ClinicalTrials.gov Registration Data Element Definitions for Expanded Access

April 18, 2017

This document describes the definitions for registration data elements submitted to ClinicalTrials.gov for expanded access records. Such records provide information about investigational products that are made available through expanded access for patients who do not qualify for enrollment in a clinical trial. For investigational drug products (including biological products) this includes all expanded access types under section 561 of the Federal Food, Drug, and Cosmetic Act: (1) for individual patients, including emergency use; (2) for intermediate-size patient populations; and (3) under a treatment IND or treatment protocol.

Only one expanded access record should be created for any given investigational product, even if the investigational product is being made available for individual patient expanded access (that is, the responsible party should not create an expanded access record for each instance of individual patient access).These definitions for expanded access records are mostly adapted from 42 CFR Part 11.

Data element entries are annotated with symbols to indicate generally what information is required to be submitted (and under which circumstances). The responsible party must ensure that the information provided complies with any applicable laws, regulations, or policies. For more information about some of the relevant requirements, see Support Materials.

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* Required

*§ Required if initial submission date is on or after January 18, 2017

[*] Conditionally required

▼1. Study Identification

- **Unique Protocol Identification Number** *
  Definition: Any unique identifier assigned by the sponsor to refer to the availability of its investigational product for expanded access use or to identify the expanded access record.
  Limit: 30 characters.
- **Brief Title** *
  Definition: A short title identifying the expanded access, written in language intended for the lay public.
  Limit: 300 characters.

Acronym [*]
Definition: An acronym or abbreviation used publicly to identify the expanded access, if any.
Limit: 14 characters.

- **Official Title** [*] (*Optional if Expanded Access Type is "Individual Patients"*)
Definition: The title of the expanded access program corresponding to the title that has been submitted to the U.S. Food and Drug Administration (FDA) for that program, if any.
Limit: 600 characters.
- **Secondary ID** [*] (*Optional if Expanded Access Type is "Individual Patients"*)
Definition: An identifier(s) (ID), if any, other than the organization's Unique Protocol Identification Number or the NCT number that is assigned to the expanded access record. This includes any unique identifier assigned by other publicly available clinical trial or expanded access registries.
Limit: 30 characters.

  If there is a Secondary ID, then the following information must be provided:
  Limit: 119 characters.

  - **Secondary ID Type** [*]
  Definition: A description of the type of Secondary ID. Select one.

    - U.S. National Institutes of Health (NIH) Grant/Contract Award Number: In the Secondary ID field, include activity code, institute code, and 6-digit serial number. Other components of the full award number (type code, support year and suffix, if applicable) are optional.
    - Other Grant/Funding Number: Identifier assigned by a funding organization other than the U.S. NIH; also required to enter the name of the funding organization.
    - Registry Identifier: Number assigned by a clinical trial registry (for example, a registry that is part of the World Health Organization [WHO] Registry Network); also required to enter the name of the clinical trial registry.
    - EudraCT Number: Identifier assigned by the European Medicines Agency Clinical Trials Database (EudraCT).
    - Other Identifier: Also required to enter a brief description of the identifier (for example, name of organization that issued the identifier).
  - **Description** [*]
  Definition: If a Secondary ID Type of "Other Grant/Funding Number," "Registry Identifier," or "Other Identifier" is selected, provide the name of the funding organization, clinical trial registry, or organization that issued the identifier.
- **Study Type** *
Definition: The nature of the investigation or investigational use for which clinical study

information is being submitted. Select the "Expanded Access" menu item. (For more information on data requirements for Interventional or Observational Study Types, see Protocol Registration Data Element Definitions).

- Interventional: Participants are assigned prospectively to an intervention or interventions according to a protocol to evaluate the effect of the intervention(s) on biomedical or other health related outcomes.

- Observational: Studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Participants in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the study participants. This includes when participants receive interventions as part of routine medical care, and a researcher studies the effect of the intervention.

    - Patient Registry
      Definition: An observational study that is also considered to be a Patient Registry. This type of study should only be registered once in the PRS, by the sponsor responsible for the primary data collection and analysis.

      Note: The Agency for Healthcare Research and Quality (AHRQ) defines a Patient Registry as including an organized system that uses observational methods to collect uniform data (clinical and other) prospectively for a population defined by a particular disorder/disease, condition (including susceptibility to a disorder), or exposure (including products, health care services, and/or procedures) and that serves a predetermined scientific, clinical, or policy purpose. Patient registries may be single purpose or on-going data collection programs that address one or more questions.

- Expanded Access: An investigational drug product (including biological product) available through expanded access for patients who do not qualify for enrollment in a clinical trial. Expanded Access includes all expanded access types under section 561 of the Federal Food, Drug, and Cosmetic Act: (1) for individual patients, including emergency use; (2) for intermediate-size patient populations; and (3) under a treatment IND or treatment protocol.

    - **Expanded Access Type** * §
      Definition: The type(s) of expanded access for which the investigational drug product (including a biological product) is available, as specified in U.S. Food and Drug Administration (FDA) regulations. Select all that apply.
        - Not Applicable: Expanded access is for a product other than an investigational drug product (for example, device product) covered by FDA expanded access regulations (21 CFR 312)

- Individual Patients: For individual participants, including for emergency use, as specified in 21 CFR 312.310
- Intermediate-size Population: For intermediate-size participant populations, as specified in 21 CFR 312.315
- Treatment IND/Protocol: Under a treatment IND or treatment protocol, as specified in 21 CFR 312.320

▼2. Study Status

- **Record Verification Date** *
  Definition: The date on which the responsible party last verified the information in the entire expanded access record, even if no additional or updated information is being submitted.

Expanded Access Status *
Definition: The status of availability of the investigational drug product (including a biological product) through expanded access. Select one.

- Available: Expanded access is currently available.
- No longer available: Expanded access was available previously but is not currently available and is not expected to be available in the future.
- Temporarily not available: Expanded access was previously available, is not currently available, but is expected to be available in the future.
- Approved for marketing: Expanded access was available previously, but is not currently available because the product has been approved, licensed, or cleared by the U.S. Food and Drug Administration.

▼3. Sponsor/Collaborators

Responsible Party, by Official Title *
Definition: An indication of whether the responsible party is the sponsor, the sponsor-investigator, or a principal investigator designated by the sponsor to be the responsible party. Select one.

- Sponsor: The entity (for example, corporation or agency) that initiates the study
- Principal Investigator: The individual designated as responsible party by the sponsor (see Note)
- Sponsor-Investigator: The individual who both initiates and conducts the study

Note: The sponsor may designate a principal investigator as the responsible party if such principal investigator meets all of the following requirements: is responsible for conducting the

study; has access to and control over the data from the study; has the right to publish the results of the study; and has the ability to meet all of the requirements for submitting and updating clinical study information.

Investigator Information [*]
If the Responsible Party, by Official Title is either "Principal Investigator" or "Sponsor-Investigator," the following is required:

- **Investigator Name**: Name of the investigator, including first and last name
- **Investigator Official Title**: The official title of the investigator at the primary organizational affiliation
  Limit: 254 characters.
- **Investigator Affiliation**: Primary organizational affiliation of the individual
  Limit: 160 characters.

Name of the Sponsor *
Definition: The name of the entity that is the sponsor of the expanded access
Limit: 160 characters.

Note: When a clinical study is conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE holder is considered the sponsor.

Collaborators
Definition: Other organizations (if any) providing support, including funding, design, implementation, data analysis and reporting. The responsible party is responsible for confirming all collaborators before listing them.
Limit: 160 characters.

▼4. Oversight

- **Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information**
  Definition: Complete the following information regarding an IND or IDE for the expanded access as defined under U.S. Food and Drug Administration (FDA) regulations in 21 CFR 312.3 or 21 CFR 812, respectively.

- **U.S. Food and Drug Administration IND or IDE** *
  Definition: Indicate whether there is an IND or IDE for the expanded access. Select Yes/No.(*Will not be made public - for administrative purposes only*)

  If the investigational product is being made available for expanded access under an IND or IDE, the following are required:

  -

- **FDA Center** [*]
  Definition: The name or abbreviation of the FDA center with which the IND or IDE is filed. Select one. (*Will not be made public - for administrative purposes only.*)
  - CDER: Center for Drug Evaluation and Research
  - CBER: Center for Biologics Evaluation and Research
  - CDRH: Center for Devices and Radiological Health

  IND or IDE Number [*]
  Definition: IND or IDE number assigned by the FDA center. (*Will not be made public - for administrative purposes only.*)

  IND Serial Number [*]
  Definition: For an IND, the IND serial number, as defined in 21 CFR 312.23(e), if any, assigned to the expanded access. (*Will not be made public - for administrative purposes only.*)

5. Study Description

- **Brief Summary** *
  Definition: A short description of the availability of expanded access, including the procedure for requesting the investigational product.
  Limit: 5000 characters.

- **Detailed Description**
  Definition: Extended description of the expanded access, including more technical information (as compared to the Brief Summary), if desired. Do not duplicate information recorded in other data elements, such as Eligibility Criteria.
  Limit: 32,000 characters.

6. Conditions and Keywords

- **Conditions or Focus of Study** [*] (*Optional if Expanded Access Type is "Individual Patients"*)
  Definition: The name(s) of the disease(s) or condition(s) for which expanded access to the investigational product is available. Use, if available, appropriate descriptors from NLM's Medical Subject Headings (MeSH)-controlled vocabulary thesaurus, or terms from another vocabulary, such as the Systematized Nomenclature of Medicine—Clinical Terms (SNOMED CT), that has been mapped to MeSH within the UMLS Metathesaurus.

  Keywords
  Definition: Words or phrases that best describe the expanded access. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH)-

controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

▼7. Interventions

- **Interventions**
  Definition: Specify the investigational product available for expanded access.

  - **Intervention Type** *
    Definition: For the investigational product for which expanded access is available, the general type of intervention. Select one.

    - Drug: Including placebo
    - Device: Including sham
    - Biological/Vaccine
    - Procedure/Surgery
    - Radiation
    - Behavioral: For example, psychotherapy, lifestyle counseling
    - Genetic: Including gene transfer, stem cell and recombinant DNA
    - Dietary Supplement: For example, vitamins, minerals
    - Combination Product: Combining a drug and device, a biological product and device; a drug and biological product; or a drug, biological product, and device
    - Diagnostic Test: For example, imaging, in vitro
    - Other

  - **Intervention Name(s)** *
    Definition: A brief descriptive name used to refer to the investigational product that is available through expanded access. A non-proprietary name of the intervention must be used, if available. If a non-proprietary name is not available, a brief descriptive name or identifier must be used.
    Limit: 200 characters.

  - **Other Intervention Name(s)** [*] (*Optional if Expanded Access Type is "Individual Patients"*)
    Definition: Other current and former name(s) or alias(es), if any, different from the Intervention Name(s), that the sponsor has used publicly to identify the intervention, including, but not limited to, past or present names such as brand name(s), or serial numbers.
    Limit: 200 characters.

- **Intervention Description** [*] (*Optional if Expanded Access Type is "Individual Patients"*)
  Definition: Details that can be made public about each intervention, other than the Intervention Name(s) or Other Intervention Name(s), sufficient to distinguish the intervention from other, similar interventions that are available through expanded access or in clinical studies.
  Limit: 1000 characters.

▼8. Eligibility

- **Sex/Gender** [*] (*Optional if Expanded Access Type is "Individual Patients"*)
  Definition: The sex and, if applicable, gender of the patients for whom expanded access is available.

  - **Sex** [*]
    Definition: The sex of the patients who may obtain expanded access to the investigational product. Select one.

    Note: "Sex" means a person's classification as male or female based on biological distinctions.

    - All: Indicates that expanded access is not limited based on the sex of patients
    - Female: Indicates that only female patients may obtain expanded access
    - Male: Indicates that only male patients may obtain expanded access

  - **Gender Based** [*]
    Definition: If applicable, indicate whether expanded access availability is based on gender of the patient. Select one.

    Note: "Gender" means a person's self-representation of gender identity.

    - Yes: Expanded access availability is based on gender
    - No: Expanded access availability is not based on gender

    - **Gender Eligibility Description** [*]
      Definition: If expanded access availability is based on gender, provide descriptive information about gender criteria.

- **Age Limits** [*] (*Optional if Expanded Access Type is "Individual Patients"*)
  Definition: The minimum and maximum age of patients eligible for the expanded access, provided in relevant units of time.
  - **Minimum Age** [*]
    Definition: The numerical value, if any, for the minimum age a patient must meet to be eligible for the expanded access.
  - **Unit of Time** [*]
    Select one.
    - Years
    - Months
    - Weeks
    - Days
    - Hours
    - Minutes
    - N/A (No limit)
  - **Maximum Age** [*]
    Definition: The numerical value, if any, for the maximum age a patient can be to be eligible for the expanded access.
  - **Unit of Time** [*]
    Select one.
    - Years
    - Months
    - Weeks
    - Days
    - Hours
    - Minutes
    - N/A (No limit)

- **Eligibility Criteria** [*] (*Optional if Expanded Access Type is "Individual Patients"*)
  Definition: A limited list of criteria for determining who is eligible to receive the investigational product through expanded access, provided in terms of inclusion and exclusion criteria and suitable for assisting potential patients in identifying investigational products of interest for which expanded access is available.
  Limit: 15,000 characters.

▼9. Contacts, Locations, and Investigator Information

- **Central Contact Person** *
  Definition: The name or official title, toll-free telephone number, and email address of a person to whom questions concerning expanded access can be addressed. Include the following information:

  - **First Name**
  - **Middle Initial**
  - **Last Name or Official Title** *
  - **Degree**
  - **Phone**: * Toll free phone number of the Central Contact Person. Use the format 800-555-5555 within the United States and Canada. If outside the United States and Canada, provide the full phone number, including the country code.
  - **Ext**: Phone extension, if needed
  - **Email**: * Electronic mail address of the central contact person

- **Central Contact Backup**
  Definition: Person to contact if Central Contact is not available. Include the following information:

  - **First Name**
  - **Middle Initial**
  - **Last Name or Official Title**
  - **Degree**
  - **Phone**: Toll free phone number of the Central Contact Backup. Use the format 800-555-5555 within the United States and Canada. If outside the United States and Canada, provide the full phone number, including the country code.
  - **Ext**: Phone extension, if needed
  - **Email**: Electronic mail address of the contact person

- **Overall Study Officials**
  Definition: Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator. Include the following information:

  - **First Name**
  - **Middle Initial**
  - **Last Name**
  - **Degree**

- **Organizational Affiliation**: Full name of the official's organization. If none, specify Unaffiliated.
  Limit: 255 characters.
- **Official's Role**: Position or function of the official. Select one.
  - Study Chair
  - Study Director
  - Study Principal Investigator

- **Facility Information**
  Definition: For each facility participating in providing expanded access to an investigational product, the following information:

  - **Facility Name**: * § Full name of the organization where expanded access is available
    Limit: 254 characters.
  - **City**: *
  - **State/Province**: * Required for U.S. locations (including territories of the United States)
  - **ZIP/Postal Code**: * § Required for U.S. locations (including territories of the United States)
  - **Country** *

  Facility Contact
  Definition: For each facility participating in in providing expanded access to an investigational drug product, the following information:

  - **First Name**
  - **Middle Initial**
  - **Last Name or Official Title**
  - **Degree**
  - **Phone**: Office phone of the facility contact person.
  - **Ext**: Phone extension, if needed
  - **Email**: Electronic mail address of the facility contact person

- **Facility Contact Backup**
  Definition: Person to contact if Facility Contact is not available (that is, a second contact person).

- **Investigators** (at the expanded access location). Including the following information:

    - **First Name**
    - **Middle Initial**
    - **Last Name**
    - **Degree**
    - **Role**: Select one.
        - Site Principal Investigator
        - Site Sub-Investigator

- Contact information character limits:

    - First Name: 62 characters
    - Last Name: 62 characters
    - Degree: 30 characters
    - Phone: 30 characters
    - Phone Ext: 14 characters
    - Email: 254 characters

▼10. References

- **Citations**
  Definition: Citations to publications related to the expanded access: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.
  Limit: 2000 characters.

    - **PubMed Identifier**
      Definition: PMID for the citation in MEDLINE

    - **Citation**
      Definition: A bibliographic reference in NLM's MEDLINE format
      Limit: 2000 characters.

    - **Results Reference?**
      Definition: Indicate if the reference provided reports on results from this expanded access. Select Yes/No.

Links
Definition: A web site directly relevant to the expanded access may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

- **URL**
  Definition: Complete URL, including http:// or https://
  Limit: 3999 characters.

  Description
  Definition: Title or brief description of the linked page.
  Limit: 254 characters.

Responsible Party Contact Information * § (*Provided as part of User Information or Organization Information in a PRS Account*)
Definition: Administrative information to identify and enable communication with the responsible party by telephone, email, and regular mail or delivery service. Responsible Party Contact Information is for the individual who is the responsible party or of a designated employee of the organization that is the responsible party. (*Will not be made public - for administrative purposes only*.)

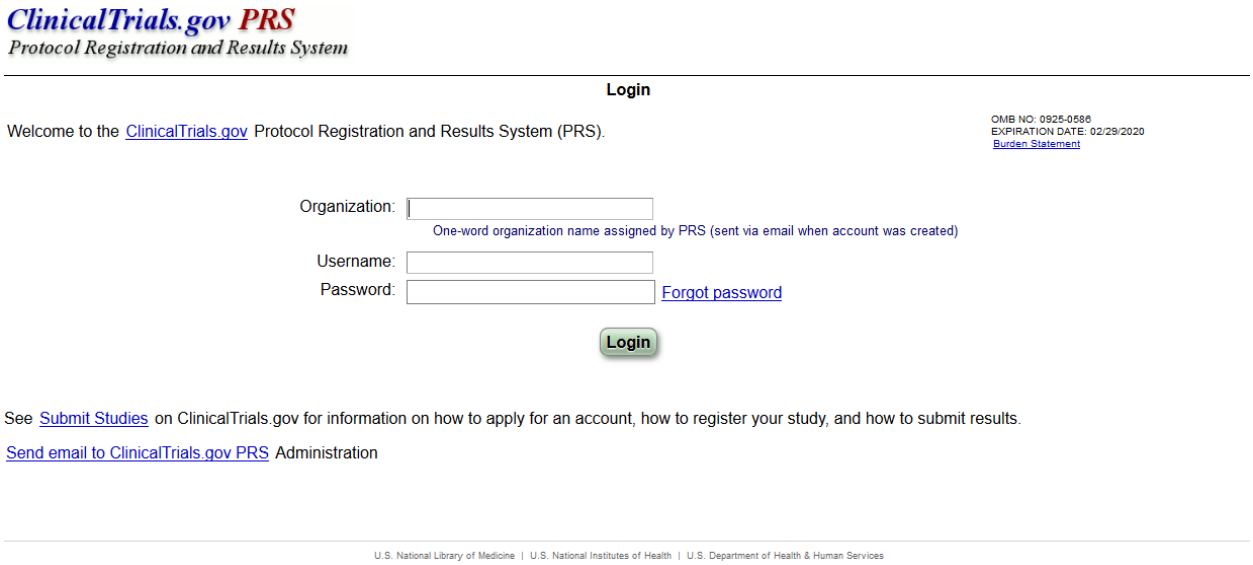
Note: "Responsible party" means with respect to a clinical study, the sponsor of the clinical study, as defined in 21 CFR 50.3; or the principal investigator of such clinical study if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the study, has access to and control over the data from the clinical study, has the right to publish the results of the study, and has the ability to meet all of the requirements for the submission of clinical study information. For a pediatric postmarket surveillance of a device product that is not a clinical trial, the responsible party is the entity who FDA orders to conduct the pediatric postmarket surveillance of the device product.

- Name of Individual *
- Official Title *
- Physical Address *
  - Name of Organizational Affiliation *
  - Street Address *
  - City *
  - State/Province *
  - ZIP/Postal Code *
  - Country *

- Mailing Address * (*If different from Physical Address*)
  - Name of Organizational Affiliation *
  - Street Address *
  - City *
  - State/Province *
  - ZIP/Postal Code *
  - Country *
- Phone: * Use the format 800-555-5555 within the United States and Canada. Otherwise, provide the full number, including the country code.
- Ext: Phone extension, if needed
- Email: * Electronic mail address

▼History of Changes

- 2017-01-18: Document updated with data element changes per the FDAAA 801 final rule (42 CFR Part 11).
- 2017-04-18: Formatting and typographical errors were corrected.



OMB NO: 0925-0586
EXPIRATION DATE: 02/29/2020
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 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.

Create New Record

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. **Studies may only be registered by the Responsible Party.** The Responsible Party for a clinical study is the Sponsor, Sponsor-Investigator, or Sponsor-designated Principal Investigator who meets specific requirements.
   - When a study is subject to U.S. Food and Drug Administration regulations and conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE Holder is considered the Sponsor or Sponsor-Investigator.
   - When a study is not conducted under an IND or IDE, the entity or single person who initiates the study, by preparing and/or planning the study, and who has authority and control over the study, is considered the Sponsor or Sponsor-Investigator.
2. **Use the PRS account of the Sponsor or Sponsor-Investigator to register the study.** If the Sponsor has designated the Principal Investigator to be the Responsible Party for a study, that study must be registered using the PRS account of the Sponsor.
3. **Multi-site studies are NOT registered by individual sites.** If this is a multi-site study it must be registered only once, by the Responsible Party (IND/IDE holder or the person or organization who initiates the study and who has authority and control over the study) or its designated principal investigator (PI).
4. **Coordinate with all collaborators before registering.** If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization (or designated PI), as Responsible Party is registering the study.
5. **Refer to the ClinicalTrials.gov Review of Protocol Submissions document** for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.

Help Definitions

* Organization's Unique Protocol ID:

* Brief Title:

Special Characters

[*] Acronym: (if any)

If specified, will be included at end of Brief Title in parentheses.

* Study Type:

- Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol
- Observational participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care
- Expanded Access availability of an experimental drug or device outside of a clinical trial protocol

Type:
- ☐ Not Applicable
- ☐ Individual Patients
- ☐ Intermediate-size Population
- ☐ Treatment IND/Protocol

Check all that apply.

Check "Not Applicable" if expanded access does not involve a U.S. FDA-regulated drug product.

ClinicalTrials.gov Registration Data Element Definitions for Expanded Access Records

Continue Cancel

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

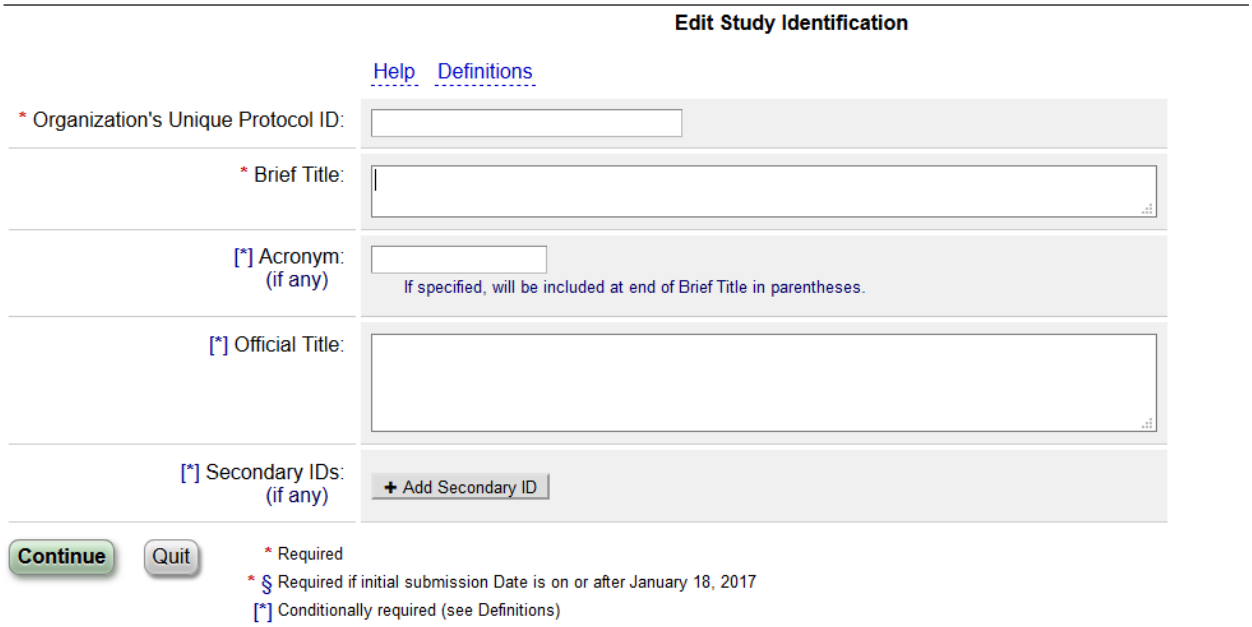
The following web pages allow data entry for each protocol module:

- Study Identification
- Study Status
- Sponsor/Collaborators
- Oversight
- Description
- Conditions
- Study Design
- Groups and Interventions
- Outcome Measures
- Eligibility
- Contacts/Locations
- References

On each page, select Continue to save data entered and proceed to the next page.

On any page, select Quit to stop entering data. Data entered on previous pages will be retained. To complete data entry later, open the record from the home page.

OK



Edit Study Identification

Help Definitions

* Organization's Unique Protocol ID:

* Brief Title:

[*] Acronym: (if any)
If specified, will be included at end of Brief Title in parentheses.

[*] Official Title:

[*] Secondary IDs: (if any)
+ Add Secondary ID

Continue Quit

* Required
* § Required if initial submission Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

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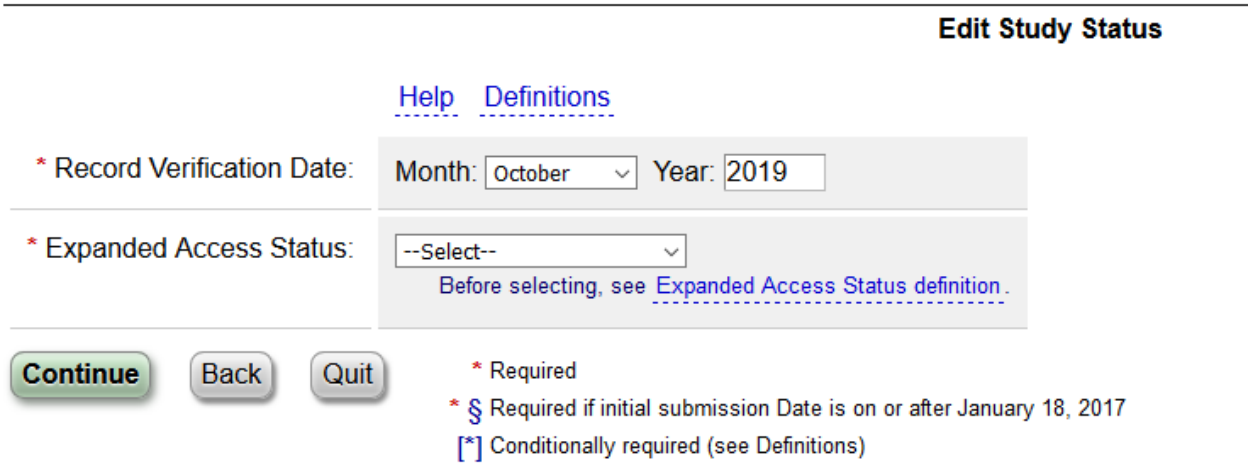


Edit Study Status

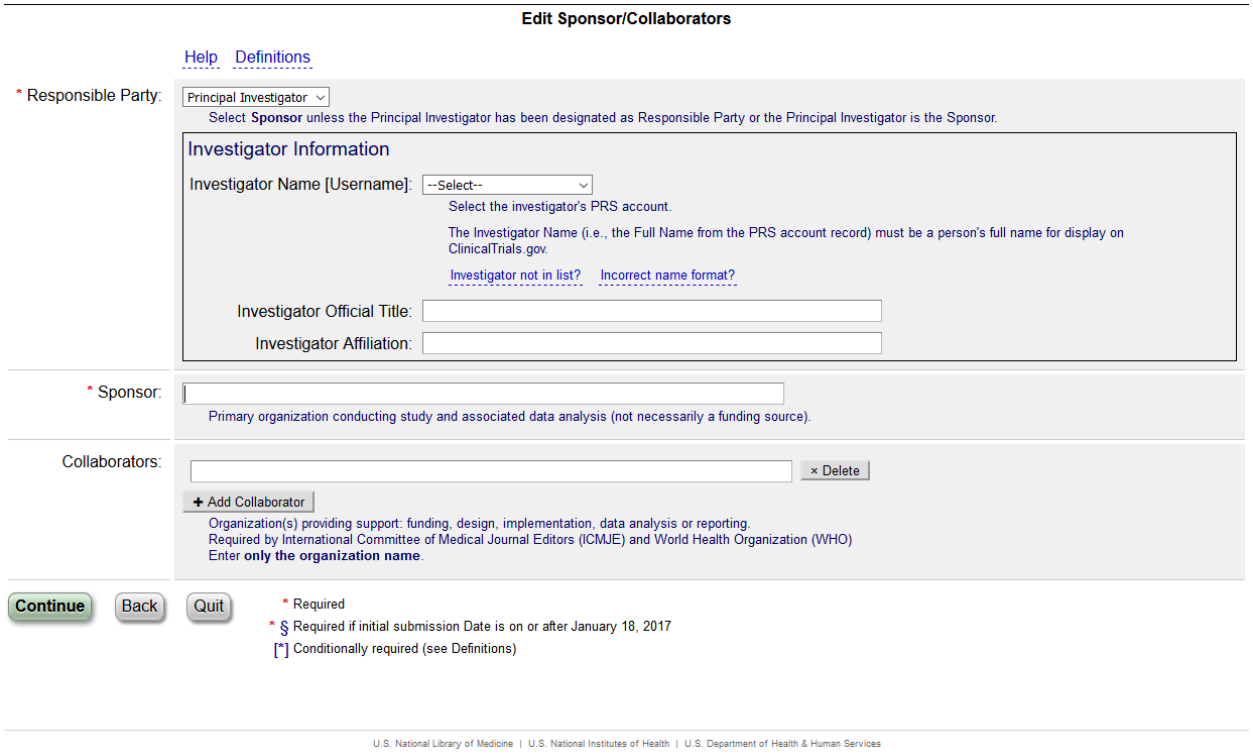
Help Definitions

* Record Verification Date: Month: October Year: 2019

* Expanded Access Status: --Select--
Before selecting, see Expanded Access Status definition.

Continue Back Quit

* Required
* § Required if initial submission Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)



Edit Sponsor/Collaborators

Help Definitions

* Responsible Party: Principal Investigator

Select **Sponsor** unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.

Investigator Information

Investigator Name [Username]: --Select--

Select the investigator's PRS account.

The Investigator Name (i.e., the Full Name from the PRS account record) must be a person's full name for display on ClinicalTrials.gov.

Investigator not in list? Incorrect name format?

Investigator Official Title:

Investigator Affiliation:

* Sponsor:

Primary organization conducting study and associated data analysis (not necessarily a funding source).

Collaborators: × Delete

+ Add Collaborator

Organization(s) providing support: funding, design, implementation, data analysis or reporting.
Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO)
Enter **only the organization name**.

Continue Back Quit

* Required
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[*] Conditionally required (see Definitions)

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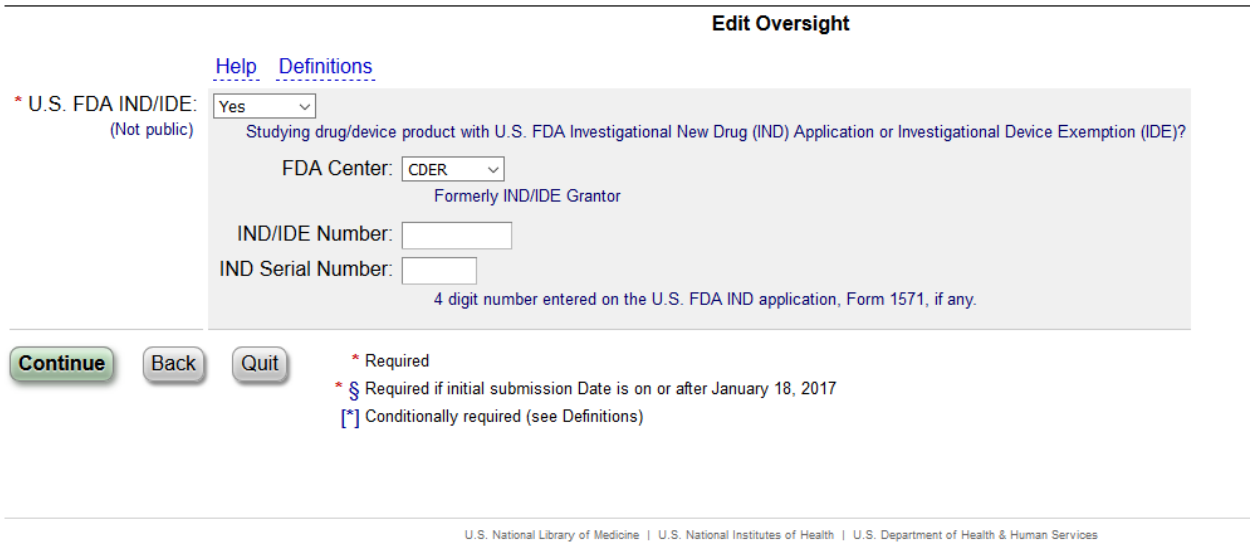

Edit Oversight

Help Definitions

* U.S. FDA IND/IDE: Yes
(Not public)

Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

FDA Center: CDER

Formerly IND/IDE Grantor

IND/IDE Number:

IND Serial Number:

4 digit number entered on the U.S. FDA IND application, Form 1571, if any.

Continue Back Quit

* Required
* § Required if initial submission Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

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Edit Study Description

Help Definitions

* Brief Summary:

Special Characters

Detailed Description:

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

Continue Back Quit

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[*] Conditionally required (see Definitions)

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Edit Conditions

Help Definitions

[*] Conditions or Focus of Study: × Delete

Search MeSH, the National Library of Medicine's Medical Subject Headings, for valid condition terms.

If there are no conditions under study, enter brief description of focus of study instead.

+ Add Condition

Keywords: + Add Keyword

Continue Back Quit

* Required
* § Required if initial submission Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Interventions

Help Definitions

Interventions:

* Intervention Type: --Select--

* Intervention Name:

For a drug, use generic name if established.
Use the same name as in the associated Arm/Group Description(s).

[*] Other Intervention Names: (if any) × Delete

+ Add Other Name

Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.

[*] Intervention Description:

Do not repeat information already included in arm/group descriptions.

× Delete Intervention

+ Add Intervention

Continue Back Quit

* Required
* § Required if initial submission Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Eligibility

Help Definitions

[*] Sex: --Select--

Biological sex of eligible participants.

[*] Gender Based: Yes

If applicable, indicate if participant eligibility is based on self-representation of gender identity.

Gender Eligibility Description:

[*] Age Limits: Minimum: --Select-- Maximum: --Select--

[*] Eligibility Criteria:

Inclusion Criteria:
-

Exclusion Criteria:
-

Special Characters

Continue Back Quit

* Required
* § Required if initial submission Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Overall Contacts

Help Definitions

* Central Contact Person: First Name: MI: Last Name: Degree: Phone: Ext: Email:

The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Central Contact Backup: First Name: MI: Last Name: Degree: Phone: Ext: Email:

Overall Study Officials: + Add Study Official

Save Cancel

* Required
* § Required if initial submission Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Edit Location

Help Definitions

* Facility: Name: City: State/Province: Maryland ZIP/Postal Code: Country: United States

Facility Contact: First Name: MI: Last Name: Degree: Phone: Ext: Email:

Facility Contact Backup: First Name: MI: Last Name: Degree: Phone: Ext: Email:

The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Investigators: + Add Investigator

Save Cancel

* Required
* § Required if initial submission Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

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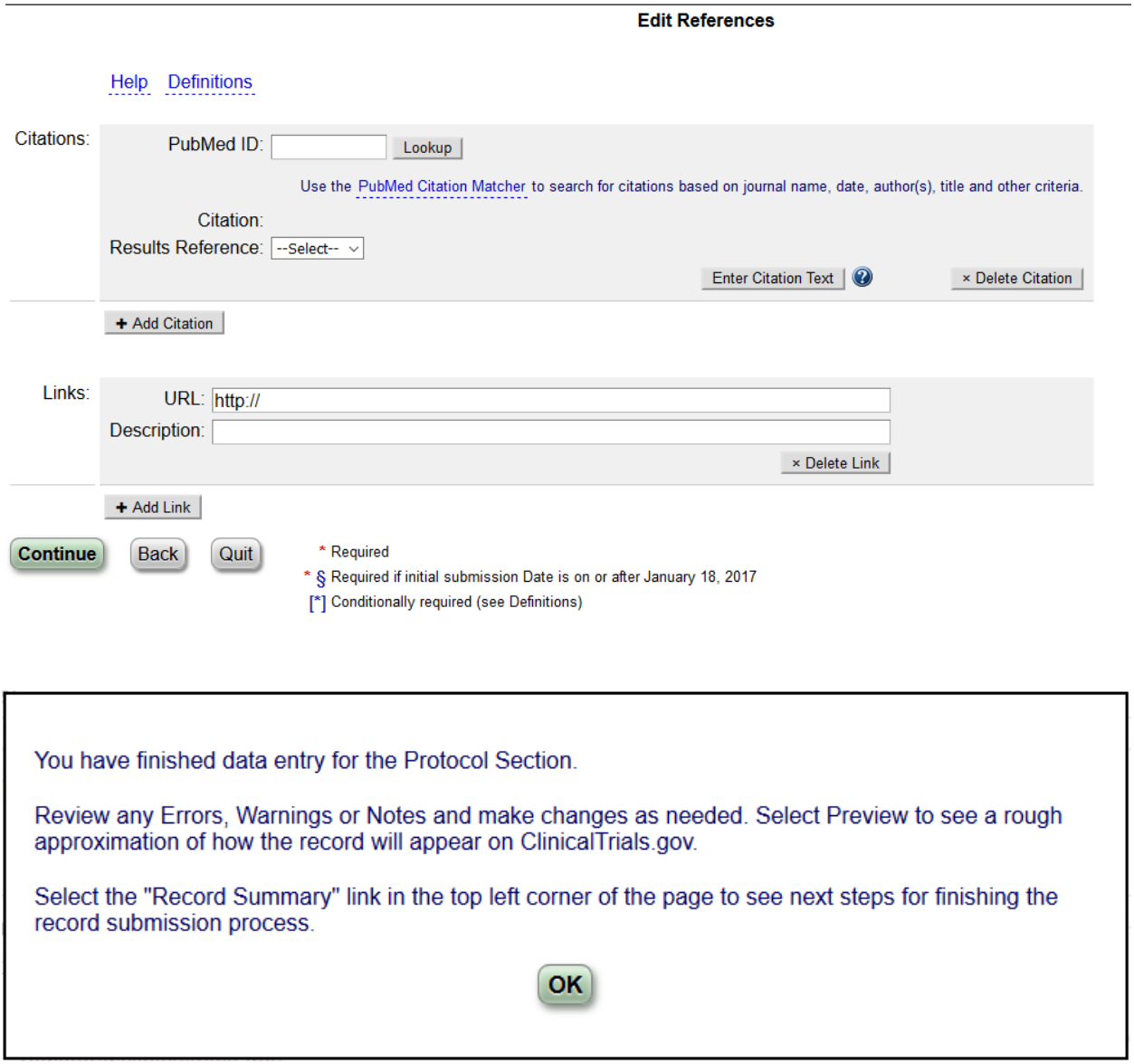
Edit References
Help Definitions
Citations:
PubMed ID:
Lookup
Use the PubMed Citation Matcher to search for citations based on journal name, date, author(s), title and other criteria.
Citation:
Results Reference:
--Select--
Enter Citation Text
× Delete Citation
+ Add Citation
Links:
URL: http://
Description:
× Delete Link
+ Add Link
Continue
Back
Quit
* Required
* § Required if initial submission Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

You have finished data entry for the Protocol Section.
Review any Errors, Warnings or Notes and make changes as needed. Select Preview to see a rough approximation of how the record will appear on ClinicalTrials.gov.
Select the "Record Summary" link in the top left corner of the page to see next steps for finishing the record submission process.
OK