Monday Morning Practice Pearls #12

You submitted a SAE/AESI to the sponsor, what else needs to happen with the event information?

There is a subset of AEs that need to be reported more quickly to regulatory groups (i.e., sooner than routine data submissions, continuing reviews, or annual reports). This reporting includes serious adverse events (SAEs) and adverse events of special interest (AESI) as defined in the protocol. The AE data submitted on the sponsor SAE form/database must also be captured on the AE case report form (CRF)/database.

The following AE information should be the same on the AE CRF as on the SAE form, for each applicable AE:

- Start date
- AE term
- Grade
- Attribution
- Stop date, if applicable.

Since the AE data is entered by 2 different members of the research team (i.e., the research coordinator completes the SAE form whereas the data manager completes the AE CRF), it is important to ensure the data is the same.

The research coordinator should perform a quality assurance (QA) check on the 2 "forms" (i.e., verify this data). If this is done, there should be no discrepancies or queries generated due to conflicting data.

Below are some tips to stay on top of this QA activity:

- Ensure that documentation about the expedited AE is in CRIS
- Research coordinator should ensure that the SAE form has been sent to the appropriate data manager
- QA check the AE data to ensure the same data is on the AE CRF and the SAE form

NOTE: For CTEP studies, please review the available CTEP resources and/or contact CCR OEC.