



National Institute of
Allergy and
Infectious Diseases



Regulatory
Support
Center

DAERS Access User Guide for EAE Reporter and Submitter Rights

I. Definitions

DAIDS Adverse Experience Reporting System (DAERS): An internet-based system used by DAIDS Clinical Research Sites (CRSs) to report Expedited Adverse Events (EAEs) to the DAIDS Regulatory Support Center (RSC) Safety Office. DAERS creates a centralized location for accessing EAE information for reporting purposes

Site Enrollment Module: The module in DAERS that enables DAIDS Clinical Research Sites (CRSs) to enroll and update CRS staff information.

Reporter: Any CRS staff member, such as a nurse or data manager, whom the Investigator of Record (IoR) has authorized to initiate EAE reports in DAERS. The Reporter is not required to provide an attestation form.

Submitter: Any study physician, listed on either the Form FDA 1572 or the DAIDS IoR Agreement, who is responsible for electronically signing and submitting EAE reports.

II. Obtaining DAERS Access – An Overview

All CRSs must have access to DAERS after site activation, but before the protocol begins. Each CRS must have *at least* two (2) staff who, among themselves, have a combination of DAERS Reporter and Submitter rights.

The following steps (explained in more detail in the section below) should be taken by CRS leadership and selected staff to obtain access to DAERS:

- A. **Requesting access:** The CRS Leader or CRS Coordinator requests access for selected CRS staff through the Site Enrollment Module.
- B. **Training:** CRS staff complete the web-based Expedited Adverse Event (EAE) Reporting eLearning Course on the DAIDS Learning Portal. The course certificate will be automatically sent to NIAIDS CRMS Support.
- C. **Submitters only:** Submitters also must email an accurately completed, signed, electronic copy of the 21 CFR Part 11 – Attestation and Agreement for Electronic Signatures form to the DAIDS RSC Safety Office at DAIDSRSCSafetyOffice@tech-res.com.



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III. Requesting Access to DAERS

A. Site Enrollment Module

The CRS Leader or CRS Coordinator requests DAERS access for their CRS staff using the Site Enrollment Module in DAERS for all protocols with EAE reportability to DAIDS. They must provide the user's name, contact information (e-mail, phone, and fax) and DAERS role (i.e., Reporter, Submitter) for each protocol.

Below are brief instructions for CRS Leaders or CRS Coordinators on how to use the Site Enrollment Module. For more detailed instructions, please click on the following link: [DAERS user guides](#).

1. Contact NIAID CRMS Support at CRMSSupport@niaid.nih.gov for access to the Site Enrollment Module.
2. Log in to the Site Enrollment Module by using the username and password provided by NIAID CRMS Support. The login page can be accessed by clicking on the following the link: [NIAID CRMS EAE Reporting module](#).
3. Click on the “**EAE Reporting**” icon.
4. Click the **Person** menu on the horizontal navigation bar and then click “**New Request**”.
5. If the CRS Leader or CRS Coordinator is associated with more than one CRS, select the correct Site ID from the drop-down list and click “**Search**”.
6. From the table listing all CRS staff, click on the “**Edit**” button for the selected CRS staff that requires access to report or submit EAEs.
7. Proceed with completing contact information and assign protocol(s) with requested DAERS role (i.e., Reporter, Submitter).
8. On the **Review Current Request** screen, click on the “**Add/Edit Another Person**” button to continue adding CRS staff for access to protocol(s).
9. On the **Review Current Request** screen, click on the “**Submit All**” button to submit the request to NIAID CRMS Support.

Note: CRS Leader/Coordinator action for Site Enrollment Module not applicable for DAIDS Non-Network sites. Follow the requirements specified in the site activation checklist.

B. Training

Training is provided in a web-based format that is designed to be self-paced to offer flexibility and accessibility. The training is a required part of the overall process of obtaining access to DAERS, and the certificate documenting training completion is automatically sent to NIAID CRMS at CRMSSupport@niaid.nih.gov.

The DAIDS Expedited Adverse Event Reporting eLearning Course can be found in the DAIDS Learning Portal at: <https://daidslearningportal.niaid.nih.gov/>. If you do not have an existing user account, please contact DAIDS Learning Portal Help Desk.

1. If you have an existing user account, log into the DAIDS Learning Portal and complete a keyword search using any of the following terms “DAERS, Clinical, Safety, Adverse Event (AE) Reporting, Systems”.

C. Submitters Only: Electronic Signature Attestation Form

Each study physician must email an accurately completed, signed, electronic copy of the 21 CFR Part 11 – Attestation and Agreement for Electronic Signatures form to the DAIDS RSC Safety Office at DAIDSRSCSafetyOffice@tech-res.com. This form must be emailed for each CRS the study physician has been designated to be a submitter within DAERS.

Study physicians must also be listed on the FDA 1572 or IoRA forms for the study and CRS they are requesting DAERS access for. The form may be accessed by clicking on the following link: [Physician Electronic Signature Attestation Form](#).

Note: Mailed hard copy of the Electronic Signature Attestation Form is no longer required.

IV. Contact Information

A. For DAERS Access

NIAID CRMS Support

Phone: +1 (240) 778-2517

Email: CRMSSupport@niaid.nih.gov

B. For Training

DAIDS Training Support Team

Email: Support-daidslearningportal@niaid.nih.gov

Website: <https://daidslearningportal.niaid.nih.gov/>

C. For Electronic and Original Attestation Forms

DAIDS RSC Safety Office

Phone: +1 (800) 537-9979 (Toll free) or +1 (301) 897-1709

Email: DAIDSRSCSafetyOffice@tech-res.com

Fax: +1 (800) 275-7619 (Toll free) or +1 (301) 897-1710