



# DAIDS RSC Spotlight



National Institute of Allergy and Infectious Diseases



Regulatory Support Center

## Coming Soon! DAIDS Expedited Adverse Event (EAE) Reporting eLearning Course

### What's New?

Coming in July 2017, DAIDS will launch a new safety eLearning course called the "DAIDS Expedited Adverse Event (EAE) Reporting eLearning Course."

This course is required for all new reporters and submitters who do not have DAIDS Adverse Experience Reporting System (DAERS) access at the time this new Safety eLearning course is launched. Reporters and submitters with current DAERS access at the time of this launch will not be required to take this course. *Please note that this course will be available on the DAIDS Learning Portal (DLP) for anyone with a DLP account and is interested in learning about safety reporting.*



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

### What are the course requirements?

To obtain DAERS access, you must take all three modules sequentially, and achieve a passing score of 80 % for each module. For each module, you will be allowed 3 attempts to take the module knowledge assessment. If you fail after the 3rd attempt, you will be locked out of this course in the DLP and will not be able to continue to the next module until remediation has been completed. If you are a reporter/submitter you will need to send a request to unlock the course to DAIDS RSC Safety. *Please note that if you are taking this course for informational purposes only and not for obtaining DAERS access the same lock out process will apply. You will need to contact the DLP Helpdesk to unlock your account.*

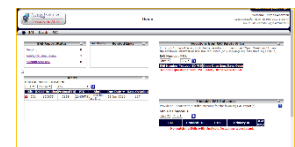
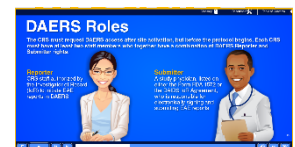
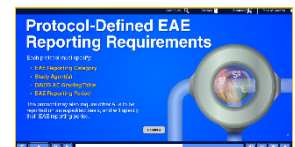
### What's the course goal?

The overall goal of this course is to train the CRS staff on how to assess and report Expedited Adverse Events (EAEs) to DAIDS using DAERS.

### What's covered in this course?

The 4 modules covered in this course are:

- **Introduction: DAIDS Expedited Adverse Event (EAE) Reporting eLearning Course**  
*The module will describe the course goals and objective, course requirements, and how to navigate within an eLearning module.*
- **Module 1: Expedited Adverse Event (EAE) Reporting Process**  
*This module serves as the foundation of this course. Knowing how to assess AEs and understanding the EAE reporting requirements are important concepts to be able to enter information into DAERS. Topics covered in this module include assessing AEs, explaining the EAE reporting requirements, identifying primary adverse events, and the EAE reporting timeline and process.*
- **Module 2: DAIDS Adverse Experience Reporting System (DAERS)**  
*In this module, you will learn about the purpose and use of DAERS, the difference between the reporter and submitter roles, and the DAERS training requirements. This module will also cover how to complete and submit the Attestation and Agreement for Electronic Signature form, as well as how to use the Site Enrollment Module (SEM) to request DAERS access for a reporter and submitter.*
- **Module 3: Creating and Submitting an EAE Report**  
*The third and final module will show you how to create, submit and update an EAE report.*



### Who should be contacted for more information?

Email: DAIDSRSCSafetyOffice@tech-res.com • Phone: 1 (800) 537-9979 (USA toll-free) or 1 (301) 897-1709 (Outside USA)