Best Practice and Procedure

Management of Primary and Study Completion Dates in Institutional Clinical Trial Management System and on ClinicalTrials.gov

Susan Hmwe, City of Hope Comprehensive Cancer Center

Scott Patton, Stanford University

Meredith Rhodes, University of Wisconsin-Madison

Carlee Brueser, Duke University

Best Practice

- All clinical trials with a public ClinicalTrials.gov record are maintained in an Institutional Clinical Trial Management System (CTMS)
- There exists a CTMS report to determine: 1) Anticipated Primary Completion Date (PCD) and Study Completion Date (SCD) fields that are in the past, and 2) Studies that are Open to Accrual or Suspended and have not enrolled a participant in the past 9 months, triggering the study team to make updates based on the following formula:
    - PCD = Actual Study Start Date + Accrual Duration + Time Point where data collection is complete to answer the Primary Outcome
    - SCD = Actual Study Start Date + Accrual Duration + Time Point where data collection is complete from all enrolled participants per protocol
- Responsible Party / Institutional Protocol Registration and Results System (PRS) Administrator updates PCD and SCD in the ClinicalTrials.gov PRS for release to the public record based on CTMS

- For studies that have ClinicalTrials.gov records but completion dates are not maintained in an Institutional CTMS, PRS Administrators pull a monthly Planning Report to identify studies for which Anticipated PCD and SCD are pending in the next month to follow up with teams on the status of their study to update the ClinicalTrials.gov record as relevant.
- Use a 6-month verification process for ClinicalTrials.gov records that Require Results

Procedure

Purpose

The purpose of this Standard Operating Procedure (SOP) is to provide guidance for entering and updating the Primary Completion Date (PCD) and Study Completion Date (SCD) in an Institution's Clinical Trial Management System (CTMS) and the Protocol Registration and Results System (PRS) to maintain the public ClinicalTrials.gov record.

Procedure for PCD and SCD Update of Institutional CTMS and ClinicalTrials.gov Records

NOTE: this example shows an algorithm for a study in which primary outcome data is collected at 6 months and secondary outcome data is also collected at 6 months.

1) **Initial entry of Anticipated PCD and SCD in CTMS**
   - Prior to activating the study, relevant team member enters the initial Anticipated PCD and SCD into the CTMS based on the following formula:
     - [Date of Activation] + [Accrual Duration] + [6 months] = Anticipated PCD
     - [Date of Activation] + [Accrual Duration] + [6 months] = Anticipated SCD

2) **Update Anticipated PCD and SCD for studies with a current status of "Open to Accrual" or "Suspended"**
   - **Study Amendments:** For IRB-approved Protocol Amendments that change the accrual duration period, relevant team member updates the Anticipated PCD and SCD in the CTMS using the new accrual duration. This is applicable for all studies in the CTMS with a status of "Open to accrual" or "Suspended"
     - [Date of activation] + [**New** Accrual Duration] + [6 months] = Anticipated PCD

- [Date of activation] + [**New** Accrual Duration] + [6 months] = Anticipated SCD

- **Monthly PCD and SCD update options include:** CTMS Support team develops a PCD and SCD Verification Report to be sent monthly to the study team. This report will identify studies for which PCD and SCD dates need to be reviewed and updated in the CTMS. Relevant team member updates Anticipated PCD and SCD in the CTMS based on the following formula:
  - [Date of activation] + [Accrual Duration] + [6 months] = Anticipated PCD
  - [Date of activation] + [Accrual Duration] + [6 months] = Anticipated SCD

3) Update PCD and SCD for studies "Closed to Accrual"

- **Study "Closed to Accrual":** Prior to changing the study status in the CTMS to "Closed to Accrual", relevant team member verifies and updates the Anticipated PCD and SCD in the CTMS accordingly. Since the study is now "Closed to Accrual", the Anticipated PCD and SCD will follow a revised formula:
  - [Date of Last Enrollment] + [Time Frame for Primary Outcome Data Collection] = Anticipated PCD
  - [Date of Last of Enrollment] + [Time Frame for Secondary Outcome / Adverse Events Data Collection] = Anticipated SCD

4) Update PCD and SCD from Anticipated to Actual Upon Final Data Collection

- Confirm with Study Team (PI, Study Coordinator, Biostatistician) the dates of final data collection
- Update the Actual completion dates in the CTMS
  - Date primary outcome data collected from all enrolled participants = Actual PCD
  - Date data collection is complete from all enrolled participants = Actual SCD

5) **Institutional PRS Administrator / ClinicalTrials.gov Team:** Registers and Maintains completion dates in the PRS to align with the CTMS

- **PRS Administrator** will run a monthly Planning Report from the PRS
  - to identify records with Anticipated PCD and SCDs pending in the next month and reach out to study team members to the update PCD and SCD on the ClinicalTrials.gov record as necessary

- to ensure that studies requiring results are verified at 6 month intervals to ensure study teams will have the opportunity to request a Good Cause Extension for results should the study be Terminated early

Glossary

CTMS: Clinical Trial Management System - A software system used to manage clinical studies in an Institution's clinical research portfolio. A CTMS is designed to maintain and manage planning, performing, billing and reporting, maintain participant contact information, and track deadlines and milestones.

PCD: Primary Completion Date - Per final rule in 42 CFR 11.10(a), Primary Completion Date is defined as the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated. This means the last date *primary outcome measure data* are obtained from an enrolled participant.

PI: Principal Investigator

PRS: Protocol Registration and Results System

SCD: Study Completion Date - Per final rule in 42 CFR 11.10(a), Study Completion Date is defined as the date the final subject was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events, whether the clinical trial was concluded according to pre-specified protocol or was terminated. This means the last date *any study data* are obtained from an enrolled participant (may be the same as the primary completion date).

Document History

- 17 June 2022: initial draft written by Susan Hmwe, City of Hope
- 19 July 2022: review by Scott Patton, Stanford
- 22 August 2022: review by Meredith Rhodes, UW-Madison
- 31 August 2022: review by Carlee Brueser, Duke University
- 13 February 2023: edits by Susan Hmwe, City of Hope
- 15 February 2023: formatting by Meredith Rhodes, UW-Madison
- 5 September 2023: Accessibility Review by Meredith Rhodes, UW-Madison