

Delayed Results

(Optional)

A responsible party may delay the deadline for submitting results information if one of the two certification conditions below applies to the clinical study and the certification is submitted prior to the date of (i.e., the day before) the standard submission deadline for results information. The standard submission deadline for results information is no later than 1 year after the ACT's primary completion date. Alternatively, the responsible party may request an extension of the results submission deadline for good cause if the request is submitted prior to the date (i.e., the day before) that results information would otherwise be due. The good cause extension request must be granted or denied by the NIH Director. Responsible parties may appeal denied requests or the NIH-identified earlier deadline specified in a granted extension request. [The Good Cause Extension Request Process and Criteria](#) (PDF; January 2024) explains to responsible parties the process of submitting a good cause extension request or appeal, the information to include in such requests, and the criteria NIH uses to evaluate such requests.

Delay Results Type [*]:

Select one

- **Certify Initial Approval:** Trial studies an FDA-regulated drug product (including a biological product) or device product that was not approved, licensed or cleared by FDA for any use before the Primary Completion Date of the trial, and the sponsor intends to continue with product development and is either seeking, or may at a future date seek, FDA approval, licensure, or clearance of the drug product (including a biological product) or device product under study.
- **Certify New Use:** Trial studies an FDA-regulated drug product (including a biological product) or device product that previously has been approved, licensed, or cleared, for which the manufacturer is the sponsor of the trial and for which an application or premarket notification seeking approval, licensure, or clearance of the use being studied (which is not included in the labeling of the approved, licensed, or cleared drug, product (including a biologic product) or device product) has been filed or will be filed within one year with FDA.
- Extension: Request, for good cause, an extension of the deadline for submitting results information

Note:

If a responsible party who is both the manufacturer of the drug product (including a biological product) or device product studied in an applicable clinical trial and the sponsor of the applicable clinical trial submits a certification under "Certify New Use," that responsible party must submit such a certification for each applicable clinical trial that meets the following criteria: (1) the applicable clinical trial is required to be

submitted in an application or premarket notification seeking approval, licensure, or clearance of a new use; (2) the applicable clinical trial studies the same drug product (including a biological product) or device product for the same use as studied in the applicable clinical trial for which the initial certification was submitted. [42 U.S.C. 282 (j)(3)(E)(v)(II) and 42 CFR 11.44(b)(3)]

Intervention Name(s)

Definition: Provide the name of one or more drugs, biological products or devices to which the certification applies. For drugs use generic name; for other types of interventions provide a brief descriptive name. The name(s) entered should match Intervention Name(s) provided in the protocol section.

FDA Application Number(s)

Definition: Provide at least one FDA application number (for example, NDA, BLA, or PMA number), if available, when Delay Results Type is "Certify Initial Approval" or "Certify New Use."

Classic PRS

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the ClinicalTrials.gov Protocol Registration and Results System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 03/31/2026
[Burden Statement](#)

NOTICE

The Modernized PRS is now the primary website for Protocol Registration. After logging in, you will be directed to the new website. The Classic PRS remains available for users who need to access features that have not yet been migrated to the Modernized PRS.

Organization:
One-word organization name assigned by PRS (sent via email when account was created)
Username:
Password: [Forgot password](#)

Login

See [How to Apply](#) on ClinicalTrials.gov for information on how to apply for a PRS account.
See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.
[Send email to ClinicalTrials.gov PRS Administration.](#)

[U.S. National Library of Medicine](#) | [U.S. National Institutes of Health](#) | [U.S. Department of Health & Human Services](#) | [HHS Vulnerability Disclosure](#)

OMB No: 0925-0586
EXPIRATION DATE: 03/31/2026

Public reporting burden for this collection of information is estimated to average from 15 minutes to 45 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a current valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0586). Do not return the completed form to this address.

Edit Delayed Results Information

[Definitions](#)

* Delay Results Type:	<input type="text" value="Certify Initial Approval"/>
Intervention Name(s):	<input type="text"/> <small>Specify the name of the intervention to which the Certify New Use or Certify Initial Approval applies. The name entered should match the Intervention Name in the Protocol Section.</small>
FDA Application Number(s):	Add Application Number <input type="text"/> <small>Provide an FDA application number (e.g., NDA, BLA, or PMA number), if available, when delay is due to certification for initial approval or new use.</small>
Requested Submission Date:	Not Applicable
Explanation:	Not Applicable

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

****Implementation of this feature is currently in progress for the Modernized PRS**