



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.

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

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

Submitter: Any study physician who will submit and electronically sign EAE reports in DAERS. Per DAIDS policy, all Submitters must be study physicians listed on either the Form FDA 1572 or the DAIDS Investigator of Record Agreement (IoRA) form. These documents must be submitted to the DAIDS Protocol Registration Office at the DAIDS RSC during protocol registration.

II. Obtaining DAERS Access – An Overview

All CRSs must have access to DAERS before a study begins to report EAEs to DAIDS. 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 select CRS staff through the DAERS Site Enrollment Module.
- B. DAERS training: Selected CRS staff complete the web-based DAERS training on the DAIDS Learning Portal *and* send their certificate documenting DAERS training completion to NIAIDS CRMS Support.
- C. Submitters only: Submitters also must mail a signed, original, hard copy study physician Attestation and Agreement for Electronic Signatures form to the DAIDS RSC Safety Office.

III. Requesting Access to DAERS

A. DAERS 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



National Institute of
Allergy and
Infectious Diseases



Regulatory
Support
Center

(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 DAERS Site Enrollment Module.
2. Log in to the DAERS 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. 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.

Note: If the CRS Leader or CRS Coordinator is affiliated with more than one CRS, they will have to select a Site ID from the drop-down list and click “**Search**” first before proceeding forward and clicking on the “**Edit**” button.

6. Proceed with completing contact information, assign protocol(s) with associated DAERS role (i.e., Reporter, Submitter).
7. On the **Review Current Request** screen, click on the “**Add/Edit Another Person**” button to continue adding CRS staff for access to protocol(s).
8. On the **Review Current Request** screen, click on the “**Submit All**” button to submit the request to NIAID CRMS Support.

B. DAERS 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 DAERS training completion must be sent to NIAID CRMS at CRMSSupport@niaid.nih.gov.

DAERS training can be found in the Learning Management System (LMS). The LMS is part of the DAIDS Learning Portal. For more information, please visit the [DAIDS Learning Portal](#).

1. If you do not have an existing user account, please visit the following link to request an account: [DAIDS Learning Portal User Registration page](#).
2. If you have an existing user account, log into the LMS and complete a keyword search with the term “DAERS”.



National Institute of
Allergy and
Infectious Diseases



Regulatory
Support
Center

C. Submitters Only: Electronic Signature Attestation Form

Each study physician submitter must mail an accurately completed, signed, original 21 CFR Part 11 – Attestation and Agreement for Electronic Signatures form to the DAIDS RSC Safety Office. This form must be mailed in for each CRS the study physician has been designated to be a submitter within DAERS. The form may be accessed by clicking on the following link: [Physician Electronic Signature Attestation Form](#). Additionally, submitters must be study physicians listed on the FDA 1572 or IoRA forms for the study and CRS they are requesting DAERS access.

Note: To expedite access, an electronic version of the electronic signature attestation form will be accepted with the understanding that the original, hard copy is being mailed. Access to DAERS will be revoked if the hard copy is not received after the request was received per the following timeline:

- Domestic sites: within 2 weeks
- Foreign sites: within 4 weeks

IV. Contact Information

A. For DAERS Access and Training

NIAID CRMS Support

Phone: +1 (240) 778-2517

Email: CRMSSupport@niaid.nih.gov

B. 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

Mail: DAIDS RSC Safety Office
6500 Rock Spring Drive, Suite 650
Bethesda, MD 20817 (USA)