

DAIDS Adverse Experience Reporting System (DAERS) Reference Guide for Site Reporters and Study Physicians

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DAERS Reference Guide for Site Reporters
and Study Physicians

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Introduction to the DAERS

What Is DAERS?

The DAIDS Adverse Experience Reporting System (DAERS) enables DAIDS clinical research sites to report Expedited Adverse Events (EAEs) effectively, in accordance with the safety reporting guidelines set forth by DAIDS, FDA, and ICH for the conduct of human subject clinical trials. The DAERS is a Web-based system that enables immediate reporting of and access to EAEs. Built-in data validation checks and lists of values ensure accuracy of data capture. Moreover, data entry is minimized because certain information, such as protocol, participant and site information, is already captured by other DAIDS components.

What Can I Do with DAERS?

Create and submit EAE reports to RSC electronically. In addition you can update EAE reports to provide additional information, search EAEs, and view EAE information for the applicable study site. The system provides an optional tool that helps in determining whether an Adverse Event should be reported as an Expedited Adverse Event.

Who Is DAERS Intended for?

DAERS is intended for Clinical Research Site Physicians and staffs that are participating in DAIDS-sponsored clinical trials.

How Can I Access DAERS?

Users with a DAERS account can access the system through the following link: <https://ncrms.niaid.nih.gov>.

NIAID Clinical Research Management System

The NIAID (National Institute of Allergy and Infectious Diseases) Clinical Research Management System (CRMS) supports the managing of clinical research funded by (or otherwise supported by) DAIDS, the Division of Allergy, Immunology and Transplantation (DAIT), Division of Microbiology and Infectious Diseases (DMID), and the Vaccine Research Center (VRC).

Note: All NIAID CRMS applications are accessible only through Internet Explorer (IE) 11 (with Compatibility View turned Off) and Google Chrome.

After logging in, you can navigate to NIAID CRMS applications from the NIAID CRMS home page.



Terms You Should Know	
TERM	DEFINITION
EAE Report Type	Initial – Original EAE report sent to RSC.
	Update – Follow-up version of the report submitted to RSC with additional information.
EAE Report Status	Pending – An EAE report is started by the Study Reporter or Study Physician, but it is not finished.
	Ready for Final Review – The EAE report contains all required elements and is ready to be reviewed by the Study Physician.
	Submitted to RSC – The EAE Report has been reviewed by the Study Physician and submitted to RSC. Users may then add to the report through an update.
	Withdrawn – RSC accepted request for withdrawal from the site.

Terms You Should Know	
TERM	DEFINITION
Timeframe for Expedited Reporting	<p>An EAE report should be created and submitted to RSC by the site until the end of the third reporting day from the date of site awareness, otherwise it is considered late. The criteria for calculating the three reporting days are as follows:</p> <ul style="list-style-type: none"> Monday through Friday count as reporting days. Holidays that occur on a Monday through Friday count as reporting days. Saturday and Sunday are considered non-reporting days, even if another country/region/area might identify other days of the week to be non-reporting days (e.g., Sunday & Monday). Reporting days are counted in local time. A reporting day starts at 12:00 am and ends at 11:59 pm. A day is counted as a reporting day regardless of the time of the day that awareness occurred <p>The day a site indicates that site personnel became aware of an EAE that meets reporting criteria shall count as day 1 if that day occurs on a reporting day (i.e., Monday through Friday). If that day occurs on a Saturday or Sunday then the next reporting day shall count as day 1.</p>
Electronic Signature	<p>During the process of submitting an EAE Report to RSC, the Study Physician reviews and signs with an electronic signature (username and password) to indicate that the EAE Report is accurate and complete. Before a Study Physician can electronically sign or have access to DAERS, the following requirements must be met:</p> <p>Each Study Physician must mail to the RSC the original completed and signed 21 CFR Part 11 – Attestation and Agreement for Electronic Signatures form for each site which designates the Physician as a submitter within the DAERS system and each Study Physician must be listed on the FDA 1572 or IoR Agreement form for their study and site.</p> <p>Note: To expedite access, an electronic version of the document will be accepted with the understanding that the hard copy is mailed. Access to DAERS will be revoked if the hard copy is not received within two weeks.</p> <p>You may access the form by clicking on https://rsc.niaid.nih.gov/sites/default/files/physician-electronic-signature-attestation-form.pdf</p> <p>MAIL THE ORIGINAL SIGNED ATTESTATION FORM(S) TO: DAIDS Safety Office 6500 Rock Spring Drive, Suite 650 Bethesda, MD 20817</p>
Request	<p>A Request is the submission of changes for the site staff regarding access to DAERS for new users, modification of access to protocols for existing users, and/or inactivation of access in the Site Enrollment Module for existing users. Each Request is associated with a four digit Request ID.</p> <p>Note: Requests are also generated upon submission of a Registration Packet in DPRS (DAIDS Protocol Registration System). Specifically, on the DPRS Person Information screen, the users can indicate which site staff requires Reporter and/or Submitter access to DAERS. When the PRO approves the submission, the Request will display on the View Request page of the DAERS Site Enrollment Module.</p>

Terms You Should Know	
TERM	DEFINITION
Request Status	<p>Draft — Request for changes for the site is yet to be submitted to NIAID CRMS Support.</p> <p>Submitted — Request for changes for the site is submitted to NIAID CRMS Support</p> <p>In Progress — NIAID CRMS Support is processing the request submitted by the site.</p> <p>Completed — NIAID CRMS Support has completed processing of the Request submitted by the site.</p> <p>*Completed — NIAID CRMS Support has completed processing of the Request submitted by the site with some outstanding issues.</p>

Obtaining DAERS Support

Obtaining Support

To report a problem, make a suggestion, or request regarding DAERS, contact NIAID CRMS Support directly by telephone or e-mail. Live assistance is available 8:30 A.M. to 5:30 P.M. U.S. Eastern Time, Monday through Friday (excluding holidays). You may also submit a ticket request from within DAERS through the NIAID CRMS Support web page. Once you contact NIAID CRMS Support, you will receive a confirmation e-mail with a unique ticket number.

Note: When in doubt, please copy both NIAID CRMS Support and DAIDS RSC Safety Office.

①

Contact Information for NIAID CRMS Support

Phone: (1) (240) 778 - 2517

E-mail: CRMSSupport@niaid.nih.gov

②

Submit a Problem or Suggestion/Request or View My Ticket Status

You can report a problem or make a suggestion/request from within DAERS.

To Submit from DAERS

1. From within the application, go to the top right navigation bar and point to **Help**.
2. Click **NIAID CRMS Support** from the drop-down list.
The links to contact NIAID CRMS Support display on a web page.
3. Click one of the following links:

- **Report a problem**
- **Make a suggestion or request**

The NIAID CRMS Support Submission form displays.

4. Enter the required information into the submission form.
5. Click **Submit**.

An e-mail is sent that confirms your submission and provides a ticket number to reference the submission in the future.

To View My Ticket Status

1. From within the application, go to the top right navigation bar and point to **Help**.
2. Click **NIAID CRMS Support** from the drop-down list.
The links to contact NIAID CRMS Support display on a Web page.
3. Click **Search my tickets**.
4. Locate the ticket from the list of your submitted tickets currently in the database.

Tip: Use the Quick Search option to locate the ticket.

5. View the current status of the selected ticket, ask for further assistance, or submit comments and requests.

③

Access the online help system

Section 2

From the top right navigation bar, point to **Help**, and then click one of the following:

- **[Page] Help**
Opens DAERS Help to the topic associated with the page in your current view. This is commonly referred to as context sensitive help.
Click **Show** in the upper left corner to open the complete DAERS Help for access to other topics to view.
- **DAERS Help**
Opens Help to the **Welcome** page of DAERS Help. This is a complete version of Help that includes access to the Table of Contents (TOC), Index, Search, and Glossary features.

④

Contact Information for RSC

For questions on the DAIDS EAE manual or EAE reporting requirements, contact RSC Safety Office.

Phone: 1-800-537-9979 (U.S. only) or 301-897-1709

E-mail: DAIDSRSCSafetyOffice@tech-res.com

Fax: 1-800-275-7619 (U.S. only) or 301-897-1710

Mail: DAIDS Safety Office, 6500 Rock Spring Drive, Suite 650, Bethesda, MD 20817

Access to RSC

Instructions for DAERS and necessary documents can be found on the RSC website

<https://rsc.niaid.nih.gov/clinical-research-sites/daids-adverse-experience-reporting-system>. You can access the RSC website by clicking on **RSC** from the horizontal menu bar.

Section 3

Using Common Functions

There are standard features used throughout DAERS. The following sections provide descriptions of these features and their use.

Using Fields

The following are the field types used within DAERS and a description of each, along with the attributes associated with a field and instructions on how to use the field.

- **Smart Search** — As you type in a field marked with the Smart Search icon, the system searches through the database for the best match. You can select a match from the drop-down list and edit the text. If there is no match, the text turns red. When you leave the field, the text turns black.

Tip: Press the space bar to display the first 100 values in the drop-down list.

- **Text Box** — A single line rectangular box in which you can type text or select from smart search.
- **Text Area** — A multiline rectangular box in which you can type text, such as comments or description. In the large text areas, as you type information, DAERS gives you a running count of remaining characters just below the text area.
- ***** (Asterisk) — Displays next to a required field.
- **!** (Exclamation point) — An indicator that the value you entered or selected is incorrect. Correct the entry or click **Save** to view the error message.
- **ToolTip** — A pop-up appears for three seconds when you hover the cursor over a field, providing the definition or other pertinent information for the field or column label. Can also display for links and pop-ups.

Using Calendar

In a calendar field, type the date in DD/MM/YYYY format or select a date from the pop-up calendar. Dates display the international format: DD-MON-YYYY (example: 18-Apr-2007).



To Select a Date from a Calendar Field

1. Click **Calendar**  to open the **Calendar** dialog

box.

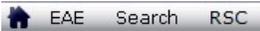
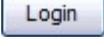
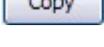
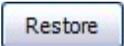
2. Click the backward or forward arrows in the top corners to increase or decrease the month and year values until the correct calendar displays. You can also click the drop-down arrow in the month and year fields to select the month and year values from the list.
3. Click directly on any day of the selected calendar view.

The **Calendar** dialog box closes and the date you selected populates the **Date** field.

Using Buttons

Buttons and navigation features used within DAERS.

Section 3

	Identifies field as smart search.
	Opens a Calendar to select a date.
	Opens in PDF format.
	Return to your Home page from anywhere in the application.
	Print a page.
	Add a row.
	Delete a row.
	DAERS menu bar.
	Opens to View or Print, or Saves an Additional Information document.
	Saves the record to the database.
	Ends an action.
	Removes contents from fields on a page.
	Closes a dialog box.
	Removes a record or deletes a report.
	Submits user ID and password to access DAERS.
	Modify a pending report or an individual record.
	Creates a new record.
	Go to next page.
	Copy current EAE report to create new EAE report.
	Returns the information in the fields to the previously saved value. If no values have been saved, the fields will be reset to their default values.
	Runs a query based on your selections.

Section 3



Update information in a previously submitted to RSC EAE Report.



The section has been completed.



Confirms an action.



In the EAE Report completion check, denotes that the section has not been completed.



Move back or forward one page.

In the Alert Web Part, denotes a report that is past due for submission to RSC.



Goes to the first or last page.



In the EAE Report completion check, denotes that the field is required for completion of the report.



Drop-down lists the number of pages within the table. Select a page number to display a specific page (sometimes faster than using the forward button).



Indicates that the field was marked with an issue on the EAE Report Issues Checklist.



Sort table column contents in alphanumeric order. Hover over the column heading to activate the arrow icon.



Field on the faxed report contained data that was illegible.



Closes the page or box from the upper right corner of the page.



Field on the faxed report did not have data available.



Expands or minimizes a section on a page.



Field on the faxed report contained data that was incorrect/inaccurate.

Icons

Common icons used within DAERS.



Execute search on Alert Web Part.



Indicates that the report is being entered by RSC and is locked for Site user.



Indicator of designated recipient for EAE submission notification identified by the Study Physician.



Identifies help tip. Hover your mouse over these icons to see a text popup explaining a feature or element of the interface.

Section 4

DAERS User Roles Matrix

The DAERS recognizes your Role and associated site studies when you first log on to the system and organizes the information accordingly. The following Roles are available in the application:

DAERS User Roles	
USER ROLE	FUNCTIONS/TASKS
Reporter	Site study staff responsible for creating EAE reports. Have the ability to create and check a report for completion, search, and view reports.
Submitter	Study Physicians have the ability to create, sign, submit EAEs to RSC, search and view reports. Note: In order to use the DAERS, each study physician at your site must: <ul style="list-style-type: none">• Provide a signed copy of the “21 CFR Part 11 – Attestation and Agreement for Electronic Signatures”• Be listed on the appropriate FDA Form 1572 or Investigator of Record Agreement. Updates to any of these forms must be forwarded to the RSC.

DAERS User Maintenance

Adding Users to DAERS

1. The CRS Leader or CRS Coordinator must request access for site staff using the Site Enrollment Module in DAERS. They must provide the User's name, contact information (e-mail, phone, fax) and the DAERS role by protocol.

Note: While submitting a registration packet in the DAIDS Protocol Registration System (DPRS), you can use the Person Information screen to specify the list of personnel (e.g., sub investigators, IoRs) associated with a study, and to indicate who requires Reporter and/or Submitter access to DAERS. This screen is only accessible when completing the following submission types: Initial, Change in IoR, Updated I572, and Updated IoR Form. Upon approval of the submission by the PRO, the Person Information screen is locked and cannot be modified.

2. All new users must complete DAERS training.
3. In addition, the following requirements apply per role:
 - a. Reporters

Will only have access to report EAE's on protocols that have at least one Physician who also has access to submit EAEs on those protocols.
 - b. Submitters
 - i. Must mail an Electronic Signature attestation form to RSC. To expedite access, an electronic version of the document will be accepted with the understanding that the hard copy is mailed. Access will be revoked if the hard copy is not received within 2 weeks.
 - ii. Must be on the I572 or IoR Agreement forms. RSC will verify the site's request for submitters against the documents the site has filed with RSC. If updates are required, please provide the revised forms through the normal process with RSC.

Maintenance of DAERS Users

Note: CRS Leaders and CRS Coordinators will not be able to request access to a new protocol until the protocol registration for that site is approved. Such approval is granted in the Protocol Registration module.

Also, note that while submitting a registration packet in the DPRS, you can use the Person Information screen to indicate who requires Reporter and/or Submitter access to DAERS. This screen is only accessible when completing the following submission types: Initial, Change in IoR, Updated I572, and Updated IoR Form. Upon approval of the submission by the PRO, the Person Information screen is

locked and cannot be modified.

CRS Leaders and CRS Coordinators are responsible for maintaining their DAERS User's Information through the Site Enrollment Module. This includes the following scenarios:

- a. If additional people join the organization, sites must follow the process to add users to DAERS.
- b. When a site registers to a new EAE reporting DAIDS protocol, the CRS Leader or CRS Coordinator must request access for the users who have been identified for the role of Submitter or Reporter for that particular protocol, and submit the associated documentation to the RSC. (Physician Electronic Signature Attestation Form - If the submitter is not a current user of the DAERS system)
- c. When a user leaves the site's organization or no longer requires access to DAERS, the CRS Leader or CRS Coordinator is responsible for notifying NIAID CRMS Support to remove the user's rights by using the DAERS Site Enrollment Module.
- d. When a site deregisters from a protocol, contact NIAID CRMS Support. All communication should include site ID and site name.

Overview of DAERS Search Page

Adverse Experience Reporting
DIVISION OF AIDS

Search

Welcome Constance Benson
Last successful login: 31-AUG-2015 4:49 PM
No. of unsuccessful login attempts: 0

EAE Search Person EAE Notification Recipients RSC

To find an EAE, please enter/modify the criteria on the page and then click the Search button

EAE Number: Report Status: Report Type:

Protocol Number: Status Date From: Status Date To:

Participant ID: Site ID:

Reporter Name: Show current report versions Show all report versions

EAE Number	Protocol Number	PID	Primary AE	Grade	Reporter Name	Report Type	Report Status	Report Status Date	Action
2015-108095	A5321	73597	test 8-28 AB	4 - Life threatening	Benson, Constance A.	Initial	Submitted to RSC	28-Aug-2015	<input type="button" value="Update"/> <input type="button" value="Copy"/>
2015-107858-4	A5298	72002	MI requiring stent placement	3 - Severe	Meixner, Linda	Update	Submitted to RSC	27-May-2015	<input type="button" value="Update"/> <input type="button" value="Copy"/>
2013-105636-4	A5311	73554	Probable RHS (Rifampine Hypersensitivity)	3 - Severe	Potter, Paula	Update	Submitted to RSC	31-Mar-2014	<input type="button" value="Update"/> <input type="button" value="Copy"/>
2013-106343-3	A5298	72002	Prostate cancer	3 - Severe	Meixner, Linda	Update	Submitted to RSC	16-Dec-2013	<input type="button" value="Update"/> <input type="button" value="Copy"/>
2013-106345	A5298	72002	facial squamous cell carcinoma	3 - Severe	Meixner, Linda	Initial	Submitted to RSC	08-Nov-2013	<input type="button" value="Update"/> <input type="button" value="Copy"/>
2013-106299-1	A5298	73473	Death unknown cause	5 - Death	Meixner, Linda	Update	Submitted to RSC	25-Oct-2013	<input type="button" value="Update"/> <input type="button" value="Copy"/>
2013-105740-5	A5298	73453	prostate cancer	3 - Severe	Meixner, Linda	Update	Submitted to RSC	20-Sep-2013	<input type="button" value="Update"/> <input type="button" value="Copy"/>
2013-105270-2	A5298	73465	Perirectal abscess	3 - Severe	Meixner, Linda	Update	Submitted to RSC	18-Sep-2013	<input type="button" value="Update"/> <input type="button" value="Copy"/>
2012-104940	A5298	73477	Invasive squamous cell carcinoma anal verge	3 - Severe	Meixner, Linda	Initial	Submitted to RSC	06-Nov-2012	<input type="button" value="Update"/> <input type="button" value="Copy"/>
2012-104688-6	A5294	73488	Accidental overdose	3 - Severe	Hoffman, Julie	Update	Submitted to RSC	23-Sep-2012	<input type="button" value="Update"/> <input type="button" value="Copy"/>

Figure 1: Search Results.

- 1 Select criteria, then click **Search**.
 - 2 Columns can be sorted in ascending (A, B, C or 1, 2, 3) or descending (C, B, A or 3, 2, 1) order by clicking the column header.
 - 3 Search results can be quickly viewed by clicking page controls to move forward or backward, or selecting a page from the page counter.
 - 4 From the EAE Number column, click PDF  next to a report to view the selected report in PDF format.
 - 5 From the Report Status column, click the status link to view the status history of the EAE report in a pop-up window, and then click **Close** to return to the Search page.
 - 6 Click **Export to Excel** to export the results of the search to a Microsoft Excel spreadsheet. A dialog box opens with the options to click **Open** to immediately open the results in an Excel spreadsheet, or click **Save** to save the results to a file location to view later.
 - 7 Select the type of report action to accomplish:
 - **Modify** – Edit pending reports until final review.
 - **Delete** – Delete reports until submitted to RSC.
 - **Review** – Report is ready for final review by Study Physician.
 - **Update** – Create an update on a report once it has been submitted to RSC, an unlimited number of updates can be created.
 - **Copy** – Create an EAE report by copying a Ready for Final Review or Submitted to RSC report.
 -  – Denotes that the EAE report is currently being modified by RSC on behalf of the site to reflect changes submitted via fax or e-mail and therefore the EAE report is locked for the site user.
- Note:** Action buttons will not be available for reports that have newer versions available or are associated with closed studies. Reports currently being modified by RSC to reflect changes submitted via fax or e-mail will be read only. The action button will be available once RSC has completed their modifications and the report is in “Submitted to RSC” status.

Using the DAERS Home Page and Search

The screenshot shows the DAERS Home Page with the following sections and highlighted features:

- EAE Report Status:** A table showing report counts by status: Pending (0), Ready for Final Review (0), and Submitted to RSC (103). A red circle '1' highlights the 'Ready for Final Review' link.
- Related Links:** A section with an 'Add/Modify' link highlighted by a red circle '2'.
- Alerts:** A section with search filters for Site ID, Protocol ID, and Alert. A red circle '4' highlights the search area, and a message states 'No matching Alerts for EAE Reports were found.'
- Questions from RSC Safety Office:** A section with search filters for EAE Number and PID. A red circle '3' highlights the search area. A message states 'No open questions from RSC Safety Office were found. To view the closed questions, click View Questions'.
- Unstable EAE Outcomes:** A section with search filters for Site ID and Protocol ID. A red circle '5' highlights the search area. Below is a table with one entry:

EAE	Protocol ID	PID	Primary AE	# of Days
2013-108025	A5321	73597	test 8-28 AB	1

Figure 2: Home Page.

Using the Home Page

The Home page of DAERS is the starting point after login that provides links to information within a summary or "digital dashboard" format that are unique to each user. View the number of reports by status in the EAE Report Status section and a list of your personalized related information links that aid you in your work in the Related Links section. Site users also can view a section that displays alerts for initial EAE reports that have not yet been submitted to RSC.

1 Using the EAE Report Status Web Part

The number of EAE reports for the protocols you are working on at your site is in the DAERS list within these status categories:

- Pending
- Ready for Final Review
- Submitted to RSC

Select the category link to view the reports from the selected category on the Search page. The Search page displays each report matching the category selected in a table list view. You can then select from that list an action from the Action column.

2 Using the Related Links Web Part

Use this section on the Home page to create a list of links that provides additional information. An example of these links could include a link to NIAID or your network web site. Include links that provide information to assist you in completing and submitting an EAE Report.

You can add, modify, and delete from this list. Select the

add/modify link in the Related Links section header of the Home page to display the Related Links page. From this page you can add a new link, select a saved link from the table to modify, or delete a link.

To Add a Link

1. Go to the Home page, and then click the **add/modify** link to open the Related Links page.
2. Type the **Name** of the link.
3. Type the **URL** address.
4. Click **Save**.
Add successful message displays.
You can continue to add new links by selecting **New**.

To Modify a Link

1. Open the Related Links page.
2. Select the **Name** link from the table.
The selected link populates the **Name** and **URL** fields.
3. Complete the modifications and then click **Save**.
Update successful message displays.
The modified link is saved to the table list.

To Delete a Link

1. Open the Related Links page.
2. Select the **Name** link from the table.
The selected link populates the **Name** and **URL** fields.
3. Click **Delete**.
Delete successful message displays.

The link is removed from the table list.

3 Using the Questions from RSC Safety Office Web Part

This Web Part allows you to view RSC Safety Office requests for clarification and/or additional information pertaining to EAE Reports submitted by your site.

To Sort and/or Filter Questions from RSC Safety Office Web Part

By default, the EAEs in the Web Part are sorted in descending order of the Days Open column. That is, the EAE with a question that is open for the longest number of business days appears at the top of the list.

Do one of the following to sort and/or filter the EAEs by different criteria:

- Click a column heading to sort the list by that heading, and then scroll through the sorted list to locate the EAE that requires your attention.
- Filter the list by selecting from the EAE Number and/or PID drop-down menus and then click the Search icon . The list will refresh to display results matching your criteria.

You are able to see the following details for each EAE which the RSC Safety Office has questions.

Questions from RSC Safety Office Details	
FIELD	Additional Information
EAE Number	The base/initial number of the EAE for which the question is created by RSC Safety Office (e.g., 2012-100426).
Protocol ID	The number of the protocol involved in the EAE (e.g., A5175).
PID	The Participant ID on which the EAE was reported.
Open Questions	The number of open questions. The value listed is a hyperlink that you can click to open a new window, "Questions from RSC Safety office," which displays the actual questions.
Days Open	The number of business days the oldest question to the site has remained open.

To View Questions Associated with an EAE

1. On the Questions from RSC Safety Office Web Part,

click the EAE's Open Questions number hyperlink under the Open Questions column.

A pop-up window displays, listing all the questions associated with that EAE, with the oldest question at the top.

Use filters below to find RSC Safety Office questions related to a specific EAE or Participant.

EAE Number:	2012-104868	PID:	9433733	Status:	Open
EAE Number	PID	Question	Status	Days Open	
2012-104868	9433733	Please enter the first dose and last dose of the randomized active drug received. Please enter course completed/subject off study agent at AE onset for action taken.	Open	27	
2012-104868	9433733	Was the subject taking any concomitant medications, if yes please provide.	Open	27	
2012-104868	9433733	Please update the status code when the event is considered recovered/resolved.	Open	27	
2012-104868	9433733	Please provide discharge summary upon availability.	Open	27	

Figure 3: Questions from RSC Safety Office Web Part Pop-up Window

Note: You can filter the results displayed in the pop-up window by EAE Number, PID, and Status.

2. *Optional:* To view all questions associated with an EAE, select "Any" from the pop-up window's Status drop-down list.
3. *Optional:* To view only the closed questions associated with an EAE, select "Closed" from the from the pop-up window's Status drop-down list.
4. *Optional:* To view details of the EAE and/or create an Update EAE Report to respond to the RSC Safety Office, click its hyperlink.

The Search page opens in the previous window, from which you can view the full EAE report by clicking the EAE's PDF icon.

4 Using the Alerts Web Part

DAERS generates automatic alerts/messages in regular intervals by e-mail to alert the user to a potentially delayed report. The alerts fall into two categories:

- Notice that the EAE Report time frame is coming due
- Notice that the EAE Report is overdue

DAERS also provides a Web Part (or section) through which Site users can view alerts for initial EAE reports that have not yet been submitted to RSC.

To View from the Alerts Section

1. Select a **Site ID**, **Protocol ID**, and/or **Alert** value from the drop-down lists.

Note: For users with access to more than one site or protocol, the default value is "Any."

2. Click the Search icon . Search results display in a table the alerts for the initial EAE reports that match your criteria.

3. View the EAE Report details:

Icon — Two different types of icons to visually

distinguish between the two types of alerts.

Site ID — The clinical research sites associated with the user which has an EAE report pending submission or is past-due submission to RSC.

EAE Number — The EAE number of the initial report, e.g., 100426.

Protocol ID— The Protocol Number (a.k.a. legacy Protocol Number), e.g., A5175, as entered on the EAE Report.

PID — The Participant ID on which the EAE was reported.

Alert — The type of alert depending upon the initial EAE report pending submission or past-due the submission.

- Submission Deadline
- Submission Past-Due

Due Date — The due date (in international format DD-MMM-YYYY) for submitting the EAE report to RSC. For example, 12-Dec-2008 with the date displayed in the Site’s local time zone.

Days Overdue — The number of days the EAE report has been in the system past the submission due date without being submitted to RSC.

Alerts Search Fields	
PARAMETER	ADDITIONAL INFORMATION
Site ID	Select a Site ID to limit the search to a single site at which EAEs were reported from the drop-down list.
Protocol ID	Select a Protocol Number from the drop-down list.
Alert	Select an alert type from the drop-down list. Submission Deadline — Initial EAE report pending submission to RSC. Submission Past-Due — Initial EAE report past the submission deadline not yet submitted to RSC.

5 Using the Unstable EAE Outcomes Web Part

Use this Web Part to view EAE reports that have been submitted to RSC with an unstable outcome. An outcome

is “unstable” if it has one of the following codes in the Status Code at Most Recent Observation field on the Primary Adverse Event page:

- Recovering/Resolving
- Not Recovered/Not Resolved
- Unknown (with no reason selected)

An outcome is “stable” if it has one of the following codes in the Status Code at Most Recent Observation field on the Primary Adverse Event page:

- Recovered/Resolved with Sequelae
- Recovered/Resolved
- Death
- Unknown
 - With the reason “Lost to Follow up” selected
 - With the reason “Discontinued” selected

Tip: You can hover your mouse over the question mark icon  in the user interface for a reminder of what qualifies as an “unstable” outcome.

By default, this web part displays unstable outcomes for all EAE reports with which the site user is associated. This list can be filtered and/or sorted.

To Sort and/or Filter EAE Reports Submitted with an Unstable Outcome

By default, the reports in the Unstable EAE Outcomes Web Part are sorted by the Site ID column. Do one of the following to sort and/or filter the reports by different criteria:

- Click a column heading to sort the list by that heading, and then scroll through the sorted list to locate the report you want.
- Filter the list by selecting from the Site ID and/or Protocol ID drop-down menus and then click the Search icon . The list will refresh to display results matching your criteria.

As you sort and/or filter the list, you will be able to see key EAE Report details. For instructions on how to update a report, please see the section “To Update Reports Submitted with an Unstable EAE Outcome.”

Key EAE Report Details	
FIELD	ADDITIONAL INFORMATION
EAE Number	The EAE number of the latest EAE report version that was submitted to RSC with an Unstable outcome (e.g., 2010-100426-5). Clicking on the EAE Number hyperlink will take you to the Search screen.
Protocol ID	The Protocol Number (a.k.a. legacy Protocol Number), e.g., A5175.
PID	The Participant ID on which the EAE was reported.
Primary AE	The primary adverse event verbatim text as entered on the latest version of the EAE report submitted to RSC.
# of Days	The number of days that have passed since the Initial report submission date. The count is updated daily at 12:01 am and stops once an updated version of the EAE report is submitted to RSC with a stable outcome.

To Update Reports Submitted with an Unstable EAE Outcome

- Click the report's EAE Number hyperlink under the EAE Number column.
The Search screen displays, listing all the versions of that EAE report, with the latest version at the top.
Note: For protocols that are in the status "Closed to Follow Up," "Participants Off Study and Primary Analysis Complete," or "Concluded," you must **fax** an updated EAE report to RSC.
Optional: If you want to see the details of a particular version of the EAE, click the PDF icon to open the full report.
- Depending on whether the latest version of the report is pending submission or has already been submitted to RSC, use one of the following procedures to update the report.

If the latest version of the report is pending submission to RSC:

- Click **Modify** in the Action column of the Search results table.
The Reporter and Site Information screen

displays.

- Click **Primary Adverse Event** in the vertical navigation menu.
The Primary Adverse Event screen displays.
- Update the **Status Code at Most Recent Observation** field.
- Click **Save**.
An add successful message displays.

For detailed information on completing the other fields on this page, please see the section "Adding Primary Adverse Event."

If the latest version of the report has already been submitted to RSC:

- Click **Update** in the Action column of the Search results table.
A new version of the report is created, and the Reporter and Site Information screen displays.
- Select an option under **Preferred Mode of Communication** and then click **Save**.
- Click the **Primary Adverse Event** link under the EAE Sections pane.
The Primary Adverse Event screen displays.
- Update the **Status Code at Most Recent Observation** field.
- Click **Save**.
An add successful message displays.

For detailed information on completing the fields on this page, please see the section "Adding Primary Adverse Event."

Note: Sites will also receive email alerts with a list of EAE reports that currently are pending a stable outcome. These alerts are sent once a month to CRS Leaders, CRS Coordinators, and all reporters that are associated with any EAE reports that were submitted to RSC with an unstable outcome. The email alert includes the EAE information as well as the steps required to update the EAE report.

Searching EAE Reports

The Search page helps you locate a saved EAE report and is accessed from the Home page or the DAERS menu bar. When you first login to DAERS, the Home (dashboard) page opens with links by report status unique to your role and study site protocols. Once you select the EAE report link, the Search page displays with the search results table populated with the results from the Home page. The Home page is one place to search from when you initially login, use the Search page whenever you need to locate an EAE report and run a search query within DAERS. Search results display in a table list from which you locate

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the EAE Report. You have the option to export these results to an Excel spreadsheet.

To Search for an EAE

- From the DAERS menu bar EAE option, point to **EAE**, then click **Search**.
Search page displays.
- Complete as many of the search criteria as required to narrow the search results.
- Click **Search**.
Search results display in a table based on the criteria you selected.
Note: If no criterion is selected, the system displays all EAEs that you are permitted to view.
- Optional:* Click **Export to Excel** to export the Search results to a Microsoft Excel spreadsheet.
- Find the EAE Report and click an action button from the Action column.

DAERS automatically filters to display only those protocols/studies for which there is permission to report EAEs.

Search Fields	
PARAMETER	ADDITIONAL INFORMATION
EAE Number	Type all or part of an EAE or Legacy EAE number. The only permitted symbol is the hyphen (-).
Protocol Number	Select a protocol number from the drop-down list.
Participant ID 	Type a number in this smart search field. As you type, a list of matching participant IDs display that you can select. If the number is not listed, the number you type remains in the field.
Site ID	Select a Site ID to limit the search to a single site at which EAEs were reported from the drop-down list.
Report Status	Select a status from the drop-down list.

Search Fields	
PARAMETER	ADDITIONAL INFORMATION
	<p>Pending – An EAE report is started by the Study Reporter or Study Physician, but it is not finished.</p> <p>Ready for Final Review – The EAE report contains all required elements and is ready to be reviewed by the Study Physician.</p> <p>Submitted to RSC – When the Study Physician approves and submits the EAE report to RSC. Users may then add to the report through an update.</p> <p>Withdrawn – RSC accepted request for withdrawal.</p>
Report Type	Select a type from the drop-down list. Initial —Original report submitted to RSC. Update — Once an EAE report is submitted to RSC, additional information is submitted through an update .
Status Date From	Type date or select date from the Calendar that represents the status changed since this date.
Status Date To	Type date or select date from the Calendar that represents the status changed before this date.
Reporter Name	Select a name from the drop-down list.
Show current report versions	Displays only those versions of reports that can be modified or updated.
Show all report versions	Displays all versions of the reports.

Understanding EAE Reports

The EAE Report Submission Process

Completing and submitting an EAE via DAERS is similar to the DAIDS EAE paper form. Once a study site identifies an adverse event, any study site member authorized to use DAERS may act as a Study Reporter to create an EAE report. Only an authorized person—such as the Study Physician—submits the report to the DAIDS Regulatory Support Center (RSC).

EAE Workflow

- An Adverse event occurs to a participant on a protocol.
- The clinical research site determines if the event meets DAIDS reporting criteria. Use the optional Assessment Tool to assist with this determination. However, if the assessment determines the event does not meet reporting criteria, the event can still be reported since there may be protocol-specific requirements that need to be referenced separately from the tool. When in doubt, please consult the protocol, your site investigator, or contact the RSC.
- The Site Reporter creates an EAE Report, entering data in mandatory and optional fields. An EAE Report number is assigned when the Reporter and Site Information section is saved. Once the Reporter and Site Information page is saved, DAERS then assigns a unique 6-digit number to the EAE Report, example: 100014.
- Reporter receives an automatic notification e-mail from the system of the new report details.
- At this point, the Applicable EAE Report Sections page displays, providing the user an option to select the sections for which they have information. Later, the user can change the selection at any time by accessing the individual section.
- Fields in each section are either optional for completion or mandatory to complete the report for final review and then submission to RSC. The more information users provide initially limits further questions from RSC.
- The Site Reporter performs a completion check to validate that all information is accurate and complete. The Site Reporter runs a completion check to confirm that the report is ready for final review by the Study Physician (the Study Physician can also elect to run a completion check).
- The system sends e-mails to selected Study Physicians for the clinical research protocol and site combination that the report is completed and ready for final review. The Site Reporter is copied on the e-mail.
- The Study Physician logs on the system and does the final review, signs with an electronic signature to verify the report is accurate and complete, and then submits the EAE to the RSC.
- If the report is submitted more than three reporting days after reporting the event (after 11:59 P.M. of the third reporting day, Monday-Friday), an explanation must be provided before the electronic signature.
- The system sends e-mail notifications to the RSC, DMC, ICC, Site Reporter, CRS Coordinator and Study Physicians for the protocol and site combination confirming the EAE Report submission.
- After submitting an initial report, an unrestricted number of updates to the report can be submitted following a similar process.
- Once submitted to RSC, the EAE number becomes associated with the year of submission, example: 2008-100014. If Update reports are submitted, you can track the number of updates by looking at the last number: 2008-100014-3. Explanation: EAE Report Number 100014 was submitted in the year 2008 and three update reports have been submitted.

Viewing a Report's Context Header

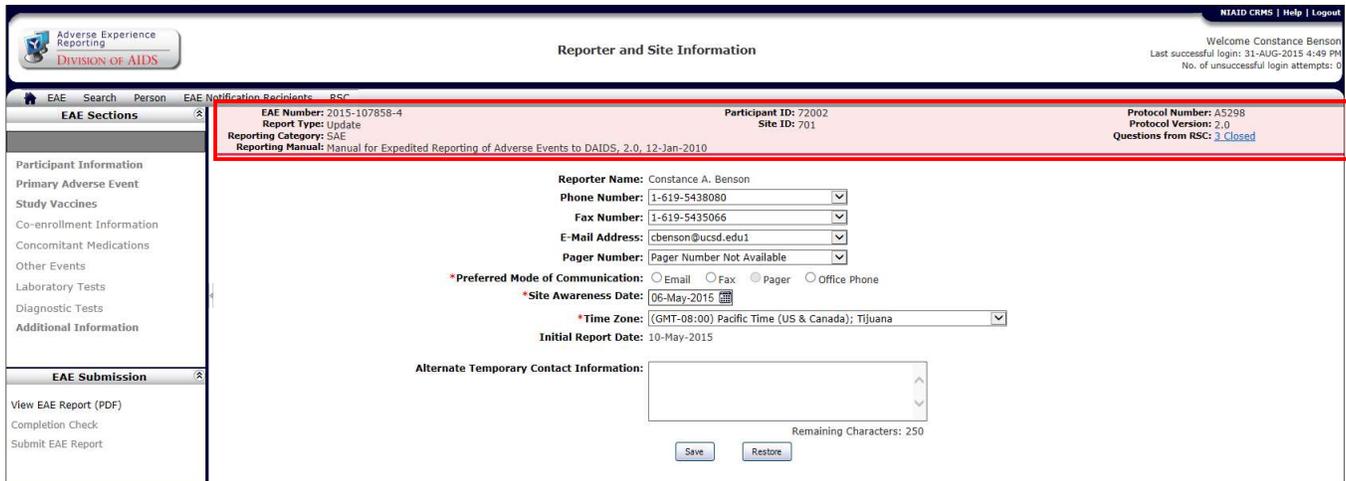


Figure 4: The Context Header of the Reporter and Site Information page.

The Context Header appears just beneath the DAERS menu bar of all EAE sections. It displays important background information about the EAE Report (such as the EAE Number, Reporting Category, Site ID, Reporting Manual, etc.). The purpose of this area is to provide pertinent, at-a-glance reference information as you create a new EAE Report or modify an existing one. The table below describes each of the Context Header's fields.

Context Header Fields

FIELD	DESCRIPTION
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EAE Number	<p>Displays the unique EAE identification number assigned by the system upon creation of an EAE report. This number can have up to four parts: a unique six-digit ID, the year of submission, an update number, and a legacy EAE number.</p> <p>For example, take the number 2008-100014-3 (2004-0185). The first number in the chain ("2008") refers to the year the report was submitted. The second number ("100014") is the six-digit ID generated by DAERS. The third number ("3") indicates that this is the third version of the report. (This number will not appear if the report is on its initial version.) The last number</p>
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Context Header Fields

FIELD	DESCRIPTION
-------	-------------

	enclosed in parentheses ("2004-0185") is the legacy number—i.e., the number the EAE had before it was migrated from another information system.
Participant ID	Displays the Participant ID for whom the report was created.
Protocol Number	Displays the Protocol Number (a.k.a. legacy Protocol Number) as entered on the EAE Report (e.g., A5175).
Report Type	Displays the Report Type.
Site ID	Displays the ID of the clinical research site at which the EAE report was created.
Protocol Version	Displays the Protocol Version number as entered on the EAE report.
Reporting Category	Displays the Reporting Method and Level of Reporting, based on the protocol's unique reporting requirements. For protocols associated with multiple

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Context Header Fields

FIELD	DESCRIPTION
	reporting methods, the system displays the user-selected Reporting Method. The Reporting Category is displayed in the following format: Reporting Method (Level of Reporting). For example, this field might read "EAE (Other)," where "EAE" is the Reporting Method and "Other" is the Level of Reporting. If there is no Level of Reporting associated with the protocol then only the reporting Method is displayed.
Questions from RSC	Displays the number of RSC Safety Office requests for clarification and/or additional information pertaining for the report, as well as the status of the questions.
Reporting Manual	Displays the Reporting Manual associated with the protocol for which the EAE report is created. This field shows the manual's version number and year of publication.

Assessing Adverse Events

Figure 5: Assessment Tool for protocols associated with Manual for Expedited Reporting of Adverse Events to DAIDS v1.0.

Figure 6: Assessment Tool for protocols associated with Manual for Expedited Reporting of Adverse Events to DAIDS v2.0

Using the Assessment Tool

The Assessment Tool is an optional method to assist the clinical research sites in determining if an adverse event meets the criteria for expedited reporting to the DAIDS RSC. If you are in doubt as to whether or not to submit an EAE Report for an event, you may use the optional Assessment Tool. The results list at the top of the page and act as a guide to help you decide if the adverse event that occurred to a participant under a particular protocol is reportable. The assessment lists any protocol-specific exceptions (i.e., Version 2.0 section 6.3.7 pg 89). However, the event can still be reported since there may be protocol-specific requirements that need to be

referenced separately from the tool. When in doubt, please consult the protocol, your site investigator, or contact the RSC.

To Create an Assessment

1. From the **EAE** menu option, point to **New**, and then click **Assessment**.
The Assessment Tool page displays.
2. Complete the Assessment Tool fields.
3. Click **Run Assessment Tool**.
The Assessment Tool page displays a message above the fields that an EAE Report is required or not. You have the **option** to create an EAE report.

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4. Click **Create New EAE** to begin the process of creating a report.
5. *Optional:* Click **Modify Assessment Tool** to amend criteria, or click Clear to empty field values and enter new criteria, and then click **Run Assessment Tool**.

If there are no numbers displaying in the list fields contact NIAID CRMS Support for assistance, your user name needs to be actively associated with a protocol for values to display

DAERS automatically filters to display only those protocols/studies for which there is permission to report EAEs.

Fields prefaced with a red asterisk (*) indicate a required field.

Assessment Tool Fields	
FIELD	DESCRIPTION
*Site ID	Select a site for the current user from the drop-down list. (Populates the next field with the protocols associated to the selected site for the current user).
*Protocol Number	Select the Protocol Number associated to the Site ID selected in the field above from the drop-down list. (Populates the next field with the protocol versions associated to the selected protocol).
*Protocol Version	Select the protocol version associated to the selected Protocol ID that the participant was on at the time of the Adverse Event from the drop-down list. (Populates the Protocol Full Title pre-populated field).
Protocol Full Title	This field is automatically pre-populated after the protocol ID and version field values are selected.
*Level of Reporting	Note: This field will only be displayed for protocols associated with EAE reporting Manual for Expedited Reporting of Adverse

Assessment Tool Fields	
FIELD	DESCRIPTION
	Events to DAIDS v1.0. This field populates based on the protocol. If the protocol has more than one level, Select a level of reporting applicable to the report from the drop-down list. - Standard - Intensive - Targeted - Other
*DAIDS AE Reporting Method	Note: This field will only be displayed for protocols associated with Manual for Expedited Reporting of Adverse Events to DAIDS v2.0. This field displays the reporting method based on the protocol. - SAE - SUSAR
*Primary AE	Type one term that best describes the nature of the adverse event being reported. You can use medical abbreviations.
*Seriousness Criteria	For protocols associated with EAE reporting Manual for Expedited Reporting of Adverse Events to DAIDS v1.0. Select one or more criteria that identify the seriousness of the outcome of the adverse event. <ul style="list-style-type: none"> • Death • Life-threatening • Hospitalization or prolongation of existing hospitalization. • Persistent or significant disability/incapacity • Congenital anomaly/birth defect • None of above but is a protocol specific reporting requirement, including Grade 3 events as required by the intensive level of EAE

Assessment Tool Fields	
FIELD	DESCRIPTION
	<p>reporting.</p> <ul style="list-style-type: none"> None of above, but is of sufficient concern to report to DAIDS <p>Note: If you select either one of the "None" checkboxes, the system shall clear and disable all other seriousness criteria checkboxes.</p> <p>For protocols associated with Manual for Expedited Reporting of Adverse Events to DAIDS v2.0. Select one or more criteria that identify the seriousness of the outcome of the adverse event.</p> <ul style="list-style-type: none"> Results in Death Is life-threatening Requires inpatient hospitalization or prolongation of existing hospitalization Results in persistent or significant disability/incapacity Is a congenital anomaly/birth defect Other important medical event that may jeopardize the subject or that may require intervention to prevent outcomes listed above. None of the above, this is not an SAE, but is a protocol-specific reporting requirement None of the above, this is not an SAE, but is of sufficient concern to report to DAIDS <p>Note: If you select either one of the "None" or "Other important" checkboxes, the system shall clear and disable all other seriousness criteria checkboxes, including the other "None" (and vice versa).</p>
*Severity Grade of Primary AE	Select the most appropriate term from the drop-down list that describes the intensity (severity)

Assessment Tool Fields	
FIELD	DESCRIPTION
	<p>of the adverse event to the Investigational agent.</p> <p>1 – Mild 2 – Moderate 3 – Severe 4 – Life threatening 5 – Death</p>
*Relationship to Study Agent	<p>Select the term from the drop-down list that reflects judgment of causal association (highest relationship) between the adverse event and the study product (there can be multiple products). For protocols associated with Manual for Expedited Reporting of Adverse Events to DAIDS v1.0, select one of the below</p> <p>1 – Definitely Related 2 – Probably Related 3 – Possibly Related 4 – Probably Not Related 5 – Not Related 6 – Pending (temporary assignment in cases of death in which insufficient information is initially available to assess relatedness)</p> <p>For protocols associated with EAE reporting Manual for Expedited Reporting of Adverse Events to DAIDS v2.0. Select one of the below: Related Not Related</p>
*Expectedness	If the AE Reporting Method is SUSAR or Level of Reporting is Targeted , select whether this event was expected or not.

Generating and Completing EAE Reports

Working in Validation and Normal Mode

You can easily work on an EAE report in DAERS. There are two page modes to assist you. When you login, DAERS defaults to the Normal mode view, which is the most common way to work in DAERS. The Normal mode is the data entry mode. For performance it is better to run in Normal mode and use Validation mode as a check. You can switch to Validation mode at any time to run a check for errors prior to completing the EAE report. When you work in Normal Mode, the menu bar display is Validation Mode. Toggle back and forth between the two modes as necessary.

Tip: You must save your changes on a page before switching modes, otherwise they will be lost.

The Validation mode is a check for requirements for successful completion while you are creating or modifying an EAE report. DAERS displays a symbol next to each section listed in the navigation area to alert you to any necessary actions needed to validate the section. A Correct symbol  indicates the section of the EAE Report is completed. An Error symbol  indicates there are errors in the section that need to be corrected in order to complete the EAE.

Although the validation mode is similar to the completion check, it is only a guide. You must still run the completion check before submission.

To Switch to Validation Mode from Normal Mode

1. Click **Validation Mode** on the DAERS menu bar from the Normal mode view to display the page in Validation mode view.
2. Select a section with an error  from the vertical navigation menu.
Example:  Primary Adverse Event. This means that the page Primary Adverse Event is required for completion.
3. Correct errors or complete page.
4. Click **Save**.

To Switch to Normal Mode from Validation Mode

Click Normal Mode on the DAERS toolbar from the Validation mode view to display the page in Normal mode view.

Creating an EAE Report

An EAE report should be created at the time the study site becomes aware of a serious adverse event and then submitted to the DAIDS RSC by 11:59 P.M. on the third reporting day (Monday through Friday). If the timeline is

exceeded, the Study Reporter must enter a reason at the prompt on successful completion. The Study Physician validates this reason and can modify the reason before submission.

To Create a New EAE

1. If this page is not reached from the Assessment Tool, from the **EAE** menu option, point to **New**, and then click **EAE Report**.

The Create New EAE page displays.

2. Complete the new EAE fields.
3. Click **Next**.

The Reporter and Site Information page displays.

Note: The Existing EAEs page may display if the Participant ID (PID) matches another unsubmitted EAE report. The existing EAE may be any type or status.

Fields prefaced with a red asterisk (*) indicate a required field.

Create EAE Report Fields

FIELD	DESCRIPTION
*Site ID	The field is populated with the sites the user is associated with. If the user belongs to more than one site, click  and select the site the participant was enrolled at the time of the adverse event. (Your selection populates the next field with the protocols associated to the selected site. The list will only display those protocols the site is reregistered to.)
*Protocol Number	The field is populated with the protocols the selected site is registered to. Select the Protocol Number the participant was enrolled on at the time of the adverse event. (The next field pre-populates with the protocol versions associated to the selected protocol. The list will only display those versions of the protocol the site is registered to.)

Create EAE Report Fields	
FIELD	DESCRIPTION
*Protocol Version	The field is populated with the protocol versions the site is registered to for the selected protocol. Click  and select the Protocol Version in which the participant was registered at the time the adverse event occurred. (The next field pre-populates with the Protocol Full Title for the selected protocol version.)
Protocol Full Title	Displays the full title of the protocol. This field is automatically pre-populated after the Protocol Number and Protocol Version field values are selected.
*Participant ID 	Type a PID number in this smart search  field. If the Participant data is provided by the DMC (<i>Data Management Center</i>), then as you type a list of matching Participant IDs display. Select a number, or if the number is not listed, the number you type remains in the field.
Participant Information	Displays the Date of Birth, Sex at Birth and Race of the selected participant if the information has been provided by the DMC.

Checking Existing EAE Reports by PID

During the process of creating a new report, if the Participant ID (PID) number matches another EAE report, the Existing EAEs page opens to display a table of all EAE reports created for the same PID number. Review this list to verify that there is not already a listing for the proposed EAE report.

Note: There are no time constraints in the list of matching EAE reports. All reports are listed, regardless of type or status.

To Update an EAE if it is a Duplicate

- If a pending report for the adverse event already exists, click the EAE Number link from the table to

begin modifying the report. The Reporter and Site Information page displays.

- *Optional:* Click  to review the report before clicking the EAE Number link to modify the report.

Note: Reports currently being modified by RSC to reflect changes submitted via fax or e-mail will be read

only and will be displayed with a Lock  icon. The PDF report and the link will be available once RSC has completed their modifications.

- If the report is already submitted to RSC, you can create an update to the report.
 - Conduct a search for the report, and then click Update in the Action column of the Search results table.

To Select an Action if an EAE is NOT a Duplicate

- Click **Create New Report** located below the table to create a new report.
- The Reporter and Site Information page displays.

Adding EAE Report Sections

Adding Reporter and Site Information

Use the Reporter and Site Information page to view the reporter name at the site, then enter their preferred contact information and mode of communication, and date when the site first became aware of the primary adverse event. The system populates the fields with the name and contact information for the user logged into the system.

The Reporter and Site Information page displays for a new EAE after you save the Create New EAE page, and for a previously saved report after you select modify or review from the Search page. You can also select the page from the vertical navigation menu after you open a report.

Note: Before a report is submitted, if you open a report to modify for which you are not the reporter, you are prompted to change the reporter name to make yourself the reporter. If selected, all related fields automatically populate with your user login information.

To Enter Reporter and Site Information

1. Complete the Reporter and Site Information fields.
2. *Optional:* Click Back to Create New EAE before a save to edit site protocol and participant information, then return to the Reporter and Site Information page. This button only displays when you are creating a new report.

Note: Once the information on the Reporter and Site Information screen has been saved and the EAE number has been created, the site, protocol and participant information for this report cannot be modified.

3. Click **Save**.
If the creation of the EAE Report is successful, the "EAE Created Successfully" message displays with a unique EAE number assigned by the system, the EAE Report Submission due date, and the Applicable EAE Sections floating page displays.
If an updated or modified report, a successful update message displays.
4. *Optional:* Click Restore before a save to cancel any changes and restore previous values.

Fields prefaced with a red asterisk (*) indicate a required field.

Reporter and Site Information Fields	
FIELD	DESCRIPTION
Reporter Name	Displays the name of the

Reporter and Site Information Fields	
FIELD	DESCRIPTION
	reporter. For new reports, this field is pre-populated with the name of the user logged into the system. The Change Reporter button is visible if the user logged into the system is not the same as the reporter name.
Change Reporter	Click  and the system pre-populates the fields with the new name and contact information of the user logged into the system. Only displays for a pending report when the user modifying the report is different from the Reporter saved to the report.
Phone Number Fax Number E-mail Address Pager Number	These fields will be pre-populated with contact information. However, if more than one type of contact information exists, you should select the preferred mode from the options under Preferred Mode of Communication .
Temporary E-mail Address	If the reporter does not have a valid e-mail address listed, the Temporary E-mail Address field will display. Type e-mail address in a valid e-mail address format, e.g., name@dot.com. If a temporary e-mail address is provided for the reporter, when you save the page, a warning message displays for you to contact NIAID CRMS Support and provide the e-mail address to be added to the system for future use.
*Preferred Mode of Communication	Select one preferred mode of communication: Phone, Fax, Email, or Pager. Only those options with contact information selected are active.

Reporter and Site Information Fields	
FIELD	DESCRIPTION
*Site Awareness Date	Lets users type in the date (e.g., in DD/MM/YYYY format) in the box or click  to select a date from the Calendar of when site became aware of primary adverse event. Note: Site awareness should not change unless correcting a mistake.
*Time Zone	Pre-populated with the clinical research site's time zone. May be changed by selecting a Time Zone from drop-down list.
Initial Report Date	Displays the date the initial report was submitted to RSC. This only displays when the EAE is an Update.
*Reporting Method	Displays the options a user has for specifying the Reporting Method for the adverse event. Whatever option you select will be displayed both in the Context Header and in the EAE report PDF. Note: This field will only appear if the protocol has multiple Reporting Methods. It will not appear if the protocol has only one Reporting Method.
Alternate Temporary Contact Information	Type text that provides information such as phone, fax, e-mail, and pager numbers if this information will be different in the short-term. For example, contact information for when on travel and not at the preferred contact.

Adding Applicable EAE Report Sections

As you start the process of creating an EAE report, you have an option to customize the report. After you complete and save the Reporter and Site Information, a floating page, Applicable EAE Report Sections, displays a list of the pre-defined report sections and then questions for each of the sections applicable to the EAE. By

answering these questions, the system identifies which sections to highlight for completing the EAE Report. Once you save your answers, the page closes and you are back in the Reporter and Site Information page. The EAE Sections that you selected to complete the report display in the vertical navigation menu in BOLD type. You can complete each section in any order.

Note: The more information you provide initially in the report limits further questions from RSC after submission.

To Add Sections to the EAE using the Applicable EAE Report Sections page

1. Complete and save the Reporter and Site Information page (for a new report only).

The Applicable EAE Report Sections floating page displays with two sections: Pre-defined Report Sections and Sections Applicable to this EAE.

2. Select **Yes** or **No** to each question to determine if that section is applicable to this EAE.
 - **Co-enrollment Information** — Was the participant enrolled in another DAIDS protocol at the time of the Primary AE?
 - **Concomitant Medications** — Was the participant taking any concomitant medications at the time the Primary AE occurred?
 - **Other Events** — Are there any other clinically significant events associated with the Primary AE?
 - **Laboratory Tests** — Are there any relevant laboratory tests?
 - **Diagnostic Tests** — Were there any diagnostic tests taken at the time the Primary AE occurred?
 - **Additional Information** — Is there any additional information or supporting documentation for this Primary AE?

3. Click **Save**.

4. Click **OK** at the message prompt.

EAE created successfully message displays above the fields with an additional message of the due date for the EAE Report Submission.

5. *Optional:* Click **Cancel** to abort completing the Applicable EAE Report Sections page, then click **OK** confirming the action from the message prompt.

Note: Click **Cancel** to abort completing the Sections page, then click **OK** confirming the action from the message prompt. The system will assign a unique EAE number on creation of this EAE report and the report will be in "Pending" status.

Adding Participant Information

The Participant Information page is used to collect detailed information regarding the study participant

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involved in the event, including age, sex, and HIV status.

To Enter Participant Information

1. From the EAE Sections in the vertical navigation menu, click Participant Information.

Participant Information page displays

2. Complete the Participant Information fields.

Note: If the DMC provided Participant information to NIAID CRMS, one or more of the following fields will be populated: Date of Birth (DOB), Sex, Race, and Ethnicity.

This information may be updated if it does not match the participant's records.

3. Click **Save**.

Add Successful message displays above the fields.

Note: If the Add is not successful, a message displays and the errors identified (!) on the page.

Fields prefaced with a red asterisk (*) indicate a required field.

Participant Information Fields	
FIELD	DESCRIPTION
Participant ID	<p>To change or update the participant ID (PID), type a different PID in this field. When you start typing, PIDs provided by the DMC display for you to select. You can continue typing without selecting a PID from the list. When you finish typing the PID, click Change PID.</p> <p>If the PID you enter is provided by the DMC, DAERS automatically updates applicable fields on the page with information provided by the DMC.</p> <p>If the PID you enter is not provided by the DMC, the data fields containing information normally provided by the DMC are blank. You must manually enter this information. When you are finished, click Save to confirm the changes.</p> <p>Note: The ability to change the PID only applies to initial EAE reports. Once a report is submitted, the PID cannot be modified.</p>
Date of Birth	Click to select the Participant's Day,

Participant Information Fields	
FIELD	DESCRIPTION
	<p>Month, Year of birth. You may enter partial date information if the complete date is unknown.</p> <p>Note: This may be pre-populated by PID information from DMC and may be updated.</p>
*Age	<p>Enter the age of the participant at the onset of the adverse event. This field is automatically populated based on Date of Birth entered and may be updated.</p> <p>Type number in the Age box, and then select a unit of time from the drop-down list (this field becomes mandatory once there is a value in the age field).</p> <p>Note: The system calculates age based on date report was created and the date of birth.</p>
*Sex at Birth	<p>Type in the field or click to select Male, Female, or Unknown. This may be pre-populated by PID information from DMC and may be updated. (If you select Female or Unknown, the next field, Pregnant becomes mandatory.)</p>
Pregnant	Click Yes, No, or Unknown. If you select Yes, the next field, Duration becomes mandatory.
If Yes, Duration	Type the number of weeks of the pregnancy.
Height	<p>Enter the height of the participant at the onset of the event. Type number, and then select unit of measurement (inches or centimeters). Value must be between 11.811 and 98.425 inches or between 30 and 250 centimeters. The field allows up to two decimal places.</p>

Participant Information Fields	
FIELD	DESCRIPTION
Weight	Enter the weight of the participant at the onset of the event. Type number, and then select unit of measurement (grams, pounds or kilograms). Value must be between 700 and 14000 grams, or between 1 and 545 kilograms or between 2 and 1200 pounds.
BSA	DAERS automatically calculates the Body Surface Area value from height and weight and displays the value. Note: The formula is Dubois and Dubois Formula as below: BSA (m ²) = 0.20247 x (Height(m) ^{0.725}) x (Weight(kg) ^{0.425})
Ethnicity	Select an Ethnic Group: This may be pre-populated by PID information from DMC and may be updated.
Other	If Other is selected in the Ethnicity field, type an Ethnicity group other than what is listed in this mandatory field.
*Race	Select one or more Race options. This may be pre-populated by PID information from DMC and may be updated.
Other	If Other is selected in the Race field, type a Race other than what is listed in this mandatory field.
HIV Status	Select the HIV status of the participant: <ul style="list-style-type: none"> • HIV Infected—Infection with HIV confirmed by laboratory test(s). • HIV Uninfected—Absence of HIV infection confirmed by laboratory test(s). • Unknown—Exposed to HIV and HIV testing not yet done or results not yet confirmed.

Participant Information Fields	
FIELD	DESCRIPTION
	HIV testing performed; results not yet available. No documented history of HIV testing.
If you selected the status as "HIV Infected", the remaining HIV fields become visible and require information. These fields are shaded if you selected the status as "HIV Uninfected" the HIV Status Test date is required.	
Last HIV Status Test Date	Type date or select date from the Calendar of when the HIV status was confirmed. If unsure of date, enter the date and select the Estimated? checkbox. If unknown, select the Unknown checkbox.
Most Recent CD4 Count 	In the Recent CD4 smart search box, Type number and then select the Unit of Measure from the drop-down list of cells/mm ³ , or %. You can enter a custom value (10e21) but it must include a number and only the letter, "e" may be used. Press the space bar and select a Pending, Unknown, or Custom value. Type P, or U to select specific Pending or Unknown values.
Most Recent CD4 Count Date	Type date of the last CD4 Count test in DD/MM/YYYY format or click  and select date from the Calendar. If unsure of the exact date, enter the date and select the Estimated? <input type="checkbox"/> , or if the date is unknown, select the Unknown <input type="checkbox"/> .
Most Recent HIV Viral Load 	In the Recent HIV smart search  box, <ul style="list-style-type: none"> • Type number. You can enter a custom value but it must include a number and only the letter, "e" may be used. • Press the space bar and select a Pending, Unknown,

Participant Information Fields	
FIELD	DESCRIPTION
	<p>or Custom value.</p> <ul style="list-style-type: none"> Type P, or U to select specific Pending or Unknown values. <p>You can enter values of greater (>) than or lesser than (<) (If you enter a value, you must also select a value in the Method field below)</p>
Most Recent HIV Viral Load Date	Type date of the last HIV Viral Load test in DD/MM/YYYY format or click  and select date from the Calendar. If unsure of the exact date, enter the date and select the Estimated? <input type="checkbox"/> , or if the date is unknown, select the Unknown <input type="checkbox"/> .
Method	Click  and select a method (<i>bdNA, NASBA, PCR</i>) of the HIV Viral Load test. (This is a mandatory field when a value is entered in the Most Recent HIV Viral Load field)
If the Participant Date of Birth (DOB) is less than one year, the following Gestational fields are enabled.	
Gestational Age at Birth	Select Weeks or Unknown from the drop-down list.
APGAR (1 min)	(APGAR Score at 1 minute) Select a value of 1 – 10, or Unknown from the drop-down list.
APGAR (5 min)	(APGAR Score at 5 minutes) Select a value of 1 – 10, or Unknown from the drop-down list.
APGAR (10 min)	(APGAR Score at 10 minutes) Select a value of 1 – 10, or Unknown from the drop-down list
Weight at Birth	Type weight in gms.

Participant Information Fields	
FIELD	DESCRIPTION
Head Circumference	Type head circumference in cms.
Breastfed	Select Yes, or No option.
Comments	Type information that is pertinent to the participant.

Adding Primary Adverse Event

Select the Primary Adverse Event section from the vertical navigation menu to add information that best describes the nature of the adverse event being reported using the DAIDS reporting criteria. If the event is reportable, enter information about the severity and onset date. Before the report can be completed, additional information for the most recent observation and a narrative case summary for the primary event must be added.

If you created the report from the Assessment Tool, the adverse event and severity fields are pre-populated with information that you entered to run the assessment. Although pre-populated, the information can be modified.

To Enter Primary Adverse Event

- From the **EAE Sections** in the vertical navigation menu, click **Primary Adverse Event**.
- Select **Yes** or **No** for the "Is this a Serious Adverse Event (SAE) as defined by ICH?" question.
- Select all of the seriousness **categories** that apply for the adverse event.

Note: If you selected Yes in Step 2, a seriousness criteria of "None of the above" *cannot* be selected. If you selected No in Step 2, a seriousness criteria of "None of the Above" *must* be selected.

For protocols associated with Manual for Expedited Reporting of Adverse Events to DAIDS v1.0, select from the following options:

- Death
- Life-threatening
- Hospitalization or prolongation of existing hospitalization
- Persistent or significant disability/incapacity
- Congenital anomaly/birth defect
- None of the above, but is a **protocol-specific reporting requirement**, including Grade 3 events as required by the Intensive level of AE reporting

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- None of the above, but is of sufficient concern to report to DAIDS (specify reason).

For protocols associated with EAE reporting Manual for Expedited Reporting of Adverse Events to DAIDS v2.0, select from the following options:

- Results in Death
- Is life-threatening
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is a congenital anomaly/birth defect
- Other important medical event that may jeopardize the subject or that may require intervention to prevent outcomes listed above.
- None of the above, this is not an SAE, but is a protocol-specific reporting requirement
- None of the above, this is not an SAE, but is of sufficient concern to report to DAIDS (specify reason).

- If you select the **None of the Above, but is of sufficient concern to report to DAIDS** (specify reason) option, the EAE/SAE Report Submission Not Required dialog box opens.
- Type a brief explanation as to why you are reporting this event in the text box.
- Click **Save**.

The dialog box closes. To edit after Save, click the **Specify Reason** link.

- Complete the Primary Adverse Event fields.
 - If you **increase** the grade during an update, the Explanation of Severity Grade Increase dialog box opens.

Note: Any ongoing event that increases in severity to a higher grade than previously reported must be reported as a **new report** if the protocol is associated with EAE reporting Manual for Expedited Reporting of Adverse Events to DAIDS v1.0.
 - Type an explanation for submitting an update report substantiating the increase in severity grade.
 - Click **Save**.

The dialog box closes. To edit after Save, click the **Specify Reason** link.

- Click **Save**.

Add Successful message displays. If the Add is not successful, a message displays and the errors are identified (!) on the page.

Fields prefaced with a red asterisk (*) indicate a required field.

Primary Adverse Event Fields	
FIELD	DESCRIPTION
Is this a Serious Adverse Event (SAE) as defined by ICH?	Select Yes or No.
*Select all the categories that apply for the adverse event or other important medical event or select one of the options for "None of the Above"	Select the checkboxes that apply to the adverse event seriousness criteria. Note: If you selected Yes in Step 2, a seriousness criteria of "None of the above" <i>cannot</i> be selected. If you selected No in Step 2, a seriousness criteria of "None of the Above" <i>must</i> be selected.
*Primary AE	Type text that describes the adverse event verbatim.
*Severity Grade of Primary AE	Select a severity grade of the event from the drop-down list.
Date of Death	Select the Day, Month, and Year of death from the drop-down list. If unsure of the date, enter the date and select the Estimated? checkbox. This field is only enabled (and therefore only mandatory) when the site chooses in step 3 the category "Death" (manual 1.0) or "Results in Death" (manual 2.0). Note: The date cannot be in the future, be greater than the Site Awareness Date if this is an initial EAE report, be before the Date of Birth, or be before the Onset Date.

Primary Adverse Event Fields	
FIELD	DESCRIPTION
*Onset Date	Type date or select date from the Calendar. If unsure of the date, enter the date and select the Estimated? checkbox. Note: The Onset Date cannot be after the Site Awareness Date.
Did this AE result in a Fetal Loss?	Select Yes or No. Note: This field is disabled if the EAE Report was created on a male participant; it is enabled and optional if the EAE Report was created on a female participant or if the system doesn't know the participant's sex at birth.
Date of Fetal Loss	Type the date of the fetal loss. Note: This field only displays if you select "Yes" for "Did this AE result in a Fetal Loss?" If displayed, this field is mandatory to save the page.
Country of AE Origin	Select a country in which the event occurred from the drop-down list. Note: This field will only be displayed for protocols associated with the Manual for Expedited Reporting of Adverse Events to DAIDS v2.0.
The next three fields are not mandatory to save the page, but must be completed before the final review.	
Status Code at Most Recent Observation	Select the code from the drop-down list that applies to the most recent observation. Note: The outcome is considered "unstable" if you select one of the following codes: <ul style="list-style-type: none"> • Recovering/Resolving • Not Recovered/Not Resolved • Unknown (with no reason selected) The outcome is considered

Primary Adverse Event Fields	
FIELD	DESCRIPTION
	"stable" if you select one of the following codes: <ul style="list-style-type: none"> • Recovered/Resolved with Sequelae • Recovered/Resolved • Death • Unknown <ul style="list-style-type: none"> ○ With the reason "Lost to Follow up" selected -or- ○ With the reason "Discontinued" selected
Specify Reason for Status Code	Select a reason for the status code. Note: This field only displays if you select "Unknown" from the drop-down list in the previous field.
Chronic Condition?	Select the checkbox if this is a chronic condition that is not likely to resolve. Note: This field displays only if you are creating EAEs on Manual v2.0 and you select "Not Recovered/Not Resolved" from the drop-down list in the Status Code at Most Recent Observation field.
Status Date	Type the date of the most recent observation or select date from the Calendar. Note: The observation Status Date cannot be before the Site Awareness Date.
Narrative Case Summary	Type text that includes clinical course, therapeutic measures, outcome, relevant past medical history, any other contributing factors, alternative etiologies, and other relevant information. Note: The system will autosave this field to prevent the loss of data if you are logged out the system. Changes should be saved

Primary Adverse Event Fields	
FIELD	DESCRIPTION
	before navigating away from this page.

Adding Study Agents

Select the Study Agents section from the vertical navigation menu to add information regarding the dosing, schedule, and supplier of one or more study agents (other than vaccines) administered to the participant prior to the onset of the adverse event. Once you add a study record, it is listed in a table at the bottom of the Study Agents page.

To Enter a Study Agent

- From the **EAE Sections** in the vertical navigation menu, click **Study Agents**. Study Agents page displays.
- Complete the Study Agent fields.
- Click **Save**. Add Successful message displays.
Note: If the Add is not successful, a message displays and the errors are identified (!) on the page.
- Optional:* Click **New** to add another study agent, or select a record from the grid by clicking on the study agent, to delete or modify.

Fields prefaced with a red asterisk (*) indicate a required field.

Study Agents Fields	
FIELD	DESCRIPTION
*Study Agent/Product 	<p>When you start typing the name of a study agent/product, this smart search field displays a list of possible matches for you to select the correct one and to find the best agent/product match. The list is determined by the study. There can be multiple agents/products.</p> <p>Note: Only generic study agents names are provided and not the Brand name. If the selected study agent/product is a combination drug, then individual attribution for each of the components of the</p>

Study Agents Fields	
FIELD	DESCRIPTION
	combination must be provided, along with the attribution for the combination itself.
*Relationship to Primary AE	<p>Click the drop-down list to select the code that reflects the Study Physician's assessment of the relationship between the Primary AE and the study agents.</p> <p>For protocols associated with version 2.0 of the Manual for Expedited Reporting of Adverse Events to DAIDS, select one of the below:</p> <p>Related Not Related</p> <p>For protocols associated with version 1.0 of the Manual for Expedited Reporting of Adverse Events to DAIDS, select one of the below:</p> <p>1 – Definitely Related 2 – Probably Related 3 – Possibly Related 4 – Probably Not Related 5 – Not Related 6 – Pending (temporary assignment for death)</p>
*Individual Attribution	<p>For each component listed, select the value from the drop-down list that indicates the relationship of the component to the primary adverse event.</p> <p>Note: For version 1.0 of the Manual for Expedited Reporting of Adverse Events to DAIDS, if Pending (temporary assignment for death) is selected in Relationship to Primary AE, then you must set the individual attribution of all components to Pending (temporary assignment of death).</p>
Study Arm/Group	Type text to identify the study arm or study group, to which the participant was assigned on the

Study Agents Fields	
FIELD	DESCRIPTION
	blinded study.
Dose	Type the dosage of the study agent administered to the participant prior to the onset of the adverse event, and then select the unit of measure from the drop-down list. This field accepts a slash (/) between numbers if a combination study drug is entered. Each number corresponds with a drug in the combination.
Date of First Dose	Type date or select date from the Calendar of when the participant took the first dose of the study agent. If unsure of date, select the Estimated? checkbox.
Date of Last Dose	Type the date or select date from the Calendar of when the participant took the last dose of the study agent prior to the onset of the adverse event. If unsure of date, select the Estimated? checkbox.
Route of Administration	Select how the participant received the study agent (example: orally, intravenously) from the drop-down list. If the route is not listed, select the Show more routes checkbox next to the field to view an expanded list. If still not listed, select “Other” at the end of the list. Type the route of administration in the Other field.
Schedule of Administration	Select the schedule for administering the drug to the participant (example: BID-twice a

Study Agents Fields	
FIELD	DESCRIPTION
	day). If not listed, select “Other” at the end of the list. Type schedule in the *Other field.
Site of Administration	Select a value from the drop-down list to indicate where the study agent was administered to the participant. If the site is not listed, select “Other” at the end of the list. Type the site of administration in the *Other field.
Total Number of Administrations Only visible where study agents are microbicides	Type the number of microbicide applications, and then select time in weeks or months for administering the application from the in preceding drop-down list.
Action Taken with Study Agent/Product	Select the action from the drop-down list that was taken by the study physician following the onset date for the adverse event.
Action Date	Type date or select the date from the Calendar of when the Study Physician's action was taken with the study agents. Note: Action date must be on or after site awareness date.
Distributed by DAIDS	Select the Yes or No option to specify if the study agents were obtained from DAIDS. If “No” is selected, additional information is required in the Manufacturer field that becomes visible when the study agent is obtained outside of DAIDS.
*Manufacturer This field is only visible if the study agent is not distributed by DAIDS.	Select the name of the study agent manufacturer from the drop-down list. If the manufacturer is not listed,

Study Agents Fields	
FIELD	DESCRIPTION
	select "Other". Type the manufacturer name in the *Other field. If you do not know the manufacturer name, select Unknown . The distributor name is required in the Distributor field that becomes visible.
*Distributor This field is only visible if the Manufacturer of the study agent is unknown.	Type the name of the distributor when the study agent is obtained by some other means, such as the study site, and the manufacturer is unknown.
Was this study agent/product administered on a cyclic schedule?	Select Yes or No option. Select Yes if the study agents were administered on a schedule that recurs in cycle. If Yes , the next field becomes active.
*Did the Adverse Event occur during a dosing cycle	Select Yes or No option. Depending on your selection, the following fields become active.
Active fields if Yes selected for AE occurring during cyclic schedule:	
*Highest dose in this cycle	Type the highest dose given to the participant during the current cycle prior to the onset of the adverse event, and then select the unit of measure from the drop-down list. This field accepts using a slash (/) between doses if a combination study drug is entered. Each number corresponds with a drug in the combination.
*Date this cycle started	Type date or select date from the Calendar.
Date previous cycle started	Type date or select date from the Calendar.

Study Agents Fields	
FIELD	DESCRIPTION
Number of Previous Cycles	Type the total number of previously completed cycles. Note: If number of previous cycles is zero, the date previous cycle started is not required.
Active fields if No selected for AE <u>not</u> occurring during cyclic schedule:	
*Highest Dose in previous cycle	Type the highest dose given to the participant during the previous cycle, and then select the unit of measure from the drop-down list. This field accepts using a slash (/) between doses if a combination study drug is entered. Each number corresponds with a drug in the combination.
*Last dose in previous cycle	Type the last dose given to the participant during the previous cycle, and then select the unit of measure from the drop-down list. If combination drugs, use slashes to set off the number corresponding with a drug in the combination.
*Date previous cycle started	Type date or select date from the Calendar.
*Number of Previous Cycles	Type the total number of previously completed cycles.
Comments	Provide additional information about the study agents.

Adding Study Vaccines

Select the Study Vaccines section from the vertical navigation menu to add information regarding each vaccine administered to the participant prior to the onset of the adverse event. Once you add a vaccine, it lists in a table on the Study Vaccines page.

The Study Vaccines page is divided into two sections. The Vaccine Regimen section captures the details of the entire

schema of study vaccines. If the Study Vaccines grid is not populated, then you can enter information in this section the first time you add the vaccine. Once saved, the fields are display-only until you select the Edit Regimen link to make edits. The Vaccine Details section gathers information regarding the dosing, administration, and the supplier of the study vaccine. Details in this section can be updated.

To Enter a Study Vaccine

- From the **EAE Sections** in the vertical navigation menu, click **Study Vaccines**.
Study Vaccines page displays.
- Complete the fields in the Vaccine Regimen and Vaccine Details sections.
- Click **Save**.
Add Successful message displays.
Note: If the Add is not successful, a message displays and the errors are identified (!) on the page.
- Optional:* Once a study vaccine record is saved, you can edit the Vaccine Regimen information by selecting the record from the table, and then select the **Edit Regimen** link at the top right of the section.
- Optional:* Click **New** to add another study vaccine, or select a record to delete and then click **Delete**.

Fields prefaced with a red asterisk (*) indicate a required field.

Study Vaccines Fields Vaccine Regimen Section	
FIELD	DESCRIPTION
*Study Arm/Group	Type text that specifies the study arm or study group, to which the participant was assigned on the blinded study.
Action Taken with Study Vaccine Regimen	Select Study Physician's action managing the vaccine regimen after awareness of the adverse event from the drop-down list.
Action Date	Type date of the Study Physician's action or select date from the Calendar. Note: Action date must be on or after site awareness date.
Comments	Type text that provides additional information about the study

Study Vaccines Fields Vaccine Regimen Section	
FIELD	DESCRIPTION
	vaccines and their regimen/schema.

Fields prefaced with a red asterisk (*) indicate a required field.

Study Vaccines Fields Vaccine Details Section	
FIELD	DESCRIPTION
*Study Vaccine	Select the vaccine administered to the participant from the pre-populated list of all study vaccine products listed with the protocol on which the EAE is being reported.
*Relationship to Primary AE	Select the code from the drop-down list that reflects the Study Physician's assessment of the relationship between the Primary Adverse Event and the study vaccines. For protocols associated with Manual for Expedited Reporting of Adverse Events to DAIDS v1.0. Select one of the below 1 – Definitely Related 2 – Probably Related 3 – Possibly Related 4 – Probably Not Related 5 – Not Related 6 – Pending (temporary assignment in cases of death in which insufficient information is initially available to assess relatedness) For protocols associated with Manual for Expedited Reporting of Adverse Events to DAIDS v2.0, select one of the below: Related Not Related
Dose	Type the dosage of the study vaccine administered to the participant prior to the onset of the adverse event, and then select

Study Vaccines Fields Vaccine Details Section	
FIELD	DESCRIPTION
	<p>the unit of measurement from the drop-down list. Example: 20 mg</p> <p>This field accepts using a slash (/) between numbers if a combination study drug is entered. Each number corresponds with a drug in the combination.</p>
Route of Administration	<p>Select a value from the drop-down list for how the study vaccine was administered to the participant.</p> <p>Note: This field may be pre-populated based on the Study Vaccine selected. Select Show more routes to modify the route.</p> <p>If the route is not listed, select the Show more routes checkbox next to the field to view an expanded list.</p> <p>If still not listed, select “Other” at the end of the list. Type the route of administration in the *Other field.</p>
Site of Administration	<p>Select a value from the drop-down list to indicate the site where the study vaccine was administered to the participant.</p> <p>Note: This field may be pre-populated based on the Study Vaccine selected. Select Show more sites to modify the site.</p> <p>If the site is not listed, select the Show more sites checkbox next to the field to view an expanded list.</p> <p>If still not listed, select “Other” at the end of the list. Type the site of administration in the *Other field.</p>
Dates of Administration	Type date or select date from the Calendar of the individual

Study Vaccines Fields Vaccine Details Section	
FIELD	DESCRIPTION
	administration of the study vaccine.
Body Side	<p>Select the side of the body (i.e., right or left) the injection was given from the drop-down list, corresponding with the route of administration, site of administration, and vaccine administration date.</p> <p>To enter a row of Administration Details information, click the Add button to the right of the line of information. More than one row can be added by clicking the Add button after entering the administration details information. Click the Remove button to the right of the line of information to remove a row.</p>
Distributed by DAIDS	<p>Select Yes or No if DAIDS distributed the study vaccines.</p> <p>If “No” is selected, additional information is required in the Manufacturer field that becomes visible when the study vaccine is obtained outside of DAIDS.</p>
*Manufacturer This field is only visible if the study agent is not distributed by DAIDS.	<p>Select the name of the study vaccine manufacturer from the drop-down list.</p> <p>If the manufacturer is not listed, select “Other”. Type the manufacturer name in the *Other field.</p> <p>If you do not know the manufacturer name, select Unknown. The distributor name is required in the Distributor field that becomes visible.</p>
*Distributor This field is only visible if the	Type the name of the distributor when the study vaccine is obtained by some other means, such as the study site, and the

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Study Vaccines Fields Vaccine Details Section

FIELD	DESCRIPTION
Manufacturer of the study agent is unknown.	manufacturer is unknown.

Adding Study Procedures

The Study Procedures screen is only applicable to protocols where a procedural intervention is the study focus.

Select the Study Procedures section to add information regarding one or more study procedures administered to a participant prior to the onset of the adverse event. Once you add a study procedure record, it is listed in a table at the bottom of the page.

To Enter a Study Procedure

1. From the **EAE Sections** in the vertical navigation menu, click **Study Procedures**.

The Study Procedures page opens.

2. Complete the Study Procedures fields.
3. Click **Save**.

An add successful message displays.

Note: If the add is not successful, one or more error messages display, and errors are identified on the page with a red exclamation (!) mark.

4. *Optional:* Click **New** to add another study procedure, or select another record from the table to modify or delete.

Fields prefaced with a red asterisk (*) indicate a required field.

Study Procedures Fields	
FIELD	DESCRIPTION
*Study Procedure	When you start typing the name of a study procedure, this smart search field  displays a list of possible matches for you to select. The list is determined by the study.
*Relationship to Primary AE	Select the code from the drop-down list that reflects the Study Physician's assessment of the relationship between the Primary Adverse Event and the Study Procedure.
Study Arm/Group	Type text to identify the study arm or study group to which the participant was assigned on the blinded study.
*Date of Procedure	Type the date of the procedure in DD/MM/YYYY format (e.g., 25/03/2008) or click and select a

Study Procedures Fields

FIELD	DESCRIPTION
	date from the Calendar.
Comments	Provide additional information about the study procedure.

Adding Co-enrollment Information

Select the Co-enrollment Information section from the vertical navigation menu to list other DAIDS-sponsored protocols that the participant was enrolled on at the time of the adverse event. If there are other studies, a separate report may be required. Please check the protocol or call RSC if you are unsure. Once you add a co-enrollment record, it lists in a table on the Co-enrollment Information page.

Reminder: Just completing this section does not count as reporting it for both studies.

To Enter Co-enrollment Information

1. From the EAE Sections in the vertical navigation menu, click **Co-enrollment Information** to open the Co-Enrollment Information page.
2. Complete the Co-enrollment Information fields.
3. Click **Save**.

Add Successful message displays.

Note: If the Add is not successful, a message displays and the errors are identified (!) on the page. **IMPORTANT:**

- Check the co-enrolled protocol(s) for EAE reporting requirements.
 - You must submit a separate EAE for each co-enrolled protocol in which the event is reportable.
 - For questions regarding EAE reporting requirements, contact RSC at DAIDSRSCSafetyOffice@tech-res.com.
4. *Optional:* Click **New** to add another co-enrollment protocol, or select a record to delete and then click **Delete**.

Fields prefaced with a red asterisk (*) indicate a required field. Shaded fields indicate a field that you cannot modify.

Co enrollment Information Fields	
FIELD	DESCRIPTION
*Was the participant enrolled in another DAIDS protocol at the time of the Primary AE?	Select Yes or No option. If Yes , the next field becomes mandatory.
Co-enrolled Protocol Number	Type a DAIDS Protocol in this

Co enrollment Information Fields

FIELD	DESCRIPTION
	smart search  field or select from the list the protocol(s) the participant was co-participating when the EAE occurred.
Network/Non-Network	Pre-populates with the Network ID associated with the selected Protocol Number or if non-network, the Lead Organization displays. Can be multiple networks, separated in semi-colon format.
Comments	Provide additional information about the listing of co-enrolled protocol.

Adding Concomitant Medications

Select the Concomitant Medications section from the vertical navigation menu to list any concomitant medications that a participant took outside of the study that may have contributed to the primary adverse event. Do not include medications used to treat the adverse event. Any additional concomitant medications being taken at the onset of the primary adverse event, should be uploaded in the Additional Information page, faxed, or e-mailed to the DAIDS RSC. Any combination of these means can be used to list the concomitant medications for the participant.

To Enter a Concomitant Medication

1. From the **EAE Sections** in the vertical navigation menu, click **Concomitant Medications**. Concomitant Medications Information page displays.
2. Complete the Concomitant Medications table fields.

Note: Add one medication at a time. If more medications need to be added, click **Add more medications**.

3. Click **Save**. Add Successful message displays.

Note: If the Add is not successful, a message displays and the errors are identified (!) on the page.
4. *Optional:* Click **New** to add another medication, or select a record to delete, and then click **Delete**.

Fields prefaced with a red asterisk (*) indicate a required field. Shaded fields indicate a field that you cannot modify.

Concomitant Medications Fields	
FIELD	DESCRIPTION
*Check all that apply	<p>If there are any concomitant medications taken at the onset of the Primary AE, select all methods of delivery that apply on how the information will be delivered.</p> <ul style="list-style-type: none"> • None. No concomitant medications were taken at the onset of the adverse event • Entered below. Enter in the form below on this page • Uploaded in DAERS. Upload through the Additional Information page • Faxed to RSC. Fax separately from the online report submission • E-mailed to RSC. E-mail separately from the online report submission <p>Note: RSC must create an update to upload the information that has been faxed or e-mailed to RSC.</p>
Medication	Type the name of the medication taken outside the study by the participant at the time the AE occurred.
Approximate Duration of Use	Type the length of time the participant took the medication, and then select the unit of measure applied, such as weeks. Decimal points are allowed, for example, 1.5 for one and a half.
Date of Last Dose	Type date or select date from the Calendar of the last date the participant took the concomitant medication prior to the onset of the adverse event.
Indication	Type text that provides the reason, condition, or

Concomitant Medications Fields	
FIELD	DESCRIPTION
	circumstance for taking the concomitant medication.
Contributory to AE?	Select Yes, No, Unknown option to assess if the concomitant medication contributed to the adverse event.
Route of Administration	Select the administration route on how the medication was taken from the drop-down list.
Schedule of Administration	Select the administration route on how often the medication was taken from the drop-down list.
Comments	Type text that provides additional information about the listing of concomitant medications.

Adding Other Events

The Other Event section is selected to list other clinically significant adverse events that occurred for the patient at the same time as the primary adverse event. Once you add an event, it lists in a table on the Other Events page.

To Enter Other Events

1. From the **EAE Sections** in the vertical navigation menu, click **Other Events**. Other Events page displays.
2. Complete the Other Events fields.
3. Click **Save**. Add Successful message displays.
Note: If the Add is not successful, a message displays and the errors are identified (!) on the page.
4. *Optional:* Click **New** to add another event, or select a record to delete and then click **Delete**.

Fields prefaced with a red asterisk (*) indicate a required field.

Other Events Fields	
FIELD	DESCRIPTION
*Are there any other clinically	Select Yes or No option.

Other Events Fields	
FIELD	DESCRIPTION
significant events associated with the Primary AE?	If Yes , the *Event Description field becomes mandatory.
Event Description	Type descriptive text for any clinically significant event. Note: Until you type text, the other fields remain inactive.
Severity Grade	Select the severity or intensity of the other event being reported from the drop-down list.
Onset Date	Type onset date for the other event or select the date from the Calendar. If you are unsure of the Selected date, select the Estimated? checkbox.
Comments	Type text that provides additional information regarding the other event.

Adding Laboratory Tests

Select the Laboratory Tests section from the vertical navigation menu to collect information concerning relevant laboratory tests that help explain the nature, severity, and/or complications of the primary adverse event and its relationship to the study agents. This page displays the list of currently saved tests within the same table as to add a new test.

To Enter a Laboratory Test

- From the **EAE Sections** in the vertical navigation menu, click **Laboratory Tests**.
Laboratory Tests page displays.
- Select the methods of delivering the lab information.
If you select the **Entered Below** option, select the first available blank row in the Test Name column and then complete the Laboratory Tests table fields.
Note: You can add more than one test at a time. If another row is needed to add more tests, click **Add more tests**  below the table.
- Click **Save**.
Record Saved Successfully message displays.

Note: If the Add is not successful, a message displays and the errors are identified (!) on the page.

- Optional:* To delete a record, locate the record in the table and at the end of the row, click the delete icon .

Fields prefaced with a red asterisk (*) indicate a required field. Shaded fields indicate a field that you cannot modify.

Laboratory Tests Fields

FIELD	DESCRIPTION
*Check all that apply	Indicates the method for reporting the laboratory tests conducted. None is automatically selected if "no" was selected on applicable EAE page. To select other options, deselect None <input type="checkbox"/> then select one or more options. If there were any laboratory tests relevant to the adverse event taken after the onset of the Primary AE, Select all methods of delivery that apply on how the information was sent to RSC. <ul style="list-style-type: none"> None. No laboratory tests were conducted at the onset of the adverse event or provided on the report. Entered below. If the site specified laboratory tests on the paper form, select this option to enter in the form below. Uploaded in DAERS. Select this option to if any supporting documentation was sent and must be uploaded through the Additional Information page. Faxed to RSC. Select this option if the site faxed separately from the online report submission. E-mailed to RSC. Select this option if the site e-mailed separately from the online report submission.

Laboratory Tests Fields	
FIELD	DESCRIPTION
	<p>Note: RSC must create an update to upload the information that has been faxed or e-mailed to RSC.</p> <p>If you selected Entered Below, the fields become active in the table and the Test Name field is mandatory.</p>
Test Name 	<p>Type a laboratory test name in this smart search field that is relevant to the Primary AE. There can be multiple tests.</p> <p>Note: You can enter the same laboratory test name twice to indicate changes in the participant between labs.</p> <p>As you type, a list of matching test names display that you can select. If the name is not listed, the test name you type remains in the field.</p> <p>If the lab test is a microbiology test, then the Micro checkbox appears pre-selected, under the test name field.</p> <p>If you type a test name that is not listed, you can indicate that it is a microbiology lab test by selecting the Micro checkbox.</p>
Collection date	<p>Type date or select date from the Calendar of when the laboratory specimen was obtained (not reported).</p> <p>If unsure of date, select the Estimated? checkbox.</p> <p>If test results are not yet available at the time of submitting the report, select the Pending checkbox.</p>
Test Value and Reference Range	<p>Type a positive, negative, decimal, or exponents value in the Value field.</p> <p>Type in the From and To range</p>

Laboratory Tests Fields	
FIELD	DESCRIPTION
	<p>fields, decimal or exponents values, and then select a unit of measurement from the Units drop-down list.</p> <p>This is a required field if the test results are not pending.</p>
Infectious Agent 	<p>Only displays for microbiology laboratory tests.</p> <p>Type an infectious agent name in this smart search field.</p> <p>As you type, a list of matching names display that you can select. If the name is not listed, the agent name you type remains in the field.</p>
Body Site 	<p>Only displays for microbiology laboratory tests.</p> <p>Type the area of body that the laboratory specimen was taken from in this smart search field.</p> <p>As you type, a list of matching names display that you can select. If the name is not listed, the body site name you type remains in the field.</p>
Comments	<p>If the report is not pending, provide additional information about the laboratory tests.</p>

Adding Diagnostic Tests

Select the Diagnostic Tests section from the vertical navigation menu to list non-laboratory diagnostic tests that help explain the nature, severity, and/or complications of the primary adverse event and its relationship to the study agents.

To Enter a Diagnostic Test

- From the **EAE Sections** in the vertical navigation menu, click **Diagnostic Tests**.
Diagnostic Tests page displays.
- Select the methods of delivering the diagnostic information to RSC.
If you select the **Entered Below** option, complete

the Diagnostic Tests fields.

Note: Add one test at a time.

3. Click **Save**.

Save Successful message displays.

Note: If the Add is not successful, a message displays and the errors are identified (!) on the page.

4. *Optional:* Click **New** to add additional information, or select a record to delete, and then click **Delete**.

Fields prefaced with a red asterisk (*) indicate a required field. Shaded fields indicate a field that you cannot modify.

Diagnostic Test Fields	
FIELD	DESCRIPTION
<p>*Please list relevant diagnostic tests conducted at the time the Primary AE occurred?</p>	<p>Indicates the method for reporting the diagnostic tests conducted. None is automatically selected. To select other options, deselect None <input type="checkbox"/> then select one or more options. If there were any diagnostic tests relevant to the adverse event taken after the onset of the Primary AE, select one or more delivery options.</p> <ul style="list-style-type: none"> • None. No diagnostic tests were taken at the onset of the adverse event. This option cannot be selected with any other value. • Entered below. If there were any diagnostic tests relevant to the primary adverse event, enter the details in the form below the options. • Uploaded in DAERS. Upload through the Additional Information page. • Faxed to RSC. Fax separately from the online report submission. Indicate this on the Additional Information page. • E-mailed to RSC. E-mail separately from the online report submission. Indicate this on the Additional Information page.

Diagnostic Test Fields	
FIELD	DESCRIPTION
	<p>If you select, Entered Below, the Test Name field becomes active and is mandatory.</p> <p>Note: RSC must create an update to upload the information that has been faxed or e-mailed to RSC.</p>
Test Name 	<p>Type a diagnostic test name in this smart search field.</p> <p>As you type, a list of matching names display that you can select. If the name is not listed, the test name you type remains in the field.</p> <p>Enter information then the next fields become active.</p>
Body Area 	<p>Type the area of body that was tested in this smart search field.</p> <p>As you type, a list of matching names display that you can select. If the name is not listed, the body area you type remains in the field.</p>
Test Date	<p>Type date or select the date from the Calendar.</p> <p>If unsure of date, select the Estimated? checkbox.</p> <p>If test results are not yet available at the time of submitting the report, select the Results Pending checkbox.</p>
Test Result/Comments	<p>If the report is not pending, type text that provides the test results and any additional information.</p>

Adding Additional Information

Use this section to provide documents separately from the EAE Report pertinent to the adverse event being reported. Documents can be easily uploaded to this page or submitted as e-mail attachments or fax documentation outside of DAERS.

To Enter Additional Information

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- From the **EAE Sections** in the vertical navigation menu, click **Additional Information**.
Additional Information page displays.
 - Complete the Additional Information fields.
 - Select a checkbox to confirm all personally identifiable information has been removed (only for uploaded documents).
 - Click **Save**.
Save Successful message displays.
Note: If the Add is not successful, a message displays and the errors are identified (!) on the page.
 - Optional:* Click **New** to add additional information, or select a record to delete, and then click **Delete**.
- Fields prefaced with a red asterisk (*) indicate a required field. Shaded fields indicate a field that you cannot modify.

Additional Information Fields	
FIELD	DESCRIPTION
*Is there any additional information or supporting documentation for this Primary AE?	Select either Yes or No. If yes is selected the associated EAE section becomes mandatory.
*Associated EAE Section	Select the EAE section from the drop-down list for which separate documentation is uploaded, faxed, or e-mailed. Once you make a selection, the next field becomes active. Note: An asterisk appears next to the sections in which you have indicated in the report that additional information will be provided.
*Do you want to upload, fax, and/or e-mail this document?	Select the method of delivery from the options: Upload, Fax, or E-mail . Until you select, the other fields remain shaded. If you select Upload , only these fields are active: Attach Document, Document Type (see below). If you select Fax or E-mail , only the Document Details and

Additional Information Fields	
FIELD	DESCRIPTION
	Date Sent to RSC fields require information. Note: This field pre-populates if selections were made in the sections of the report.
Attach Document	Follow these steps to attach a document: (1) Click Browse . The Choose File dialog box opens. (2) Select a file on your computer, and then click Open . The File size must be 5MB or less. Note: After you attach the document, a disclaimer displays.
(select option)	If you selected to upload, you must select the checkbox next to the following disclaimer: I have removed all personally identifiable information from this document.
*Document Type	Select the document type from the drop-down list. If not listed, select "Other", then type the document type in the Other, Specify field.
Date Sent to RSC	Type date or select the date from the Calendar. This is required if the method is e-mailed or faxed to RSC. Select the Estimated? checkbox if the date is not explicitly known.
Document Details	Type text that provides descriptive information regarding the document being attached or sent separately.

Completing Completion Check and Submitting EAE Reports

Viewing an EAE Report (PDF)

The purpose of the EAE Report (PDF format) is to provide a printer-friendly EAE Report that combines and consolidates all the information entered into DAERS and uploaded documents into a report format. You can view the report at any time by clicking on the PDF icon from the Search results table or the View EAE Report (PDF) link on the vertical navigation menu before and after the completion check. Any dates noted on the report are displayed in the site's time zone (user selected site).

To View an EAE Report:

1. View the PDF Report in one of two ways:
 - From the EAE Submission pane of the vertical navigation menu, click the View EAE Report (PDF) link.
 - From the Search results page, click the PDF icon in the EAE Number column of the table that displays the search results.

Note: The PDF report will not be available for reports currently being modified by RSC to reflect changes submitted via fax or e-mail. The PDF report will be available once RSC has completed their modifications.

The EAE Report opens in Adobe Acrobat.

2. Scroll through the report using either the scroll bar or by page counter.

Note: The PDF report displays general information about the EAE at the top of each page. For updated reports, the end of the report will display a list of all changes. For updated reports, the end of report will display a list of all changes that were made since the previous submission.

3. *Optional:* If the report has uploaded attachments, select in the Upload column of the Additional Information table at any time to view the attachment.
4. Click Close in the top right menu.
Last page viewed displays.

Note: You may also elect other actions while viewing the report, such as Print and Save. The reports submitted prior to the release of DAERS have been migrated from an existing RSC system. The information available on the migrated report does not represent the complete submitted report. The complete faxed report is available from RSC upon request.

RSC Modified Reports: display of flags for invalid data in each field when modified by RSC

Note: Reports that have been faxed to RSC and entered into DAERS on the site's behalf may have indicators for fields identifying issues with data when entering the report. The legend for these indicators is

located at the bottom of the PDF report.

Completing a Successful Completion Check of an EAE Report

Until a completion check verifies accuracy, an EAE report cannot be submitted to the DAIDS RSC. A completion check validates each mandatory field and report requirement. If there are errors, the errors list as hyperlinks to the appropriate page. Once a report is successfully checked, the system automatically sends an e-mail to all Study Physicians for that protocol and site, as well as the Reporter, that the report is ready for final review. A completion check may be run by any person authorized by the study site, but only the Study Physician may submit the EAE report to RSC.

To Run a Completion Check

1. Select **Completion Check** from the vertical navigation menu.
The Completion Check page displays in validation mode with each section marked with a status symbol in the vertical navigation menu.
Errors list by section in the main content area of the Completion Check page.
2. *Optional:* Click the printer icon to the right of the text above the list to print the Completion Check page to use as a checklist.
3. If there are errors, click an error link to go to the associated section and correct the error, then run completion check again and select another error to correct.
4. Finish correcting errors, then select **Completion Check** again.
All sections validate as correct .
5. If the report is more than three reporting days (11:59 P.M. of the third reporting day, Monday-Friday) after the Site Awareness Date, type a reason in the corresponding text box.
Note: This does not display if the report is an Update report.
6. Select the name(s) of the Study Physicians who are responsible for reviewing and submitting the EAE Report. The e-mail notification will be sent to only those Study Physicians selected. Click the Select All option to send the e-mail to all Study Physicians listed.

Note: If no Study Physicians have been approved to review and submit reports for the selected protocol, the system will send an e-mail to the CRS Leader and CRS Coordinator. The report cannot be submitted to RSC until a Study Physician has been provided access

rights to submit reports for the selected protocol.

7. For updated versions of the report, reasons must be provided for all changes made to the report since the previous submission.
8. Click **Complete**.
Completion Check Confirmation page displays with completion check successful message.

The report status is Ready for Final Review. E-mails notifications are sent to the Site Reporter, the selected Study Physicians and the CRS Coordinator for the clinical research site informing them of the completed report, and the report may now be reviewed and submitted by the Study Physician.

Completion Check Steps for an Update Report

The Completion Check for an Update Report follows the same procedures as a pending report, plus requires that each change from the previous report lists in a table and includes a reason for a change.

- Locate the record, then in the **Reason** column, begin entering text in the smart-search field for the reason the change was made to the previous EAE report submission.
- *Optional:* If multiple fields have the same reason, select the checkboxes in the far-right column for each field. If all the fields have the same reason, select the checkbox at the top of the column to automatically select all fields. Then enter text in the **Reason** field above the table, and click **Apply to Selected**.

Note: If this was a completion check for a new version (Update) of a submitted report and no Update changes are confirmed, a message displays below the DAERS menu bar that the EAE Report cannot be completed.

Confirming EAE Report Completion

The Completion Check Confirmation printable page displays once the completion check is correct. Completion successful message displays on a new Completion Check Confirmation page with a summary of the basic report information (EAE Number, Report Type, Reporter Name, Primary AE, Severity Grade of Primary AE, Completed Date and Time) and reminders.

The application automatically sends an e-mail notification message to the selected Study Physicians, CRS Coordinator and Reported report is ready for review and submission to RSC.

To Complete Confirmation

1. Verify accuracy in the Completion Check Confirmation Information pre-populated fields and take note of the submission reminders.
2. *Optional:* Click the printer icon to the right of the text to print this page for your records.

3. Click **Back to Search**.

Search page displays.

Submitting an EAE Report to RSC

The Submit an EAE Report section can be accessed after a successful completion check. Study Physicians, CRS Coordinator, as well as the Site Reporter of the EAE, are automatically notified by e-mail that the EAE Report is ready for review. The Study Physician logs in and verifies accuracy of the report information. After reviewing the report, the Study Physician enters their electronic signature before submitting the report electronically to RSC.

The EAE Report is submitted to RSC and e-mail notifications are automatically sent to the CRS Coordinator, Site Reporter, selected study physicians, DMC (if applicable) and ICC (if applicable). If desired, additional recipients can be included to receive the e-mail notification.

To Submit an EAE Report

1. Find the report in the Search results page, then click Review from the Action column.

Note: Reports currently being modified by RSC to reflect changes submitted via fax or e-mail will be read only. The action button will be available once RSC has completed their modifications.

Submit EAE Report page displays with a page message.

Note: If the submitter is also the reporter, then the **Submit EAE Report** link can be selected from the vertical navigation menu.

2. Verify accuracy of the report information by selecting View EAE Report (PDF), or each section of the report from the vertical navigation menu and make necessary edits.
3. Verify accuracy of the Site Awareness Date, and Reporter Name pre-populated fields on the Submit an EAE page.
4. Complete the authorization signature fields to submit the report with your electronic signature.
 - a. Type user login name in the ***Study Physician Username** field.
 - b. Type user login password in the ***Study Physician Password** field.
 - c. Confirm that the report is accurate and complete by selecting the signature checkbox to acknowledge by signature.
5. If report is being submitted more than three reporting days after the Site Awareness Date, type reason in the corresponding text box.

Note: This does not display if the report is an Update

report.

6. If the report is an Update report to a submitted report, click Review Changes and complete the additional steps required to review each change from the previous report.

Reason for Report Changes floating window displays with each change made between the previous and current report listed in a table.

- a. Verify accuracy of each change and make any required updates.
- b. Locate the record, then in the **Reason** column, highlight previous text in the smart-search field and begin typing new reason.

If multiple fields have the same reason, select the checkboxes in the far-right column for each field. If all the fields have the same reason, click the checkbox at the top of the column to automatically select all fields. Then enter text in the **Reason** field above the table, and click **Apply to Selected**.

- c. Click **Save** and then **Close** to return to the Submit EAE page.

Note: Recipients added by the submitter and indicated to be notified for all future EAE submissions shall be populated on the EAE Notifications Recipients screen.

7. *Optional:* Type e-mail addresses in the text box of the E-mail Address field to forward a summary of report to additional recipients.

If more than one address, separate with semi-colon. Example: jdoe@nih.gov.com;jsmith@maryland.edu

8. Click **Submit**.

If you have added or modified e-mail addresses of EAE submission notification recipients in the text box of the E-mail Address field, the Manage EAE submission notification recipient E-mail address pop-up is displayed. Review the changes and click on **Save**.

If you have not added or modified EAE submission notification recipient e-mail addresses, the Submission Confirmation page is displayed.

The EAE Report is submitted to RSC and e-mail notifications are automatically sent to the CRS Coordinator, Site Reporter, selected study physicians, DMC (if applicable) and ICC (if applicable).

Manage EAE Submission Notification Recipients

If you have added e-mail address(s) or modified an existing EAE submission notification recipient e-mail address(s), you can choose to apply the changes to all

future EAE submissions for the selected protocol in the Manage EAE Notification Recipients screen.

1. If you have added e-mail address(s) of additional recipients, verify the e-mail address of the recipient and complete the Add Recipient Information fields.
2. If you have removed any pre-defined recipients, you can remove them from the list of pre-defined recipients for this protocol by completing the Modify Recipient Information fields.
3. Click **Save** to save the changes on the page.
4. *Optional:* Click **Close** to close the window and proceed to the Submission Confirmation page.

Note: Once this window is closed, you cannot open it again.

Note: You may contact your CRS Coordinator or CRS Leader to add the recipients for the submission notification through the EAE Notification Recipients screen.

The  icon designates recipient added by the submitter during submission of an EAE report.

Fields prefaced with a red asterisk (*) indicate a required field. Shaded fields indicate a field that you cannot modify.

Manage EAE Submission Notification Recipients Information Fields

FIELD	DESCRIPTION
Added E-mail Address	The field is pre-populated with the recipient e-mail address added to the previously saved recipients list.
Select which recipient(s) to add to future EAE notification	If you want the recipient to be notified for all events for this Protocol and Site, select checkbox. Note: When the box is checked, the Enter Recipient Name and Enter Reason fields are mandatory.
*Enter Recipient Name	Type in the name of the recipient of EAE submission notification e-mail.
*Enter Reason	Type the reason for including the recipient for EAE submission notification e-mail.
Removed E-mail Address	The field is pre-populated from the list of pre-defined recipient e-mail address(s) which were not

Manage EAE Submission Notification Recipients Information Fields	
FIELD	DESCRIPTION
	selected for EAE Report submission notification.
Select which recipient(s) to remove from the future EAE notifications	If you do not want the recipient to receive submission notification for future EAE's for the selected protocol, select checkbox.
Recipient Name	The Recipient name is pre-populated from recipients list.
Enter Reason	Type the reason for not including the recipient for EAE submission notification e-mail.

Submission Steps for an Update Report

The Submission process for an Update Report follows the same procedures as a pending report, plus requires a review of each change from the previous report.

- Click Review Changes
 - Reason for Report Changes** floating window displays with each change made between the previous and current report listed in a table.
- Review the reasons for each of the changes and make any required updates.
- Locate the record, then in the **Reason** column, highlight previous text in the smart-search field then begin typing new reason.
- *Optional:* If multiple fields have the same reason, select the checkboxes in the far-right column for each field. If all the fields have the same reason, select the checkbox at the top of the column to automatically select all fields. Then enter text in the **Reason** field above the table, and click **Apply to Selected**.
- Click **Save** and then **Close** to return to the Submit EAE page.

Confirming EAE Report Submission

The Submission Confirmation printable page displays once the Study Physician reviews, electronically signs, and submits the EAE report.

To Complete Submission

- I. Verify accuracy in the Submission Confirmation Information pre-populated fields and take note of the submission reminders.

Electronic signature approval message displays. Automatic e-mails confirming submission in the system are sent to the Study Reporter, selected Study Physicians DMC, RSC, ICC.

2. *Optional:* Click the printer icon to the right of the text to print this page for your records.
3. Click **Back to Search**.
The Search page displays.

Modifying and Deleting EAE Reports

Modifying an EAE Report

Until a report reaches final review status, the Study Reporter can modify its contents. Once assigned to a Study Physician, only the Study Physician may modify the report before submitting it to RSC.

Note: After a report is submitted, it cannot be modified. Modifications may be submitted as update reports.

To Modify an EAE Report

1. Find the report by running a search based on selected criteria.
Search results page displays reports in a table list.
2. *Optional:* Find the report by status link (Pending, or Ready for Final Review) from the Home page.
Note: Depends on the user.
3. From the Action column, click **Modify**.
Reporter and Site Information page of the selected report displays.
4. Select sections to modify from the vertical navigation menu.

See the Search section for more information on how to conduct a search to find a report.

Deleting an EAE Report

If an EAE Report is pending it can be deleted by the Study Reporter and Study Physician but only the Study Physician can delete a report that is Ready for Final Review. Once deleted, it cannot be retrieved.

To Delete an EAE Report

1. Find the report by running a search based on selected criteria.
2. From the Search results table list, click **Delete** in the Action column.
The Delete EAE Report page displays with pre-populated fields (Site Awareness Date, Primary AE, Severity Grade of Primary AE, Created By, and Delete By).
3. Type an explanation in the **EAE Deletion Reason** mandatory text area to provide EAE key information and reason for the deletion.
4. Click **Delete**.
A Delete EAE Confirmation page displays a delete successful message as well as the date and time of the deletion, who deleted the report, and the reason for deletion.
5. *Optional:* Click **Print** displayed to the right of the Deletion Successful message to print the EAE Confirmation page for your records.
6. Click **Back to Search** to exit the EAE Delete Confirmation page.
The Search page displays all EAE Reports with the "Pending" status.

Note: Click **Cancel** to return to the Search page without saving any of the changes.

Copying an EAE Report

Adverse Experience Reporting
DIVISION OF AIDS

NTAID CRMS | Help | Logout

Welcome Constance Benson
Last successful login: 31-AUG-2015 4:49 PM
No. of unsuccessful login attempts: 0

EAE Search Person EAE Notification Recipients RSC
Site: 701 - UCSD Antiviral Research Center CRS

New EAE Report is based upon: [2015-108095](#) Participant: 73597 Protocol: A5321 v2.0
To create the new EAE Report, complete steps 1 - 3 below, then click the Create New EAE Report button.

1 - Provide the following for the new EAE Report

*Protocol Number:

*Protocol Version:

*Participant ID:

Participant Information: Participant Information for the selected participant is displayed below. If the data does not match please update on the Participant Information screen.

Date of Birth:
Sex at Birth:
Race:

2 - Provide the site awareness date for the new EAE Report

*Site Awareness Date:

3 - Select the EAE Report Sections you want to copy

Notes:

- BOLD items indicate sections of the original EAE Report that have saved data
- Participant Information Section:
 - If available, the latest demographic data provided by the DMC will be used

Select the EAE Report Sections you want to Copy:

<input type="checkbox"/> Participant Information	<input type="checkbox"/> Primary Adverse Event
<input type="checkbox"/> Demographics	<input type="checkbox"/> Adverse Event Information
<input type="checkbox"/> HIV Status	<input type="checkbox"/> Narrative Case Summary
<input type="checkbox"/> Gestational Information	
<input type="checkbox"/> Study Agents	<input type="checkbox"/> Other Events
<input type="checkbox"/> Study Vaccines	<input type="checkbox"/> Laboratory Tests
<input type="checkbox"/> Co-enrollment Information	<input type="checkbox"/> Diagnostic Tests
<input type="checkbox"/> Concomitant Medications	<input type="checkbox"/> Additional Information

Create New EAE Report Cancel

Figure 7: Copy EAE Report Page.

Copying an EAE Report

DAERS allows you to create an EAE report by copying information from previously created EAE reports for protocols and sites for which you are associated. The Copy EAE Report page allows you to select applicable EAE report sections and copy the information in a new EAE report.

To Copy information from an EAE Report

- From the Search page, find the EAE report by running a search based on the selected criteria.
- From the Search results table list, find the **Action** column, then click **Copy** to select the report for copying.

Note: Only reports which are in “Ready for Final Review” or “Submitted to RSC” status can be selected for copying.
- The application will present you with a pop-up window asking for confirmation to copy details from the selected EAE, click on **OK** to proceed to the Copy EAE Report page or click on **Cancel** to remain on Search page.
- On the Copy EAE Report page, complete the required information fields.
- Select the sections of the EAE report that you want

to copy in the new report.

- The EAE sections of original report that contain data are displayed in **bold**.

Note:

- You have the option to copy Demographics, HIV status information or/and gestational information as applicable.
 - If you select a section that has documents uploaded in DAERS, these documents will be automatically copied over to the Additional Information section of the new report even if “Additional Information” section is not selected to be copied.
- Once the selection is complete, click on **Create New EAE Report**, you may click on **Cancel** to go back to the Search page.
 - On clicking **Create New EAE Report**, the Copy Confirmation page will be displayed which will display message regarding the EAE sections selected for copying.

Note:

 - You may edit any value that is copied.
 - All attributions must be reassessed before submitting the new EAE report.

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9. Click on **OK** to create a copy of the EAE report or click on **Cancel** to return to the Copy EAE Report page for making changes.
10. After you click **OK**, the system will create a copy of the EAE report and will direct you to the Reporter and Site Information page.

Note: The Reporter and Site Information page will display the logged in user’s name and contact information.

Copying to a Protocol Using the New EAE Manual
 The protocol for which you are creating the new EAE report has registered to the latest version of the EAE manual (*Manual for Expedited Reporting of Adverse Events to DAIDS v2.0*). In this instance, the following occurs:

- If the new EAE is on a protocol that is different from the existing EAE, only study products in common with both shall be copied.
- All attribution relationships of the primary AE to the study products shall be mapped as follows:
 - Any study products having a relationship of *Definitely Related, Probably Related, Possibly Related, or Probably Not Related* becomes *Related* in the new EAE report.
 - Study products having a relationship of *Not Related* remains the same in the new EAE report.
 - Study products having a relationship of *“Pending (temporary assignment for death)”* are not copied to the newly created EAE report; you must re-enter these study products after the EAE report is created.

Copying from a Protocol Using the New EAE Manual

The existing EAE has been submitted on a protocol that has registered to the latest version of the EAE manual (*Manual for Expedited Reporting of Adverse Events to DAIDS v2.0*), whereas the new EAE is being created on a protocol that has not registered to the new manual. In this instance, the following occurs:

- Seriousness criteria: Other SAE – this option shall not be copied as it is not an option for the existing EAE manual; you must select a seriousness criteria after the EAE report is created.
- Study products shall not be available to be copied as there isn’t a way to map from an attribution of Related to an attribution of Definitely Related, Probably Related, Possibly Related, or Probably Not Related

Fields prefaced with a red asterisk (*) indicate a required field. Shaded fields indicate a field that you cannot modify.

Copy EAE Report Fields	
FIELD	DESCRIPTION
*Protocol Number	The field is populated with the protocols the selected site is registered to. Select the Protocol Number the participant was enrolled on at the time of the adverse event. (The next field pre-populates with the protocol versions associated to the selected protocol. The list will only display those versions of the protocol the site is registered to.)
*Protocol Version	The field is populated with the protocol versions the site is registered to for the selected protocol. Click  and select the Protocol Version in which the participant was registered at the time the adverse event occurred. (The next field pre-populates with the Protocol Full Title for the selected protocol version.)
*Reporting Method	Displays the options a user has for specifying the reporting method for the adverse event. Whatever option you select will be displayed both in the context area and the EAE report. Note: This field will only appear if the protocol has multiple reporting methods. It will not appear if the protocol only has one reporting method.
*Participant ID 	Type a PID number in this smart search  field. If the Participant data is provided by the DMC (<i>Data Management Center</i>), then as you type a list of matching Participant IDs display. Select a number, or if the number is not listed, the number you type remains in the field.

Copy EAE Report Fields	
FIELD	DESCRIPTION
Participant Information	<p>Note: If DMC data is available for the PID then the system will populate the DMC data.</p> <p>This field displays the Date of Birth, Sex at Birth and Race of the selected participant if the information has been provided by the DMC.</p>
*Site Awareness Date	Type date in DD/MM/YYYY format in the box or click and select date from the Calendar of when site became aware of primary adverse event.
*Select the EAE Report Sections you want to copy	Select the checkbox for the sections in the EAE report that you want to include in the new EAE report.

Updating EAE Reports

After an EAE report is submitted to RSC, an unlimited number of update reports can be submitted, each a new version to the initial report. An update report contains additional information. DAERS automatically adds the sequential number of the update to the end of the unique EAE report number. Similarly, creating the update report follows the same process as modifying a pending report.

Updating an EAE Report

The steps to submit an update are similar to creating an EAE report. Find the latest submitted report version in the Search results table list.

To Update a Submitted Report

1. Find the Submitted to RSC report by running a search based on selected criteria.
2. From the Search results table list, find the **Action** column, then click **Update** to add more information to a submitted report.

The Reporter and Site Information page displays.

3. Add additional information or modify the appropriate EAE section by selecting the section from the vertical navigation menu area.
4. Click **Save** as you complete edits in each section.
5. Select **Completion Check** from the vertical navigation menu.

The Completion Check for an Update Report follows the same procedures as an initial report, plus requires that each change from the previous report lists in a table and includes a reason for the change — to make changes, refer to the “Completing a Successful Completion Check” section.

6. Select **Submit EAE Report** from the vertical navigation menu.

The Submission process for an Update Report follows the same procedures as an initial report, except it requires a review of each change from the previous report.

- a. *Optional:* Click **Review Changes**.
- b. Reason for Report Changes floating window displays with each change made between the previous and current report
- c. Verify accuracy in the Reason for Report Changes floating window that lists each change made between the previous and current report. — to make changes, refer to “Submitting an EAE Report to RSC” section.
- d. Click **Save** and then **Close** to return to the Submit EAE page.

Printing EAE Reports

To Print a Page from DAERS

You can only print a report as a PDF-generated document. A page from DAERS can be printed from your internet browser (Microsoft Internet Explorer).

To Print a Page from DAERS

1. From the File menu option of your internet browser, click **Print**.

The **Print** dialog box displays.

2. Click **OK**.

To Print an EAE Report

To print an EAE Report, you must first view the EAE report in a PDF version.

There are two ways to access the PDF view of an EAE report:

- Click **View PDF Report** in the vertical navigation menu to display the current report in view.
- Select the **PDF**  icon in the **EAE Number** column from the Search results table.

From the PDF view, follow these steps to print the report:

- Select **Print** from the top right menu of the PDF report to open the **Print** dialog box.
- Click **OK**.

Designating EAE Notification Recipients

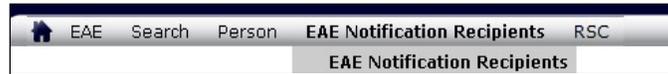


Figure 8: EAE Notification Recipients Menu on Home Page.

Figure 9: EAE Notification Recipients Page.

DAERS allows the CRS Coordinator or CRS Leader to designate recipients to receive e-mail notifications on submission of EAE reports for all or specific Protocols that the site is registered to for reporting Expedited Adverse Events in DAERS.

Designate EAE notification recipients from the Home page

1. From the DAERS menu bar, point to **EAE Notifications Recipients** menu and click on **EAE Notifications Recipients**.
2. Complete the EAE Notification Recipient fields.
3. Click on **Save** to save changes to the screen.
4. *Optional:* Click **Restore** to cancel any changes and to load the data that was last saved.
5. Click on **New** to add more recipients.

Modify recipients in the EAE notification recipients list

1. From the DAERS menu bar, point to **EAE Notifications Recipients** menu and click on **EAE Notifications Recipients**.
2. Click on the **Recipient Name** from the recipient table list.
Data populates in the Recipient Details page, modify the fields of interest.
3. Click on **Save** to save changes to the screen.
4. *Optional:* Click **Restore** to cancel any changes and to load the data that was last saved.

Remove recipients from the EAE notification recipients list

1. From the DAERS menu bar, point to **EAE Notifications Recipients** menu and click on **EAE Notifications Recipients**.
2. Click on the **Recipient Name** from the recipient table list.
Data populates in the Recipient Details page.
3. Click on **Delete**.
4. *Optional:* Click **Restore** to cancel any changes and to load the data that was last saved.

Fields prefaced with a red asterisk (*) indicate a required field. Shaded fields indicate a field that you cannot modify.

Designate EAE Notification Recipient fields

FIELD	DESCRIPTION
*Organization/Site ID	The field is populated with the sites the user is associated with. If the user belongs to more than one site, click and select the site.
*Recipient Name	Type the Recipient name in this smart search field. As you type in the field, the system searches

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Designate EAE Notification Recipient fields

FIELD	DESCRIPTION
	through the database for the best match. You can select a match from the drop-down list and edit the text. If there is no match, the text turns red. When you leave the field, the text turns black.
*Recipient E-mail	Type the Recipient E-mail address in this smart search field. As you type in the field, the system searches through the database for the best match. You can select a match from the drop-down list and edit the text. If there is no match, the text turns red. When you leave the field, the text turns black.
*Receive EAE submission notification for?	Click All Protocols, or Selected Protocols radio button.
*Protocol Number	If All Protocols has been selected in the previous field, the field will be pre-populated with all the protocols the site is registered to. If Selected Protocols has been selected in the previous field, select protocols from the list of values of all the protocols the site is registered to
*Status	Select if the recipient e-mail address entered is Active or Inactive. If Inactive, the recipient e-mail address will not be copied on the EAE submission e-mail notifications associated with the Protocol/Protocols
*Reason for Adding/Modifying	Enter the reason for creation or modification of the designated recipient.

Enrolling and Updating Site Staff in DAERS

Note: Entering information into the Site Enrollment Module constitutes a request submission to the NIAID CRMS.

1. The CRS Leader/CRS Coordinator can submit a request to NIAID CRMS Support for addition of authorized staff requiring access to DAERS. They will provide the Names, Contact Information, Roles (Submitter or Reporter) and applicable Protocols for each user of the DAERS application.
2. The CRS Leader/CRS Coordinator can also submit a request to NIAID CRMS Support for modification to Names, Contact Information, Roles (Submitter or Reporter) and/or applicable Protocols for a person associated with their CRS/Organization.
3. The CRS Leader/CRS Coordinator can also submit a request to NIAID CRMS Support to inactivate a person's account in NIAID CRMS.
4. NIAID CRMS Support and RSC Safety Office will review and process the submitted request. Once the processing is complete, NIAID CRMS will be updated with the requested changes and an e-mail notification will be sent to the site.

Viewing the Persons at a Site

Before making changes to a Site's enrollment, it is usually necessary to review the persons who are already present in NIAID CRMS for the selected Site. The New Request screen lists all Sites available so that you can view a list of the persons at the Site who are currently present in NIAID CRMS. You have the option to export the list to Microsoft® Excel or you can view the User Information Report for a site which contains detailed site personnel information for DAERS.

To Access the New Request Screen

1. From the DAERS menu bar, click **Person > New Requests**. The New Request screen displays by default.



Figure 10: New Request (Select Site) Screen.

To View Persons at the Site

1. If user is associated with more than one site, select a Site ID from the drop-down list else the default site is selected.
2. For users associated with more than one site, click **Search** to narrow results.

The New Request screen lists the persons enrolled at the Site. The red exclamation mark (!) next to a

record indicates that changes have been created for that person in draft.

Note: Click on **Clear** to clear selection, return to previous screen and start all over again.

3. *Optional:* To export the list to Microsoft® Excel, click **Export to Excel**. The View Associated Persons report displays.
4. *Optional:* To view a list of all DAERS users associated with a site, click **User Information Report**. The DAERS User Information Report displays in Microsoft Excel. The report displays a list of users associated with the selected Site, the users' contact information, and the protocols to which they have access in DAERS.

Note: You can submit a request to NIAID CRMS Support for multiple changes in your Site personnel. The submitted request will be reviewed and processed by NIAID CRMS Support.

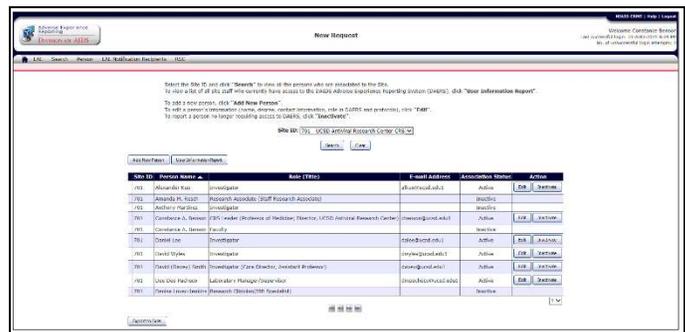


Figure 11: New Request (View Persons at Site) Screen.

Site ID	Person Name	Role (Title)	E-mail Address	Association Status
30276	Luis A. Fuentes	CRS Coordinator	laf2@columbia.edu1	Active
30276	Sharon Mannheimer	CRS Leader	sbm20@columbia.edu1	Active
30276	Tracy Hunt	Protocol/Study Coordinator	th2040@columbia.edu1	Active
30276	Wafaa El-Sadr	Investigator	wme1@columbia.edu1	Active
30276	Yves-Michel Fontaine	Protocol/Study Coordinator	yf24@columbia.edu1	Active

Figure 12: View Associated Persons Report.

Site Personnel Information For DAERS					
Person Name	Association Role (Title)	Email	Phone	DAERS Roles	DAERS Roles - Submitter
Carol Golin	Investigator	cgm@med.unc.edu1	1-919-999-9040	None	None
Cheryl J. Marcus B.S.N., R.N.	Research Clinician	cmj@med.unc.edu1	1-919-843-8761	Enter and review EAE reports for all protocols at a site	None
Clara Zelman	Research Clinician	clara_zelman@med.unc.edu1	1-919-844-8790	PAVE 100, HTN102	None
David Combs	Research Clinician	david_combs@med.unc.edu1	1-919-999-9264	PAVE 100, HTN102	None
David Ragan	Research Clinician	davidr@med.unc.edu1	1-919-862-2623	PAVE 100, HTN102	None
David M. Margolis MD	Investigator	dmarg@med.unc.edu1	1-919-999-3380	Enter and review EAE reports for all protocols at a site	HTN102, PAVE 100
Denise Filbert	Research Clinician	denise_filbert@med.unc.edu1	1-919-843-9170	PAVE 100, HTN102	None
Kelley Carpenter	Research Clinician	kelley_carpenter@med.unc.edu1	1-919-862-8629	PAVE 100, HTN102	None
Kristina Patterson MD	CRS Leader	kristina_patterson@med.unc.edu1	1-919-842-2544	Enter and review EAE reports for all protocols at a site	HTN102, PAVE 100, HTN102, PAVE 100
Susan Stevens	Research Clinician	hsusan_stevens@med.unc.edu1	1-919-843-8763	PAVE 100, HTN102	None
Susan Pedersen	CRS Coordinator	speders@med.unc.edu1	1-919-999-9713	Enter and review EAE reports for all protocols at a site	None
Susan Rotzard	Research Clinician	susan_rotzard@med.unc.edu1	1-919-843-8764	PAVE 100, HTN102	None

Figure 13: DAERS User Information Report.

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Adding a Person for a Site

Adding a new person to a site in DAERS is a four-step process:

- Enter the new person’s name and contact information.
- Select the role the person will have in DAERS.
- Select the protocols for the assigned DAERS role.
- Review and submit the request.

To Enter Name and Contact Information

1. From the DAERS menu bar, click **Person > New Requests**.
The New Request screen displays by default.
2. If user is associated with more than one site, select a Site ID from the drop-down list else the default site is selected.
3. For users associated with more than one site, click **Search** to narrow results.

The New Request screen lists the persons enrolled at the Site. The red exclamation mark (!) next to a record indicates that changes have been created for that person in draft.

Note: Click on **Clear** to clear selection, return to previous screen and start all over again.

4. Click **Add New Person**.
The Person Information screen displays.
5. Enter the name, contact information, and role of the person associated with your Site in the fields provided.
6. Click **Save & Next>** to save the information that you have entered and proceed to the Assign DAERS Roles screen or **<Previous** to return to the New Request screen without saving.

Fields prefaced with a red asterisk (*) indicate a required field. Shaded fields indicate a field that you cannot modify.

FIELD	DESCRIPTION
Prefix	Select an option from the drop down list in this field.
*First (Given)	Type in the first name of the person in this field.
Middle Name	Type in the middle name of the person in this field.

Person Information Fields

FIELD	DESCRIPTION
*Last (Family) Name	Type in the last (family) name of the person in this field.
Degree	Click on the list of values icon to select a Degree obtained by the person being added.
Title (position)	Type in the job title or position currently held by the person being added in this field.
*Association Role with Site	Select an Association role with site from the drop down list.
*Phone 1	Type in primary phone number of the person in this field. Enter extension number if any, in the Ext.: field.
Phone 2	Type in secondary phone number of the person in this field. Enter extension number if any, in the Ext.: field.
*E-mail 1	Type in primary E-mail address of the person in this field.
E-mail 2	Type in secondary E-mail address of the person in this field.
Comments	Type in comments in this field.



Figure 14: New Request (View Persons at Site) Screen.

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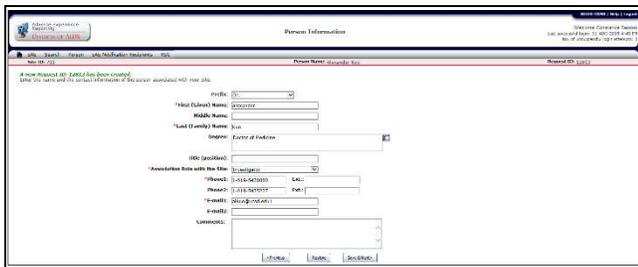


Figure 15: Person Information Screen.

To Select the Person’s DAERS Role

1. From the Assign DAERS Roles screen, select the role the person will have in DAERS.
2. Click **Save & Next>** to save the information that you have entered and proceed to the Assign Protocols screen or **<Previous** to return to the Person Information screen without saving.

Note:

- If no selection was made for DAERS roles, then review the current request screen will display on click of **Save & Next>**.
- If no roles are selected, the system provides a confirmation pop-up.
- Ensure the selection of Submitter role is based on the person listed on the 1572/IoR form.
- For the requested role of Submitter, the site is required to submit a complete electronic attestation form to RSC safety office.
- CRS Leader/CRS Coordinator have reporter access to all EAE reporting protocols the site is registered to.



Figure 16: Assign DAERS Roles Screen.

To Select the Protocols for the Assigned DAERS Role

1. From the Assign Protocols screen, select the protocols for the assigned DAERS role by clicking > or click the >> button to add all protocols at once. To unselect protocols, click < or click << to remove all protocols at once.
2. Click **Save & Next>** to save the information that you have entered and proceed to the Review Current Request screen or **<Previous** to return to the Assign DAERS Roles screen without saving.

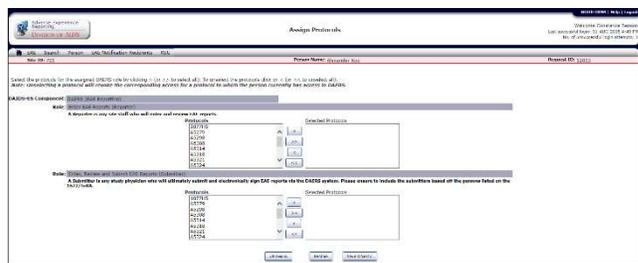


Figure 17: Assign Protocols Screen.

To Review and Submit the Request

The Review Current Request screen displays all changes requested for the Site that are not yet submitted to NIAID CRMS Support. The user can make further updates to these changes.

1. Choose from the following options:
 - To edit the changes associated with a person in this list, click the name of the person under the **Person Name** column.
 - To remove the changes associated with a person in this list, click **Discard**.
 - To add more changes to this request, click **Add or Edit Another Person**.
 - To view all the changes being requested by the site, click **View Current Request**. The Changes to Site Personnel for DAERS Report displays in PDF.
 - To submit the request to NIAID CRMS Support for processing, click **Submit All**.



Figure 18: Review Current Request Screen.

Section 18

Inactivating a Person

Inactivating a person will revoke their access from DAERS.

To Inactivate a Person’s DAERS Access

1. From the DAERS menu bar, click **Person > New Requests**. This will display the New Request screen.
2. If user is associated with more than one site, select a Site ID from the drop-down list else the default site is selected.
3. For users associated with more than one site, click **Search** to narrow results.

The New Request screen lists the persons enrolled at the Site. The red exclamation mark (!) next to a record indicates that changes have been created for that person in draft.

Note: Click on **Clear** to clear selection, return to previous screen and start all over again.

4. Click the **Inactivate** button next to the person for whom you want to request removal of access to DAERS or removal of access to an organization/site. The Inactivate Person screen displays.
5. Provide a reason for inactivation in the field provided.
6. Click **Save**.
7. Choose from the following options:

- To edit the reason for inactivation, click the name of the person under the **“Person Name”** column.
- To remove the line item, click **Discard**.
- To add more changes to this request, click **Add or Edit Another Person**.
- To view all the changes being requested by the site, click **View Current Request**. The Changes to Site Personnel for DAERS is displayed in PDF.
- To submit the request to NIAID CRMS Support for processing, click **Submit All**.



Figure 25: Inactivate a Person Screen.



Figure 26: Review Current Request Screen.

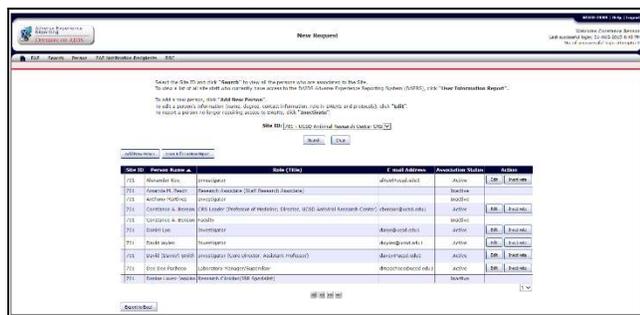


Figure 24: New Request (View Persons at Site) Screen.

Section 18

Viewing Requests

The View Requests screen lists all the requests created by your sites. This screen will also display any requests submitted through DPRS.

To Access View Requests

- From the DAERS menu bar, click **Person > View Requests** to display the View Requests screen.



Figure 27: View Requests Screen.

Each request has a unique ID, along with a Site ID, name of requestor, status, status date, and comments. Possible values in the Status column include the following:

- Draft** — Request for changes for the site is yet to be submitted to NIAID CRMS Support.
- Submitted** — Request for changes for the site is submitted to NIAID CRMS Support
- In Progress** — NIAID CRMS Support is processing the request submitted by the site.
- Completed** — NIAID CRMS Support has completed processing of the Request submitted by the site.
- *Completed** — NIAID CRMS Support has completed processing of the Request submitted by the site with some outstanding issues.

Furthermore, the DAIDS-ES Comments field displays comments entered by the NIAID CRMS Support team for that Request ID.

If you like, you can click **Export to Excel** to view the details in an Excel spreadsheet.

To Search on a Request

Users can filter requests based on any known information. Search options include:

- Request ID** – Type in the request number and click Search.
- Site ID** – Click on the drop-down menu, select the desired Site, and click Search.
- Request Status** – Choose between the available radio buttons and click Search.

To View Details of a Request

- Click the Request ID of the desired request. (If you click on a request that is in the Draft status, you can make changes to it).

Request ID	Site ID	Requested By	Status	Status Date	DAIDS ES Comments
9800	791	UCSD Antiviral Research Center CRIS/Research Laboratory	Submitted	21-Mar-2014	Details
9811	791	UCSD Antiviral Research Center CRIS/ESG	Submitted	07-Mar-2014	Details
9825	791	UCSD Antiviral Research Center CRIS/ESG	Submitted	21-Mar-2014	Details
9826	791	UCSD Antiviral Research Center CRIS/ESG	Submitted	09-Feb-2014	Details

Figure 28: Request ID Numbers.

- Review the request details. An e-mail notification will be sent to the CRS Coordinator/ CRS Leader when a request is in the Submitted, Completed, or *Completed status.

To Generate the Person Information Report

An alternative to clicking through various requests is to use the Person Information Report. This functionality allows for the user to generate a report that presents each line item request for the desired user and their associated role requested, associated protocol, and associated site.

- From the View Requests screen, click on the **Person Name** drop-down menu and select the desired user.
- Select **Details** and save the Person Information Report.
- Open the Excel file to view the report. Columns include Request ID, Request Date, Request Item Completed, and Requested Role.

Site ID	Request ID	Request Date	Request Status	Request Item Completed	Person Name	Request Type	Change Type	Requested Role	Protocol ID	Alteration Form?	On 157?	Treated?	DAIDS ES Support Comments
S095	9805	8-Apr-14	Submitted	Yes	Michael Bolars	Add	User/Contact Info	N/A	N/A	Invalid	No	No	
S095	9805	8-Apr-14	Submitted	No	Michael Bolars	Add	DAERS Access	Submitter	P1113	Invalid	No	No	
S095	9816	14-Apr-14	Submitted	No	Michael Bolars	Add	DAERS Access	Submitter	P1026	No	Yes	No	Incomplete alteration

Figure 29: Person Information Report Output.

To View All the Changes Submitted by the Site

- From the View Requests screen, click the Request ID for an entered request. This will open a PDF report titled “Changes to Site Personnel for DAERS.” The middle columns of the report display the current value in DAIDS (“Currently in DAIDS-ES”) and the changed value requested by the Site (“Requested Information”).

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DAERS” PDF showing a deletion.

Changes to Site Personnel for DAERS			
Request ID: 2007		Request Status: Draft	
Request Date: 02/24/2009 9:29:07 PM (GMT-05:00) Eastern Time (US & Canada)		Requested By: Stacy Carroll	
Site Name: Wake County Health and Human Services CRS		Site ID: 30076	
Site Address: 10 Sunnybrook Road,Raleigh, NC, 27630-4049,United States			
Update Person: Cheryl J. Marcus			
Currently in DAIDS-ES		Requested Information	Request Type
Prefix:			
First Name:	Cheryl	Cheryl	No Change
Middle Name:	J.	J.	No Change
Last Name:	Marcus	Marcus	No Change
Role:	Research Clinician	Research Clinician	No Change
Title:			
Degree:	Bachelor of Science in Nursing Registered Nurse	Bachelor of Science in Nursing Registered Nurse	No Change No Change
Phone 1:	1-919-843-8761	1-919-843-8761	No Change
Phone 2:			
E-mail 1:	cjmc@med.unc.edu	cjmc@med.unc.edu	No Change
E-mail 2:			
List of Protocol(s) on which EAE's can be Reported:		A5001	Add
List of Protocol(s) on which EAE's can be Submitted:			
Overall Comments:			

Figure 30: Example of a “Changes to Site Personnel for DAERS” PDF.

The PDF also includes a column for displaying the following request types:

- Add: Request to add a new value
- No Change: Keep the existing value
- Update: Request to change to an existing value
- Delete: Request to remove an existing value

Figure 31 displays an example of how the PDF will look when a request is deleted.

Changes to Site Personnel for DAERS	
Request ID: 2004	
Request Status: Draft	
Request Date: 3/31/2010 4:40:59 PM (GMT-05:00) Eastern Time (US & Canada)	
Requested By: Stacy Carroll	
Site Name: Massachusetts General Hospital ACTG CRS	
Site ID: 101	
Site Address: 55 Fruit Street,ACTG, Cox 626,Boston, MA, 02114,United States	
Inactivate Person(s) - Name	Reason for Inactivation
Eric S. Rosenberg	No longer at the site

Figure 31: Example of a “Changes to Site Personnel for

Managing Site Staff Access using the Person Information screen in DPRS

During submission of a registration packet in DPRS, you can use the Person Information screen to add a person to a site and indicate their role in DAERS, i.e., whether they need Reporter or Submitter access. You can also use the Person Information screen to modify or remove a person’s access to DAERS. However, you can only do this while submitting a new (or updating an existing) registration packet for an EAE reporting protocol for the following submission types: Initial, Change in IoR, Updated I572, and Updated IoR Form. Upon approval of the submission by the PRO, the system generates a request to NIAID CRMS Support to provide the requested staff with access to the protocol in DAERS to report or submit expedited adverse events. The Request will appear on the View Request page in the DAERS Site Enrollment Module.

Protocol Registration
DIVISION OF AIDS

Person Information

Welcome Carol Guth
Last successful login: 4-SEP-2015 6:11 PM
No. of unsuccessful login attempts: 0

Submission Search Submissions Manage Designated Sites Reports Tools

In the grid below:

- List all persons who are named in the attached 1572/IoRA Form for this protocol
- List any persons not named in the attached 1572/IoRA Form, who need access to DAERS (i.e., Reporter role) for this protocol

For each person listed:

- In the "DAERS role" column, select the applicable role or select none
- In the "Listed on 1572/IoRA Form?" column, select "Yes" or "No"

Notes:

- Changes are processed when the current submission is approved.
- Once approved, this information will not be available for further modifications unless an updated submission packet is created (applies to Change of IoR, Updated I572 and Updated IoR form submission types)
- Your CRS Coordinator may use Site Enrollment Module in DAERS to provide updated site staff information.

View FDA 1572

* Person Name	* Association Role	* Contact Information	* DAERS Role ?	* Listed on 1572/IoRA Form?
Antoinette Lewis	Research Clinician	Email: antoinette_lewis@rush.edu1 Phone: 1-312-9425865 Ext:	Reporter Access to All Protocols	<input type="radio"/> Yes <input checked="" type="radio"/> No
Beverly E. Sha	CRS Leader	Email: bsha@rush.edu1 Phone: 1-312-9425865 Ext:	Submitter	<input checked="" type="radio"/> Yes <input type="radio"/> No
Brett Williams	Investigator	Email: Brett_Williams@rush.edu1 Phone: 1-312-9425865 Ext:	Submitter Access Pending	<input checked="" type="radio"/> Yes <input type="radio"/> No
Janice Fritsche	CRS Coordinator	Email: Janice_Fritsche@rush.edu1 Phone: 1-312-9424810 Ext:	Reporter Access to All Protocols	<input checked="" type="radio"/> Yes <input type="radio"/> No
Joan Swiatek	Research Clinician	Email: Joan_A_Swiatek@rsh.net1 Phone: 1-312-9425865 Ext:	Submitter	<input checked="" type="radio"/> Yes <input type="radio"/> No
Mariam Aziz	Investigator	Email: Mariam_aziz@rush.edu1 Phone: 1-312-9425865 Ext:	Submitter	<input checked="" type="radio"/> Yes <input type="radio"/> No
Mark Mall	Protocol/Study Coordinat	Email: mark_mall@rush.edu Phone: 312-942-5865 Ext:	Submitter	<input checked="" type="radio"/> Yes <input type="radio"/> No
Tondria Green	Research Clinician	Email: Tondria_Green@rush.edu1 Phone: 1-312-9425865 Ext:	Submitter	<input checked="" type="radio"/> Yes <input type="radio"/> No

Add another person

Save Restore

Figure 32: Person Information Screen in DPRS (DAIDS Protocol Registration System).

Adding a new person to a site and indicating their DAERS role via the DPRS

When creating a new submission in the DPRS, or when updating an existing submission for an EAE reporting protocol, you can use the Person Information screen to indicate all the site staff who require access to DAERS for reporting or submitting Expedited Adverse Events.

You can only access the Person Information screen for the following submission types: Initial, Change in IoR, Updated I572, and Updated IoR Form. Moreover, you can only *modify* the information when the status of the submission is “Pending Submission” or “Review in Progress.” On approval of the submission, the Person Information screen will be read-only.

To add a new person and indicate their DAERS role via DPRS

1. Use one of the following methods to go to the Person Information screen.

When creating a new submission:

- a. Point to the **Submission** menu and choose **New Submission**.
- b. At the New Submission screen, fill in the required fields and select an applicable submission type.
- c. Click **Next**. This will expand the page to display additional fields and buttons.
- d. Scroll down and click the **Person Information** button, which is near the bottom of the page.



Figure 33: Person Information Button

When updating an existing submission:

- a. Click the **Search Submissions** menu.
- b. At the Search Submissions screen, use the search parameters to find the submission for which you want to add/modify person information.
- c. Click **Search**. Search results will display on the same page in a table.

- d. Click the **View Submitter** icon under the View Submitter column for the submission.

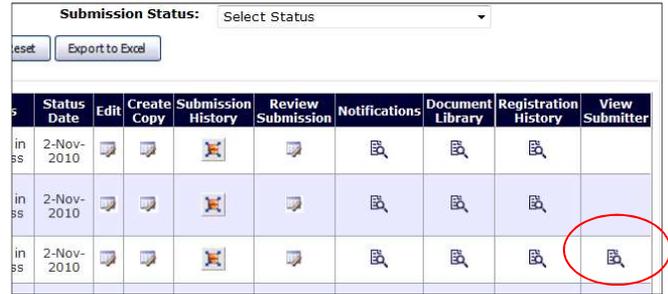


Figure 34: View Submitter Icon

By default, the Person Information screen will show the following information:

- The site’s Investigator of Record as selected on the New Submission screen
- The CRS Coordinator who has reporter access to DAERS for all EAE reporting protocols the site is registered to
- The CRS Leader who has reporter access to DAERS for all EAE reporting protocols the site is registered to
- Any other site personnel who have Reporter or Submitter access to this protocol.

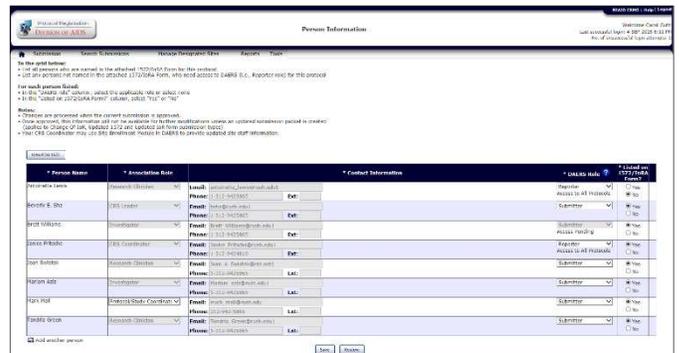


Figure 35: Person Information Screen in Protocol Registration

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- Click the **Add Another Person** icon at the bottom left corner of the table. This will display a new table row.

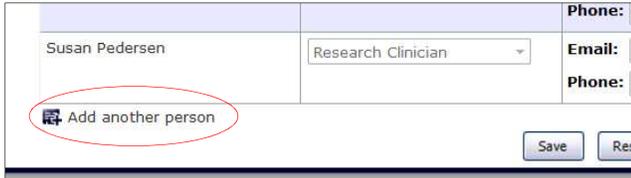


Figure 36: Add another person.

Note: The system will not permit you to add any duplicate record for site staff. Furthermore, when you add a new row, a new column will appear with a button that lets you remove the row you just added.

- Under the Person Name column of the new row, click the **Select Person Name** drop-down and choose a name from the list.

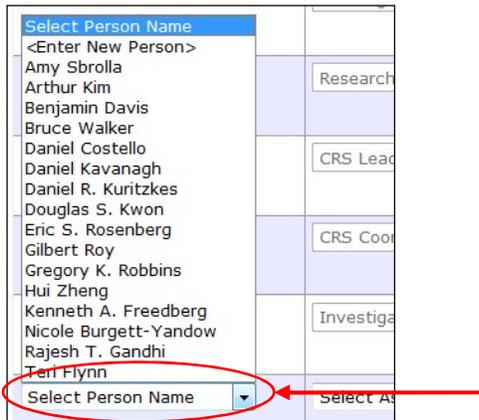


Figure 37: Select Person Name

Once you select a name, the other fields will be populated with association role and contact information. If you do not see the appropriate name in the drop down list, then choose **Enter New Person** from the list. This will display empty fields in which to enter the new person's first, middle, and last name. (See Figure 38).



Figure 38: Enter New Person Fields.

- Complete the following fields:
Note: Depending on the selection you made in the previous step, some of these fields may already be

populated.

- Under the Association Role column, select the person's association role.
- Under the Contact Information column, enter the person's email, phone number, and phone extension in the appropriate fields.
- Under the DAERS Role column, select the person's DAERS role. For more information about the meaning of the DAERS roles, please see the 'DAERS User Roles Matrix' topic above.

Note: The DAERS role cannot be selected as "None" for records marked as "Access to all Protocols"

- Under the List on I572/IORA Form column, choose Yes or No.
- Optional.* Click **Restore** at any time to clear any of the values you entered. You can also click **Remove** at any time to remove the record for new persons that were added.
 - Once you are finished making changes, click **Save**.
 - Click **Back to Submission** to return to the **New Submission** page and submit the registration packet.

Once you submit the packet, the person information you added will create a new request in the DAERS Site Enrollment Module. To view the request, log into DAERS and click **Person > View Requests**, and click on the Request

Fields prefaced with a red asterisk (*) indicate a required field.

Person Information Fields

FIELD	DESCRIPTION
*Person Name	Select the full name of the person associated with the study from the drop down list. If <Enter New Person> is selected, type the First Name, Middle Name, and Last Name.
*Association Role	Displays the Association Role with the site. (e.g., Research Clinician, Investigator, CRS Leader, etc.). Note: For new person, select the Association Role from the drop down list.

Person Information Fields	
FIELD	DESCRIPTION
* Contact Information	<p>Displays the contact information for E-mail, Phone, and Extension. This will be pre-populated with information from Master Contact.</p> <p>Note: For a new person, enter the contact information for E-mail, Phone and Extension.</p>
* DAERS Role	<p>Select the role the person will have in DAERS.</p> <ul style="list-style-type: none"> • Reporter - Site staff responsible for creating EAE reports but cannot sign and submit them. • Submitter – Site Staff responsible for reviewing and, submitting, EAE reports. • None – Site staff does not require access to DAERS (but is listed on the I572/loRA form) <p>(See the DAERS User Roles Matrix for more details on the permissions each role has.)</p> <p>Note: This column will only be displayed for submissions for protocols that require EAE reporting to DAIDS. For non-EAE reporting protocols, there will be no DAERS Role.</p>
* Listed on I572/loRA Form?	<p>Click Yes or No to indicate whether the person has been specified in the FDA I572 or loRA form or not.</p>

Modifying and/or Removing a Person's Access to DAERS via the DPRS

While submitting an updated submission type of Change in IoR, Updated I572, or Updated IoR Form for an EAE reporting protocol, you can go to the Person Information screen in the DPRS to modify a person's access to DAERS for this protocol. You can also remove a person's access to DAERS from this screen.

To modify a person's access to DAERS via the DPRS

1. Point to the **Submission** menu on the horizontal navigation bar and choose **New Submission**.
2. At the New Submission screen, fill in the required fields and select an applicable submission type.
3. Click **Next**. This will expand the page to display additional fields and buttons.
4. Scroll down and click the **Person Information** button, which is near the bottom of the page. This will display the Person Information screen, which by default will show the following information:
 - All site staff who have access to this protocol in DAERS
 - All site staff who were entered on the Person Information screen in the previous approved submission for this protocol
 - All site staff for whom a request for access to DAERS was submitted via the Site Enrollment and is pending completion
5. Under the DAERS Role column, use the drop-down menus to change a person's DAERS role.

Note: The DAERS role cannot be changed for records that are marked as "Access pending." Additionally, the DAERS role cannot be changed to "None" for records marked as "Access to all Protocols."
6. Under the Listed on I572/IoRA Form? column, select Yes or No for all the persons listed.

Note: If you selected "None" under the DAERS Role column and "No" under the Listed on I572/IoRA Form? column, the system will generate a request to remove that person's access to the DAERS application for this protocol. Once the request is completed by NIAID CRMS Support, that person's name will be removed from the Person Information screen for subsequent submissions for this protocol.

7. Click **Save**. On approval of this submission by the PRO, a Request will be submitted to NIAID CRMS Support for the changes indicated for the site staff access for this protocol.

To remove a person's access to DAERS via the DPRS

To remove a person's access to DAERS for a protocol, but to keep them listed on the Person Information screen:

1. At the Person Information screen, under the DAERS Role column, select "None" from the drop-down menu for the person whose access you want to remove.
2. Under the Listed on I572/IoRA Form? column, select **Yes**.
3. Click **Save**. The system will generate a Request to remove that person's access to the DAERS application for this protocol.

To remove a person's access to DAERS for a protocol AND to remove them from the Person Information screen:

1. At the Person Information screen, under the DAERS Role column, select "None" from the drop-down menu for the person whose access you want to remove.
2. Under the Listed on I572/IoRA Form? column, select **No**.
3. Click **Save**. The system will generate a request to remove that person's access to the DAERS application for this protocol. Once the request is completed by NIAID CRMS Support, that person's name will be removed from the Person Information screen for subsequent submissions for this protocol.

To remove a person from Person Information screen for a non-EAE reporting protocol:

1. At the Person Information screen, under the listed on I572/IoRA Form? column, select **No**.
2. Click **Save**. That person's name will be removed from the Person Information screen for subsequent submissions for this protocol.

Note: If this submission is updated in the future, the person's name and contact information will not appear in the Person Information screen. The person can, however, be added back to the screen using the "Add Another Person" button. Please see the topic 'Adding a new person to a site and indicating their DAERS role via the DPRS' above for instructions on how to do this.