



Spotlight



Need help Reporting Expedited Adverse Events to DAIDS?

Refer to the *Quick Reference Cards* available on the DAIDS RSC Website to facilitate the reporting process.

1. What are Quick Reference Cards?

- A reference tool that has concise information on the steps to be followed while reporting an expedited adverse event (EAE) to DAIDS via the DAIDS Adverse Experience Reporting System (DAERS).
- Easy to print portable tool that can be shared with other members at the clinical research site who are involved in the EAE reporting process.

2. What information is available in the Quick Reference Cards?

- Quick Reference Card IA & IB: The Adverse Event Checklist will enable you to ensure consistency and completeness of the clinical information you are submitting via DAERS.
- Quick Reference Card IIA: The Narrative Case Summary guides you on how to write a comprehensive “medical story” that will include information on predisposing factors, treatment measures, hospital course, diagnostic/laboratory work-up, outcome, past medical history, alternative etiologies, and other relevant information.
- Quick Reference Card IIB: Discusses the essentials of adverse event reporting; from evaluating a case to identifying an adverse event and following it to resolution/stabilization.

3. Where can you find the Quick Reference Cards?

- The Quick Reference Cards are posted on the DAIDS Regulatory Support Center website on the Safety and Pharmacovigilance page (<http://rsc.tech-res.com/safetyandpharmacovigilance/>). The direct link to the Quick Reference Cards is <http://rsc.tech-res.com/safetyandpharmacovigilance/safetytraining.aspx#QRC>.

Please contact the DAIDS RSC Safety Office via email at 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 Safety and Pharmacovigilance Team and the DAIDS RSC Safety Office