Attachment 7 – Request for the Extension of the Results Information Submission Deadline

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.

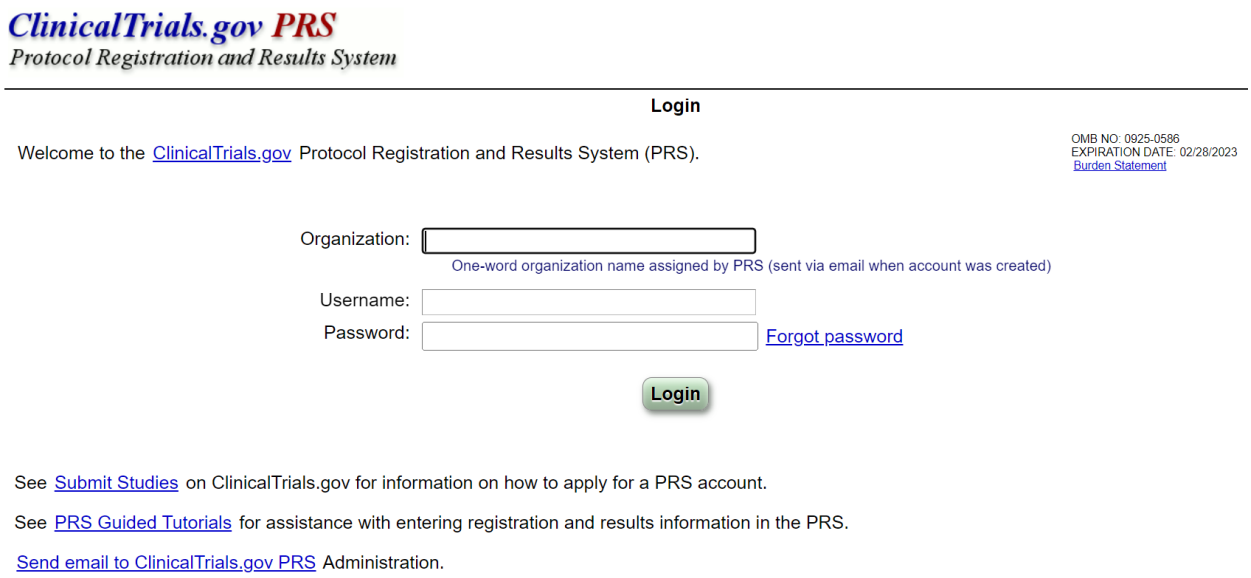
Delay Results Type [*] : Select one

- 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)]

Requested Submission Date [*] (*Required when Delay Results Type is "Extension."*)
Definition: Estimate of the date on which the clinical study results information will be submitted, if the Delay Results Type is "Extension".

Explanation [*] (*Required when Delay Results Type is "Extension."*)
Definition: Description of the reason(s) why clinical study 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. Note that "pending publication" and delays in data analysis for unspecified causes are not considered good cause for an extension.
Limit: 999 characters.



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:	Extension 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):	Not Applicable
FDA Application Number(s):	Not Applicable
Requested Submission Date:	Month: -- Please Select -- Year: * The estimated date on which the clinical trial results information will be submitted is required for good cause extension requests as specified in 42 CFR 11.44(e)
Explanation:	Characters remaining: 999 * Explanation is required when delay is due to extension.

OK Validate Cancel Delete