



Monday Morning Practice Pearls #76

Who should be notified when a primary completion date (PCD) is met for one of my clinical trials?

It is the PI's responsibility to know when the PCD has been reached. The PSO Manager must be notified by the PI or designee within 30 days when the actual PCD is reached.

When a research protocol is registered with ClinicalTrials.gov by the Clinical Center (CC), an anticipated primary completion date (PCD) and study completion date (SCD) is 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). The dates are initially the best guesstimate and will need to be updated during the life of the protocol. The PCD is particularly important since results reporting occurs within 1 year of the actual PCD.

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

These two dates are submitted by PSO in the CC's PROTRAK Query System (PQS) which nightly feeds into clinicaltrials.gov.

The nightly feed into clinicaltrials.gov informs the OPS.

If you have any questions related to the PCD or need help in determining the actual date, please contact the [Office of Education and Compliance](#).

For more information on PCD, see [M2P2 #41](#) *What is the primary completion date (PCD) and the anticipated completion date (ACD)? Why are these dates important?*