

Information about DAIDS Safety Training Resources

The following information describes the components of safety training that are being made available as training resources. In an effort to facilitate coordination and harmonization of safety training across networks and DAIDS, please notify [Ling Chin](#), Team Leader for DAIDS Safety and Pharmacovigilance Team, or [Jane Reynolds](#), DAIDS Learning Coordination Officer, as soon as a training need is anticipated.

What is the DAIDS Safety and Pharmacovigilance Team?

The Safety and Pharmacovigilance Team (SPT) is within the Office for Policy in Clinical Research Operations (OPCRO), and was set up to establish standards for safety and pharmacovigilance across DAIDS and DAIDS-funded clinical trials. SPT serves as the subject matter expert and advisor in matters related to safety and pharmacovigilance, and develops relevant policies, standard operating procedures, guidance, training and quality assurance standards. SPT works with the Regulatory Compliance Center (DAIDS contractor) in all areas related to expedited reporting of adverse events (AEs), and is responsible for the review of all safety reports before submission to FDA.

What is Safety Training?

Safety Training is defined as training that pertains to assuring safety in clinical trials, including:

- Safety monitoring commensurate with risks relevant to the study, intervention, population, and indication
- Roles and responsibilities of site MD and team regarding subject safety
- Protocol specifications for safety
- Protocol specifications for AE monitoring: data capture, expedited reporting, AE assessment
- Safety monitoring oversight, e.g., study team, safety monitoring team, sponsor medical monitor
- Safety monitoring oversight by independent entities, e.g., Safety Monitoring Committee (SMC), Institutional Review Board (IRB), International Ethics Committee (IEC), Data and Safety Monitoring Board (DSMB)

What Safety Training components are currently available?

- Safety Workshop
- EAE
- DAERS
- Core EAE slide deck (for protocol-specific EAE reporting)

What support is available for safety training?

- Consultation support on identified training topics according to emerging needs, or content for protocol-specific slides
- Training support on topics related to AE management or protocol-specific expedited reporting
- SPT and safety training support staff at RCC can work with the Medical Officers to develop or provide EAE training
 - If there are specific issues that arise, whether protocol-specific, or site(s)-specific, ad hoc requests for training to address those specific issues may be made, and if resources permit, RCC can assist with such training as well

What is the Safety Workshop?

An integrated, comprehensive approach to safety training beyond EAE reporting that is delivered in two 4-hour sessions. It includes:

- Part I: Basic Principles: didactic content on the regulatory environment regarding safety, safety monitoring, safety reporting. Includes definitions, regulations, guidance documents, roles and responsibilities of key study personnel.
- Part II: Putting Principles into Practice: EAE module, hands-on practice with expedited reporting. Includes structured case discussions to foster an understanding of AE terminology, assessment of the AE, and putting a high quality, comprehensive narrative together. Quick Reference Cards are provided as tools to aid the exercise.
- Structured Case Discussions in both Part I and Part II: cases are selected from actual EAEs received by DAIDS, and selected to illustrate specific points. Cases are accompanied by Case Handouts, Specific Questions to be addressed by the groups, and final Teaching Points. Cases will be selected to address current issues/misunderstandings as they arise.
- Note: When possible, DAERS training is offered following the Safety Workshop as part of this integrative approach. DAERS training covers the technical aspects of accessing and using DAERS. Any EAE content questions are directed to SPT/RCC staff or the appropriate MO when they are present for this session.

The safety workshop slide sets can be found at <http://rcc.tech-res.com/safetyandpharmacovigilance/>

What is EAE Training?

EAE training is about the submission of expedited AE reports to DAIDS. It is offered as an integrated part of the Safety Workshop or as a single module.

- Single Module: focus is on EAE form completion; training lasts up to 4 hours and includes core AE/SAE content, definitions, assessment terminology, and basic EAE form completion. Depending on the needs of the trainees and as time allows, EAE training can include other modules, such as identification of an AE, AE terminology, putting together a comprehensive narrative, and assessment of the AE, with the goal of submitting a high quality, medically assessed adverse event report to the sponsor (DAIDS).
- Integrated Component: focused on EAE completion, complementary to Safety Workshop, offered during Part II of the Safety Workshop. Actual case discussions are included for small group discussion.

The EAE training slide sets can be found at <http://rcc.tech-res.com/safetyandpharmacovigilance/>

What is DAERS Training?

It is training on the use of the web-based application for electronic reporting of EAEs. It is offered on a regular basis by live Webcast, as well as most DAIDS Regional Training Events as part of the integrated Safety Training. It is also available for Network meetings by request.

DAERS Training for Sites:

- Site and staff training requests for the DAERS Web-based Application need to be submitted to the DAIDS ES.
- Send an e-mail with your request to DAIDS-ESSupport@niaid.nih.gov.

DAERS Training for Network Meetings:

- Each network has a Training Representative or group who is responsible to coordinate and facilitate training requests.
- Submit all requests for network meetings via the Network Training Representative. If you need assistance to identify this person or group, please contact Jane Reynolds at DAIDS or Christie Villa at HANC. They will work with you and the appropriate Network Training Representative to facilitate the request.

What is the Core EAE Slide Deck?

It is a core set of slides for protocol-specific EAE training which allows for customization as necessary.

- Recommended as the EAE training platform for all protocol-specific training so that terms and definitions are used consistently
- Easily supplemented with protocol-specific safety and AE information by DAIDS MO and the Protocol Training Team located on the RCC website at <http://rcc.tech-res.com/safetyandpharmacovigilance/>
- Accessed from the HANC Training Resources Page under Safety Training at <http://www.hanc.info/Training/Pages/Training.aspx>

How do I ask for safety training support?

The following persons are involved in coordination of safety training, and they can facilitate all safety training requests:

- Ling Chin in DAIDS SPT (lchin@niaid.nih.gov)
- Jane Reynolds in DAIDS PTQAB (reynoldsma@niaid.nih.gov)
- Christie Villa at HANC (cvilla@fhcrc.org)
- Network Training Representatives prefer to be the main point of contact for all training needs from the sites and networks, including safety training. They will communicate requests to DAIDS.
 - For training at a network meeting, please direct requests for training through the appropriate Network Training Representative. Jane Reynolds can provide guidance on this process.
 - The full Safety Workshop can be provided if there is adequate time commitment at a network meeting or other training events. Otherwise, modules from the Safety Workshop can be delivered to accommodate various time commitments.