M²P²

Monday Morning Practice Pearls #41

What is the primary completion date (PCD) and the anticipated completion date (ACD)? Why are these dates important?

Background Information

ClinicalTrials.gov is a registry and results database of publicly and privately supported clinical studies conducted around the world. It was launched in 2000. Study registration and result reporting is required for certain types of clinical trials per Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801). The proposed NIH Policy will require that all clinical trials, even those who do not meet the FDAAA requirement, be registered with and have results reported in ClinicalTrials.gov.

Impact on the NIH Intramural Research Program (IRP)

The CC Office of Protocol Services (OPS) registers all the NIH IRP clinical trials to ClincalTrials.gov. Much of the information required for registration is obtained from the IRB protocol application and data entered in the CC PROTRAK Query System (PQS). However, the result reporting is done by the PI. For the CCR, Lisa King facilitates this process.

What determines when results are reported?

When a research protocol is registered with ClinicalTrials.gov, the primary completion date (PCD) and the study completion date (SCD) are required information. The dates are determined based on accrual rate and protocol activities and are fluid (i.e., they will need to be updated during the study). Results reporting occurs 1 year after the PCD.

Term	Definition
Primary Completion Date (PCD)	Date that the final subject will or was examined or received an intervention for the purposes collection of data for the primary outcome
Study completion date	Final date on which data was (or is expected to be) collected

What is the responsibility of the Research Coordinator related to the PCD and SCD?

- Know the dates submitted via PQS for the PCD and SCD
  - Work with PI and protocol support office manager to determine/confirm the PCD and SCD as requested
- Inform your protocol support office manager if the dates need to be changed.
- Remember that the dates are initially the best guesstimate and will need to be updated during the life of the protocol

Revised January 2023