



CLINICAL TRIALS REGISTRATION AND RESULTS REPORTING TASKFORCE

RECORD MAINTENANCE

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DISCLAIMER

This presentation represents the professional opinions of the contributors, based on their experience up to the present, April 2025. While every effort has been made to ensure accuracy, this content should not be considered definitive, and it is not intended to replace primary sources for ClinicalTrials.gov requirements.

GOT FEEDBACK?

- Help us improve these materials by answering our anonymous 2-question survey.



CHANGES THAT REQUIRE UPDATES WITHIN 30 DAYS OF EVENT OR IRB APPROVAL

- Study status (recruiting, active not enrolling, etc.)
- Intervention description changes
- Addition or subtraction of “Arms”
- Outcome Measures
- Enrollment Targets and actual enrollment once completed
- Inclusion/Exclusion Criteria
- ***Planned conclusion of data collection***



USING DETAILED DESCRIPTION FOR UPDATES

- If outcome measures are changing, update Detailed Description field
 - Publishers compare ClinicalTrials.gov records to what is being published. If major changes are happening to the focus, it's best to note them contemporaneously (once they receive IRB approval) in the Detailed Description free text field



SOME AMENDMENTS MAY BEGIN A NEW TRIAL!

Is your IRB application trying to cover one study or two?

Example:

Pilot study of Intervention X in 2 small arms

Amendment when federal funding is granted:

Clinical Trial of Interventions X + Y combined in new populations

This should be a new registration! (possibly with a new protocol and IRB ID #)

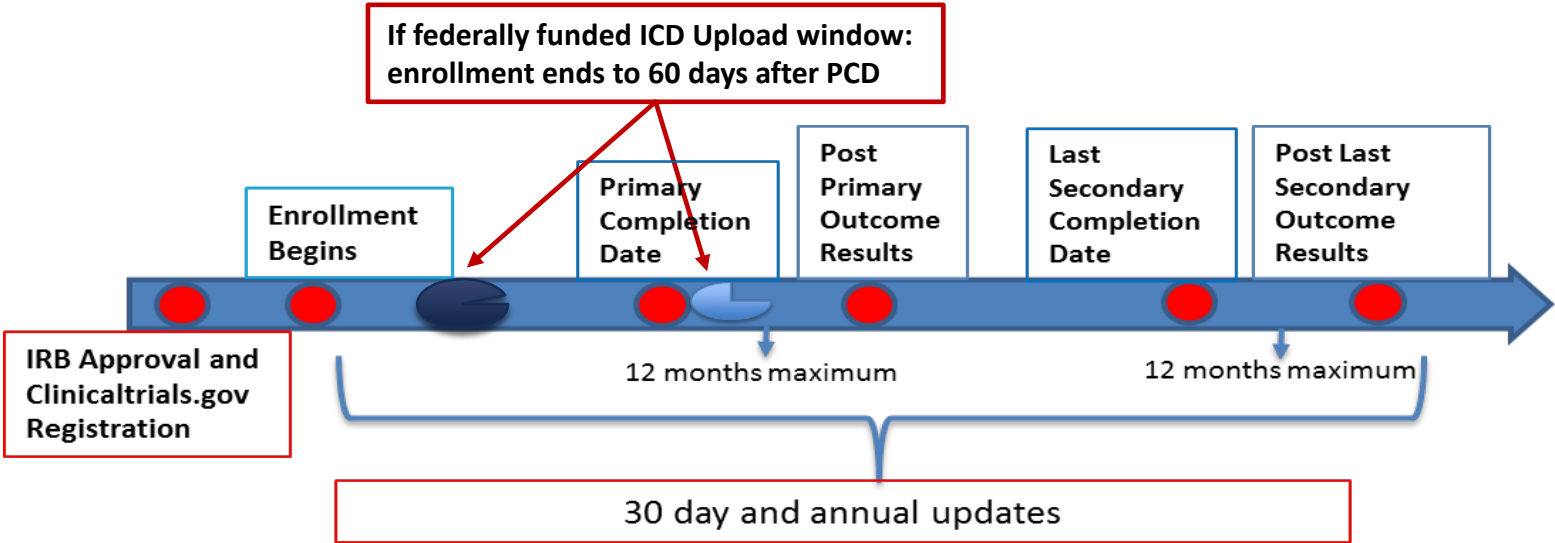


CRUCIAL TERMINOLOGY REGARDING DEADLINES AND UPDATES

- **Primary Completion Date (PCD):** final date of data collection for the (latest) primary outcome measure
- **Study Completion Date (SCD)** means the final date of data collection for (latest) secondary outcome measure and AEs
 - **NOTE:** neither of these match any particular date in IRB, except SCD may be related to when you are just “dealing with data”
- Annually, review anticipated PCD & SCD for accuracy
- When data collection is complete, update PCD and SCD to **actual** dates of last data collection

PCD & SCD AFFECT RESULTS DUE DATES!

PRS administrators can only send reminders based on what's in ClinicalTrials.gov.
If PCD is not updated, we could miss a regulatory deadline (to upload ICD if federal; to post results)





TEST YOUR SKILL

- Primary Outcome Measure Time Frame: 4 weeks after 1st dose
- Last Secondary Outcome Measure Time Frame 12 weeks after 1st dose
- If last consent and first dose was 9/3/2022, what should Anticipated PCD be?
(approx. 9/30/2022)
What should Anticipated SCD be?
(approx. 11/25/2022)
- By when does Actual Enrollment need to be updated?
(10/2/2022)



TERMINATED TRIALS HAVE PITFALLS

- **Terminated:** Study halted prematurely and permanently. Participants are no longer being examined – **Results will still be required**
 - Actual PCD and SCD should reflect last date any enrolled participant received treatment
 - If trial is terminated long after the last participant's treatment has ended (with hopes accrual would improve) then RP can request delay in results reporting, but **only prior to results deadline** (1 year after PCD)

TERMINATED TRIALS HAVE PITFALLS - EXAMPLE

The plan

- Recruit from July 2019 – July 2021
- All Primary and Secondary Outcome Measure data collected at time of enrollment
- Results expected to be due in July 2022 (one year after final data collection)

What actually happened

- Recruitment and data collection from July 2019 – March 2020
- Study activity was put on hold in March 2020 due to the COVID-19 pandemic
- Study was terminated in June 2021 due to lack of resources

Results were due in March 2021



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 - **If a trial is not active for 9 months or more, consider requesting an extension preemptively**