



# Spotlight



## Release of the DAIDS Adverse Experience Reporting System (DAERS) Site User Instructional Guide for EAE Reporting, Version 1.0

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The Division of AIDS (DAIDS) Safety and Pharmacovigilance Team (SPT) has released the *DAERS Site User Instructional Guide for EAE Reporting, Version 1.0*, which is an instructional guide that assists clinical research site staff with expedited reporting to DAIDS through DAERS. It is available on the DAIDS Regulatory Support Center (RSC) website at <http://rsc.tech-res.com/safetyandpharmacovigilance/expeditedreportingdaers.aspx>

### **What is the DAIDS Adverse Experience Reporting System (DAERS)?**

DAERS is a web-based system that enables immediate reporting of and access to expedited adverse events (EAEs). Built-in data validation checks and value lists ensure accuracy of data capture. Moreover, data entry is minimized because certain information, such as protocol, participant, and site information, is already captured by other DAIDS Enterprise System (DAIDS-ES) components.

### **When should I use DAERS?**

Clinical Research Sites (CRSs) should use DAERS to create and submit EAEs to DAIDS. In addition, DAERS can be used to update EAE reports upon receipt of additional information, search for EAEs, and view CRS-specific EAE information. The system provides an optional tool that helps determine whether an adverse event (AE) should be reported as an EAE.

### **What is the DAERS Site User Instruction Guide for EAE Reporting?**

This instructional guide shows the user how to enter values in each field in DAERS. Examples are provided for each field to help the user select the correct value. It also provides the user with special instructions to keep in mind while entering values, where applicable.

### **When should I use the DAERS Site User Instruction Guide for EAE Reporting?**

If you are a new DAERS reporter or submitter, this document will provide additional clarity on how to use DAERS. Even if you are an experienced DAERS user, this guide is a great reference tool and will further your understanding of the system.

Please contact the DAIDS RSC Safety Office via email at [DAIDSRSCSAFETYOFFICE@tech-res.com](mailto:DAIDSRSCSAFETYOFFICE@tech-res.com) or by phone at +301-897-1709 or 1-800-537-9979 (USA only) for questions or clarifications.

Thank you,  
*DAIDS RSC Safety Office*