Monday Morning Practice Pearls #77

What is a Good Cause Extension (GCE) for reporting results in ClinicalTrials.gov?

There may be times when it is appropriate to request to extend the submission deadline for clinical trials results reporting to ClinicalTrials.gov. Examples that may be considered "Good Cause" include:

- Need to preserve scientific integrity of study for which data collection is ongoing (i.e., situation that would impair or otherwise bias the ongoing collection, analysis, and/or interpretation of data for secondary outcome(s).
- Emergencies that would prevent timely submission of clinical trial results information (i.e., data collection sites were affected by natural disasters)
- Reporting delays due to unexpected personal emergency circumstances (i.e., death or extended personal illness)

Examples that would be considered "Not Good Cause" include:

- Certification of delay should have been submitted rather than a good cause extension request.
- Awaiting journal publication: A study must report clinical trial results information even if the data have not yet been published.
- Pending FDA or other regulatory/health agency review (i.e., A study must report clinical trial results information even if the data are under FDA or other regulatory/health agency review)
- Ongoing data analysis without sufficient explanation (i.e., Analysis that is not yet complete, without further explanation, is not adequate justification for "good cause.")
- Events that might reasonably have been avoided (i.e., transition planning for key staff members who leave an organization)

What is the process to request a GCE?

- The PI (i.e., the Responsible Party [RP]) will discuss the request for a GCE with Lisa King
- PI will send Lisa an email and include:
    - a complete description of the reason(s) why clinical trial results information cannot be provided according to the deadline, with sufficient detail to justify good cause for the extension and to allow for the evaluation of the request.
    - an estimated date (month/day/year) on which the clinical trial results information will be submitted. Typically, 30 days after original results submission deadline.
- Lisa will email Dr. Gulley the extension justification and proposed deadline for approval.
- Once Dr. Gulley approves, Lisa will forward the email of approval along with the request for Dr. Chan's review via the OPS CC Scientific Review central mailbox, also including the extension justification and proposed deadline.
- OPS will then submit the extension request to Dr. Chan.

- Once Dr. Chan renders a decision Lisa will be notified by OPS.
- Lisa will notify the PI the request to submit a GCE is approved.
- Lisa will then submit the request through the ClinicalTrials.gov Protocol Registration and Results System (PRS) PRIOR to the date clinical trials results information is due (i.e., standard results submission deadline)
- The RP will be notified via email if GCE is approved or denied.
- There is an appeal process if denied.

Below is a scenario to illustrate the GCE request process:

- Last subject examined for primary outcome on April 4, 2022
- No additional participants accrued so in February 2023, PI requests 6-month extension to the results. That means the new PCD would be October 4, 2023 (i.e., April 4, 2023 + 6 months).
- GCE approved and anticipated PCD is pushed to October 4, 2023
- PI attempts to recruit additional participants
- No additional participant(s) are enrolled:
    - If no other participants are recruited, the anticipated PCD of October 4, 2023 is updated to actual PCD of April 24, 2022. Lisa will work with the PI to submit results. Because a 6-month extension was granted, PI has until October 4, 2023, to report results.
    - NOTE: PCD remains in the actual PCD in ClincialTrials.gov. The extension applies to the results reporting so no penalties incur.
    - It is possible to request a second extension for good cause.
- If additional participant(s) are enrolled:
    - PCD updated in ClinicalTrials.gov (by PSO) and marked as "Anticipated" (***requires PI to inform PSO of the change***)
    - Extension would now be void as one-year requirement resets.

IMPORTANT REMINDER: Please track your protocol accrual and primary completion date to help avoid a delay in reporting.