Best Practice

ClinicalTrials.gov Results Reporting Extensions and Delay Certification Requests

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Purpose

This document explains when and how an investigator can request an extension of the results submission deadline through a *good cause extension* (GCE) request or *delay certification*. Of these mechanisms, in general only GCE requests are available for academic investigator-initiated trials.

Background

For Applicable Clinical Trials (ACTs) and NIH-funded clinical trials in scope of the NIH Dissemination Policy, results must be submitted within 1 year of the trial's primary completion date (42 CFR 11.44(a)).

The ClinicalTrials.gov regulations provide for a delay of the results reporting requirement, either through a GCE request (42 CFR 11.44(e)), or when the Responsible Party is seeking approval of an FDA-regulated intervention (42 CFR 11.44(b), 42 CFR 11.44(c)).

Requests to delay results are available only for ACTs and for NIH-funded clinical trials in scope of the NIH Dissemination Policy because these are the only trials for which the 1-year submission deadline applies under US law and policy.

Strict timing requirements apply for submission of these requests (see *Timing*, below). Requests are submitted through the Protocol Registration and Results Reporting system (PRS; see *Submission*, below).

Delay Types

Good Cause Extension (GCE): A GCE may be requested for an ACT or NIH-funded clinical trial. The request must propose a new date by which results will be submitted and include an explanation that demonstrates why results cannot be submitted by the deadline.

For examples of good cause (and *not* good cause) see: *Clinical Trials Results Information Submission: Good Cause Extension Request Process and Criteria*.[1]

- This resource provides examples that *would* and *would not* be considered good cause.
- A pending publication is *not* considered to be good cause.

Delay certifications: For ACTs only, a 2-year delay certification may be submitted if the Responsible Party certifies they are filing (or intend to file) a marketing application to FDA for approval/clearance of a drug, biologic, or device that is being studied in the trial.

- *Certify Initial Approval* when seeking approval for a product that FDA has not yet approved or cleared for any use (e.g., indication or condition).
- *Certify New Use* when seeking approval for a new use of a product already approved or cleared by FDA for at least 1 use.

NOTE: The delay certification option is *not* available *if* the Responsible Party for the trial (e.g., academic investigator) is *different* than the organization that is seeking FDA approval (e.g., product manufacturer).

When and How to Request a GCE or Delay Certification

Timing: Extension requests and delay certifications must be submitted *at least 1 day prior* to the results expected date (i.e., *at least one day before* the primary completion date + 1 year).

PRS Administrators should continuously evaluate activity on ClinicalTrials.gov and discuss delay options with the investigator and research team if a trial is at risk of missing its results deadline.

Submission: To request an extension or delay certification:

1. Go to the *Record Summary* page of the ClinicalTrials.gov record.
2. Click *Delay Results.*
3. Click *Enter Delayed Results Information.*
4. Select the *Delayed Results Type.*
5. For extensions, enter the *Requested Submission Date* and (good cause) *Explanation.*
6. For delay certifications, enter the *Intervention Name(s)* and FDA application number, if available (e.g., NDA, BLA, or PMA number).
7. (Responsible Party) Submit the update to ClinicalTrials.gov for QC review.

ClinicalTrials.gov evaluates GCE requests on a case-by-case basis to determine whether the request constitutes "good cause." If denied, the Responsible Party may appeal the determination.

Best Practices

PRS Administrators should begin monitoring results due dates for all ACTs and NIH-funded clinical trials while the trials are still active to help ensure on-time results submission.

Studies at high risk for missing the GCE request deadline include:

- Studies with slow enrollment rates (potential to be terminated long after the last primary outcome measure data were collected).
- Studies with funding challenges (e.g., requesting no cost extensions or otherwise unsure of funding availability).
- For PRS Administrators with access to study data (e.g., in a Clinical trial Management System [CTMS]), if a study requiring results reporting has not enrolled a participant or collected data from any participant for about 9 months, contact to the study team to discuss study status and whether an extension request may be appropriate.

- Consider verifying study status with study teams every 6 months (versus every 12 months as required by ClinicalTrials.gov), particularly if PRS Administrators do not have access to study or enrollment data.

For completed studies, when PRS Administrators reach out to investigators and research teams to remind them of their results reporting requirements, they should:

- Include a statement that if the investigator believes that they may not be able to meet the deadline, they should reply to the email to discuss options.
- It is important to have a full discussion with investigators. For example, they may indicate that they wish to delay results reporting based on publication status, which is not a good cause explanation; however, further discussion may reveal an underlying problem that may qualify as good cause.

Glossary:

- **ACT:** Applicable Clinical Trial
- **BLA:** Biologics License Application
- **CTMS:** Clinical Trial Management System
- **FDA**: Food and Drug Administration
- **GCE:** Good Cause Extension
- **NDA:** New Drug Application
- **NIH:** National Institutes of Health
- **PMA:** Premarket Approval
- **PRS:** Protocol Registration and Results System
- **QC:** Quality Control

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