow state of the case.
Action Items	Displays a description of the action to be taken up for the LAM event.
Due Date	Displays the due date for the action item.
Print List	Displays the option to print the list.

Action Items from Central

The following is an illustration of the **Action Items from Central** tab.



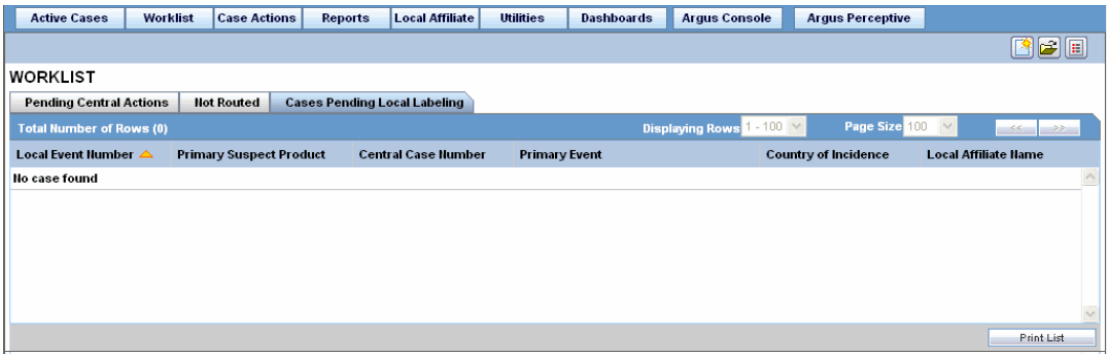
The following table lists and describes the fields on the **Action Items from Central** tab.

Field	Description
Local Event Number	Displays the local event number. The link displayed in this field helps you in viewing event information.
Central Case Number	Displays the case number with Central.
Central Workflow State	Displays the workflow state of the case.
Action Item Code	Displays a code of the action to be taken up for the LAM event.
Date Open	Displays the date since when the action has been due.
Description	Displays the description of the action.
Due Date	Displays the due date for the action item.

Field	Description
Completed	Displays the date by when the action item will be completed.
Print List	Displays the option to print the list.

Cases Pending Local Labeling Tab

The following is an illustration of the **Cases Pending Local Labeling** tab.

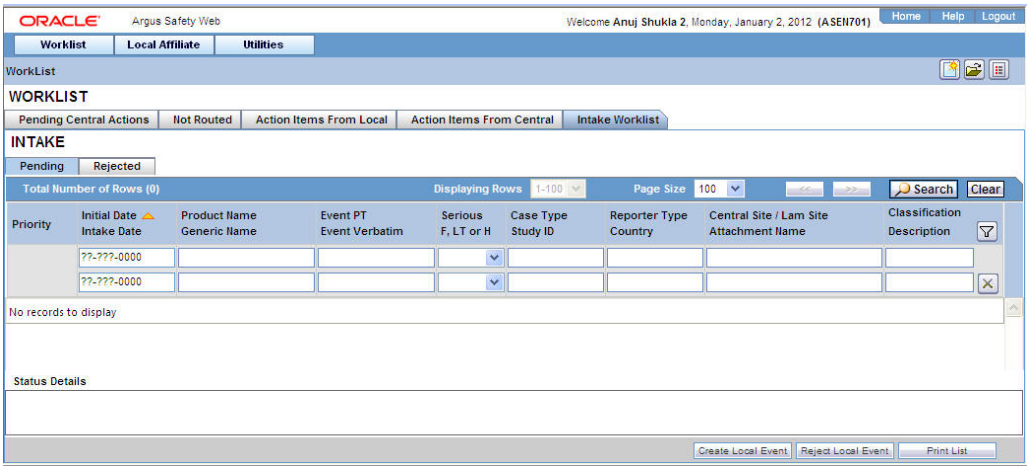


The following table lists and describes the fields on the **Cases Pending Local Labeling** tab.

Field	Description
Local Event Number	Displays the local event number. The link displayed in this field helps you in viewing event information.
Primary Suspect Product	Displays the name of the primary suspect product.
Central Case Number	Displays the case number with Central.
Primary Event	Displays the name of the primary event.
Country of Incidence	Displays the country where the adverse event occurred.
Local Affiliate Name	Displays the name of the local affiliate.

Intake Worklist

The following is an illustration of the **Intake Worklist - Pending** tab.

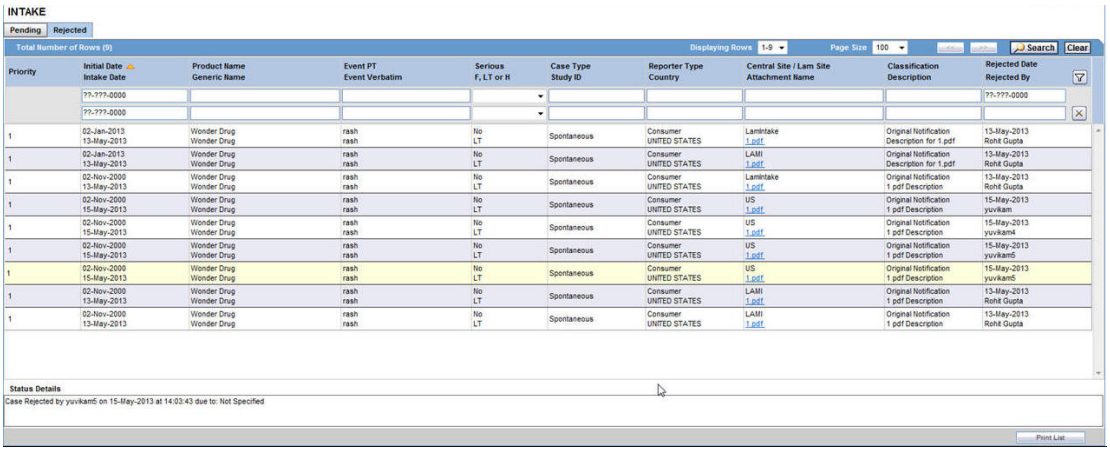


The following table lists and describes the fields on the **Intake Worklist - Pending** tab.

Field	Description
Priority	Allows the user to view the priority of the case.
Initial Date	Allows the user to view the initial receipt date of the case.
Intake Date	Allows the user to view the date the system imported the attachment within the Intake Worklist.
Product Name	Allows the user to view the Suspect Product in question.
Generic Name	Allows the user to view the generic name of the suspect product in question.
Event PT	Allows the user to view the Primary Event and Verbatim as Reported.
Event Verbatim	The following format will be used:Primary Event (Verbatim as Reported)
Serious	Allows the user to view the case-level assessments.
F, LT or H	Displays the status as Fatal (F) or Life-Threatening (LT) or Hospitalized (H). If the case is neither of the above, it displays 'No'.
Case Type	Allows the user to view the report type information.
Study ID	Allows the user to view the Study ID of the study cases. For cases where the Study ID is not present, this field is empty.
Reporter Type	Allows the user to view the Reporter Type of the study cases. For cases where the Reporter Type is not present, this field is empty.
Country	Allows the user to view the country of incident.
Central / LAM Site	Allows the user to view the current site (Oracle Argus Safety or Oracle Argus Affiliate) of the case.
Attachment	Allows the user to view the attachment which is associated to the case. If there are multiple files, these shall be separated by a comma.
Classification	Allows the user to view the attachment classifications which is associated to the attachment.
Description	Allows the user to view the attachment description which is associated to the case.

Field	Description
Status Details	Allows the user to view the details of the status associated to the case.
Accept/Reject Local Event	Allows the user to accept/reject the Local Event associated to the case.
Print List	Allows the user to print the list of cases displayed on this screen.

The following is an illustration of the **Intake Worklist - Rejected** tab.



The following table lists and describes the fields on the **Intake Worklist - Rejected** tab.

Field	Description
Priority	Allows the user to view the priority of the case.
Initial Date	Allows the user to view the initial receipt date of the case.
Intake Date	Allows the user to view the date the system imported the attachment within the Intake Worklist.
Product Name	Allows the user to view the Suspect Product in question.
Generic Name	Allows the user to view the generic name of the suspect product in question.
Event PT	Allows the user to view the Primary Event and Verbatim as Reported.
Event Verbatim	The following format will be used:Primary Event (Verbatim as Reported)
Serious	Allows the user to view the case-level assessments.
F, LT or H	Displays the status as Fatal (F) or Life-Threatening (LT) or Hospitalized (H). If the case is neither of the above, it displays 'No'.
Case Type	Allows the user to view the report type information.
Study ID	Allows the user to view the Study ID of the study cases. For cases where the Study ID is not present, this field is empty.
Reporter Type	Allows the user to view the Reporter Type of the study cases. For cases where the Reporter Type is not present, this field is empty.
Country	Allows the user to view the country of incident.

Field	Description
Central / LAM Site	Allows the user to view the current site (Argus or Affiliate) of the case.
Attachment	Allows the user to view the attachment which is associated to the case. If there are multiple files, these shall be separated by a comma.
Classification	Allows the user to view the attachment classifications which is associated to the attachment.
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.
Rejected By	Allows the user to view the name of the user who rejected the case.
Status Details	Allows the user to view the details of the status associated to the case.
Accept/Reject Local Event	Allows the user to accept/reject the Local Event associated to the case.
Print List	Allows the user to print the list of cases displayed on this screen.

Reviewing Incoming Events

You can review incoming events from the **Incoming Review** page. The page has two tabs:

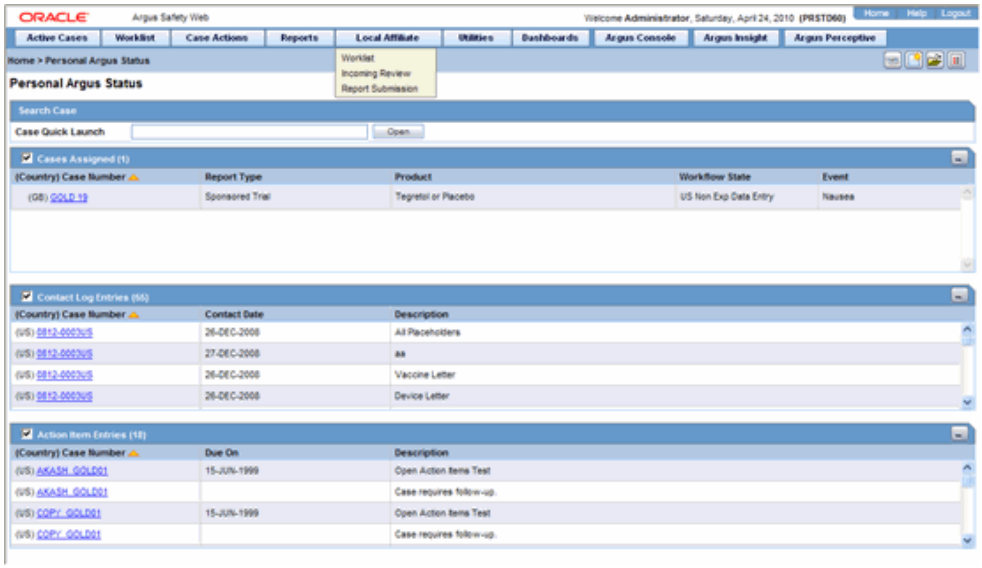
- Initial
- Follow-up

For more information, see:

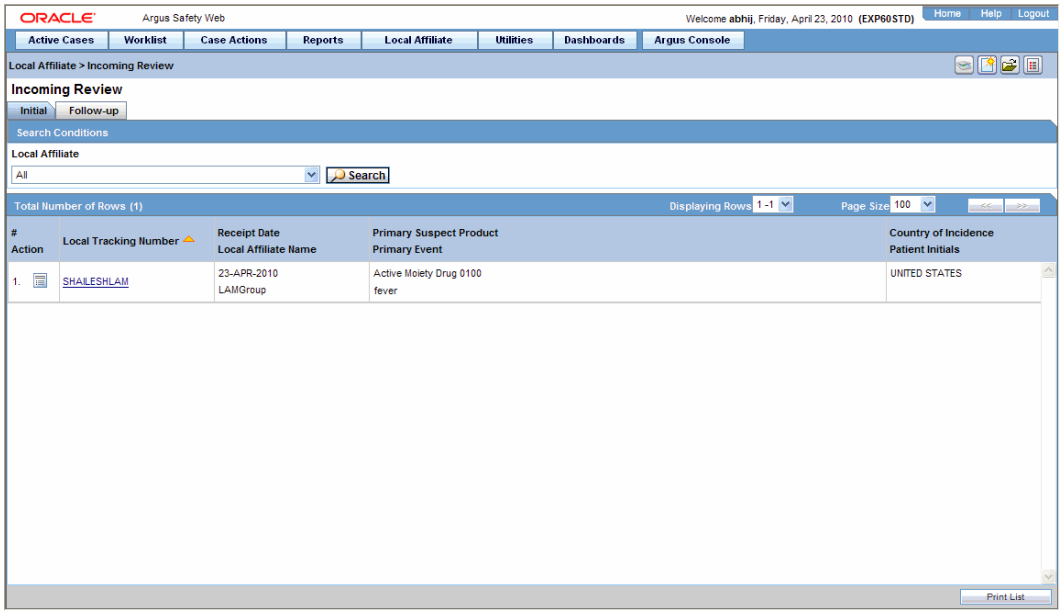
- To review incoming events

To review incoming events

1. Select **Local Affiliate** > **Incoming Review** to open the Incoming Review page.



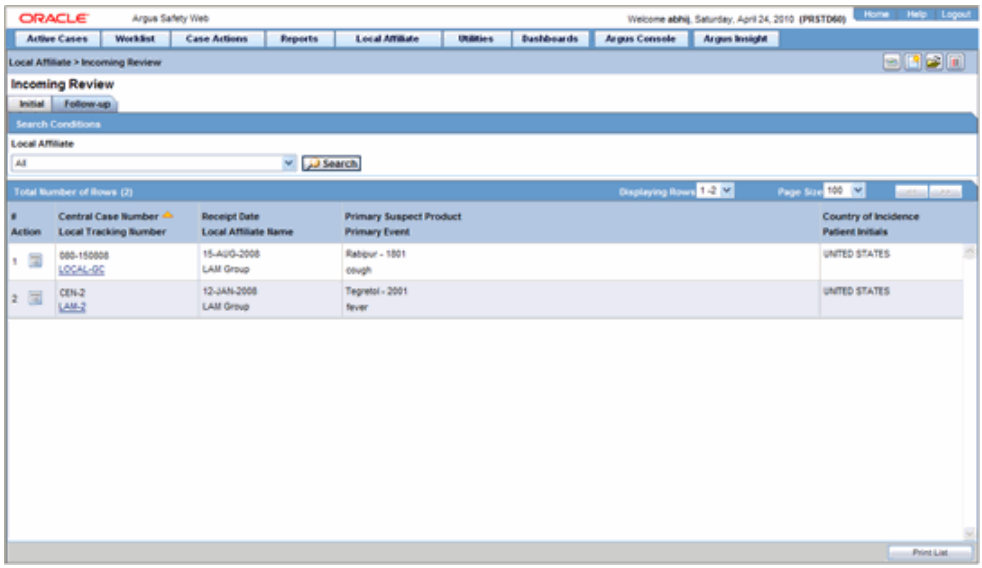
2. The system opens the Initial tab by default. On this tab you can review new incoming events.



The following table describes the fields on the **Initial** tab.

Field	Description
#	Displays the serial number of each search result.
Action	Enables you to perform an action item.
Central Case Number	Displays the central case number of the event.
Local Tracking Number	Displays the local tracking number of incoming events. Click the link displaying the local tracking number to view the follow-up information.
Receipt Date	Displays the date when the incoming events was received.
Local Affiliate Name	Displays the name of the local affiliate.
Primary Suspect Product	Displays the name of the product that is most likely to have caused the adverse event.
Primary Event	Displays the name of the primary event.
Country of Incidence	Displays the name of the country where the adverse event occurred.
Patient Initials	Displays the initials of the patient.
Print List	Displays the list of follow-up events in a PDF.

3. If you wish to review follow-up events or information click the Follow-up tab.



The following table lists and describes the fields on the **Follow-up** tab.

Field	Description
#	Displays the serial number of each search result.
Action	Enables you to perform an action item.
Central Case Number	Displays the central case number of the event.
Local Tracking Number	Displays the local tracking number of incoming events. Click the link displaying the local tracking number to view the follow-up information.
Receipt Date	Displays the date when the incoming events was received.
Local Affiliate Name	Displays the name of the local affiliate.
Primary Suspect Product	Displays the name of the product that is most likely to have caused the adverse event.
Primary Event	Displays the name of the primary event.
Country of Incidence	Displays the name of the country where the adverse event occurred.
Patient Initials	Displays the initials of the patient.
Print List	Displays the list of follow-up events in a PDF.

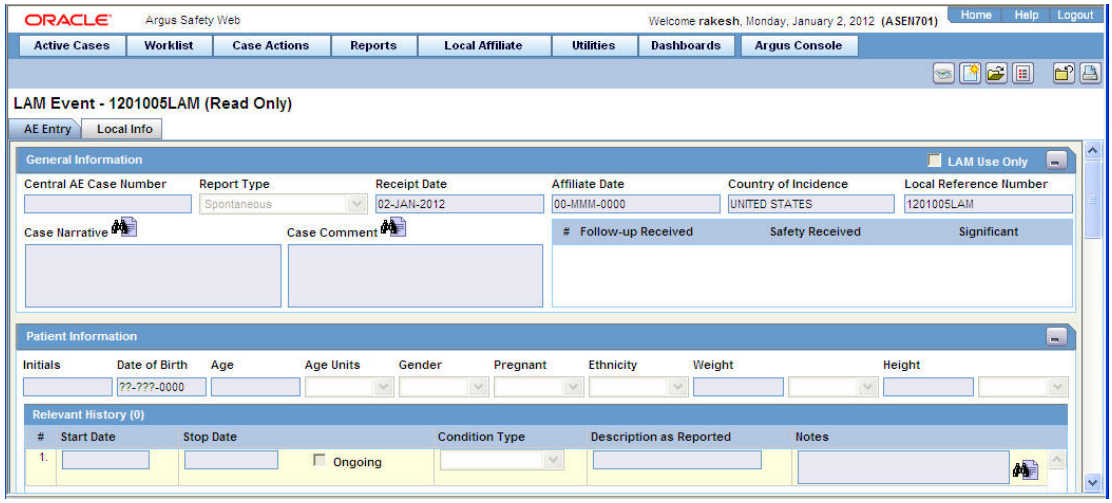
4. Under Local Affiliate, select the local affiliate whose events are to be reviewed.
5. Click **Search**. A list of matching search results is displayed.

The following table lists the columns that appear in search results:

Initial Events	Follow-up
Local Tracking Number	Central Case Number
Receipt Date	Local Tracking Number
Local Affiliate Name	Receipt Date

Initial Events	Follow-up
Primary Suspect Product	Local Affiliate Name
Country of Incidence	Primary Suspect Product
Primary Event	Country of Incidence
Patient Initials	Primary Event Patient Initials

6. To view the incoming event or follow-up information, click the link associated with the Local Tracking Number. The following review screen is displayed.



The event information viewed from here cannot be modified.

> **Tip:**
>
> You can accept follow-up information, and accept or reject local events, from the list of incoming events.

Duplicate Search

When performing a duplicate search, be aware of the following:

- You can perform a duplicate search for incoming follow-up cases.
- When you click the **Duplicate Search** dialog, the system performs a duplicate search on the selected case.
- The user can search a maximum of 1000 cases.
- The system performs the duplicate search in the same way it performs the **Central AE Bookin Dialog Dup** search.
- The system runs the duplicate search against cases in the **Central AE** database.
- The **Receipt Range Limits** checkbox enables the user to restrict the search to the last 3 months. If the checkbox is unchecked, the system runs the search against all cases.

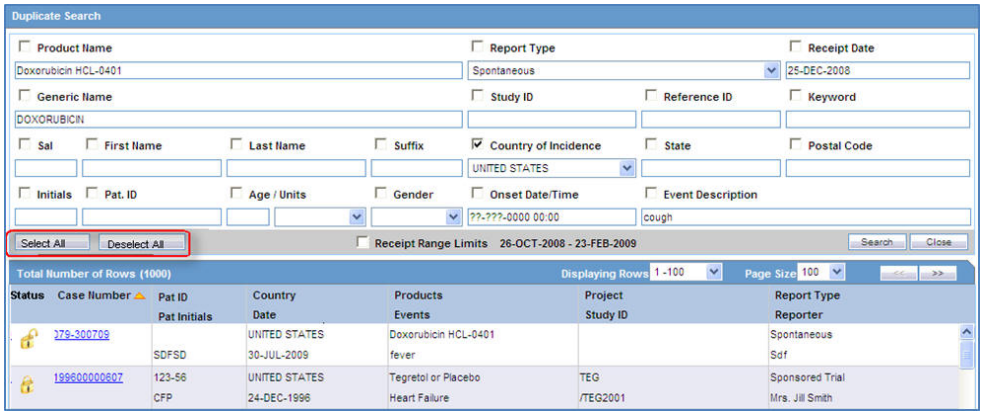
- The **Select All** and **Deselect All** buttons allow all the checkboxes associated with the Search fields to be checked/unchecked (respectively) in **Duplicate Search**.
- The system uses the **Oracle Text** profile settings for the duplicate search in Affiliate.

For more information, see:

- Searching for Duplicates

Searching for Duplicates

1. Review incoming events from Local Affiliates.
2. Click the icon associated with the required case and select **Duplicate Search**.
3. The Oracle Argus Safety **Duplicate Search** dialog opens.



4. Select the check boxes associated with the items by which the duplicate search is to be executed. Clear the check boxes that are not to be considered for duplicate search.
5. Click **Search**. A list of search results matching the specified search criteria is displayed.

   Inspect the search results to determine if the event is already associated with a previously entered case.

Accepting Local Events

1. Before accepting an event, search for duplicates to check if a similar event is not associated with a case at Central.
2. Click the icon associated with the incoming event and select **Accept Local Event**.
3. If the system is configured for manual numbering of cases, enter the Case ID Number and click **OK**.
4. If the system is configured for automatic numbering of cases, a Case ID Number is automatically allotted to the case.
5. In the Accept Local Event dialog, click **OK**.

When the case is accepted, the Accept icon appears next to the case.

For more information, see:

Accepting Events for Initial Cases

You can select the fields that need updating after clicking **Accept Local Event**. The following is an illustration of the **Incoming Review** page.

Be aware of the following when accepting local events:

- After you accept the local event, the system displays the **Affiliate Acceptance** dialog box.
- By default, the system checks **all** the elements for the affiliate event so they will be accepted in **Argus Central**.
- If an element **does not** have any data, the system **does not** display it.
- The field labels are configured in the same manner as the field labels in the **Central Case Form** fields in the Console.
- If the section is checked, all child elements are checked.
- You can check or uncheck individual entities.
- The system **does not** enable the **Accept Case** button until the following fields contain data:
  - Initial Receipt Date
  - Country of Incidence
  - Report Type
  - Any single Product Name Information
  - Any Single Event Verbatim
- When you click **Accept Initial**, the system displays the **Justification** dialog for acceptance.
- When you click **Reject Initial**, the system rejects the affiliate event.

Accepting Events for Follow-up Cases

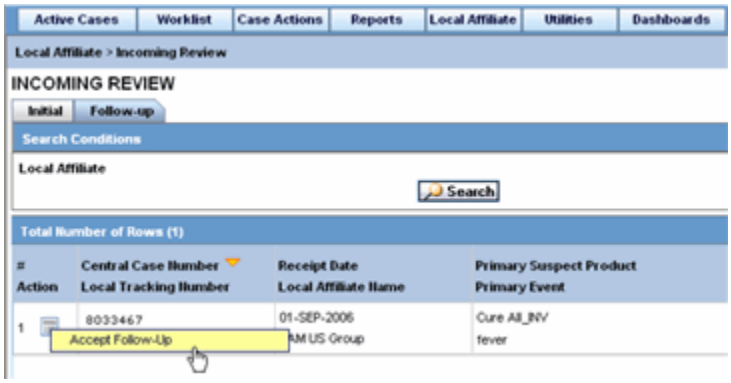
When accepting events for follow-up cases, be aware of the following:

- In the **Affiliate Acceptance** dialog box, you can select the fields that need to be updated in the Oracle Argus Safety Central case.
- By default, the system checks all the elements for the affiliate event to be accepted in Oracle Argus Safety Central.
- The acceptance order is the same as the order defined in the Oracle Argus Safety Case and the affiliate event for multiple entities (e.g., Products/Events/Reporters are compared against as entered in Oracle Argus Safety case and Oracle Argus Affiliate case).
- The system displays the elements for deleted entities in red.
- The system displays the elements for updated entities in yellow.
- The system displays the elements for added entities in grey.

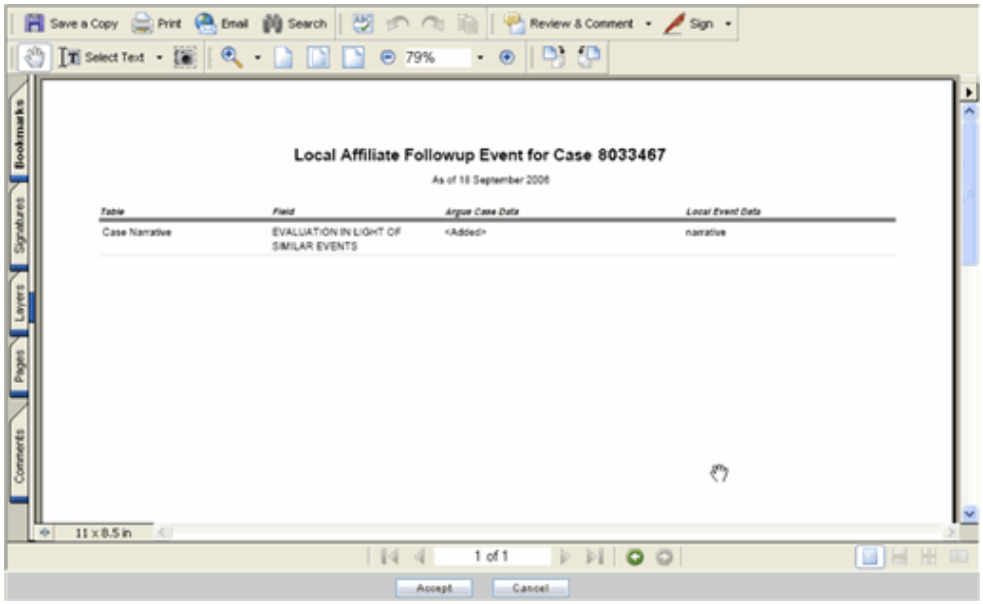
- The system displays the affiliate field labels in the **Acceptance** dialog.
- The number of follow-ups are the total number of follow-ups in the affiliate event.
- When you click **Accept Follow-up**, the system displays the **Justification** dialog for acceptance.
- When you click **Reject Follow-up**, the system rejects the follow-up affiliate event.
- The system attaches the difference report to the case after you accept the Oracle Argus Affiliate event.

Entering Follow-up Information

1. Click the icon associated with the incoming event and select **Accept Follow-up**.



2. The follow-up information appears in a new window in PDF format.



3. Review the follow-up information in the follow-up report. You can then make the appropriate changes to the case information from the Oracle Argus Safety Case Form.

> **Note:**
>
> The follow-up information appears in the **Additional Info** tab of the Case Form

4. Refer to the *Oracle Argus Safety User's Guide* for further information on entering case information on the Case Form.

For more information, see:

- Accepting Follow-ups from Oracle Argus Affiliate for Archived Cases
- Accepting Follow-ups from Affiliate for Locked Cases
- Accepting Follow-ups for Open Cases

Accepting Follow-ups from Oracle Argus Affiliate for Archived Cases

- Enter the password and required notes, to reopen the case from the Archived Case dialog.

If you are able to unarchive the case successfully, the standard routing dialog is displayed.

The system auto-populates the **"Current State"** field with the state it was archived from (such as Work in Progress).

The system auto-populates other values in the Routing dialog based on the current state following the normal or current functionality of the Routing dialog.

Accepting Follow-ups from Affiliate for Locked Cases

- Enter the password and required notes, to unlock the case from the **Locked Case** dialog.

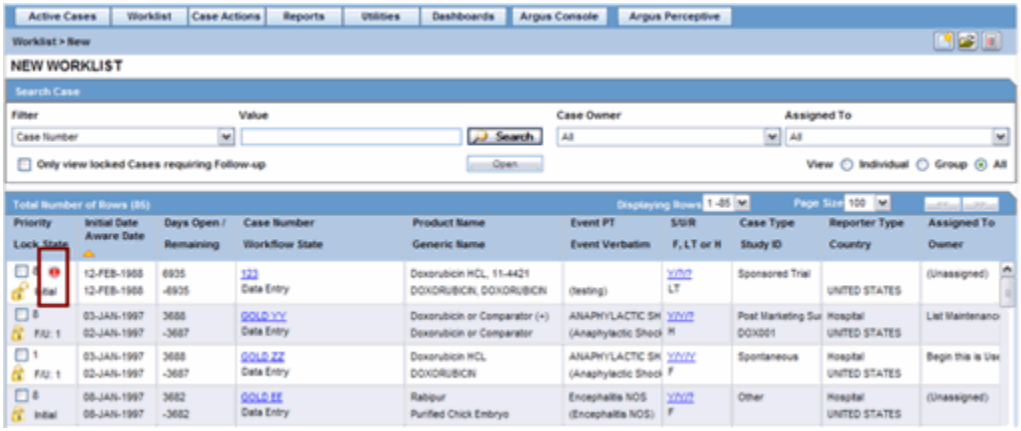
If the case is unlocked successfully, the system opens the standard routing dialog. The **Current** field is auto-populated in this dialog with the state it was currently in.

The other values in this dialog can also be auto-populated based on the current state.

Accepting Follow-ups for Open Cases

The preceding functionality of the Current State is the same for accepting follow-ups for open cases. In all scenarios, the last follow-up date entered in Oracle Argus Affiliate is auto-populated in the Oracle Argus Safety accepted case.

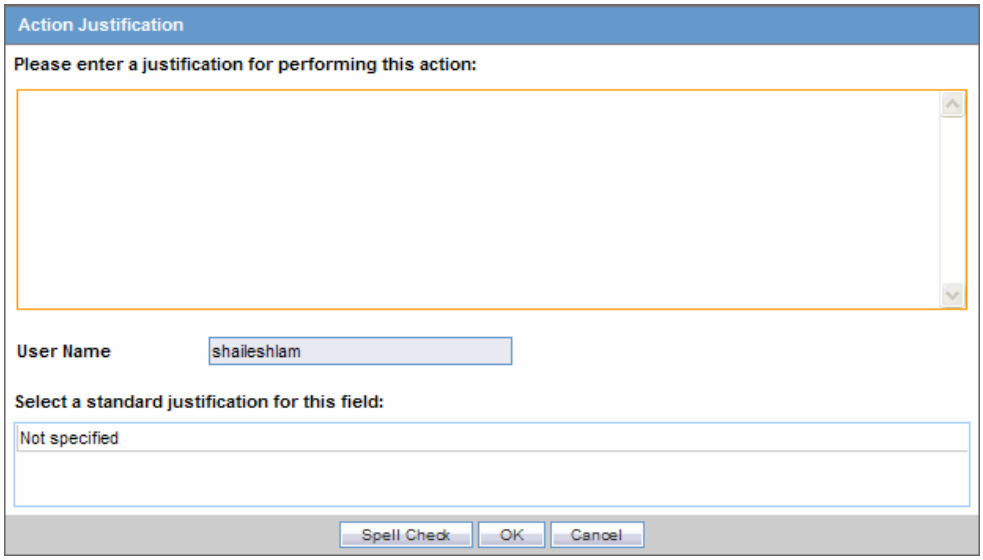
An Oracle Argus Affiliate Follow-up case is identified by a red exclamation mark in the **Worklist** > **New** section of Oracle Argus Safety.



This icon is cleared automatically after the case is routed.

Rejecting Local Events

1. Click the icon associated with the incoming event and select **Reject Local Event**.
2. Enter a justification for rejecting the event in the **Action Justification** dialog box and click **OK**.



3. In the **Reject Local Event** dialog, click **OK**.
4. When the case is rejected, the Reject icon appears adjacent to the case.
5. When the case is rejected, the action item is displayed within **LAM Worklist - LAM Action Items from Central** in both Initial and Follow-up rejection scenarios, with the following attributes:

Initial Events	Follow-up
Date	The local date of the person rejecting the case

Initial Events	Follow-up
Action Item Code	The action item code that can be configured through List Maintenance.
Action Item Description	"Case rejected by central due to" followed by the notes/ reason entered by the Oracle Argus Affiliate acceptor.
Responsible User	Set to "any".
Due Date	The due date, which is populated automatically.

Encoding Events

After a case related to the local event is created in Oracle Argus Safety, the events for the case must be encoded.

Refer to *Oracle Argus Safety User's Guide* for information on encoding events.

Locking Cases

After the events for a case are encoded, the case can be locked so that local labeling can be performed by the Oracle Argus Affiliate Users.

Refer to the *Oracle Argus Safety User's Guide* for instructions on locking a case.

Viewing Oracle Argus Affiliate Report Submission

To submit a report:

1. Select **Report Submission** from the Local Affiliate menu to open the Report Submission page.
2. Select whether you want to view **Submitted Reports only** or **Non-Submit Reports** or reports that are **Pending Submission**.
3. Enter a custom date range or select an appropriate date range under Range.
4. Click **Search**. A list of submitted or non-submitted reports appears as per the option you selected.
5. To view report details, click the icon associated with the report and select **Report Details**.
6. To open a report, click the icon associated with the report and select **View Report**.

For more information, see:

- About the Report Submission Page

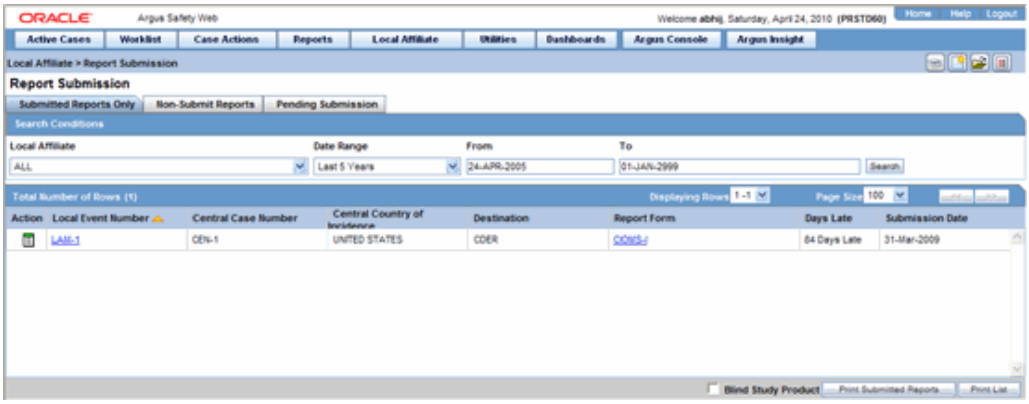
About the Report Submission Page

In this section:

- Submitted Reports Only Tab
- Non-Submit Reports Tab
- Pending Submission Tab

Submitted Reports Only Tab

The following is an illustration of the **Submitted Reports Only** tab.



The following table lists and describes the fields on the **Submitted Reports Only** tab

Field	Description
Local Affiliate	Enables you to select the local affiliate to be viewed.
Date Range	Enables you to specify a date range for searching report during a period.

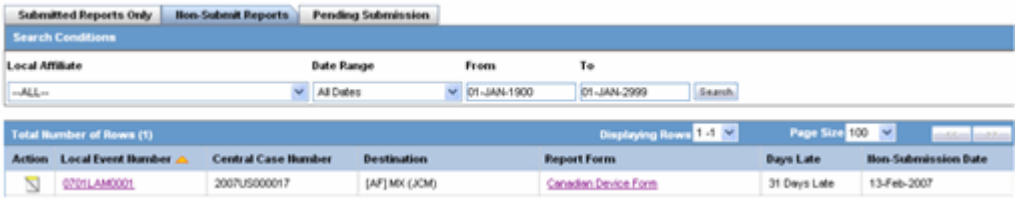
> **Note:**
>
> If a Date Range is selected, the From and To fields get populated automatically.

From	Enables you to manually enter the start date for the search period.
To	Enables you to manually enter the last date for a search period.
Action	View Report
Report Details	Enables you with the option of viewing report details.
Unsubmit Report	Enables you to un-submit the selected reports.
Local Event Number	Displays the Local Event Number of submitted reports. Click this link to view the report in a PDF.
Central Case Number	Displays the Central Case Number of submitted reports.
Central Country of Incidence	Enter the country where the adverse event occurred. Enter the partial two-character code, the country name, or the three-character code. Oracle Argus Safety will decode the entry. The Administrator can adjust the information in this list.

Field	Description
Destination	Displays the destination of submitted reports.
Report Form	Displays the type of report form for the report. Click this link to view the report in a PDF.
Days Late	Displays the days by which the report had been delayed in its submission.
Submission Date	Displays the date when the report was submitted.
Blind Study Product	Enables you to blind the study product on the Submitted Expedited reports.
Print Submitted Reports	Enables you to print the submitted reports.

Non-Submit Reports Tab

The following is an illustration of the Non-Submit Reports tab.



The following table lists and describes the fields on the **Non-Submit Reports** tab.

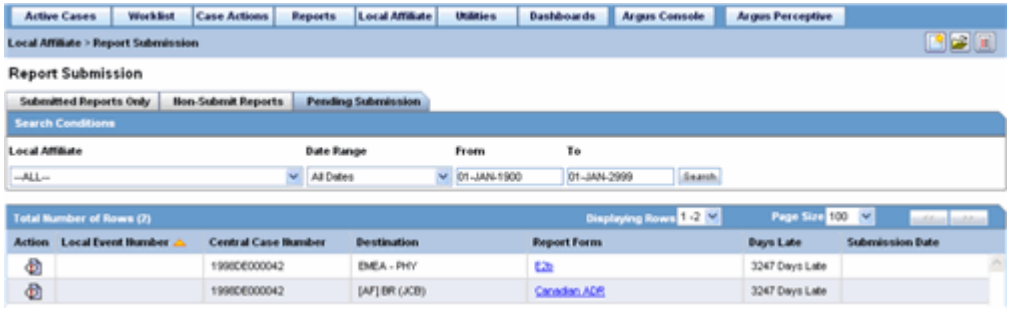
Field	Description
Local Affiliate	Enables you to select the local affiliate to be viewed.
Date Range	Enables you to specify a date range for searching report during a period.
From	Enables you to manually enter the start date for the search period.
To	Enables you to manually enter the last date for a search period.
Action	View Report
Report Details	Enables you with the option of viewing report details.
Local Event Number	Displays the Local Event Number of unsubmitted reports. Click this link to view the report in a PDF.
Central Case Number	Displays the Central Case Number of unsubmitted reports.

> **Note:**
>
> If a Date Range is selected, the From and To fields get populated automatically.

Field	Description
Central Country of Incidence	Enter the country where the adverse event occurred. Enter the partial two-character code, the country name, or the three-character code. Oracle Argus Safety will decode the entry. The Administrator can adjust the information in this list.
Destination	Displays the destination of unsubmitted reports.
Report Form	Displays the type of report form for the report. Click this link to view the report in a PDF.
Days Late	Displays the days by which the report had been delayed in its non-submission.
Non-Submission Date	Displays the date when the report was not submitted.

Pending Submission Tab

The following is an illustration of the Pending Submission tab.



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

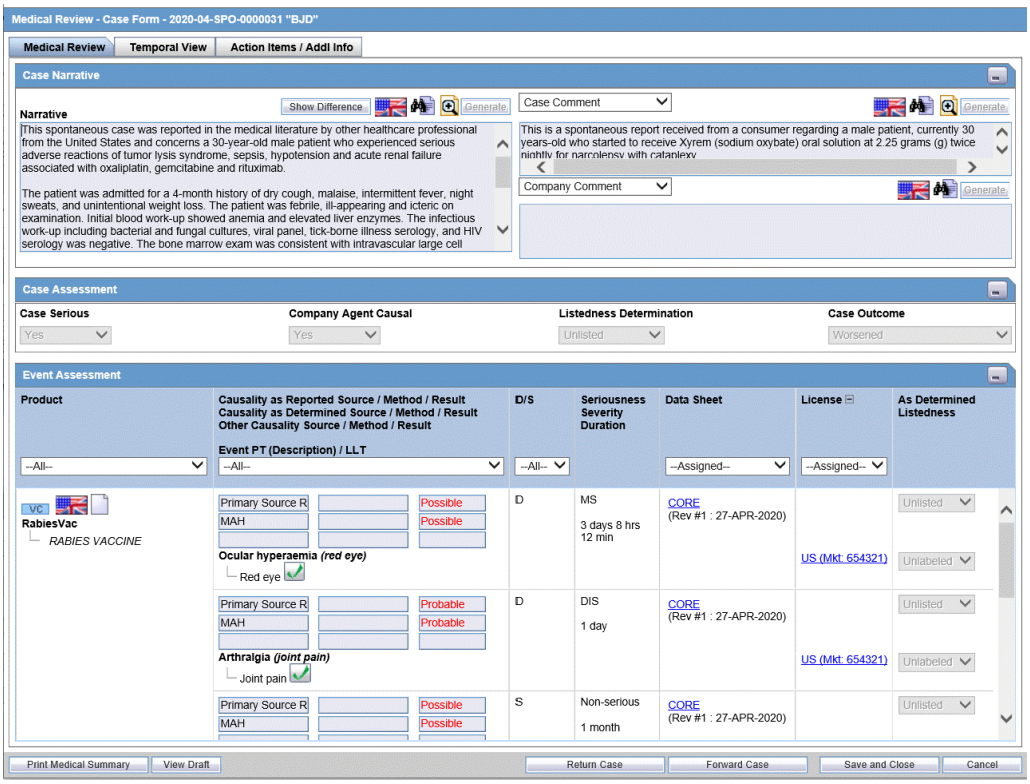
Field	Description
Local Affiliate	Enables you to select the local affiliate to be viewed.
Date Range	Enables you to specify a date range for searching report during a period.
From	Enables you to manually enter the start date for the search period.
To	Enables you to manually enter the last date for a search period.
Action	View Report

> **Note:**
>
> If a Date Range is selected, the From and To fields get populated automatically.

Field	Description
View Draft Report	Enables you to view the draft report.
Report Details	Enables you with the option of viewing report details.
Local Event Number	Displays the Local Event Number of unsubmitted reports. Click this link to view the report in a PDF.
Central Case Number	Displays the Central Case Number of unsubmitted reports.
Central Country of Incidence	Enter the country where the adverse event occurred. Enter the partial two-character code, the country name, or the three-character code. Oracle Argus Safety will decode the entry. The Administrator can adjust the information in this list.
Destination	Displays the destination of unsubmitted reports.
Report Form	Displays the type of report form for the report. Click this link to view the report in a PDF.
Days Late	Displays the days by which the report had been delayed in its non-submission.
Submission Date	Displays the date when the report was due for submission.

Medical Review

Use the **Medical Review** function to quickly and efficiently view important information in a case. The following is an illustration of the **Medical Review** screen.



> **Note:**
>
> The Medical Review section from Local Affiliate Module is a read-only section. You can view the information related to a case but cannot edit it from the Oracle Argus Affiliate's Medical Review.

For more information, see:

- To Access Medical Review
- Common Features in Medical Review
- About Medical Review
- About Temporal View
- About Action Items

To Access Medical Review

- Select **Case Actions** -- > **Medical Review** to open the Medical Review screen.

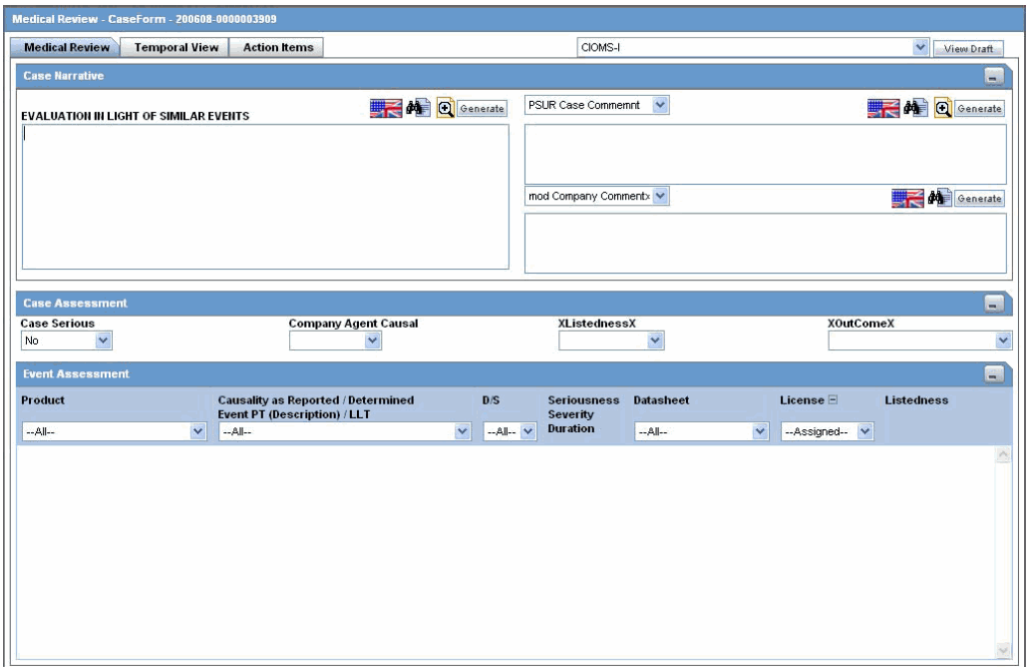
  The system opens the Medical Review screen.

Common Features in Medical Review

The following table lists and describes the common features under Medical Review.

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

About Medical Review



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

> **Note:**
>
> An (S) is displayed for Serious events.
>
> An (F) is displayed for Fatal events.
>
> An (LT) is displayed for Life Threatening events.
>
> An (H) is displayed for Hospitalized events.

For more information, see:

- Case Narrative Section
- Case Assessment
- Event Assessment

Case Narrative Section

The **Case Narrative** section is read-only and cannot be changed.

However, you can choose from the drop down options in other fields to view any of the other narrative fields.

This view is saved as a default and the next time the user opens the Medical Review for another case, this is defaulted to the narrative fields selected previously.

You cannot choose the same Narrative field in the drop down options available. The first selected narrative field is disabled in the second drop down option.

Case Assessment

The **Case Assessment** section assesses the case details.

1. Select whether the case is serious or not from the **Case Serious** drop-down list.
2. Similarly, select relevant informatio about **Company Agent Causal**, **Listedness** and **Outcome** from the drop-down lists.

Event Assessment

The **Event Assessment** section enables you to understand more about the events.

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

Field	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.
Event	This field is populated when events are entered in the **Events** tab and is displayed in the following format: • First Line - Event PT • Second Line - Verbatim • Third Line - LLT
Products	This field is populated when events are entered in the **Products** tab and is displayed in the following format: • First Line - Product Name • Second Line - Generic Name
Datasheet	Displays the datasheet(s) and its corresponding revision number and activation date that were used in assessment of the product and the event.
License	Displays the license(s) for the agent.
Reported Causality	Indicates the degree of reported causality.
Determined Causality	This field is populated automatically, along with the information entered in the Reported Causality field.
Determined Listedness	Indicates whether the system found the event on the datasheet for this product.
D/S	Displays the Diagnosis/Symptom details by **D** or **S** in line with the Events.
Seriousness Severity Duration	Display the Seriousness, Severity and the Duration of the Event.

Filtering in the Event Assessment Section

The following table describes how each field of the **Event Assessment** screen is filtered.

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

Note:

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

User Actions within Event Assessment

The following tables describes user actions and their results.

Field	Description
Click the **Datasheet** column's "plus" icon	Displays the license and datasheet views and displays the License Column and enable the "-" for the License Column.
Click **Product Name**	Displays the Product Information dialog for the selected product
Click **Event Description**	Displays the Event Information dialog for the selected event
Click **License Description**	Displays the Product Information as defined in the License Configuration
Click **Datasheet Description**	Displays all the configured terms in the datasheet

About Temporal View

Click **Temporal View** to view a read-only version of the case before routing.

The information displayed in the Temporal View tab is taken from the information entered in the Case Form section.

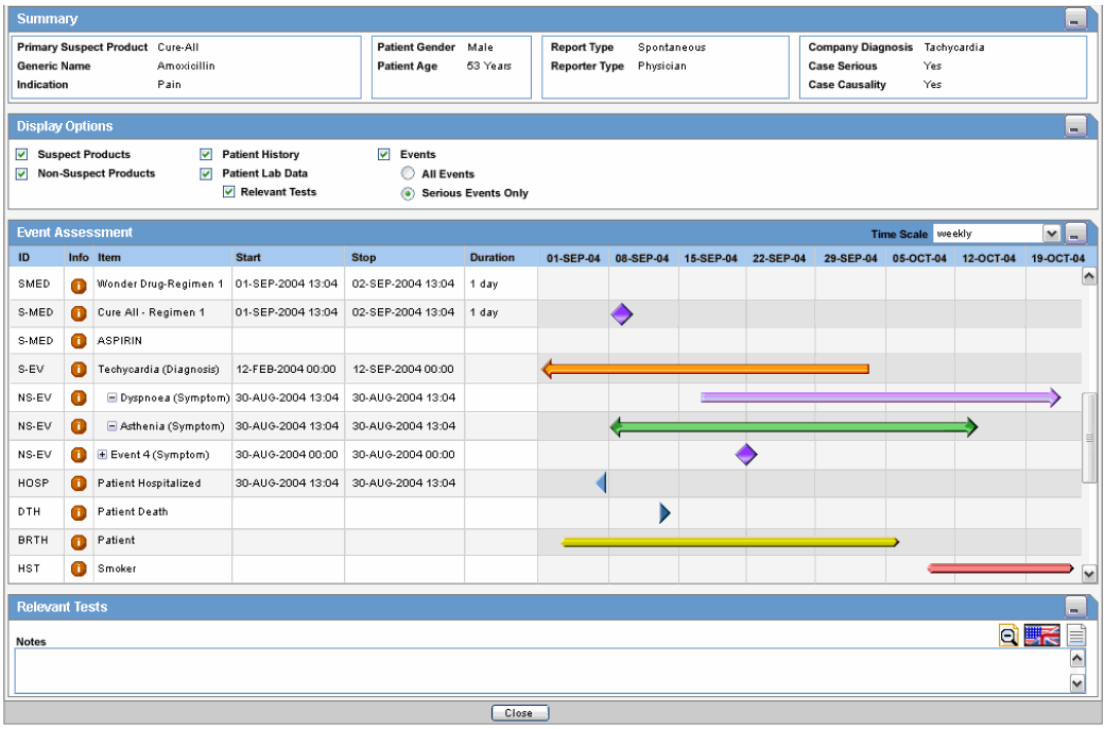
For more information, see:

- Temporal View Fields: Summary Section

- Temporal View Fields: Displays Options Section
- Temporal View Fields: Event Assessment Section
- Temporal View Fields: Relevant Tests Section

Temporal View Fields: Summary Section

The following is an illustration of the **Summary** section of the **Temporal View** tab.



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

Field	Description
Primary Suspect Product	Displays the name of the primary suspect product
Generic Name	Displays the generic name of the primary suspect product
Indication	Displays information about the product indication.
Patient Gender	Displays the gender of the patient.
Patient Age	Displays the age of the patient
Report Type	Displays the report type.
Reporter Type	Displays the type of reporter reporting the event
Company Diagnosis	Displays the company diagnosis
Case Serious	Displays whether the case is serious or not
Case Causality	Displays the case causality status

Temporal View Fields: Displays Options Section

The following table lists and describes the fields in the **Display Options** section.

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

Temporal View Fields: Event Assessment Section

The following is an illustration of the **Event Assessment** section of the **Temporal View** tab.

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

Field	Description
Time Scale	Displays the time period pertaining to the event assessment like weekly, monthly, etc.
ID	Denotes the type of event. For example, HOSP means Hospitalized
Info	Click the Info icon (i) to view details about the selected entity.
Item	Displays the item name
Start	Displays the date from when the event assessment began
Stop	Displays the last date of the event assessment
Duration	Displays the duration of the event assessment

Temporal View Fields: Relevant Tests Section

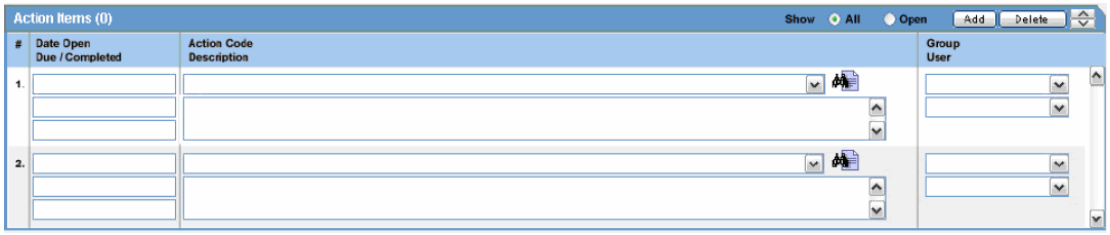
The following table lists and describes the fields in the **Relevant Tests** section.

Field	Description
Notes	Displays the notes entered, if any
Zoom/Un-zoom icon	Click the Zoom icon to view the report on a bigger scale. Click the Unzoom icon to revert to the earlier view
Flag icon	This icon displays the language text that is supported

Field	Description
Notes icon	Click this icon to view/enter notes.
Save and Close	Closes the dialog, saving any changes

About Action Items

The following is an illustration of the **Action Items** tab.



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

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

4

Oracle Argus Affiliate Configuration

The Oracle Argus Affiliate Administrator is responsible for configuring Oracle Argus Affiliate. This section includes discussions of configuration tasks.

For more information, see:

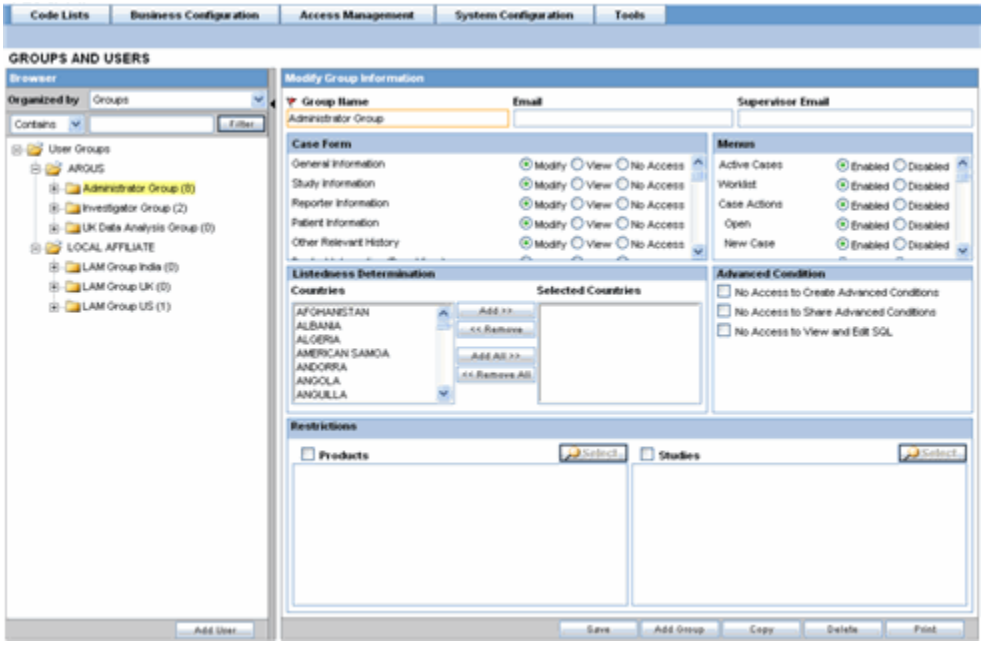
- About User Groups
- Creating User Accounts
- Viewing the Audit Log

About User Groups

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

The Administrator can configure user groups from **Argus Console** > **Access Management** > **Argus** > **Groups**. Because user group configuration can only be done from Oracle Argus Safety application, the Administrator must be logged on to Oracle Argus Safety application.

The following is an illustration of the **Groups and Users** page.



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

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

> **Tip:**
>
> If a user belongs to multiple groups, the access rights for the user will be the sum-total of the individual group access rights.
>
> Example: John Smith is an Oracle Argus Safety User and his profile has been added to 2 user-groups with different access level permissions for each group. John has access rights to the Patient Tab in one group and access rights to the General Tab in another group. In this case, John will be able to access both the Patient and the General tabs of Argus.

To add/copy/modify/delete user groups navigate to the **Access Management** > **Argus** > **Groups** section.

The following table lists and describes the fields on the **Groups and Users** page.

Field	Purpose
Group Name	Enables the administrator to enter a unique name for the group
Email	Enables the administrator to add the group email, used for case priority notification and workflow routing notification
Supervisor Email	Enables the administrator to add the Group's Supervisor Email as applicable. This e-mail address is used to send notifications when the maximum time of a case for a particular workflow state is exceeded
Menus	Lists the different menus and sub menus within a Case Form and enables the Administrator to enable or disable each of them
Listedness Determination -- Countries	Enables the administrator to assign Argus users to the group that has the rights to change the listedness determination for licenses originating in the selected countries
Default report (Argus Affiliate only)	This field lists the expedited report forms in the drop-down list

For more information, see:

- Creating a User Group
- Using Organized By

Creating a User Group

1. In the Access Management menu, click **Argus** > **Groups**.
2. Select the filtering criterion. The left panel now displays the list of Groups or Users based on the filtering criterion.

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

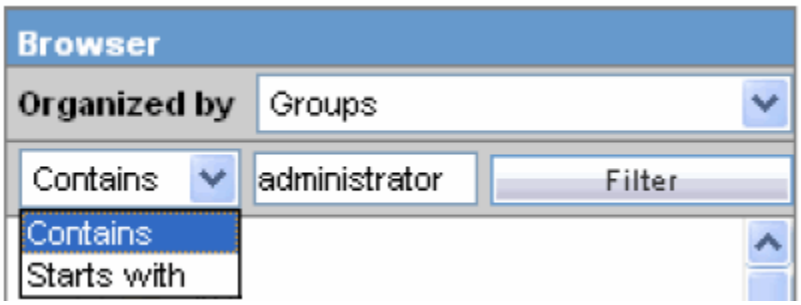
Using Organized By

The filtering browser is displayed in the top-left corner of the left panel. This section can be filtered on the basis of any of the two combinations displayed below.

For Example: If you enable Organized by Groups, then the output generated will be visible in a tree-format, in the left panel, based on the entire categorization of Groups and Users

Whereas if you enable the Organized by Users, then only the User list will be available in the tree view in the left panel.

Using the "contains" or "starts with" characters enables you can specify whether your search should contain or start with specific characters.



For example, the filtering criterion defined above will search for all Groups that contain the word "administrator".

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

> **Tip:**
>
> Select a group under LOCAL AFFILIATE in the left panel to view the details of a Oracle Argus Affiliate Group.
>
> You can alternatively click **Add Group** to create a new group.
>
> Use **Copy** to make an editable copy of an existing group.
>
> Use **Delete** to delete a group.

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

3. Enter the Email address, if applicable.
4. Enter the Supervisor Email address, if applicable.
5. In the Menus section, enable or disable access of the group, to particular items in the Oracle Argus Safety menu.

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

6. In the Listedness Determination section, select a list of countries. This enables the end user to override the listedness determination in the Event Assessment section of the Case Form for product licenses that match the countries selected in this step.
7. Click **Save** or **Add Group** to save the newly created Oracle Argus Affiliate group.

   The following table lists and describes the Groups included with factory data:

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

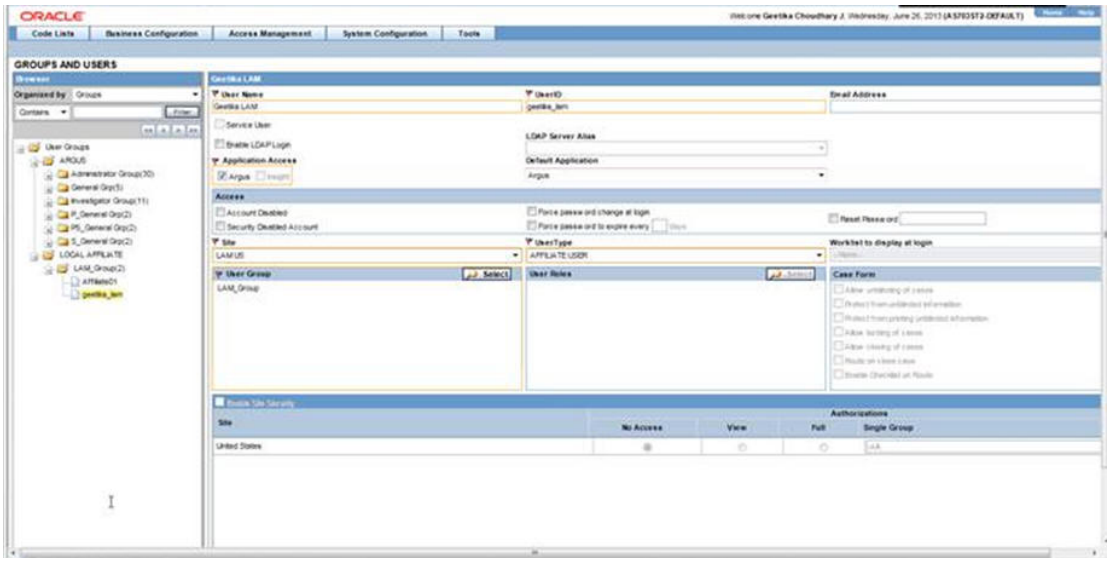
Creating User Accounts

The **User Maintenance** dialog enables the Administrator to add, copy, or delete users for the system.

Each user must be assigned to at least one group in order to determine their security level. Each group is assigned a specific security level, allowing members of the group view, modify, or have no access rights to various sections of the case form, etc.

Configuration of the users is done from **Argus Console** > **Access Management**> **Argus** > **Users**.

The following illustration shows the fields associated with this section.



For more information, see:

- Field Descriptions
- Adding Users
- Configuring the Oracle Argus Affiliate System Numbering

Field Descriptions

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

Field/Control Name	Description
User Name	Enter the full name.
User ID	Enter a unique user identification (ID).
Reset Password	Reset the password of a user to a default value specified in the common profile section.
Email Address	Enter the user's e-mail address.
Site	Assigns the user to a site. The values in this field are populated from the codelist item **User Sites**.
User Group - Select	Attaches the user to pre-configured user groups.
User Type	Select the type of user, such as an Oracle Argus Safety Japan user from the drop-down list.
Application Access	Configure user access settings for Oracle Argus Safety Console and Oracle Argus Safety. The default application access for the user can be selected from the list.

Field/Control Name	Description
Worklist to display at login	Configure users to see their worklists immediately upon login. The options are: • None (default) - Does not open any worklist when the user logs into Oracle Argus Safety. Displays personal Oracle Argus Safety status on login. • Action Items - Opens Worklist - Action Items screen for the user on login into Oracle Argus Safety • New - Opens Worklist - New screen for the user on login into Oracle Argus Safety • Open - Opens Worklist - Open screen for the user on login to Oracle Argus Safety. • Reports - Opens Worklist - Reports screen for the user on login into Oracle Argus Safety
Enable site security	If *Enable Security* is checked, the site-based data security will be enabled for the user. If the box is not checked, the user will have full access to data from all sites.
Enable LDAP Login	Authenticates users against the active directory server. When **Enable LDAP Login** is selected, all fields inside the **Access** section are disabled, excluding the **Account Disabled** option.
Account Disabled	When this option is selected, the user account is temporarily disabled to prevent users from logging in. This option is different from deleting a user as it enables the Administrator to re-activate the account at a later date.
Security Disabled Account	• When **unchecked**, the login procedure keeps track of the number of consecutive unsuccessful attempts at logging into the system. If the count reaches three, the login procedure will always fail the password validation to lock the user out. Administrators with rights to user maintenance can reset the login attempts for the user to unlock the account. • When **checked**, the login procedure that tracks the consecutive unsuccessful attempts at logging into the system do not apply.
Force password change at login	If this check box is selected, the users must change the password the first time user logs on to the system after the checkbox is checked.
Force password to expire every	Enables the Administrator to force the user's password to expire in the specified number of days.
Days	Enables the Administrator to enter the number of days after which the password should expire.
__ Days remaining	The field displays the number of days remaining for the password change.
Allow unblinding of cases	Enables the user to unblind a study case. For example, a user **without** unblinding rights will not see the Study Drug field. A user with unblinding rights sees a yellow *Unblind* tag next to concentration of product field and the *Broken by Sponsor* option in Blinding Status drop-down list is enabled. User will have to enter password when user selects Broken by Sponsor' option.
Protect from unblinded information	When checked, the user cannot view any unblinded information.
Protect from printing unblinded information	When checked, the user cannot print any unblinded information.
Allow locking of cases	Enables the user, to lock/unlock the cases.
Allow closing of cases	Enables the user to close the cases.

Field/Control Name	Description
Route on close case	Opens a routing dialog when the user closes the case.
Enable Checklist on Route	By default, this checkbox is selected. If this checkbox is not selected, the checklist for the Workflow is not displayed to the user while routing the cases, even if the rule that is being used has a checklist.

Adding Users

This section enables you to add, copy, modify or delete users for the system. When managing user accounts, be aware of the following:

- Each Oracle Argus Safety user must be assigned to at least one group in order to determine the user's security level.
- Each group is assigned a specific security level. This enables group members to view/ modify or have limited access rights to various sections of the case form, etc.
- To add/copy/modify/delete users navigate to **Argus Console** > **Access Management** > **Argus** > **Users** section.

To Create a User Group:

1. In the Access Management menu, click **Argus** > **Users**.
2. Select the filtering criterion. The left panel now displays the list of Groups or Users based on the filtering criterion.

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

For more information, see:

- Using Organized By

Using Organized By

The filtering browser is in the top-left corner of the left panel. This section can be filtered on the basis of any of the two combinations displayed below.

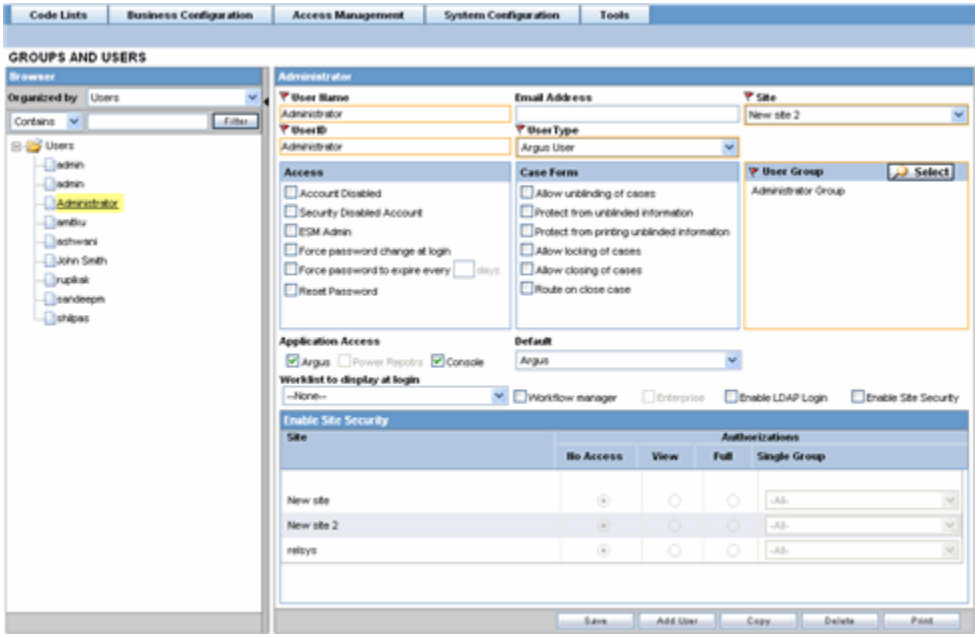
For example, if you enable **Organized by Groups**, the generated data will be visible in a tree-format, in the left panel, based on the entire categorization of Groups and Users

Whereas if you enable the **Organized by Users**, then only the User list will be available in the tree view in the left panel.

Using the contains or starts with you can specify whether your search should contain or start with specific alphabets.

For example, the filtering criterion defined above will search for all Users that contain the word "admin".

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



> **Note:**
>
> You can alternatively click **Add User** or **Add New User** to create a new user.
>
> Use **Copy** to make an editable copy of an existing user.
>
> Use **Delete** to delete a user.

2. Enter the **User Name**. This should be a unique name associated with this user.
3. Enter the **User Id**. This is the unique user name associated with the user.
4. Enter the **Email Address** of the user.
5. Select the **Site** from the drop-down list. The user is assigned to this site.
6. Select the **User Type** from the drop-down list.
7. Select the language from the drop-down list in **Modify Language Narrative**.
8. This is the language the user has access to in the multi-lingual fields.
9. Select the following options in **Access**, as per your requirements.

Field Name	Purpose
Account Disabled	Enables the administrator to disable the account.
Security Disabled Account	Enables the administrator to disable the account depending upon the number of consecutive unsuccessful login attempts. When unchecked: The login procedure keeps track of the number of consecutive unsuccessful attempts at logging into the system. If the count reaches three, the login procedure will always fail the password validation and lock the user out. Administrators with rights to user maintenance can reset the login attempts for the user to unlock the account. When checked: The login procedure to keep track of the consecutive unsuccessful attempts at logging into the system does not apply.
ESM Admin	Enables the administrator to give the Oracle Argus Safety user access to the ESM Mapping utility.
Force Password change at login	Ensures that password is changed at login. Select this field to force Oracle Argus Safety users to change their password, when they log in to the application for the first time.
Force password to expire every x days	Enter the maximum number of days for the user(s) to retain user password.
Reset Password	Select this field to reset the user password.

10. Select the following options in Case Form, as per your requirements.

Field Name	Purpose
Allow unblinding of Cases	Select this to allow the user to unblind a study case. A user with no rights of unblinding a case cannot see the Study Drug field. Users with Unblinding rights see a yellow tag "Unblind" adjoining the Concentration of product field. The Broken by Sponsor' option in Blinding Status drop-down is enabled. User has to enter password when on selecting the "Broken by Sponsor" option
Protect from unblinded information	Allows the Administrator to protect a user from unblinding information such as Study Drug, Concentration, Dosage Regimens and Total Dosage.
Protect from printing unblinded information	Select this to disable the user from printing unblinded information.
Allow locking of cases	Select this to allow the user to lock cases.
Allow closing of cases	Select this to allow the user to close cases.
Route on Close Case	Select this to disable the case routing dialog which appears when the users selects Case Actions -- Close Case on the case form.

11. Select the **User Group**.
12. Enable the **Application Access** for different applications such as Oracle Argus Safety, Power Reports or Console.
13. Select the **Default application access** from the drop-down list, for the user.

14. Select the default worklist to be displayed on logging onto Oracle Argus Safety from the Worklist to display at login drop-down list, for the user.
15. Select the **Workflow manager** checkbox to give the user more rights within the system.
16. Select the **Enterprise** checkbox to configure a 'Workflow Manager' user as an 'Enterprise user'.

    The user can view cases of any site outside its site too. This field is enabled only when the 'Workflow Manager' field is checked.
17. Select the **Enable Site Security** checkbox to enable site based security data for the user.
18. This is made possible through the **Site Access Configuration** dialog.
19. The **Site Access Configuration** section enables a user to get access to additional sites.
20. The administrator can select the access level by selecting from the options available in this dialog.

    The following table describes the access levels in this dialog:

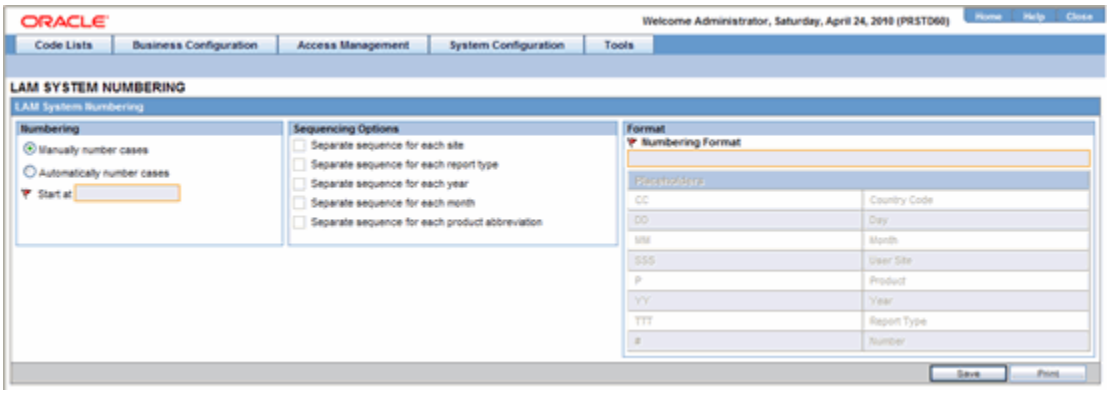
		Authorizations		
Site Access Level	**Data Access**	**Function Access**	**Summary Reports**	**Workflow**
No Access	No	None	No	No
View	Read-Only	Defined by sum of user-group membership	Yes	Yes
Full	Read/Write	Defined by sum of user-group membership (stipulated by - All - in the User Group section)	Yes	Yes
Single Group	Read/Write	Defined by single user group	Yes	Yes

21. Select the **Enable LDAP Login** checkbox to allow the user to be authenticated against the active directory server.
22. Click **Save** to add the newly created Oracle Argus Affiliate user.

Configuring the Oracle Argus Affiliate System Numbering

The system provides the ability to use multiple case numbering schemes for globally. For example, if site is used in the numbering, the system provides the option to keep separate sequences for each site. However, Oracle Argus Affiliate System Numbering configuration can only be done from Oracle Argus Safety application. Therefore, to configure the Oracle Argus Affiliate System Numbering, the Administrator must be logged on to Oracle Argus Safety application, and the System Numbering menu and the Local Affiliate sub-menu must be enabled in the User Group.

Select **Argus Console** > **System Configuration** > **System Numbering** > **Local Affiliate** to view the Oracle Argus Affiliate System Numbering screen. The following is an illustration of the **LAM System Numbering** page.



The following table lists and describes the fields on the **LAM System Numbering** page.

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

Field	Description
Placeholder	Enables the user to enter a placeholder. Placeholders are used to pickup values from the database to be used in the Case numbering format. The possible values populated in this list are: • . # -- Number: defines the digits to be used as the sequence number in the format. The field is used to display the sequence number on the case numbers. • CC-- Country code: When selected, this uses the A2 code for the country of incidence for the case number. • DD -- Day: When selected, this uses the date of the "Initial receipt date" field of the case. • MM -- month: When selected, this uses the month of the "Initial receipt date" field of the case. • P -- When selected, this uses either of the two values: 1. If report type is "Spontaneous" or " other" during booking: the system uses the value of the "Product Abbreviation" field specified in the Product configuration for the selected Primary suspect product. 2. If report type is of the type "report from study" during booking: the system uses the "Product Abbreviation" field specified in the study configuration. • SSS -- User Site: When selected this uses the Site abbreviation of the site belonging to the user who booked in the case • TTT -- Report Type: When selected this uses the report type abbreviation of the report type selected during bookin of the case • YY -- Year: When selected, this uses the year of the "Initial receipt date" field of the case.

To Configure Oracle Argus Affiliate system numbering:

1. Select the **Numbering** feature as required. This can be manual numbering or automatic numbering of cases.
2. Select the **Sequencing Options** as required.
3. Select the **Numbering Format**. Use **Placeholders** to enter the required format.

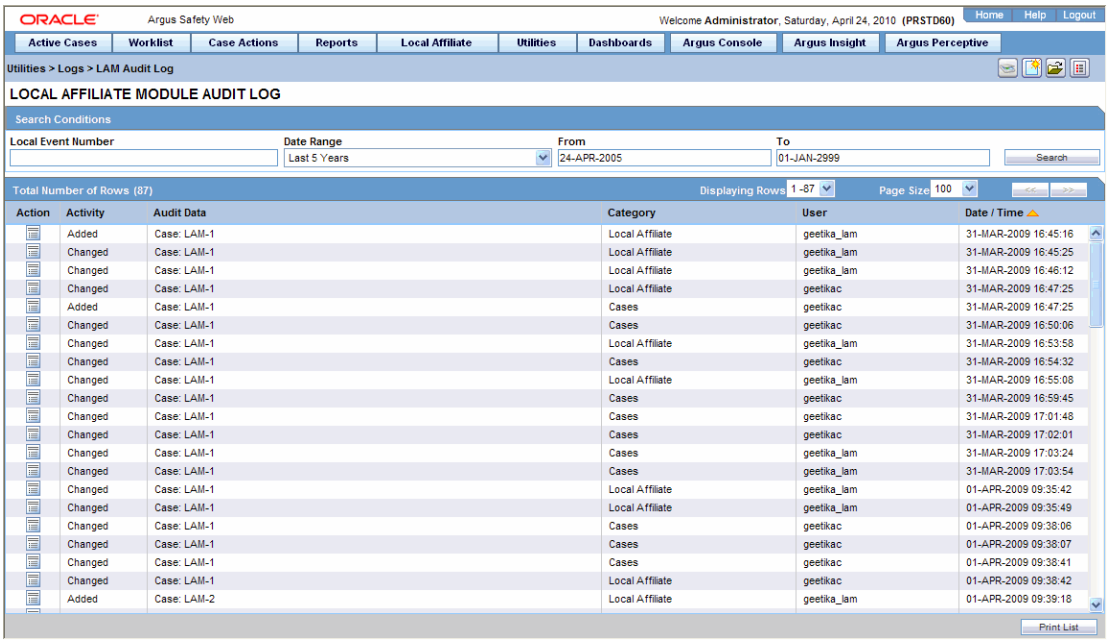
   To customize the **Numbering Format**, use the **placeholder** values.

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

   a. Click on **Country Code.** This appears in the **Numbering Format** field.
   b. Click on **Month**. This appears in the **Numbering Format** field next to the Country Code.
   c. Click on **Year**. This appears in the **Numbering Format** field next to the Country Code and Month.
   d. The final data listed in the **Numbering Format** field is the Case Numbering Format.
4. Click **Save** to save the changes made.

Viewing the Audit Log

The **LAM Audit Log** can only be viewed from the Oracle Argus Safety application. The following is an illustration of the **LAM Audit Log**.



To view the Oracle Argus Affiliate Audit Log:

1. Go to **Utilities** > **Logs** > **LAM Audit Log** to open the LAM Audit Log.
2. The following table lists and describes the fields in the LAM Audit Log.

Field	Description
Search Conditions	--
From	Enter the initial date of the time period to be searched
To	Enter the end date of the time period to be searched
Search button	Displays the results of the specified search criteria.
Total Number of Rows	--
Action	Displays the **Audit Log Details** screen
Activity	Displays the status of the activity. Displays whether it has changed or not.
Audit Data	Displays the audit data
User	Displays the last user who made changes to the case
Field	Description

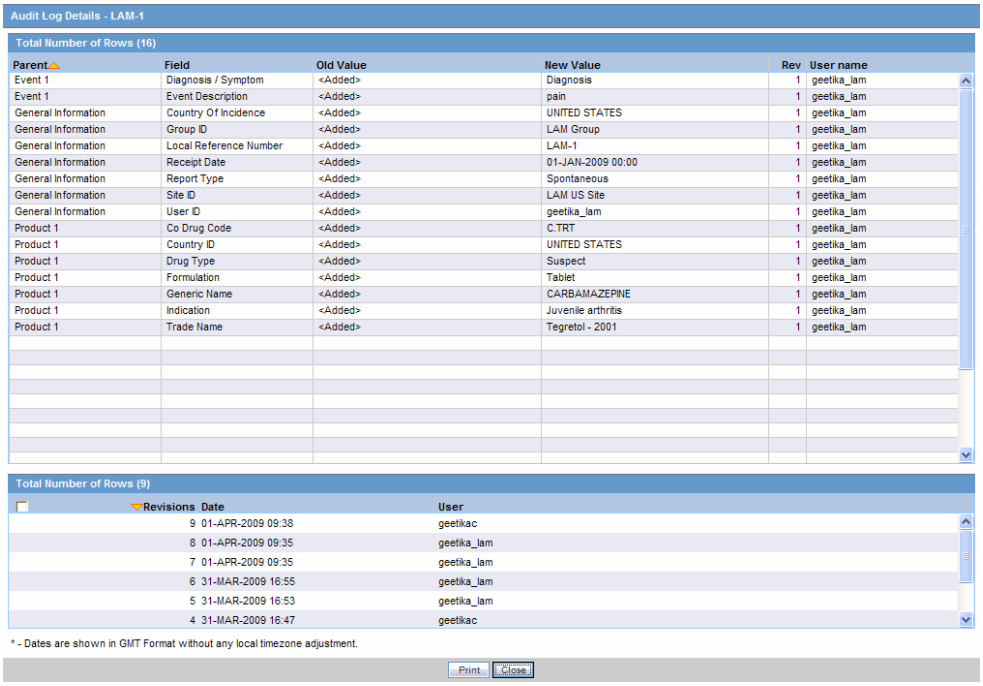
Field	Description
Date/Time	Displays the last time the case was changed. **Note:** The time displayed is as per GMT.
Print List button	Prints the list of all the logs.

For more information, see:

- Searching the Audit Log

Searching the Audit Log

1. Enter a date range for which the audit log is to be viewed. A date range can also be selected from the **Range** list.
2. Click **Search**.
3. A list of LAM Audit Log items matching the search criteria appears in **Total Number of Rows**.
4. Click the **Action** icon displayed against each search result in **Total Number of Rows** to open the **Audit Log Details** screen.



> **Note:**
>
> The lower half of the **Audit Log Details** screen displays the list of all the revisions made in the case.

The following table lists and describes the fields on the **Audit Log Details** screen.

Field	Description
Total Number of Rows	Displays the total number of rows in the list
Parent	Displays the parent page where the change has been made.
Field	Displays the field where the change has been made.
Old Value	Displays the previous value.
New Value	Displays the new, changed value.
Rev	Displays the revision number. The list is sorted in descending order of the revisions that have been made so the latest revision is displayed at the top.
User Name	Displays the name of the last user who made a change.
Revisions Date	Displays the last date when the change was made.
User	Displays the name of the user who last made the revision.

5. Click a row displaying a revision.

   The system displays the details in the upper half of the screen.

> **Tip:**
>
> Multiple selections can be made to view the details of revisions.