

Division of AIDS (DAIDS) Site Clinical Operations and Research Essentials (SCORE) Manual: Introduction to DAIDS Systems

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Introduction to DAIDS Systems

DAIDS implements systems to support its scientific, administrative, and regulatory research agenda.

Clinical Research Site (CRS) staff should understand the process of obtaining access to the various DAIDS systems and know their roles and responsibilities when utilizing these systems to perform their duties.

The Principal Investigator (PI)/Investigator of Record (IoR) has the primary responsibility for authorizing appropriate CRS staff to perform activities related to each of the DAIDS systems described in this section.

DAIDS Learning Portal (DLP)

The [DAIDS Learning Portal](#) (DLP) is a dedicated web-based training platform for CRS staff members to take online training anytime, 24 hours/day.

Courses offered on the DLP include but are not limited to the following:

- Human Subjects Protection (HSP)
- Good Clinical Practice (GCP)
- DAIDS Protocol Registration System (DPRS)
- Clinical Site Monitoring (CSM) System
- DAIDS Adverse Experience Reporting System (DAERS)
- Introduction to Quality Management

Please see the DLP for a complete listing.

The DLP system records staff training status in real time, allowing users to track training progress, review completed trainings, and obtain completion certificates.

Using DLP

Who should take DLP courses?

- CRS Staff members working directly with study participants or participant data
- Community Advisory Board (CAB) members
- Collaborating partners

Note: To access trainings within the DLP, the user account must reference an active DAIDS CRS number.

To create a user account, follow these steps:

1. Access the [DAIDS Learning Portal](#) and select “Create New Account.”

2. Complete the “New Account” form including your DAIDS CRS number.
3. DLP support will provide access to DLP.

For questions, contact support-daidslearningportal@niaid.nih.gov

The CRSs can also conduct group trainings using specific courses in the DLP. After finishing any site-based group training, attendees must:

1. Document attendance by signing and dating a training log. An example of a training log template is provided in the [CRS Personnel Qualification, Training and Responsibilities](#) section of this manual.
2. Send the log to the Training Support Team at support-daidslearningportal@niaid.nih.gov.

A support team member will add this course to attendees’ DLP transcripts, and attendees can then print out their completion certificates.

NIAID Clinical Research Management System

National Institute of Allergy and Infectious Diseases (NIAID) Clinical Research Management System (CRMS) enhances the management of clinical research (funded by or otherwise supported by several NIAID divisions, including DAIDS) by supporting scientific, advisory, and regulatory processes.

Within NIAID CRMS, DAIDS has developed a set of components, including the Site Hub, DAIDS Protocol Registration System (DPRS), Clinical Site Monitoring (CSM) System, and DAIDS Adverse Experience and Reporting System (DAERS), to support its specific requirements. This section gives an overview of these systems for CRS staff who will need to utilize them.

NIAID CRMS components are available at: <https://ncrms.niaid.nih.gov>.

The PI/IoR, CRS Leader or CTU Coordinator must inform the Office of Clinical Site Oversight (OCSO) Program Officer (PO) of any staff departure or role change to ensure that access to all electronic systems is revoked promptly.

Note: Due to federal information security guidelines, the NIAID CRMS password expires every 120 days. Contact [NIAID CRMS Support](#) to get a temporary password, Monday through Friday, 8:30 am-5:30 pm Eastern Time.

Site Hub

CRSs are required to use this centralized online data repository for tracking staff members who are working on DAIDS clinical trials. The data tracked includes contact information, HSP/GCP certifications, and other requested site information.

Human Subjects Protection /Good Clinical Practice Training Tracking

The Site Hub tracks site personnel HSP and GCP training statuses, including courses that have expired (or will expire within 90 days). Staff from Clinical Trials Units (CTUs), CRSs, and Protocol Specific (PS) sites curate Site Hub's content. OCSO POs use the data to ensure that all CRS staff members have current HSP and GCP training certifications on file, consistent with the HSP/GCP training requirements described in the "CRS Personnel Qualification, Training and Responsibilities" section of this manual.

Site Population Characteristics

The Site Hub collects site population characteristics for each CRS and any additional locations. DAIDS and the DAIDS Clinical Trials Networks use this information to identify sites with access to populations appropriate for newly-proposed clinical trials.

Essential Contacts/Site Profile Entry

The Site Hub also captures Essential Contacts and Site Profile information for all DAIDS CRSs. For CRSs that are affiliated with a CTU, this information is first entered by CTU personnel from the affiliated CTU at the time of the grant re-competition. CRSs confirm the data throughout the grant cycle.

Updates should be made to the Essential Contacts during the grant cycle as necessary for changes in Key Personnel and/or contact information.

Note: CRS staff must submit and receive OCSO PO approval for changes in Key Personnel before updating the *Essential Contacts form*. Request any such changes per the "DAIDS Key Personnel Identification and Change" sub-section of this manual.

Using Site Hub

Who should access the Site Hub?

- Clinical and administrative staff members maintaining the HSP/GCP personnel training records and other site-related information as requested through the Site Hub
- CTU staff members entering their CRS's Essential Contacts and Site Profile information at the beginning of each grant cycle and updates as needed

Access to the Site Hub, including 'Edit' access, is automatically granted to the Key Personnel (e.g., the CTU PI, CTU Coordinator, CRS Leader, and CRS Coordinator) listed in NIAID CRMS and is restricted by role. CTU and CRS staff with 'Edit' access may update the Site Hub for their affiliated CRS personnel, including the following activities:

- Enter training completion dates and upload a copy of the HSP/GCP training certificate for each CRS staff member.
- Review and update CRS staff listing as appropriate.
- Review and update CRS population characteristics.

CTU staff with 'Edit' access may also update the Site Hub for the affiliated CTU Administrative Office staff for the above activities.

DAIDS and Network Leadership and Operations Centers (LOC) personnel have 'Read only' access, which permits CTU and CRS content review. Network LOC personnel have access only to CRSs within their respective networks.

Note: Requests for additional CRS staff members to access Site Hub may be made by Key Personnel via email by contacting NIAID CRMS Support at CRMSsupport@niaid.nih.gov. Once access is granted, users receive a confirmation email from NIAID CRMS Support Staff. Access approval may take several days to complete.

DAIDS Protocol Registration System

The DPRS is a web-based system which enables CRSs to submit and subsequently track required documents to the Regulatory Support Center (RSC) Protocol Registration Office (PRO). It is the official centralized repository for all information relating to protocol registration. With DPRS, CRS staff members can:

- Electronically upload protocol registration documents
- Track/monitor progress of submissions
- Provide corrections/updates
- Respond to reminders and/or notifications
- View registration reports

The RSC provides day-to-day support for all regulatory activities and uses DPRS to exchange information directly with systems used by Network (e.g., LOCs, Data Management Centers [DMCs]) and other collaborators. This ensures efficient integration of regulatory information in support of DAIDS clinical trial activity.

Using the DPRS System

Who should use DAIDS Protocol Registration System (DPRS)?

- CRS staff members involved in preparing, submitting, and tracking protocol registration documents. CRS leadership should identify such staff members as needing access to the system.
- RSC staff, under DAIDS oversight, must review all CRS protocol registration materials.

CRS staff must electronically upload and track the site's essential regulatory documents and PI/IoR information as described in the [Protocol Registration Manual](#). The *Protocol*

Registration Policy and *Protocol Registration Manual* are accessible from the RSC website for additional information.

Note: DPRS training in the DLP is required for system access. The course takes about an hour.

Upon completion of the DRPS System training course:

1. Email request for access to DPRS to [NIAID CRMS Support](#).
2. NIAID CRMS Support will obtain required approvals.
3. Upon receipt of approval, NIAID CRMS Support will grant access and notify users of access to DPRS.

If DPRS login details are not received, contact NIAID CRMS Support.

DAIDS Clinical Site Monitoring System

The CSM system is the official source of information for all DAIDS CRSs and study monitoring functions (both the clinic and pharmacy) to capture, track, and view site and study monitoring information.

The CSM System enables:

- Electronic submission of the Pre-Visit Letter (PVL), Announced Work Order (AWO) and final Site Monitoring Report (SMR) to the CRSs.
- Review and acknowledgements of site-monitoring visit documents.
- Addressing/tracking monitoring issues entered by the OCSO PO and/or Pharmaceutical Affairs Branch (PAB) representative.

Using the CSM system

Who uses the CSM system?

- DAIDS
- Monitoring contractors
- PI/IoR
- CRS staff, including pharmacy staff members, that interact with monitoring contractors, acknowledge monitoring reports, and address monitoring issues entered by the OCSO PO and/or PAB representative

The following activities are completed through the system:

- The assigned monitoring contractor generates and submits PVLs, AWOs and SMRs to the CSM.
- The CSM announces posted PVLs, AWOs and SMRs to appointed CRS personnel via email notification.
- The OCSO PO uses the CSM System to review SMRs generated by monitoring contractors as part of their oversight responsibilities.

- The PAB, which provides oversight of the Clinical Research Products Management Center (CRPMC), reviews Pharmacy Visit Reports generated by the monitoring contractor.
- After reviewing the reports, OCSO POs and PAB representatives enter monitoring findings into the system that the relevant CRS staff address. CRS staff members, on the other hand:
 - Acknowledge PVLs and AWOs.
 - Access relevant site monitoring visit documents.
 - Review and respond to monitoring findings that the OCSO PO and PAB representative identify.

Note: CSM system training on the DLP is required for system access. The course takes about an hour.

Upon completion of the DLP CSM training course:

1. Email request for access to CSM to [NIAID CRMS Support](#).
2. NIAID CRMS Support will obtain required approvals from OCSO PO. This process is required for any new clinic and pharmacy staff at a site who will interact with clinical site monitors and address monitoring issues in the CSM system.
3. Upon receipt of approval, NIAID CRMS Support will grant access and notify users of access to CSM.

If CSM login details are not received, contact NIAID CRMS Support.

Note: A maximum of five CRS staff members can have access to the clinical section of the CSM. The Pharmacist of Record (PoR) receives separate access to the pharmacy section of the CSM. Sites with multiple clinical trials may have more than one PoR with access. PoRs are not included in the aforementioned limit of five.

DAIDS Adverse Experience Reporting System

DAERS is a web-based system CRSs use to report Expedited Adverse Events (EAEs) to the RSC Safety Office. DAERS creates a centralized location for accessing EAE information for reporting purposes. CRS staff members can use DAERS to create, review, approve, update, and submit EAE reports.

DAIDS also uses DAERS to electronically distribute Investigator's Brochures (IBs) to CRSs. Information regarding this process is available on the [Safety Information Distribution Page](#).

Using DAERS

The Site Enrollment Module (SEM) located within DAERS enables CRS users to manage access and contact information for other CRS staff members and to designate reporter and submitter duties within the system.

There are two main roles in using the system: 1) Reporter and 2) Submitter.

The Reporter -- any appropriately delegated CRS staff member, such as a nurse or data manager, whom the PI/IoR has authorized to initiate EAE reports in DAERS.

The Submitter -- any study physician, listed on either the Form FDA 1572 or DAIDS IoR Form, responsible for electronically signing and submitting EAE reports in DAERS. A submitter can also initiate EAE reports in DAERS.

Notes:

- Submitter access is provided per study based on Submitter Verification completed by DAIDS RSC.
- Reporter access is provided per site.
- More than one of each role can be assigned to a single study or to multiple ones having EAE reportability to DAIDS. To make the designations, the CRS must provide the user's name, contact information (email, phone, and fax), and the role.
- CRS staff delegated by the PI/IoR as reporter and/or submitter must complete the mandatory training courses available in DLP.

Who uses the DAERS system?

- The PI/IoR
- Individuals delegated as a "Submitter"
- Any "Reporter" that begins the report in the system for the submitter
- Anyone involved in reporting EAEs to DAIDS

Note: DAERS training on the DLP is required for system access. The course takes one to two hours.

Upon completion of the DLP DAERS training course:

1. Request access via Site Enrollment Module in DAERS or by contacting [NIAID CRMS Support](#).
2. For Reporter access, proceed to step 4
3. For Submitter access follow the additional steps below:
 - a) Submitter completes a hard copy of the [21 CFR Part 11 - Attestation and Agreement for Electronic Signatures form](#).
 - b) Submitter(s) must mail an accurate, complete, signed, original hard copy of the form to the RSC Safety Office, within two weeks for United States (U.S.) sites and four weeks for non-U.S. sites. DAIDS RSC Safety Office:
6500 Rock Spring Drive, Suite 650
Bethesda, MD 20817 (USA)
Phone: 1-800-537-9979 (toll free) or 1-301-897-1709

- c) To expedite access, email an electronic copy of the form to DAIDSRSCSafetyOffice@tech-res.com
4. NIAID CRMS Support will notify users of access to DAERS, upon completion of all applicable pre-requisites listed above.

If login details are not received, contact NIAID CRMS Support.

Note: Access to DAERS may be revoked if the hard copy of the electronic signature attestation form is not received within two weeks for U.S. sites or within four weeks for non-U.S. sites from the date of signature.

Requirements

- All CRSs must have access to DAERS after site activation but before a clinical trial begins.
- Each CRS must have at least two staff members who, between them, have a combination of DAERS Reporter and Submitter rights.
- The CRS Leader or Coordinator requests DAERS access for staff members using the SEM, as per PI/IoR delegation of duties.

Refer to the [Manual for Expedited Reporting of Adverse Events](#) and [DAERS Access User Guide for EAE Reporter and Submitter Rights](#) accessible on the RSC website.

Note: In case of a DAERS access emergency, submit EAEs on paper. Refer to the DAIDS Safety EAE Form and Completion Instructions for the DAIDS EAE Form accessible from the [RSC website](#).

DAIDS Systems Best Practices

- Create a strong password, per minimum system requirements.
- A strong password does not spell a word or series of words found in a standard dictionary or spell a word with a number added to the beginning and the end.
- A password is not based on any personal information, such as user identification, family name, pet, birthday, etc.
- Do not share your login and password with anyone for any reason.
- If you suspect someone has compromised your account, change your password immediately and report the incident to the PI/loR and OCSO PO.
- Avoid writing down your password or storing it in an insecure manner.
- Avoid using the same password for multiple accounts.
- Do not use automatic logon functionality.
- Do not leave your computer unattended while logged in. Log off every time you have finished using the system.
- Ensure you are uploading and entering the most up-to-date information.

Reference Guide to DAIDS Systems Access

DAIDS Systems'	Who needs access?	Instructions on gaining access
DAIDS Learning Portal (DLP)	Any CRS staff member working directly with study participants or participant data.	<p>No training is required to gain access.</p> <ol style="list-style-type: none"> 1. Access the DAIDS Learning Portal and select “Create New Account.” 2. Complete the “New Account” form including your DAIDS CRS number. 3. DLP support will notify users of access to DLP. 4. Contact DLP Support in case of questions.
Site Hub	<p>Clinical and administrative personnel that maintain the HSP/GCP training records and other site-related information requested through the Site Hub.</p> <p>CTU staff members that enter the Essential Contacts and Site Profile information for their CRSs at the beginning of each grant cycle.</p>	<p>No training is required to gain access.</p> <ol style="list-style-type: none"> 1. Assign one or two CRS level staff members to enter information for the entire CRS. 2. Email CRMSsupport@niaid.nih.gov to request access. 3. NIAID CRMS Support will notify users of access to Site Hub.
DAIDS Protocol Registration System (DPRS)	Only those CRS staff members that will use the system to prepare, submit, and track protocol registration documents.	<p>Training is required to gain access.</p> <ol style="list-style-type: none"> 1. Access DPRS Training on the DLP (approximately one hour). 2. Email request for access to DPRS to NIAID CRMS Support 3. NIAID CRMS Support will obtain required approvals. 4. Upon receipt of approval, NIAID CRMS Support will grant access and notify users of access to DPRS. 5. Contact NIAID CRMS Support with any questions. <p>The <i>Protocol Registration Policy</i> and <i>Protocol Registration Manual</i> are available through the DAIDS website.</p>

DAIDS Systems'	Who needs access?	Instructions on gaining access
Clinical Site Monitoring (CSM)	PI/loR, CRS staff members, including pharmacy personnel that interact with monitoring contractors and address monitoring issues in the CSM.	<p>Training is required to gain access.</p> <ol style="list-style-type: none"> 1. Assign up to five* site personnel to gain access to CSM. 2. These personnel should take CSM Training in the DLP (approximately one hour). 3. Email request for access to CSM to NIAID CRMS Support. 4. NIAID CRMS Support will obtain required approvals. 5. Upon receipt of approval, NIAID CRMS Support will grant access and notify users of access to CSM. 6. Contact NIAID CRMS Support with any questions. <p>* PoRs are not included in this limit of five</p>
DAIDS Adverse Event Reporting System (DAERS)	PI/loR, individuals delegated as the "Submitter" and included on the FDA Form 1572 or loR Form (must be a physician) as well as any "Reporter" who begins the report in the system for the submitter. Anyone involved in reporting EAEs to DAIDS.	<p>Training is required to gain access.</p> <ol style="list-style-type: none"> 1. Access DAERS training on the DLP (approximately one to two hours). 2. Request access via Site Enrollment Module in DAERS. 3. For Reporter access, proceed to step six. 4. For Submitter access follow the additional steps below: <ol style="list-style-type: none"> a) Submitter completes a hard copy of the 21 CFR Part 11 - Attestation and Agreement for Electronic Signatures form. b) Submitter(s) must mail an accurate, complete, signed, original hard copy of the form to the RSC Safety Office, within two weeks for United States (U.S.) sites and four weeks for non-U.S. sites. DAIDS RSC Safety Office: 6500 Rock Spring Drive, Suite 650 Bethesda, MD 20817 (USA) Phone: 1-800-537-9979 (toll free) or 1-301-897-1709 c) To expedite access, email an electronic copy of the form to DAIDSRSCSafetyOffice@tech-res.com 5. NIAID CRMS Support will notify users of access to DAERS, upon completion of all applicable pre-requisites listed above.

DAIDS Systems'	Who needs access?	Instructions on gaining access
Continued from above.	Continued from above.	6. Contact NIAID CRMS Support with any questions. For more information about the entire process of obtaining access, please see the DAERS User Guide for EAE Reporter and Submitter Rights .

References

1. [U.S. Code of Federal Regulations, Title 21, Parts 11, 50, 54, 56, 312 and 812](#)
2. [International Council for Harmonisation Good Clinical Practice \(ICH E6\)](#)
3. [DAIDS Learning Portal](#)
4. [DAERS Access User Guide for EAE Reporter and Submitter Rights Version 2.0
August 2017](#)
5. [Manual for Expedited Reporting of Adverse Events to DAIDS Version 2.0 January
2010](#)
6. [DAIDS Collaborator's Guide Version 1.3 January 10, 2017](#)
7. [NIAID DAIDS Regulatory Support Center \(RSC\)](#)
8. [FDA Guidance for Industry Computerized Systems Used in Clinical Investigations](#)