

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**.



ORACLE[®]
HEALTH SCIENCES

Argus Safety

Username

Password

Database

日本語 Login

03-FEB-2015 16:16:39

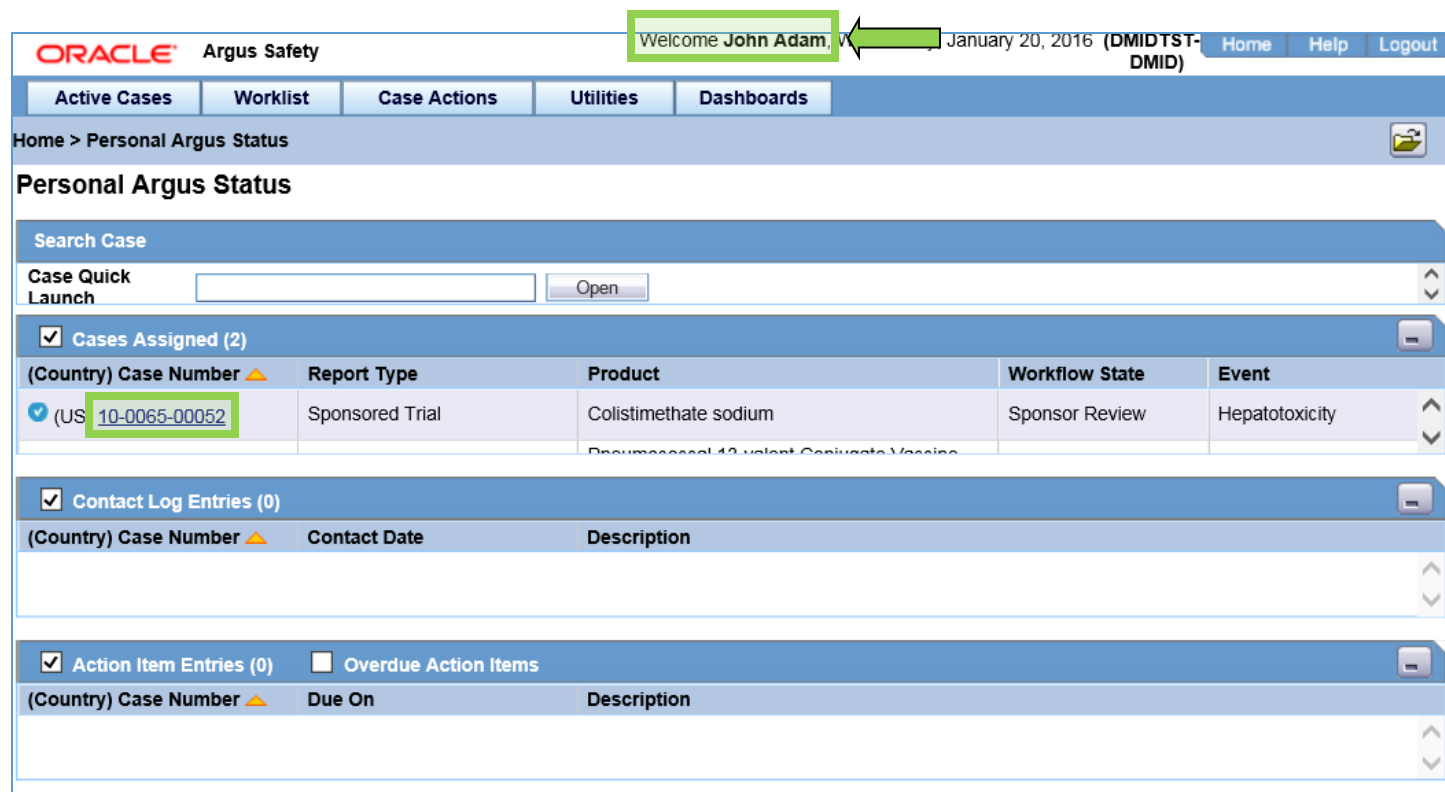
Oracle Health Sciences Safety Suite :

- Argus Safety
- Argus Safety Japan
- Argus Affiliate
- Argus Interchange
- Argus Unblinding
- Argus Analytics
- Argus Insight
- Argus Mart
- Argus Dossier
- Argus Reconciliation
- Empirica Topics
- Empirica Signal
- Empirica Study
- WebSDM
- Siebel AECM

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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.



ORACLE Argus Safety

Welcome John Adam, January 20, 2016 (DMIDTST-DMID) Home Help Logout

Active Cases Worklist Case Actions Utilities Dashboards

Home > Personal Argus Status

Personal Argus Status

Search Case

Case Quick Launch Open

☒ Cases Assigned (2)

(Country)	Case Number	Report Type	Product	Workflow State	Event
US	10-0065-00052	Sponsored Trial	Colistimethate sodium	Sponsor Review	Hepatotoxicity

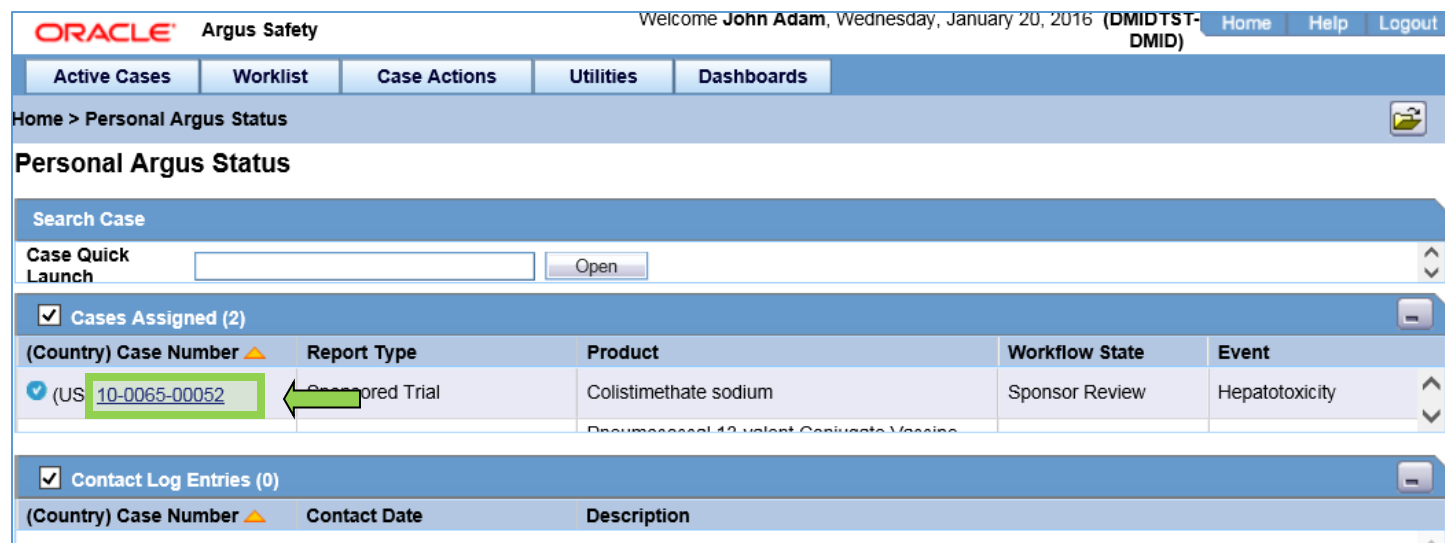
☒ Contact Log Entries (0)

(Country)	Case Number	Contact Date	Description
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☒ Action Item Entries (0) ☐ Overdue Action Items

(Country)	Case Number	Due On	Description
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2. To open a case, click the **case number link** (for example, 10-0065-00052).



ORACLE Argus Safety

Welcome John Adam, Wednesday, January 20, 2016 (DMIDTST-DMID) Home Help Logout

Active Cases Worklist Case Actions Utilities Dashboards

Home > Personal Argus Status

Personal Argus Status

Search Case

Case Quick Launch Open

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☒ Contact Log Entries (0)

(Country)	Case Number	Contact Date	Description
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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.

Oracle Argus Safety - Case Status: Sponsor Review

Form - 10-0069-00024 10-0069 "06HSF229"

General | Patient | Events | Analysis | Activities | Additional Information | Regulatory Reports

Case Information

Report Type: Sponsored Trial
 Initial Receipt Date: 01-JAN-2015
 Central Receipt Date: 00-MMM-0000
 Country: UNITED STATES
 Medically Confirm: [X]
 Initial Justification: [X]

Study Information

Project ID: 10-0069
 Study ID: 10-0069
 Center ID: U. of Cal San Fran- Tenderlon Res Ctr
 Study Phase: Phase II
 Study Name: Placebo vs. AdCHONSmt1 plus MYA-NSmt
 Other ID: [Blank]
 Study Type: Double Blinded
 Blinding Status: Blinded
 Study Description: Phase IIb, double-blinded, randomized, placebo-controlled study of HCV-uninfected male and female active IDU aged 18 to 45 years. In Stage I 60 (+/-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.
 Unblinding Date: [Blank]
 Week #: [Blank]
 Visit #: [Blank]
 Observe Study Type: Clinical Trial

Reporter Information (1)

Sal.: [Blank]
 First Name: Paul
 Middle Name: [Blank]
 Last Name: Lum
 Suffix: [Blank]
 Health Care Professional: [Blank]
 Occupation: Principal Investigator
 Address: 964 Market St, Ste 200
 Institution: [Blank]
 Institution ID: [Blank]
 Department: [Blank]
 City: San Francisco
 State/Province: CA
 Postal Code: 94102-4012
 Country: UNITED STATES
 Phone Number: [Blank]
 Alternate Phone: [Blank]
 FAX Number: [Blank]
 Reporter ID: [Blank]
 Reporter's Reference #: [Blank]
 Email Address: paul@paul.lum.edu
 Reporter Type: [Blank]
 Report Media: [Blank]
 Report Sent to Regulatory Authority by Reporter?: [X]
 Protect Confidentiality: [X]
 Primary Reporter: [X]
 Correspondence Contact: [X]

LUM, Paul

Checking all cases for the same Subject ID

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

Oracle Argus Safety - Case Status: Sponsor Review

Home > Personal Argus Status

Case Actions | Worklist | Reports | Utilities | Dashboards

Open (Ctrl+Alt+O)
 New (Ctrl+Alt+N)

Personal Argus Status

Search Case

Case Quick Launch: [Blank] Open

Case Assigned (0)

(Country)	Case Number	Report Type	Product	Workflow State	Event
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2. Under the **Search For** tab, select **Patient ID**.

Oracle Argus Safety - Case Status: Sponsor Review

Case Actions > Case Open

Case Open

Case Search Criteria

Search For: Patient ID
 Date Range: Last 30 Days
 From: 27-DEC-2015
 To: 01-JAN-2099
 Initial [X] Follow Up []
 Advanced Condition: [Blank]
 Search

Displaying Rows: 1-1
 Page Size: 100

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

Case Actions > Case Open

Case Search Criteria

Search For: Patient ID 08-0033 Date Range: Last 30 Days From: 27-DEC-2015 To: 01-JAN-2016

Product Family: Advanced Condition: (None)

Full Search (Like, soundex)

Total Number of Rows: (2)

Lock State	Case #	Date	Product	State
<input type="checkbox"/>	08-0033-00000	10-DEC-2015	Daptomycin/Cubicin	Sponsor Review
<input type="checkbox"/>	08-0033-00076	14-DEC-2015	Algorithm-based Treatment of Staphylococcus Sepsicemia	Case Processing

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.

Case Actions > Case Open

Case Search Criteria

Search For: Case # 08-0033 Date Range: Last 30 Days From: 28-DEC-2015 To: 01-JAN-2016


Product Family: Advanced Condition: (None)

Full Search (Like, soundex)

Total Number of Rows: (196)

Lock State	Case #	Date	Product	State
<input type="checkbox"/>	08-0033-00000	10-DEC-2015	Daptomycin/Cubicin	Expedited Report
<input type="checkbox"/>	08-0033-00000	12-JAN-2016	Vancomycin	Sponsor Review
<input type="checkbox"/>	08-0033-00076	14-DEC-2015	Algorithm-based Treatment of Staphylococcus Sepsicemia	Case Processing
<input type="checkbox"/>	08-0033-00076	14-DEC-2015	Vancomycin alternative	Quality Control 1

Viewing the Case Narrative and Case Causality

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

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

Case Status: Sponsor Review

General Information

Report Type: Sponsored Trial Country: UNITED STATES

Initial Receipt Date: 01-JUN-2015 Central Receipt Date: 00-MAR-2000

Amendments / Follow-ups (0)

#	Follow-up Received	Safety Received	Significant	Data Clean Up	Amendment	Amendment / Follow up Justification
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- 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 / Add Info Medical Review View Draft

Case Narrative

Narrative Show Difference Generate Case Comment Generate

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)

Company Comment Generate

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 Event PT (Description) / LLT	D/S	Seriousness Severity Duration	Data Sheet --Assigned--	As Determined Listedness
VC Placebo vs. AdCh3NSmut1 plus MVA-NSmut SD (1/1) Placebo vs. AdCh3NSmut1 plus MVA-NSmut	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:

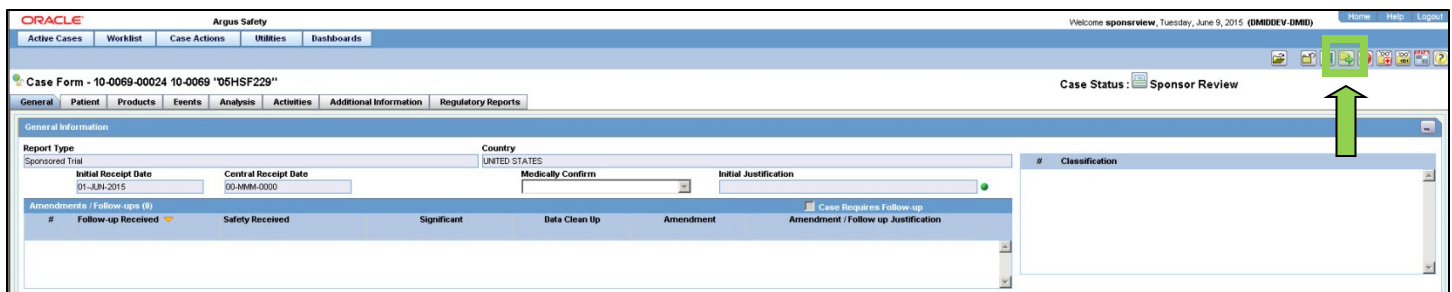
Approved: You are satisfied with the case narrative. You approve the case for queries or for closure.

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.



The screenshot shows the Oracle Argus Safety Case Form interface. The top navigation bar includes 'Active Cases', 'Worklist', 'Case Actions', 'Utilities', and 'Dashboards'. The case details section shows 'Case Form - 10-0069-00024 10-0069 '06HSF229'' and 'Case Status: Sponsor Review'. A green arrow points to the 'Case Routing' icon in the top right corner of the form.

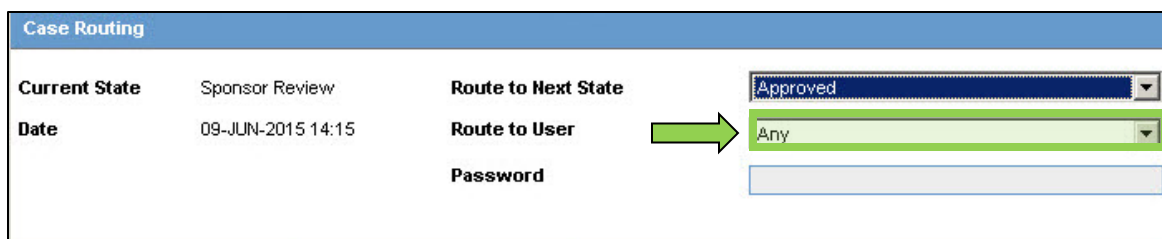
2. The **Case Routing** box will display. Go to **Route to Next State** and do the following:
 - a. Click on the drop-down menu and select an option **Approved**, **Disapproved**, or **Expedited Report**.
 - b. Enter your comments, including those related to any change request, in the **Comments** box. For example, enter "Approved by [Your Name]" or "Disapproved by [Your Name]".



The screenshot shows the 'Case Routing' dialog box. It includes fields for 'Current State' (Sponsor Review), 'Date' (09-JUN-2015 14:15), 'Route to Next State' (dropdown menu), 'Route to User', and 'Password'. The 'Route to Next State' dropdown menu is open, showing options: (Current), Approved, Disapproved, and Expedited Report. Below these fields is a table with columns: Date, User, Comments, and Routings(6). The table contains three rows of routing history.

Date	User	Comments	Routings(6)
09-JUN-2015 14:15	sponsrview		
09-JUN-2015 12:56	Linda Nguyen	Case routed from Medical Review by Linda Nguyen to Sponsor Review, sponsrview Routing to Sponsor Review	
09-JUN-2015 12:55	Linda Nguyen	Case routed from Quality Control 2 by Linda Nguyen to Medical Review, Any Routing to Medical Review	
09-JUN-2015 12:51	Linda Nguyen	Case routed from Quality Control 1 by Linda Nguyen to Quality Control 2, Any Routing to Quality Control 2	

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

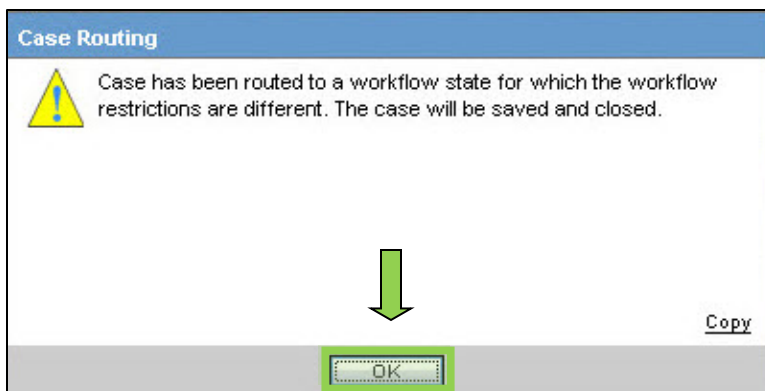


The 'Case Routing' dialog box contains the following fields:

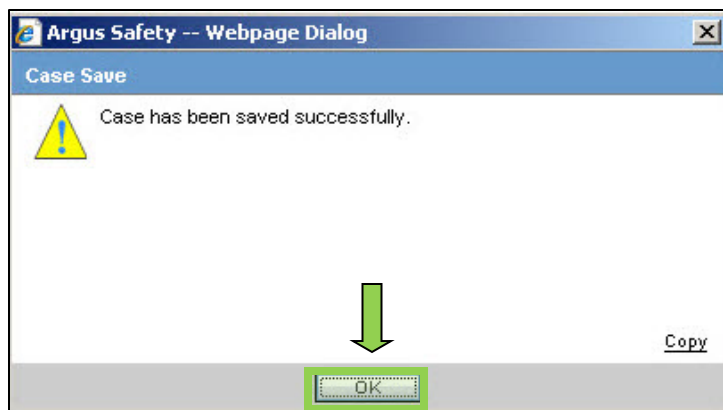
Current State	Sponsor Review	Route to Next State	Approved
Date	09-JUN-2015 14:15	Route to User	Any
		Password	

A green arrow points from the 'Route to User' field to the 'Any' option in the dropdown menu.

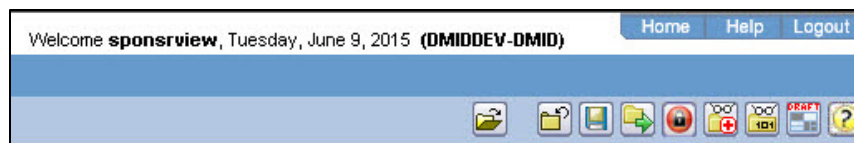
- d. A **Case Routing** box will appear stating that the case has been routed and saved successfully. Click **OK**.



- 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.

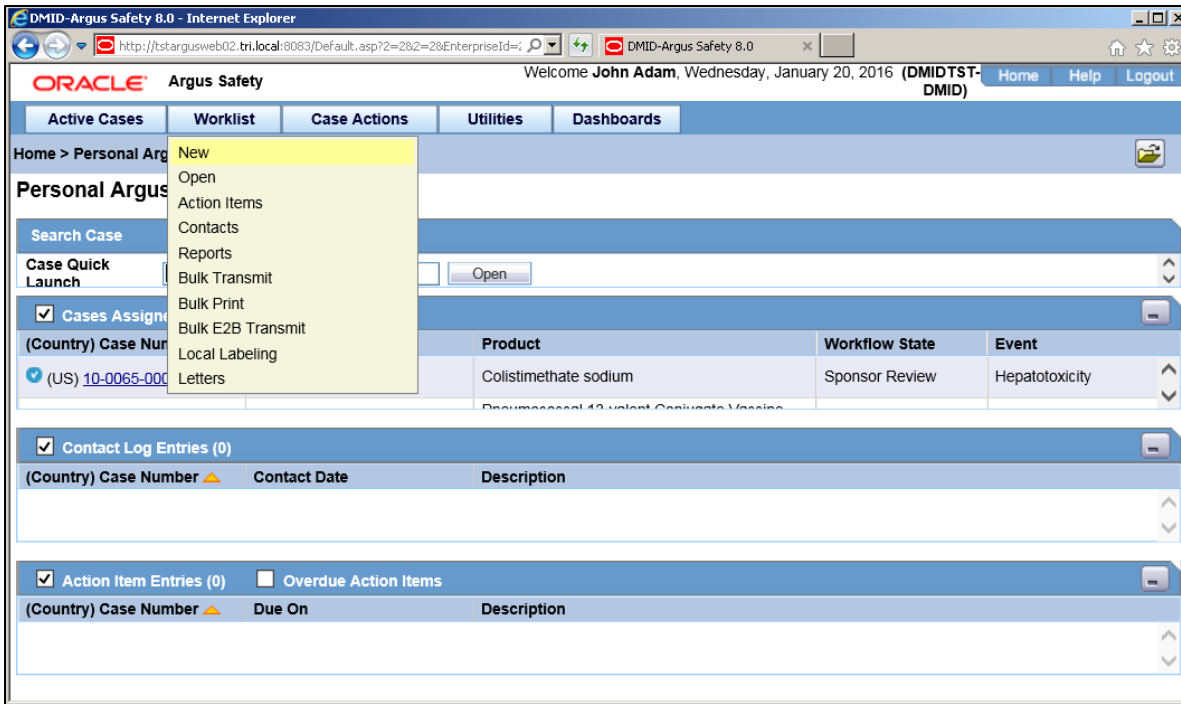


- f. Click the **Home** button in the upper right hand corner to return to the **Worklist** -> **New** page to review other cases. You must always use the **Logout** button to logout of the application. Failure to do so may lock up the application and prevent you or others from further processing the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

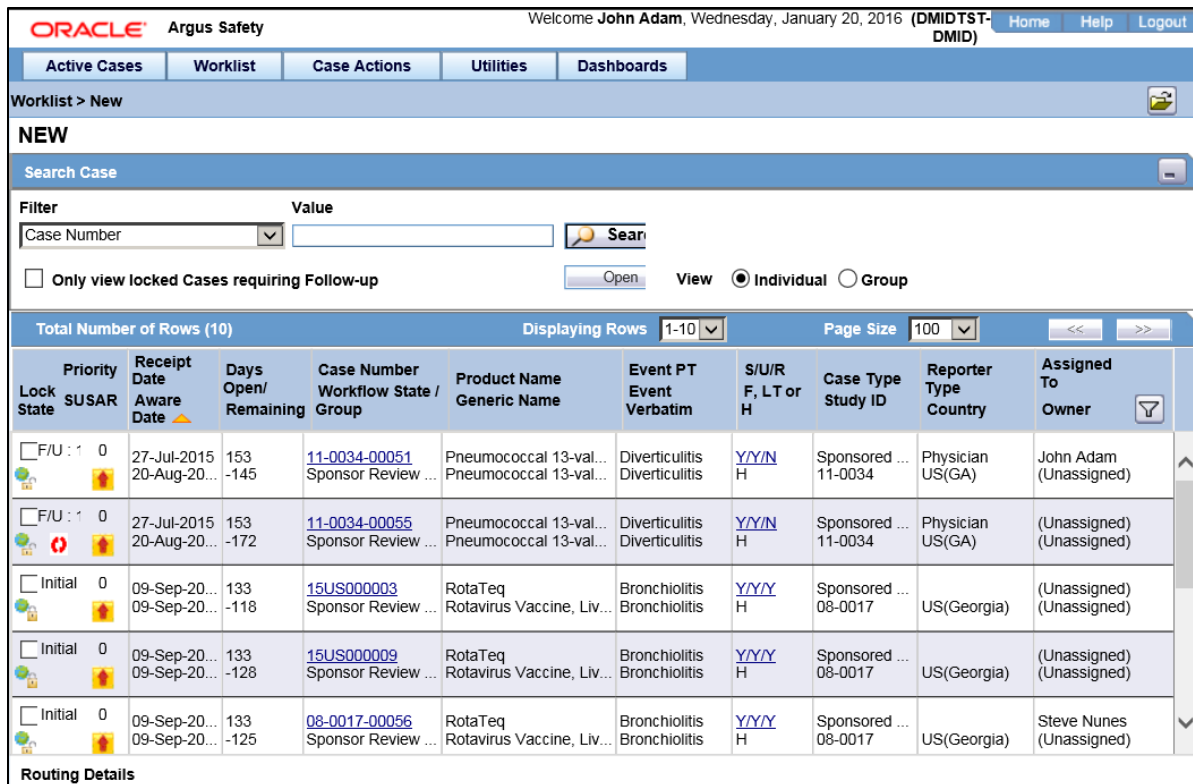


Viewing Cases Assigned to another User

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



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.



We welcome your feedback on this Workflow Process Guide. Please send your comments to training@dmidcroms.com.