

11 March 2010

The Division of AIDS (DAIDS) is pleased to announce that the newly revised Manual for Expedited Reporting of Adverse Events to DAIDS Version 2.0, as well as the template language for the expedited reporting section in protocols, has been posted to the RCC website:

<http://rcc.tech-res.com/safetyandpharmacovigilance/>

As a result of changes introduced by Version 2.0, updated versions of DAERS and the DAIDS EAE Form will be available for use beginning on April 26, 2010.

How does the availability of the Manual Version 2.0 affect your new protocols and protocols in development?

1. All new protocols that will be at the stage of DAIDS Scientific Review on May 3, 2010, and thereafter, must use the Manual Version 2.0.
2. Protocols that are currently in development or undergoing review for revisions are highly encouraged to use Manual Version 2.0. However, please be aware that DAERS will not be able to accept EAE reports using the new Manual prior to April 26, 2010.

How does the availability of the Manual Version 2.0 affect your active protocols?

1. Most protocols that are already active will need to switch to the new Manual. The plan for which protocols need to be switched will be announced when finalized.
2. DAIDS is working with network representatives to elicit their feedback regarding the implementation plan for currently active protocols.

What about training on the Manual Version 2.0?

Training on the new Manual will be available soon. We are working with network training coordinators, and additional training information will be sent as it becomes available.

We appreciate your cooperation in implementing the Manual for Expedited Reporting of Adverse Events to DAIDS Version 2.0. We will continue to work with you to make the transition as smooth as possible. If you have questions or issues about the Manual Version 2.0, please contact Ling Chin at lchin@niaid.nih.gov.

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