Dear DAIDS Sites:

Nearly all of the DAIDS sites have initiated steps to transition to DAERS and we expect the completion of the DAERS roll-out phase within the next few weeks. We would like to thank everyone for their effort and cooperation in moving DAIDS forward to electronic reporting of expedited adverse events. As we continue forward with DAERS, we offer the following updates and reminders:

DAERS must be used as the primary method for EAE reporting:
Now that the roll-out to the sites is almost completed, we are concentrating on improving the usage of the system. In the last quarter, 66% of initial EAE reports were submitted directly by the sites. Our goal is to have greater than 90% of the EAEs submitted directly in DAERS. **Once your site has been given access, DAIDS expects that all EAE reports will be submitted directly into DAERS.** We understand that sometimes there are unforeseen circumstances or emergencies that preclude use of DAERS, so we are providing clarification on the proper procedures.

DAERS Emergency Procedure FAQs:

- My physician/DAERS submitter is not available to submit the report in the DAERS system, but it is due now.
  - o The reporter should enter the EAE report into the system, save it, and then
  - o Send an email to the RCC Safety Office requesting that the RCC submit the report on your behalf. Your request must be very clear and direct to avoid potential time losses to clarify.
  - o *Within 3 reporting days a submitter must use the update feature to submit their electronic signature*
  - o *There is NO need to submit a paper copy of the EAE report*

- My internet connection is not allowing me to complete the DAERS report.
  - o Complete the paper EAE form (available on the RCC website) and email or fax to the RCC Safety Office (RCCSafetyOffice@tech-res.com / Fax #: 301-897-1710).
  - o *Please include an explanation in the email or fax cover page to explain your difficulty.*

Clarification of the EAE manual requirement for reporting EAEs within 3 days:

The DAERS system automatically calculates the due date of an EAE.

The criteria used to determine reporting days are as follows:
- Monday through Friday count as reporting days.
- Saturday and Sunday are not considered reporting days.
- U.S. or in country/local holidays that occur on a Monday through Friday count as reporting days.
- A reporting day starts at 12:00 A.M. and ends at 11:59 P.M. local time.
- A day is counted as a reporting day regardless of the time of day that awareness occurred prior to 12:00 A.M.(midnight). The day a site indicates that site personnel became aware of an EAE that meets reporting criteria shall count as day 1 if that day occurs on a reporting day (i.e., Monday through Friday). If

that day occurs on a non-reporting day (i.e., Saturday or Sunday), the next reporting day shall count as day 1.

New Features for DAERS:

The most recent release of DAERS on September 28th included the following feature for the EAE Reporting Module:

- EAE Report Alerts: Ability for site users to view, on the DAERS Home page, EAE Reports that are past due for submission to RCC or about to become past due.

If you have issues or questions about the DAERS system, including access accounts or training, please contact DAIDS-ES Support (DAIDSES-Support@digitalinfuzion.com). For EAE reporting questions, contact the RCC Safety Office (RCCSafetyOffice@tech-res.com or phone: 301-897-1709). If you are in doubt, copy both on your email.

Again, we appreciate your cooperation in implementing the DAIDS Adverse Events Reporting system. We will continue to work with you to improve both the process and system of EAE reporting.

Thank you,

Ling Chin, M.D.
Safety and Pharmacovigilance Team Leader

Peter Kim, M.D.
Product Champion and Chair, DAERS Working Group