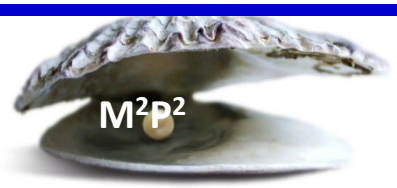

Monday Morning Practice Pearls #34

My patient has had labs drawn outside of the CC. What do I need to do as the research nurse besides ensuring that we get the results and they are scanned into CRIS?

There are basically 4 steps you need to perform for any outside labs results received that support protocol compliance or adverse event and their management. These need to be done in real time. The PSO Manager can help you.

1. Obtain copy of Clinical Laboratory Improvement Amendment Accreditation (CLIA) certificate
   a. Check this helpful link to search for a CLIA lab
      https://qcor.cms.gov/advanced_find_provider.jsp?which=4&backReport=active_CLIA.jsp
      OR
   b. Call the lab and ask for a copy
2. Obtain reference ranges
   a. When you get the lab results, make a copy
   b. Blacken all PII
   c. Scan and send to PSO Manger for uploading into the electronic regulatory file
3. Upload the lab report to CRIS
4. Work with PSO Manager to update FDA Form 1572 (if an IND study)

Why does this need to be done?

Laboratory Documents

As part of GCP guidelines (E6 4.9.4), laboratory documents are required for studies utilizing laboratory data or results. These documents ensure that all lab facilities being utilized are competent and the test results are reliable. There are 2 types of documents:

- Certifications
  - These can be state laboratory license/permit, an accreditation by the College of American Pathologists (CAP), or Clinical Laboratory Improvement Amendment Accreditation (CLIA).
- Laboratory Normal Ranges
  - Laboratory reference ranges may vary from laboratory to laboratory; therefore, it is necessary to include documentation of the laboratory's normal range values for the specific tests required in the study.

All updates to the certifications and laboratory ranges must also be maintained as long as the lab is being used.

Note: Research labs typically do not have lab certifications, e.g., CLIA, CAP, and may not have “normal” lab values.

Form 1572

Per the Form 1572, the Investigator is required to “identify clinical laboratories or testing facilities directly contributing to or supporting the clinical study (for example, diagnostic labs performing blood work, imaging centers, cardiology labs, etc.). This may include analytical labs that provide pharmacokinetic analysis, and laboratories supplying efficacy data for clinical investigations conducted under an Investigational New Drug Application (IND)”. So this is why the Form needs to be updated.