

This workflow process guide will show DMID Sponsors how to view the case narrative and then route the case to the appropriate PVG specialist in the Oracle Argus Safety System. Please note that as the DMID Sponsor you have *Read Only* access to the case and case narrative.

This workflow process guide will explain how to perform the following tasks:

[Logging in to the Oracle Argus Safety System](#)

[Opening a Case](#)

[Checking all cases for the same Subject ID](#)

[Viewing the Case Narrative and Case Causality](#)

[Routing the Case and Adding Comments](#)

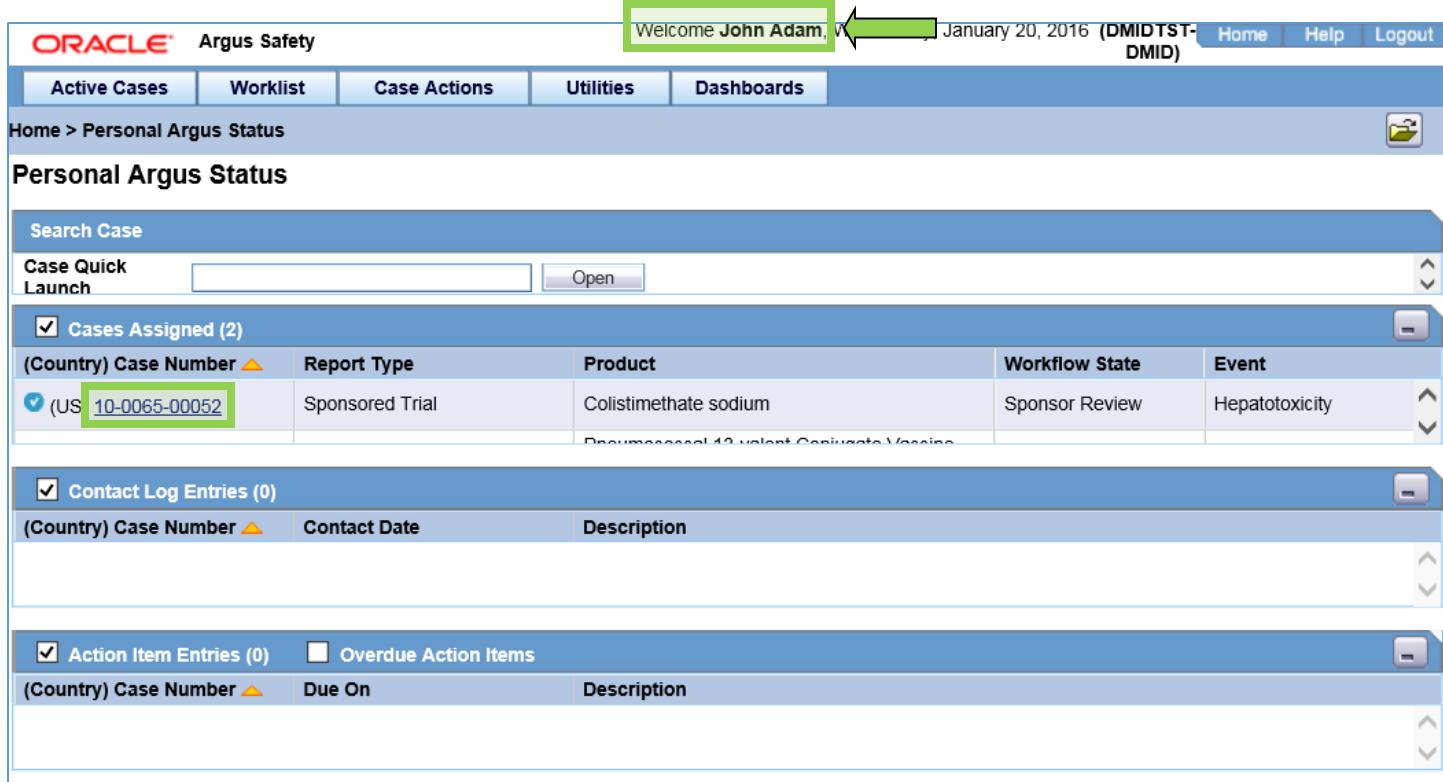
#### **Logging in to the Oracle Argus Safety System**

1. Enter your **Username** and **Password**.
2. Click **Login**.



## Opening a Case

1. After logging in, the first page Argus displays is your **Personal Dashboard**. Your **Personal Dashboard** will show all of the cases assigned to you.

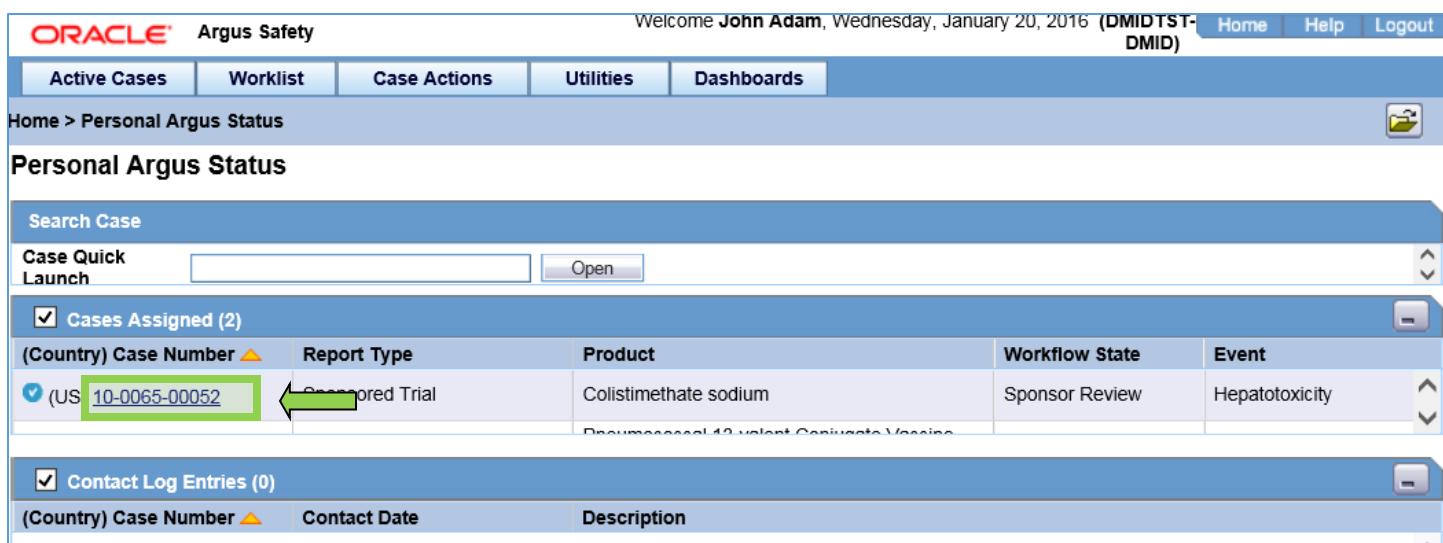


The screenshot shows the Oracle Argus Safety Personal Dashboard. At the top, the header reads "ORACLE Argus Safety" and "Welcome John Adam, Wednesday, January 20, 2016 (DMIDTST-DMID)". The navigation bar includes "Home", "Help", and "Logout". Below the header, the "Personal Argus Status" section is displayed. The "Search Case" area includes a "Case Quick Launch" input field and an "Open" button. The "Cases Assigned" section is expanded, showing a table with the following data:

(Country) Case Number	Report Type	Product	Workflow State	Event
(US) <a href="#">10-0065-00052</a>	Sponsored Trial	Colistimethate sodium	Sponsor Review	Hepatotoxicity

Below this, the "Contact Log Entries" and "Action Item Entries" sections are shown, both currently empty.

2. To open a case, click the **case number link** (for example, 10-0065-00052).



The screenshot shows the Oracle Argus Safety Personal Dashboard, identical to the first one. The "Cases Assigned" section is highlighted with a green arrow pointing to the case number [10-0065-00052](#) in the "Report Type" column.

3. The **General** tab appears after opening a case. All the fields will be grayed out and you will have **Read Only** access. You can view additional case information by selecting individual tabs.

The screenshot shows the Oracle Argus Safety interface. The top navigation bar includes 'Active Cases', 'Worklist', 'Case Actions', 'Utilities', and 'Dashboards'. The 'Case Actions' tab is active. The main content area is titled 'Case Form - 10-0069-00024 10-0069 "05HSF229"'. The 'General' tab is highlighted with a green box. Other tabs include 'Patient', 'Events', 'Analysis', 'Activities', 'Additional Information', and 'Regulatory Reports'. The 'Case Status' is 'Sponsor Review'. The 'General' tab displays fields for 'Report Type' (Sponsored Trial), 'Initial Receipt Date' (01-JUN-2015), 'Central Receipt Date' (00-MMM-2000), 'Country' (UNITED STATES), 'Medically Confirm' (checkbox), 'Initial Justification' (text area), 'Case Requires Follow-up' (checkbox), and 'Classification' (list box). Below this is the 'Amendments / Follow-ups (0)' section. The 'Study Information' section includes fields for 'Project ID' (10-0069), 'Study ID' (10-0069), 'Center ID' (U. of Cal San Fran-Tenderloin Res Ctr), 'Study Phase' (Phase II), 'Study Name' (Placebo vs. AdCh3NSm1 plus MV-A-NSm1), 'Other ID', 'Study Type' (Double Blinded), 'Blinding Status' (Blinded), 'Unblinding Date', 'Week #', 'Visit #', 'Observe Study Type' (Clinical Trial), and 'Study Description' (Phase II, double-blinded, randomized, placebo-controlled study of HCV-uninfected male and female active IDU aged 18 to 45 years. In Stage I 68 (+/-4) evaluable subjects will be enrolled and then an interim analysis of safety data will be performed. In Stage II an additional 276 (+/-4) subjects will be enrolled). The 'Reporter Information (1)' section includes fields for 'Sal.', 'First Name' (Paula), 'Middle Name', 'Last Name' (Lum), 'Suffix', 'Health Care Professional', 'Occupation' (Principal Investigator), 'Address' (954 Market St, Ste 200), 'Institution', 'Institution ID', 'Department', 'City' (San Francisco), 'Country' (UNITED STATES), 'Phone Number', 'Alternate Phone', 'FAX Number', 'Reporter ID' (94102-4012), 'Reporter Type', 'Report Media', 'Postal Code' (94102-4012), 'Reporter's Reference #', 'Email Address' (plum@php.ucsf.edu), 'Report Sent to Regulatory Authority by Reporter?' (checkbox), 'Protect Confidentiality' (checkbox), 'Primary Reporter' (checkbox), and 'Correspondence Contact' (checkbox). The bottom of the tab shows the reporter's name: LUM, Paula.

#### Checking all cases for the same Subject ID

1. Under the **Case Actions** tab, click **Open** to display the case open page.

The screenshot shows the Oracle Argus Safety interface with the 'Case Actions' tab active. The top navigation bar includes 'Active Cases', 'Worklist', 'Case Actions', 'Reports', 'Utilities', and 'Dashboards'. The 'Case Actions' tab is active. The main content area shows a table with columns: 'Home > Personal Argus Status', 'Case Actions', 'Reports', 'Utilities', and 'Dashboards'. The 'Case Actions' column contains buttons for 'Open (Ctrl+Alt+O)' and 'New (Ctrl+Alt+N)'. The 'Reports' column contains a 'Case Quick Launch' button. The 'Utilities' column contains a 'Case Assigned (0)' button. The 'Dashboards' column contains a 'Report Type' button. The table also includes columns for 'Product', 'Workflow State', and 'Event'.

2. Under the **Search For** tab, select **Patient ID**.

The screenshot shows the Oracle Argus Safety interface with the 'Case Actions > Case Open' tab active. The top navigation bar includes 'Active Cases', 'Worklist', 'Case Actions', 'Reports', 'Utilities', and 'Dashboards'. The 'Case Actions > Case Open' tab is active. The main content area is titled 'Case Open'. The 'Case Search Criteria' section includes a 'Search For' dropdown menu with options: 'Case #', 'Case Num/Ref', 'Event Term', 'Event Verbatim', 'Keyword', 'Patient ID', 'Project ID', 'Study ID', 'Prv/Stdy/Othr/Cntr/Rptr/Pat', 'Lock State', and 'Case #'. The 'Date Range' section includes 'Last 30 Days' (dropdown), 'Initial' (radio button), 'Follow Up' (radio button), 'From' (27-DEC-2015), and 'To' (01-JAN-2099). The 'Advanced Condition' section includes a dropdown menu with '(None)' and a 'Search' button. The bottom of the page includes 'Displaying Row 1-1', 'Page Size 100', and navigation buttons.

3. Enter the Patient ID and click Search to display the list of cases for the subject.

4. Right click on the **Case number** to open the **Case Summary** window. Then click on **Case Summary**, this will provide more information about the case.

## Viewing the Case Narrative and Case Causality

1. Click on the **Medical Review** icon  located on the upper righthand corner of the **General Tab** screen to open the case narrative in a separate window.

2. In the pop-up window, the case narrative will appear on the left hand side of the screen. Review the case narrative and also the information in the **As Reported Causality/As Determined Causality** box. When you have completed your review, click the **Save and Close** button. A yellow highlight appears: "Case has been saved successfully."

Medical Review - Case Form - 10-0069-00024 10-0069 "05HSF229"

Medical Review Temporal View Action Items / Addl Info Medical Review View Draft

**Case Narrative**

**Narrative**

Case number 10-0069-03584 is an investigator report of Delivery Complication in a 38 year-old female subject 05HSF229 enrolled in the DMID protocol 10-0069 entitled "A Staged Phase III Study, to Assess Safety, Efficacy and Immunogenicity of a New Hepatitis C Prophylactic Vaccine Based on Sequential Use of AdCh3NSmut1 and MVA-NSmut." Pending the DMID Medical Monitor's approval, the event has been assessed as serious, unexpected and not related to the study product.

The subject's past medical history includes bipolar disease and schizophrenia (1999) for which she was hospitalized for 3 days, tooth decay (2008), and 2 urinary tract infections (UTI) (2013). Her obstetric history includes six pregnancies (G6T5P0A1L5). Her last menstrual period (LMP)

**E2B Reporter Causality**

**Case Assessment**

Case Serious: Yes      Company Agent Causal: No      Listedness Determination: Unknown      Case Outcome:

**Event Assessment**

Product	As Reported Causality / As Determined Causality	D/S	Seriousness	Data Sheet	As Determined Listedness			
--All--	Event PT (Description) / LLT --All--	--All--	Not Related	Uterine rupture (Uterine Rupture) Uterine rupture	D	H	< Unspecified >	Unknown

**Save and Close** **Cancel**

**Note:** When the text in the **As Reported Causality/As Determined Causality** box is red, this indicates a related event.

## Routing the Case and Adding Comments

Routing the case to the next state is determined by your assessment of the case. You will approve, disapprove or expedite the case and add your comments at this step in the process. Below is a brief description of each routing state:

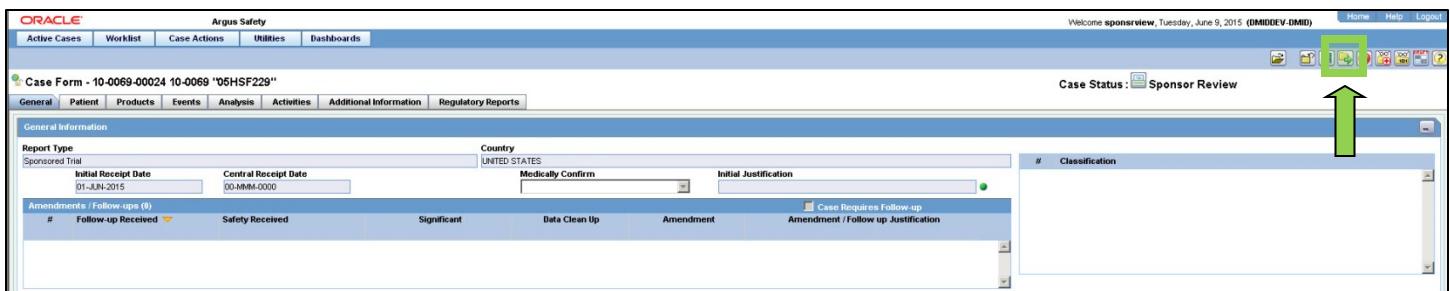
**Approved:** You are satisfied with the case narrative. You approve the case for queries or for closure.

**Disapproved:** You disapprove the case narrative and will need to provide comments explaining why you selected this option. You will reroute the case back to PVG. PVG will need to submit a new revised case narrative for your review.

**Expedited Report:** You are satisfied with the case narrative. You approve the case for queries. You have determined that a case is a serious, unexpected and suspected adverse reaction (SUSAR), and must provide comments to justify why you selected this option. The case will be routed back to PVG. PVG will draft an Expedited Safety Report and provide you with a timeline.

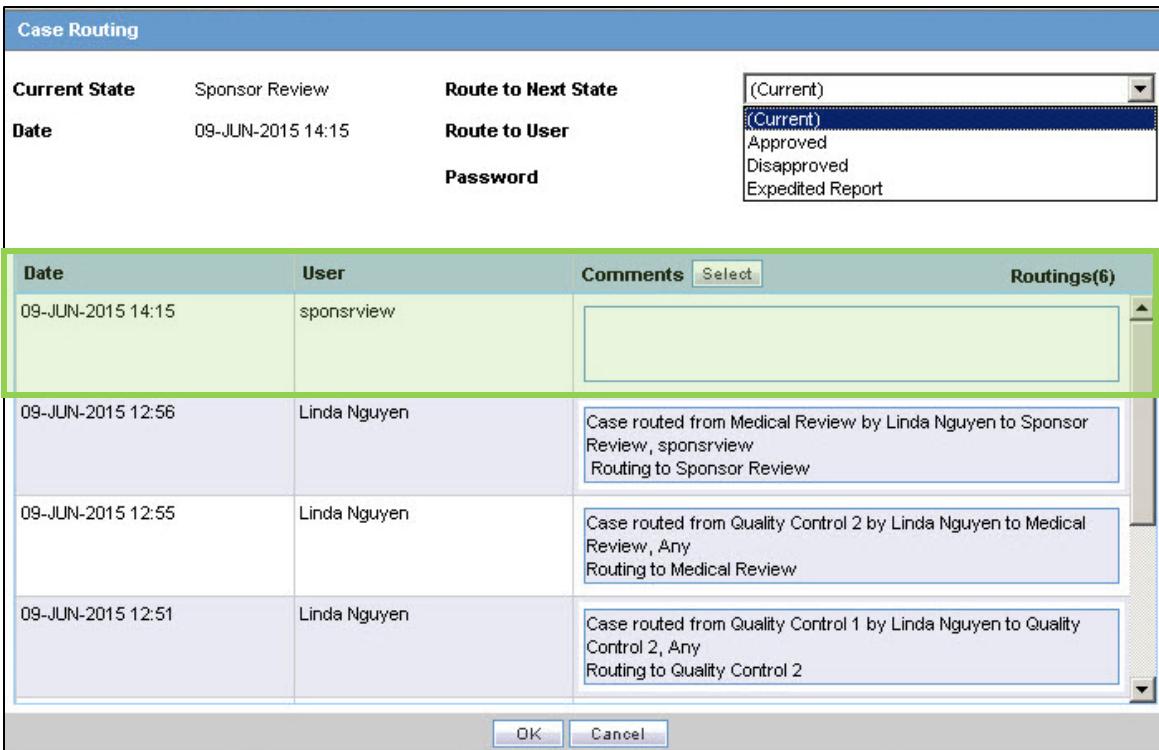
To route the case to the next state, do the following steps. **Note:** These steps are applicable to all three routing state options.

1. Click on the icon with the green arrow  on the top right side of the **General Tab** screen to open the **Case Routing** box.

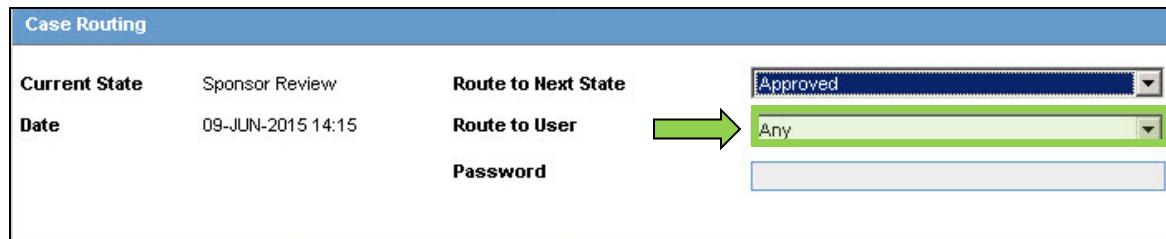


2. The **Case Routing** box will display. Go to **Route to Next State** and do the following:

- a. Click on the drop-down menu and select an option **Approved**, **Disapproved**, or **Expedited Report**.
- b. Enter your comments, including those related to any change request, in the **Comments** box. For example, enter "Approved by [Your Name]" or "Disapproved by [Your Name]".

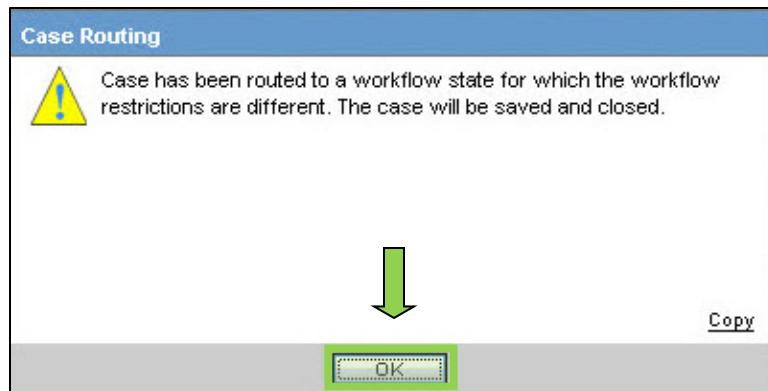
A screenshot of the 'Case Routing' dialog box. The top section shows 'Current State' as 'Sponsor Review' and 'Date' as '09-JUN-2015 14:15'. The 'Route to Next State' dropdown is open, showing '(Current)', 'Approved', 'Disapproved', and 'Expedited Report'. Below this is a table of routing history with columns: Date, User, Comments, and Routings(6). The first row is highlighted in green. The 'Comments' column for the first row contains the text: 'Case routed from Medical Review by Linda Nguyen to Sponsor Review, sponsrview Routing to Sponsor Review'. The 'Comments' column for the second row contains the text: 'Case routed from Quality Control 2 by Linda Nguyen to Medical Review, Any Routing to Medical Review'. The 'Comments' column for the third row contains the text: 'Case routed from Quality Control 1 by Linda Nguyen to Quality Control 2, Any Routing to Quality Control 2'. At the bottom are 'OK' and 'Cancel' buttons.

c. Next, click on the **Route to User** drop-down menu, and keep the default option **Any**. Click **OK**.

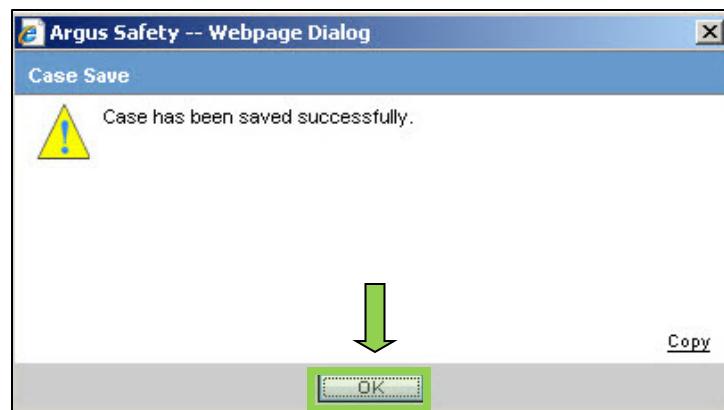


Case Routing			
Current State	Sponsor Review	Route to Next State	Approved
Date	09-JUN-2015 14:15	Route to User	Any
Password			

d. A **Case Routing** box will appear stating that the case has been routed and saved successfully. Click **OK**.



e. A **Case Save** box will appear indicating that your case has been saved successfully. When you have completed your assessment, an automated email that includes your decision and comments will be sent to [PVG@dmidcroms.com](mailto:PVG@dmidcroms.com).

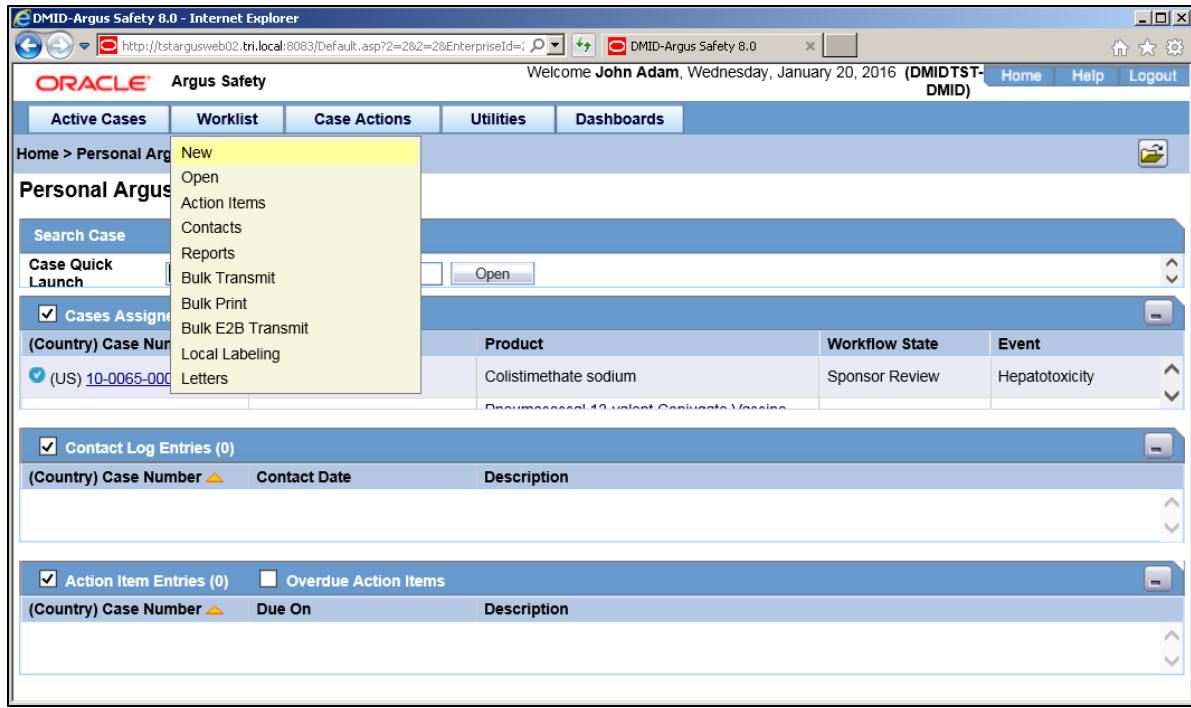


f. Click the **Home** button in the upper right hand corner to return to the **Worklist -> New** page to review other cases. You must always use the **Logout** button to logout of the application. Failure to do so may lock up the application and prevent you or others from further processing the case.



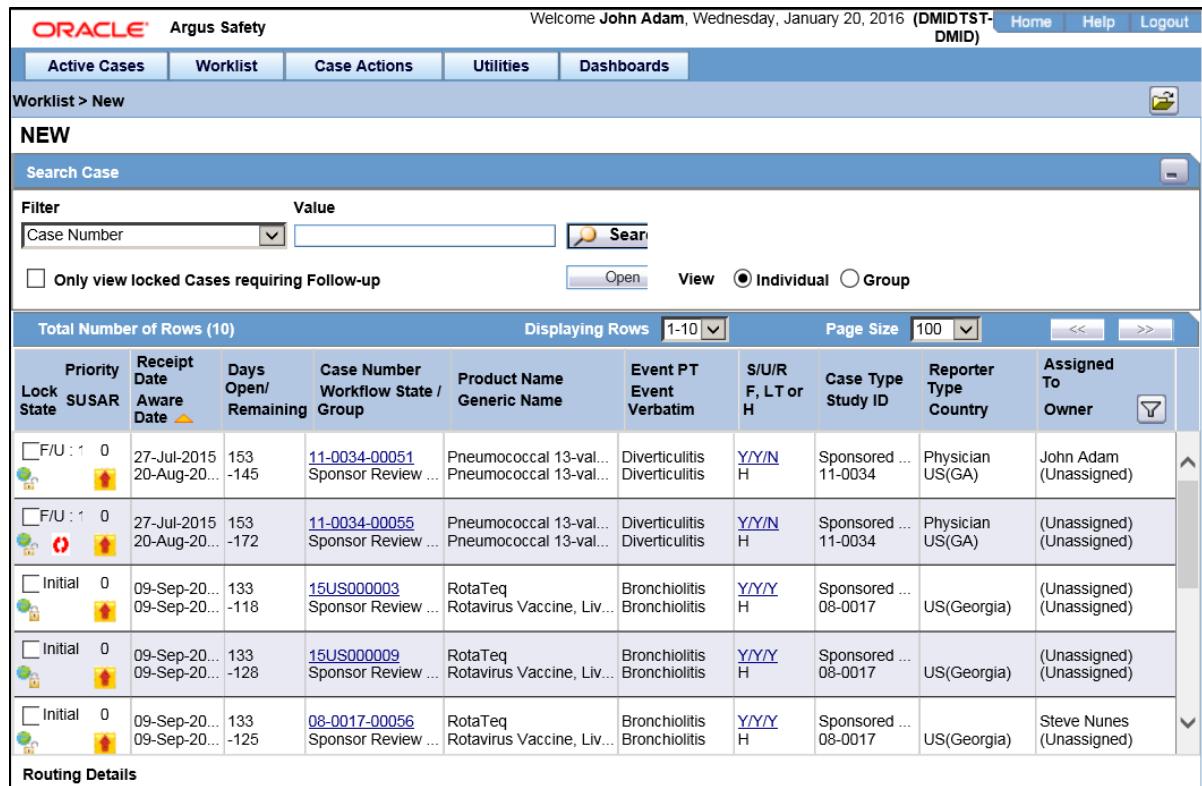
## Viewing Cases Assigned to another User

1. To view cases that are unassigned, or assigned to another user, click on the **Worklist Tab**, and go down and select **New:**



The screenshot shows the DMID-Argus Safety 8.0 software interface. The top navigation bar includes the title 'ORACLE Argus Safety', the date 'Wednesday, January 20, 2016', and links for 'Home', 'Help', and 'Logout'. The main menu bar has tabs for 'Active Cases', 'Worklist' (which is selected and highlighted in yellow), 'Case Actions', 'Utilities', and 'Dashboards'. On the left, a sidebar for 'Personal Argus' includes sections for 'Search Case', 'Case Quick Launch', and 'Cases Assigned'. A specific case is selected with the number '(Country) Case Number (US) 10-0065-000'. A context menu is open over this case, showing options: 'New', 'Open', 'Action Items', 'Contacts', 'Reports', 'Bulk Transmit', 'Bulk Print', 'Bulk E2B Transmit', 'Local Labeling', and 'Letters'. Below the menu, a table displays a single row: 'Product' (Colistimethate sodium), 'Workflow State' (Sponsor Review), and 'Event' (Hepatotoxicity). At the bottom of the interface, there are two expandable sections: 'Contact Log Entries (0)' and 'Action Item Entries (0)'.

2. You will be able to view cases assigned to others, as well as unassigned cases. As before, click on the case number to open the case.



The screenshot shows the DMID-Argus Safety 8.0 software interface with the 'Worklist' tab selected. The title bar shows 'Welcome John Adam, Wednesday, January 20, 2016 (DMIDTST-DMID)'. The main content area is titled 'Worklist > New' and contains a 'Search Case' section with a 'Filter' dropdown set to 'Case Number', a 'Value' input field, a 'Search' button, and a checkbox for 'Only view locked Cases requiring Follow-up'. Below this is a table titled 'Total Number of Rows (10)' with columns: 'Priority', 'Receipt Date', 'Days Open/ Remaining', 'Case Number / Workflow State / Group', 'Product Name / Generic Name', 'Event PT / Event Verbatim', 'S/U/R F, LT or H', 'Case Type / Study ID', 'Reporter Type / Country', and 'Assigned To / Owner'. The table lists five cases, each with a unique identifier, product name, event details, and reporter information. At the bottom of the table, there is a 'Routing Details' section.

We welcome your feedback on this Workflow Process Guide. Please send your comments to [training@dmidcroms.com](mailto:training@dmidcroms.com).