Oracle® Argus Safety

Quickstart Guide

Release 8.1.1

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Logging in

1. Open Microsoft Internet Explorer and enter the URL for Argus Safety.
2. On the Argus login screen, enter your username and password.
3. Select the appropriate database from the **Database** drop-down list and click **Login**.

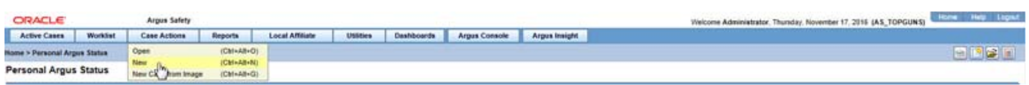
   The Home/Personal Argus Status page is displayed.

For more information, see the section **Logging In and Out** in the *Oracle Argus Safety User's Guide*.

Entering Case Data

Creating a New Case

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



2. On the Initial Case Entry page, enter the mandatory information (fields with a red flag) and click **Continue**.
3. On the BookIn screen, check the applicable checkboxes and click **BookIn**.
4. If Argus has been configured to generate a case number automatically, it is generated now.

   If the case number is not automatically generated, enter it according to your company guidelines.
5. When the case creation message appears, click **Yes**.

   Note: If you click Yes, the Case Form page appears. You can now enter case data.

   If you click No, the case is saved and closed. You can open the case and enter data at any time.

For more information, see **Creating a New Case** in the *Oracle Argus Safety User's Guide*.

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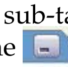
Finding an Existing Case

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

2. On the Case Search Criteria page, select the applicable search criteria and click **Search.**
3. When the system displays the search results, locate the case in the list.
4. Click the link associated with the **Case ID** to open that case in the Case Form.

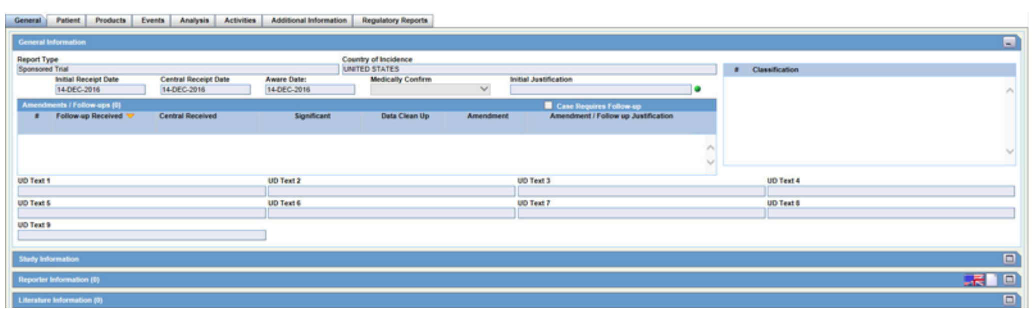
For more information, see **Finding and Opening Existing Cases** of the *Oracle Argus Safety User's Guide*.

Updating a Case

- Case data is organized on four tabs: General, Patient, Products, and Events.
- These tabs have sub-tabs and sections that further organize the information collected. Use the  button on the right side of the screen to minimize or maximize each section.
- Tabbing from field to field activates any auto-calculated fields.
- When you finish entering information for a section, tab, or sub-tab, click the **Save** icon at the top of the page.

See the following sections for information on using the tabs.

Entering General Data



For basic information on using the General tab, see **General Tab** in the *Oracle Argus Safety User's Guide*.

For details on entering data in each section of the General tab, see:

- **General Information**
- **Study Information**

- **Reporter Information**
- **Literature Information**

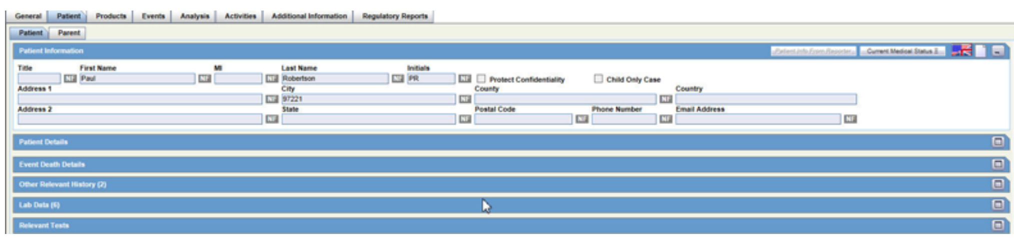
Entering Patient Data

For general information on entering Patient data, see **Patient Tab** in the *Oracle Argus Safety User's Guide*.

The Patient tab has two sub-tabs.

- Patient Tab
- Parent Tab

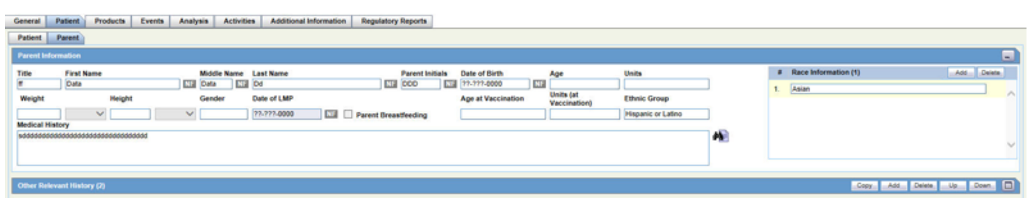
Patient Tab



For details on entering data in each section of the Patient tab, see:

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

Parent Tab



For details on entering data in each section of the Parent tab, see:

- **Parent Information**

Entering Products Data

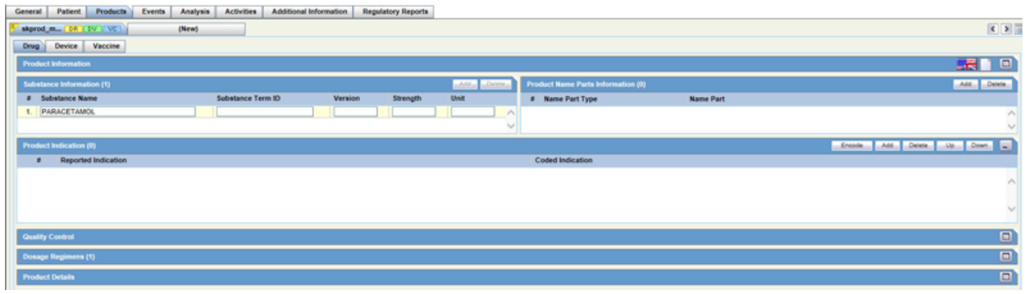
For general information on entering Products data, see **Products Tab** in the *Oracle Argus Safety User's Guide*.

The Products tab has the following sub-tabs:

- Drug Tab

- Device Tab
- Vaccine Tab

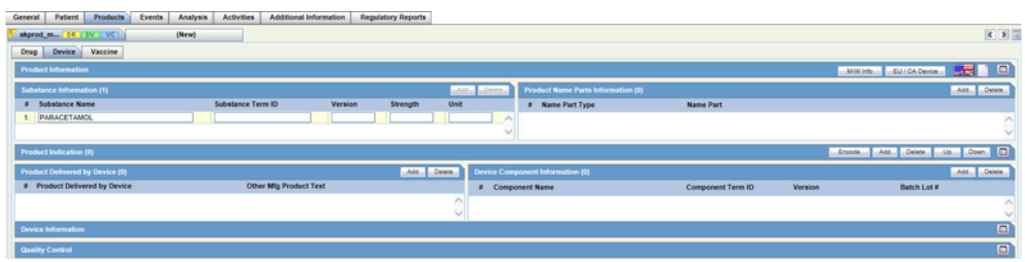
Drug Tab



For details on entering data in each section of the Drug tab, see:

- **Product Information**
- **Product Indication**
- **Quality Control**
- **Dosage Regimens**
- **Product Details**

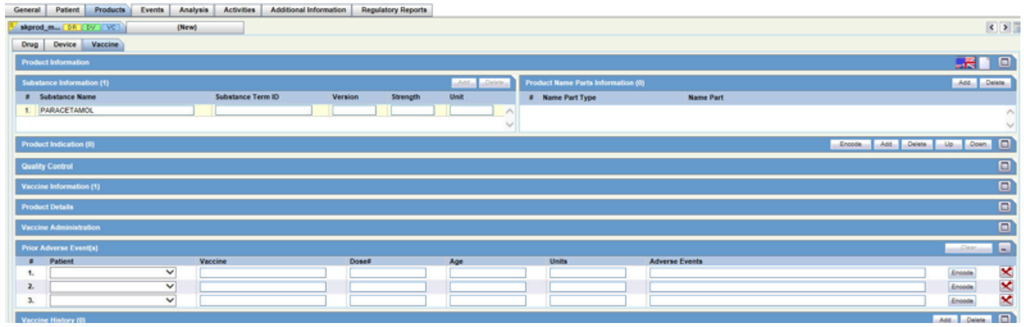
Device Tab



For details on entering data in each section of the Device tab, see:

- **Product Information**
- **Product Indication**
- **Device Information**
- **Quality Control**

Vaccine Tab



For details on entering data in each section of the Vaccine tab, see:

- **Product Information**
- **Product Details**
- **Vaccine Administration**
- **Prior Adverse Events**
- **Vaccine History**

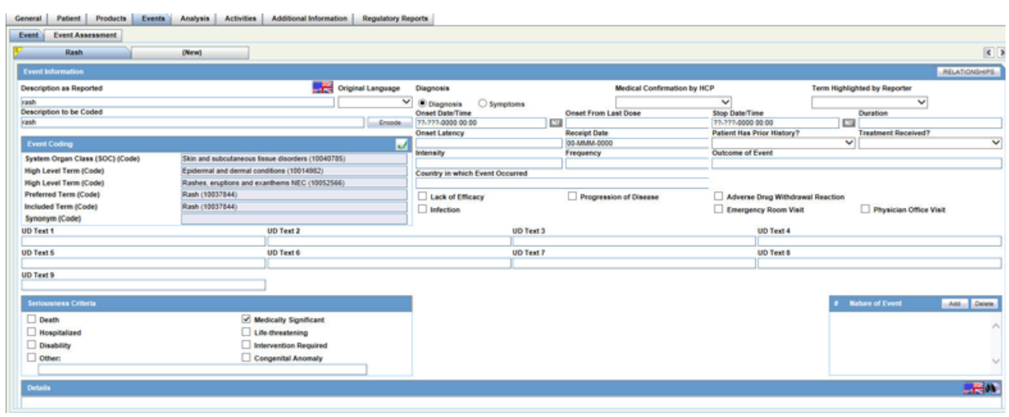
Entering Events Data

For general information on entering Events data, see **Events Tab** in the *Oracle Argus Safety User's Guide*.

The Events tab has the following sub-tabs:

- Event Tab
- Event Assessment Tab

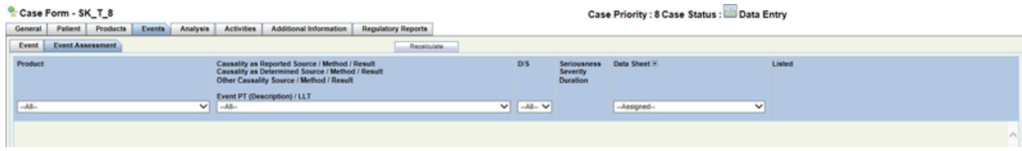
Event Tab



For details on entering data in each section of the Event tab, see:

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

Event Assessment Tab

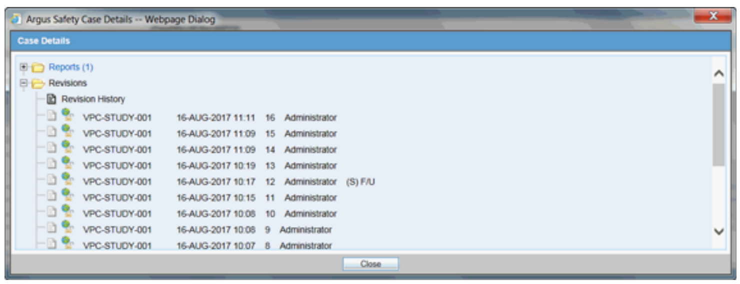


For details on entering data in each section of the Event Assessment tab, see:

- **Event Assessment Tab**

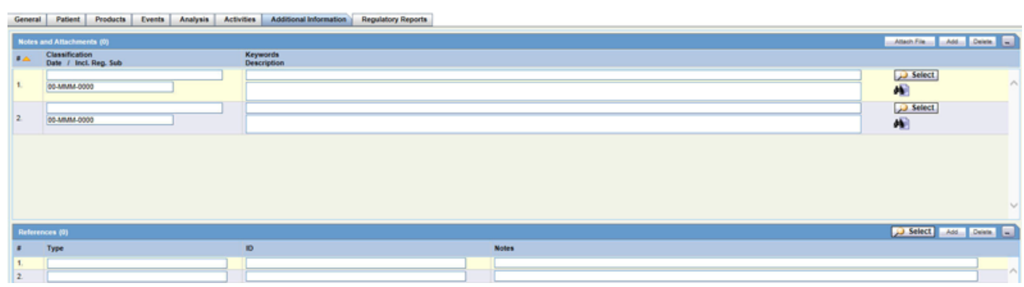
Viewing Updates made to your Case

1. Open an existing case, hover over the **Case Actions** menu and click **Case Revisions**.
2. On the Argus Safety Case Details dialog box screen, click **Revisions**.
3. From the Revision History, click on a specific revision to view the changes made.



Attaching Additional Information to your Case

1. On the Case Form page, click the **Additional Information** tab.



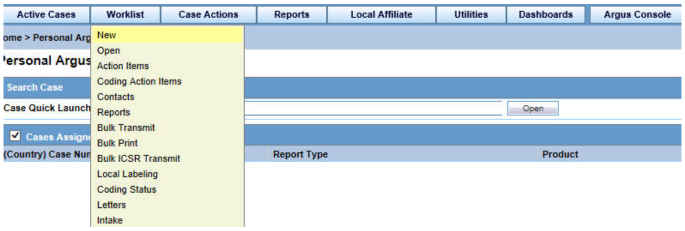
2. Enter information in the **Notes and Attachments** and **References** sections.

For basic information on using the Additional Information tab, see **Additional Information Tab** in the *Oracle Argus Safety User's Guide*.

Reviewing your Cases

Viewing New Cases in the Worklist

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



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

For details on entering data in each section of the New page, see:

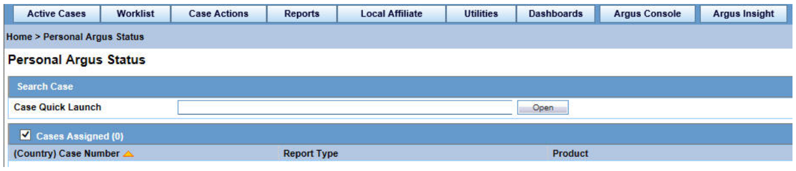
- **Filtering Functions**
- **Total Number of Rows**

Note: Once you have accepted the case, it is **Open**.

Finding a Case Assigned to you

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

   The list of cases assigned to you is displayed.



For more information, see **Case Workload** in the *Oracle Argus Safety User's Guide*.

If the Personal Argus Status Page is not your default home page, go to **Utilities** and click **Personal Argus Status**.

Viewing your Pending Action Items

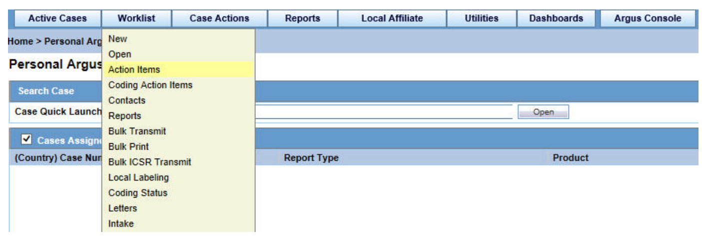
1. On the Home/Personal Argus Status page, check the **Action Item Entries** checkbox.

   The list of your pending action items is displayed.

For more information, see **Personal Argus Status** in the *Oracle Argus Safety User's Guide*.

Viewing your Worklist Action Items

1. On the Home page, hover over the **Worklist** menu and click **Action Items**.

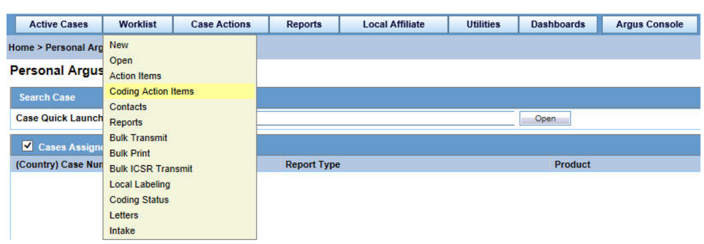


2. On the Action Items page, enter the required information and click **Search**.
3. Click **Print List**.

For more information, see **Action Items** in the *Oracle Argus Safety User's Guide*.

Viewing your Coding Action Items

1. On the Home page, hover over the **Worklist** menu and click **Coding Action Items**.



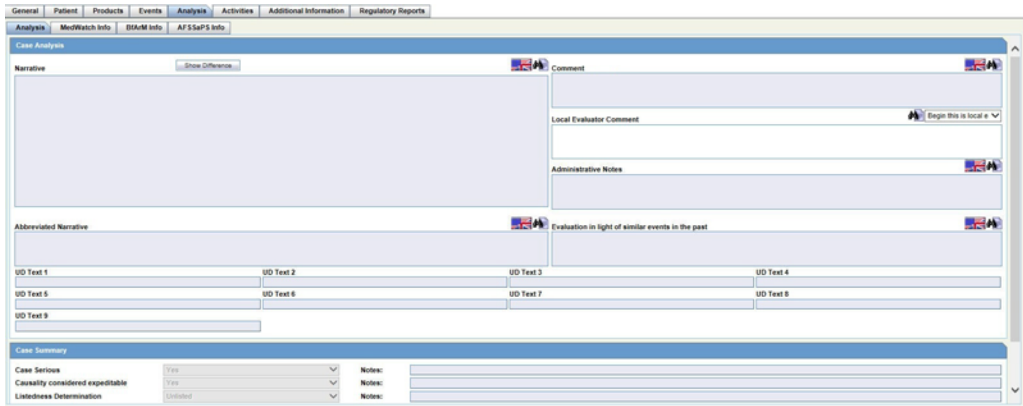
2. On the Coding Action Items page, enter the required information and click **Search**.
3. Click **Print List**.

For more information, see **Coding Action Items** in the *Oracle Argus Safety User's Guide*.

Performing a Medical Review

- When you finish entering information for a section, tab, or sub-tab, click the **Save** icon at the top of the page.

Reviewing Case Narrative

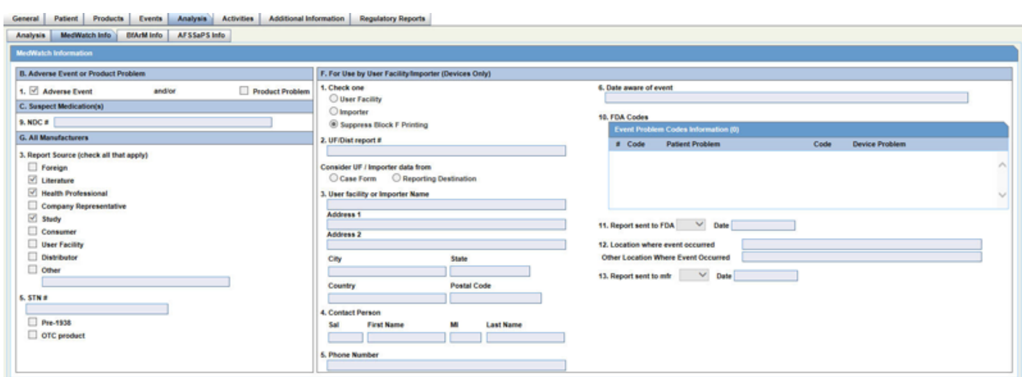


For basic information on using the Analysis tab, see **Analysis Tab** in the *Oracle Argus Safety User's Guide*.

For details on reviewing and entering data in each section of the Analysis tab, see:

- **Case Analysis**
- **Case Summary**

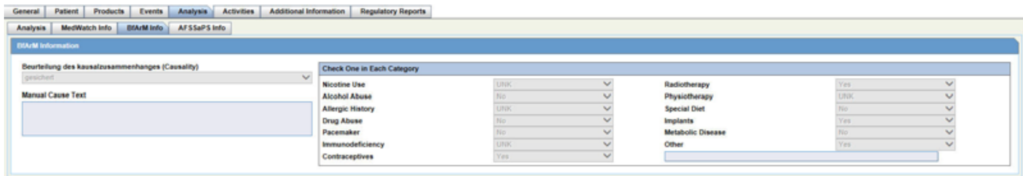
Reviewing MedWatch Information



For details on reviewing and entering data in each section of the MedWatch Info tab, see:

- **MedWatch Info Tab**

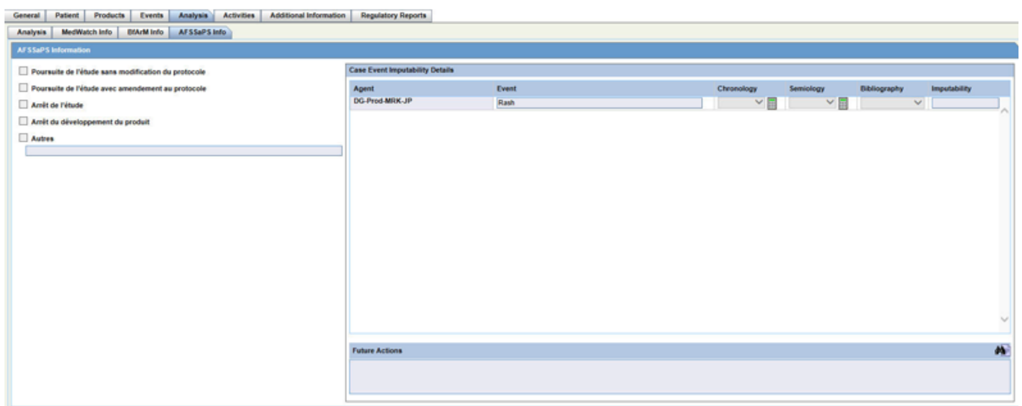
Reviewing BfArM Information



For details on reviewing and entering data in each section of the BfArM tab, see:

- **BfArM Info Tab**

Reviewing AFSSaPS Information



For details on reviewing and entering data in each section of the AFSSaPS tab, see:

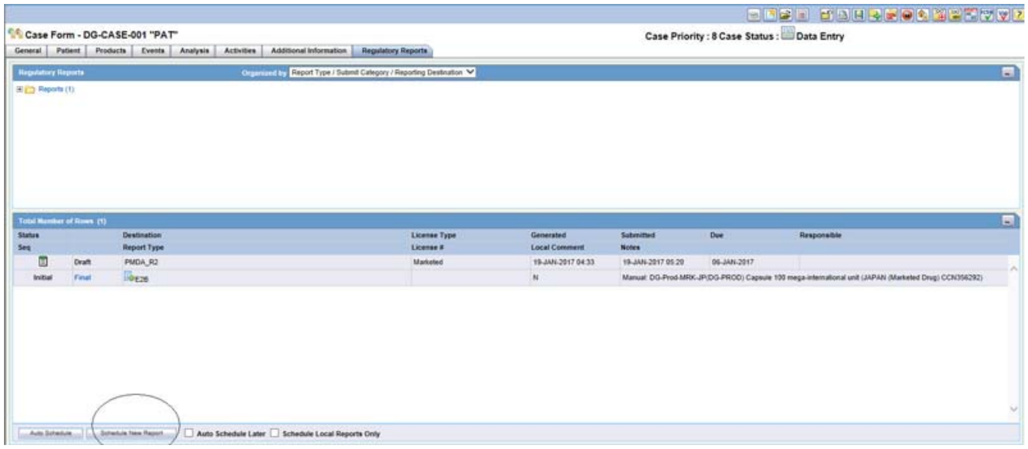
- **AFSSaPS Info Tab**

Managing your Report Submissions

The following procedures describe tasks for Expedited Reports. You can also schedule, review, generate, and transmit Periodic reports in a similar manner.

Scheduling an Expedited Report

1. Open the case for which you want to schedule a report.
2. On the Case Form page, click the **Regulatory Reports** tab.
3. On the Regulatory Reports page, click **Schedule New Report**.



4. On the Schedule New Expedited Report page, enter the required information and click **OK**.
5. Click the **Save** icon at the top of the page.

For details on using Scheduling Reports, see **Scheduling Reports** in the Argus Safety User's Guide.

Note: This section also contains instructions for **Auto-scheduling Reports**.

Reviewing a Draft Report

1. Open the case for which you want to schedule a report.

   Note: You can only view a Draft report if the relevant case is unlocked.
2. On the Case Form page, click the **Regulatory Reports** tab.
3. From the Total Number of Rows tab, locate the relevant report and click **Draft** to view the report.

For details on viewing and generating Reports, see **Generating Reports** in the Argus Safety User's Guide.

Generating an Expedited Report

1. Open the case for which you want to schedule a report.

   Note: Verify that the relevant case has been locked and the required report has been scheduled.
2. On the Case Form page, click the **Regulatory Reports** tab.
3. From the Total Number of Rows tab, locate the relevant report and click **Final** to generate the report.

For details on using Generating Reports, see **Generating Reports** in the *Oracle Argus Safety User's Guide*.

Transmitting a Report

1. On the Case Form page, click the **Reports** tab, then select **Compliance**, and then **Periodic**.

2. On the Periodic Reports page, locate the relevant report and click on the **Status** of the report.
3. On the Report Details page, click **Transmission** and then click **Transmit**.
4. On the Transmit to Recipients page, enter the required information and click **Transmit**.

You can also transmit several reports together using the **Bulk Transmit** option.

1. On the Home page, hover over the **Worklist** menu and click **Bulk Transmit**.
2. On the Bulk Transmit page, enter the required information and click **Search**.

For details on entering data in each section of the Search Case page, see:

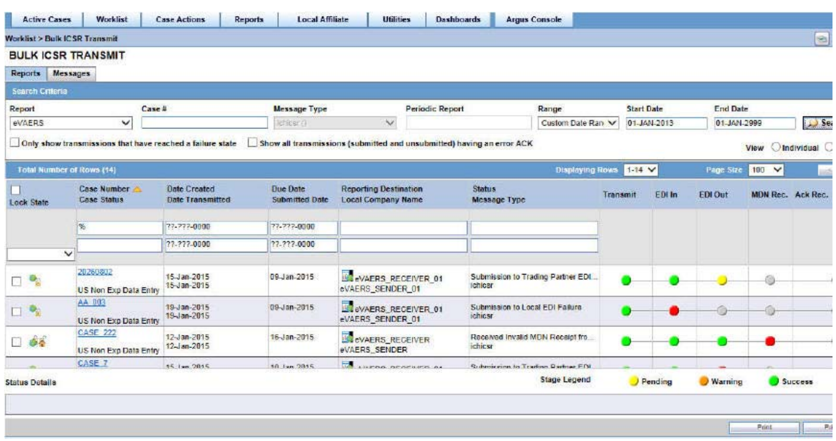
- **Total Number of Rows**
- **User Options**
- **Routing Details**

Tracking your ICSR Report Submissions

1. On the Home page, hover over the **Worklist** menu and click **Bulk ICSR Transmit**.

   For general information on tracking your submissions, see **Bulk ICSR Transmit** in the *Oracle Argus Safety User's Guide*.
2. The Bulk ICSR Transmit screen has the following sub-tabs:
   - Reports Tab
   - Messages Tab

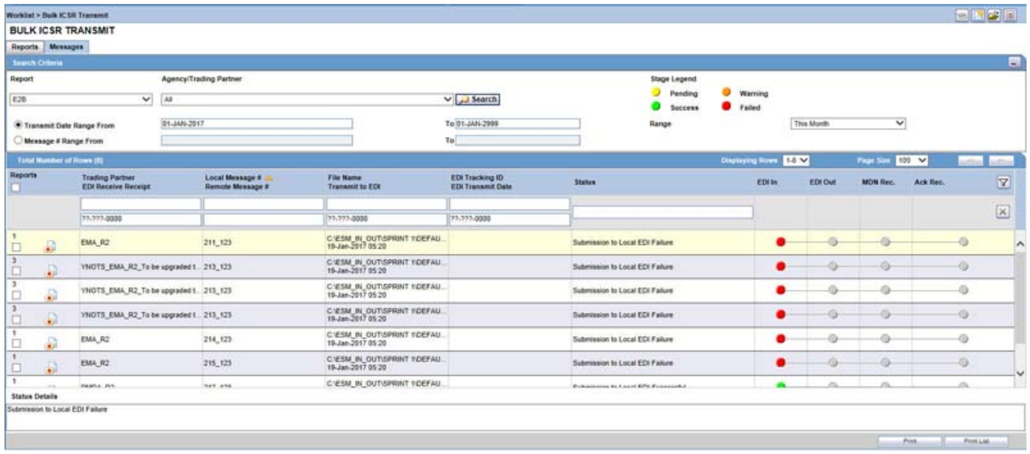
Reports Tab



For details about the sections and user options on the Reports tab, see:

- **Reports Tab**
- **Total Number of Rows**
- **Reports Tab User Options**

Messages Tab



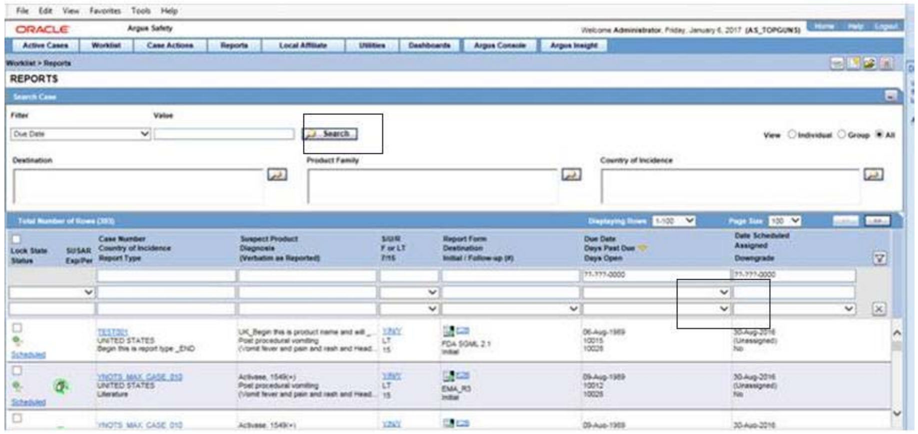
For details about the sections and user options of the Messages tab, see:

- **Messages Tab**
- **Search Criteria**
- **Total Number of Rows**
- **Message Tab User Options**

Finding an Overdue Report

1. On the Home page, hover over the **Worklist** menu and click **Reports**.
2. Click on the field **Days Past Due** on the right of the Total Number of Rows and if needed click again to show Days Past Due in descending order (arrow pointing downwards).

3. To view all reports select **ALL** at top right of the screen.
4. Click the Search button, at the top left of the screen. Overdue cases are all those reports shown as greater than 0 Days Past Due and greater than today's date.



For details on entering data in each section of the Total Number of Rows tab, see **Total Number of Rows**.

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