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MEMORANDUM

DATE: December 12, 2007

TO: Centre Representatives
Ethics Clinical Research Associates
Principal Clinical Research Associates

CC: Dr. Joe Pater, Dr. Ralph Meyer, Anna Sadura, ERG, AMG, QAO, OPS, Trial Teams

FROM: Bryn Fisher, Safety Coordinator

Serious Adverse Event Reporting change/clarification

I wish to make you aware of a change and a clarification in the reporting of serious adverse events that occur on NCIC CTG trials as follows:

1. 24 Hour Reporting.
   NCIC CTG no longer requires SAEs to be reported by telephone within 24 hours. Instead, within 24 hours, a preliminary copy of the SAE should be FAXED to the trial team. This should be followed by a hard copy of the report, updated as much as possible and signed by the investigator, within the time frame stated in the protocol.

2. Late Related Events.
   Events that are serious, unexpected and considered possibly, probably or definitely related to protocol treatment are to be reported in an expedited manner for NCIC CTG phase II and III studies. I wish to clarify that this includes events that occur during the treatment period (which includes up to 30 days after last protocol treatment administration) **and** at any time afterwards.

   For phase I trials, all serious adverse events, regardless of whether they are unexpected or related to protocol treatment, occurring during the treatment period and within 30 days after the last protocol treatment administration, must be reported in an expedited manner. Any late serious adverse event occurring after this 30-day period which is unexpected and related to protocol treatment must also be reported in an expedited manner.

   The above clarification refers only to trials not using the AdEERS web application for SAE reporting as AdEERS already addresses this issue.

Changes to the actual protocols will be made at the time of the next amendment. In the meantime, please consider the above points when reporting SAEs for your trials.

If you have any questions, please contact me.

Sincerely,

Bryn Fisher

Bryn Fisher
Safety Coordinator