Attachment 6 – Certification to Delay Submission of Results Information

ClinicalTrials.gov Results Data Element Definitions for Interventional and Observational Studies

February 1, 2021

8. 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. The extension must be granted by the NIH Director.

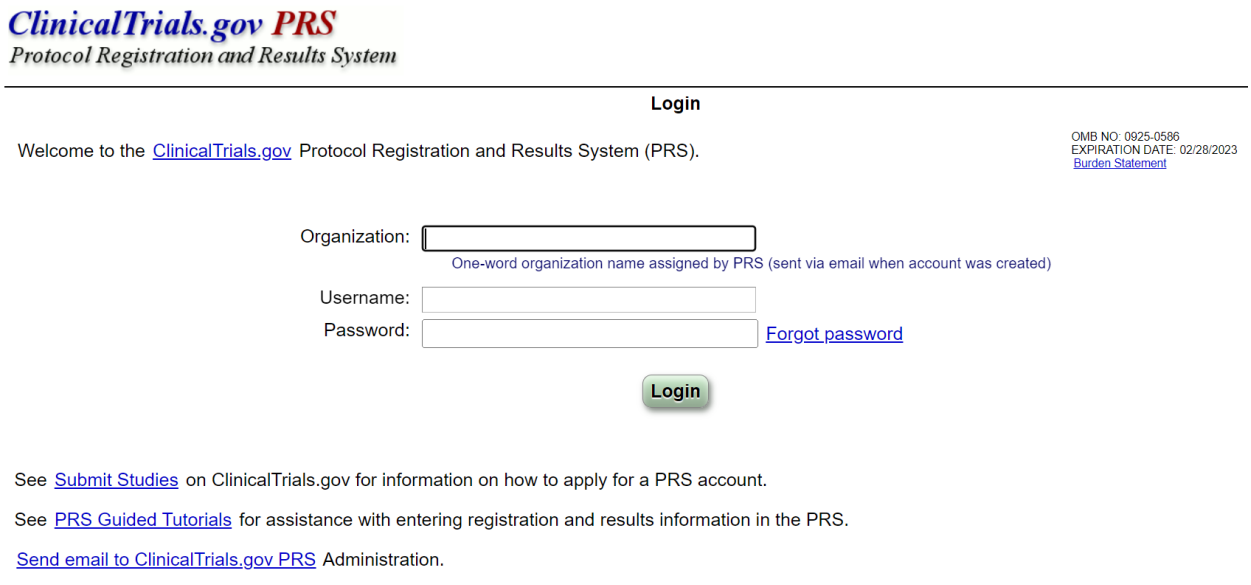
Delay Results Type [*] : Select one

- 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.

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."



OMB NO: 0925-0586
EXPIRATION DATE: 02/28/2023
Burden Statement

Public reporting burden for this collection of information is estimated to vary from 2.0 to 8.0 hours per response for registration, 10.0 to 45.0 hours per response for results information submissions, and 15 minutes to 2 hours for other submissions including certifications for delay, extension requests, and expanded access. These estimates include the time for reviewing instructions, searching existing data sources, gathering 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 currently 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

* Delayed Results Type:	Certify Initial Approval Certifications and extension requests must be submitted prior to (i.e., the day before) the results information submission would otherwise be due according to 42 CFR 11.44.
Intervention Name(s):	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.
FDA Application Number(s):	Add Application Number 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.
Requested Submission Date:	Not Applicable
Explanation:	Not Applicable

OK Validate Cancel Delete