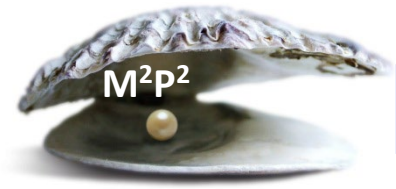

Monday Morning Practice Pearls #3

What information should be included in the narrative summary when reporting an expediate AE to the IRB or IND/IDE sponsor?

Regardless of which regulatory group you are reporting an AE to, each report will have similar elements:

- Reporter information
- Patient demographics
- Study agent/intervention (date(s) given, dose, route of administration)
- Event(s) information including severity and attribution
- *Narrative summary*

The narrative summary is the ***most important part*** of the report. The individual or group that is receiving the report typically does not know anything about the patient nor will they have the protocol readily available to them. The summary provides the background information necessary to assess the event and support the investigator's attribution.

When describing the event, provide information that puts the event in perspective including relevant patient history in chronological order:

- Clinical evaluations, assessments and diagnostic tests conducted to evaluate the event
- Treatment(s) for the event
- Relevant medical history (e.g., underlying medical conditions, prior surgeries or procedures, family history)
- Recent events that may be a contributing factor
- Concomitant medications (if not a separate section on the report form)

It may be beneficial to send related source documentation (e.g., discharge summary, radiology report) with the expedited report to the sponsor or it may be a requirement of the sponsor. These can help to explain the event, treatment, and support the differential diagnosis and/or investigator's attribution. All PII should be removed from the supporting documents and the unique study subject ID should be included. Follow the policy and procedure for the IRB or sponsor you are reporting to.

A few words about the "form"……

- NCI IRB: use PROTECT and the Reportable New Information (RNI) form to report an AE that is also an Unanticipated Problem – See *NIH IRB Researchers Guide* starting on pages 16-17.
- Sponsor: use sponsor specific form or database
    - CCR sponsored studies use the OSRO form – See OSRO forms website to access the Form, instructions and FAQs
    - CTEP sponsored studies use the CTEP-Adverse Event Reporting System (AERS) – See CTEP-AERS website for NCI guidelines and application. Note: some protocols may have AERS-RAVE integration which means that you will need to first create the AE in RAVE. This will be noted in the protocol section for expedited adverse event reporting.