Expanded Access Data Element Definitions

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 and Training Materials.

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*	Required
*§	Required if initial submission date is on or after January 18, 2017
[*]	Conditionally required
No symbol	Data element optional by ClinicalTrials.gov

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).

- EU Trial (CTIS) Number: Identifier assigned by the European Union (EU) and European Economic Area (EEA).
- 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

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.

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.

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.*)

Study Description

Brief Summary *

Definition: A short description of the availability of expanded access, including the procedure for requesting the investigational product.
Limit: 5,000 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.

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.

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: 1,000 characters.

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: 20,000 characters.

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 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

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: 2,000 characters.

PubMed Identifier

Definition: PMID for the citation in MEDLINE

Citation

Definition: A bibliographic reference in NLM's MEDLINE format
Limit: 2,000 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: 3,999 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

January 18, 2017: Document updated with data element changes per the FDAAA 801 final rule (42 CFR Part 11).

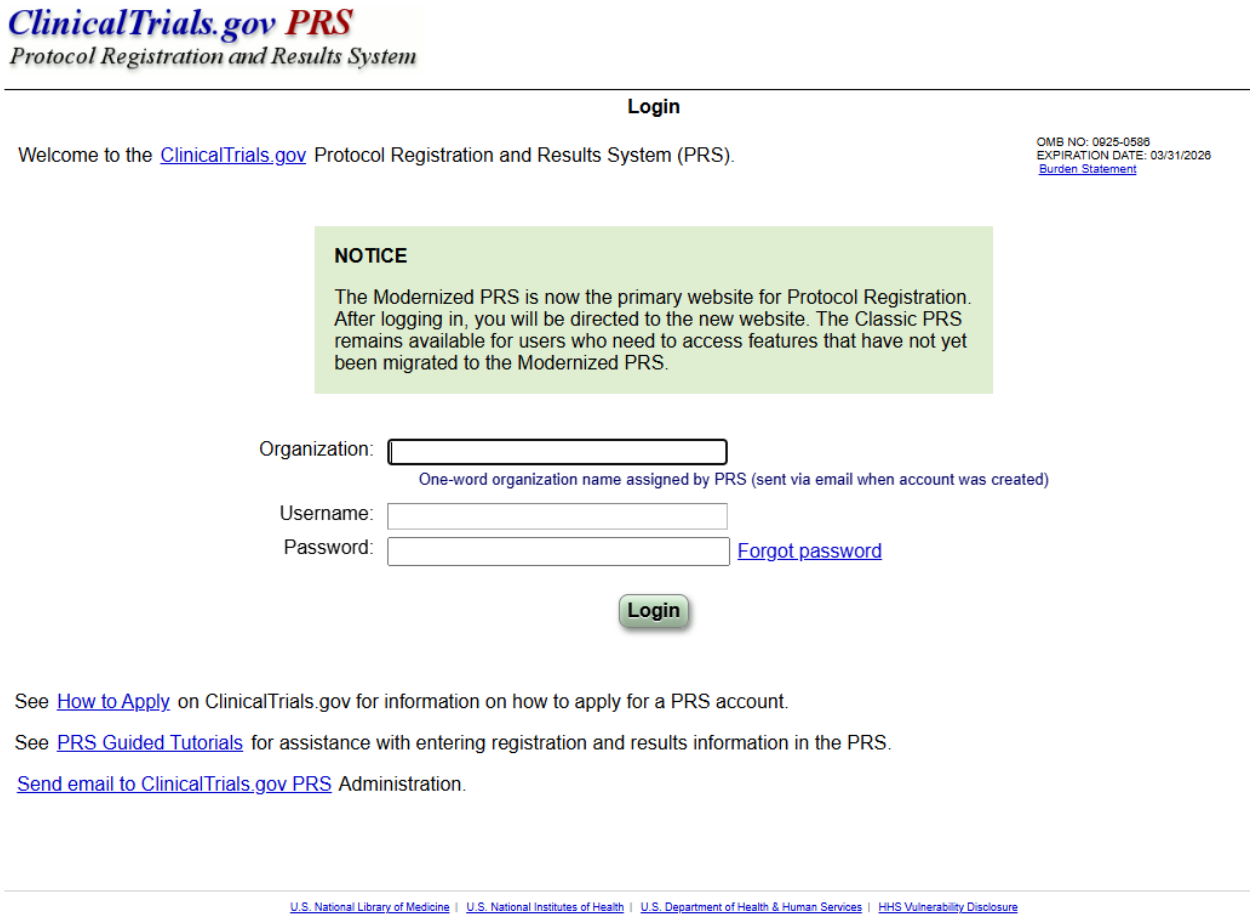
April 18, 2017: Formatting and typographical errors were corrected.

October 1, 2020: Increased field lengths.

January 9, 2024: Made formatting changes by replacing the section numbers with a left-sided menu for navigation. This was done as part of the process of moving the data element definitions pages to the modern ClinicalTrials.gov site.

June 17, 2024: Added 'EU Trial (CTIS) Number' to options for Secondary ID. Added 'No symbol' to the requirements legend to indicate data elements that are Optional. Corrected typographical errors.

Last updated on **June 17, 2024**



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.

Classic PRS

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

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

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)

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

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

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

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
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[*] 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:

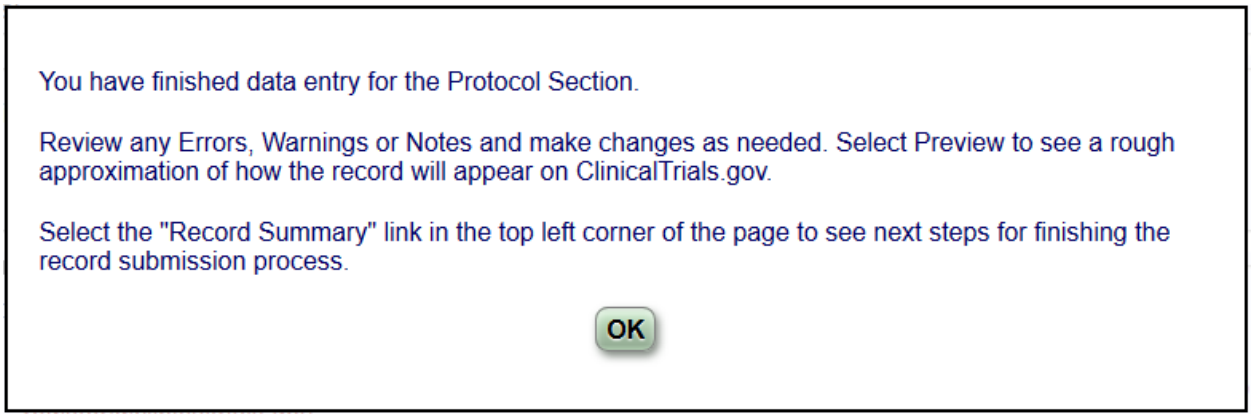
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Investigators: + Add Investigator

Save Cancel

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


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

Modernized PRS

Create New Record

Review these tips before creating a record.

Cancel record creation

Definitions

1. Use the PRS account of the study sponsor.
   a. Verify that the study sponsor (the initiator of the trial) has a PRS account and that you are using a login for that account.
   b. For help, see:
   How to Apply for a PRS Account
2. Only the responsible party can register the study.
   a. You can create the record even if you are not the responsible party, but only the responsible party can approve and submit it. The responsible party will be notified when the necessary information has been entered.
   b. For help, see:
   How do I determine who is the responsible party for a study?
3. The study should be registered only once.
   a. A study with multiple collaborators or sites should only be registered by the study's responsible party.
   b. All study sites should be listed in a single study record.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Organization's Unique Protocol ID *

30 characters allowed

Brief Title *

Write a short, easy-to-understand title that identifies the expanded access. Use title case.

300 characters allowed , at least 18 characters required

Acronym [*]

Required if one exists. It will be included in parentheses at the end of the Brief Title.

14 characters allowed

Study Type *

- ○ Interventional
  Participants are assigned to one or more interventions, based on a protocol.
- ○ Observational
  Participants are **not** assigned to interventions based on a protocol.
- ◉ Expanded Access
  Participants receive an experimental drug or device outside of a clinical trial protocol.

Expanded Access Type* § (Check all that apply)

- ○ Individual Patients (including emergency use)
- ○ Intermediate-size Population (for participant numbers smaller than those used in a treatment IND or protocol)
- ○ Treatment IND/ Protocol (for use under a treatment investigational new drug application (IND) or protocol)
- ○ Not Applicable (does not involve a U.S. FDA-regulated drug product)

Official Title [*]

Identify the expanded access program, if any. This is required unless the Expanded Access Type is "Individual Patients."

600 characters allowed

Secondary IDs [*]

These are optional if the Expanded Access Type is "Individual Patients," but should be provided for the other Expanded Access Types if they exist.

Secondary ID Type

Create Record Cancel record creation

Study Status

Definitions

Use this module to enter the start and completion dates for the study, as well as the study's recruitment status.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Record Verification Date *

Month *

Jul

Year *

2025

Expanded Access Status *

Available

Save Changes

Clear Unsaved Changes

Sponsors and Collaborators

Definitions

Use this module to enter information about the organization and individuals responsible for starting, funding, designing, and conducting the expanded access.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Responsible Party, by Official Title *

Select the type of responsible party - usually the sponsor.

- (•) Sponsor
- ( ) Principal Investigator
- ( ) Sponsor-Investigator

Name of the Sponsor *

Collaborators

Enter the **name of an organization** providing support for the expanded access.

Add Collaborator

160 characters allowed

Save Changes Clear Unsaved Changes

Oversight

Definitions

Use this module to describe oversight of the interventions involved in this expanded access.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information

U.S. FDA IND/IDE *

Is this expanded access being provided under a U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

(•) Yes

( ) No

IND/IDE Number [*]

FDA Center [*]

Select the FDA Center that the IND or IDE is filed with.

CDER

IND Serial Number [*]

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

Save Changes Clear Unsaved Changes

Study Description

Definitions

Use this module to describe the study protocol.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Brief Summary *

Use these resources to provide understandable information about the expanded access to patients, families, and health care providers
Plain language checklist for Brief Summary
Template for Brief Summary

4,999 characters left

Detailed Description

Avoid duplicating information that will be entered or uploaded elsewhere in the record.

32,000 characters allowed

Save Changes Clear Unsaved Changes

Conditions

Definitions

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Conditions or Focus of Study [*]

Enter each disease or condition impacted by the investigational product available under expanded access.
If a disease or condition isn't part of the expanded access, enter a brief description of the focus of the expanded access.

Add Condition

Keywords

Enter a word or phrase that precisely describes the expanded access to help users find the study on ClinicalTrials.gov.

Add Keyword

Save Changes

Interventions

< Back to Interventions

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Intervention Type *

Select the type of intervention.

- Select -

Intervention Name *

Enter a brief, descriptive name to refer to the intervention. Use a non-proprietary (generic) name, if available.

200 characters allowed

Other Intervention Names (if any) [*]

Enter one name at a time. Include any alternative name or number used to identify the intervention.

Add Other Name

200 characters allowed

Intervention Description [*]

Add details that will distinguish this intervention from other interventions available through expanded access or in other clinical studies.

1,000 characters allowed

+ Add Intervention Remove

Save Changes

Eligibility

Definitions

Use this module to describe the characteristics of people who can participate in the expanded access.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Sex/Gender [*]

Sex [*]

Select the biological sex of people eligible to participate in the expanded access.

- Select -

Gender Based [*]

Is a person's eligibility to participate in the expanded access according to their biological sex limited by their gender identity?

- ◯ Yes
- ◯ No

Age Limits [*]

Specify the age range of people who are eligible to participate in the expanded access.

Minimum Age [*]

- ○ No Limit (NA)
- ◉ Minimum Age Limit

Minimum Age [*]	Unit of Time [*]
	- Select -

Maximum Age [*]

- ○ No Limit (NA)
- ◉ Maximum Age Limit

Maximum Age [*]	Unit of Time [*]
	- Select -

Eligibility Criteria [*]

Inclusion Criteria:
-

Exclusion Criteria:
-

19,950 characters left

Save Changes

Contacts

< Back to Contacts and Locations

On this page, identify a central contact and study officials.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Central Contact Person

Enter the main contact person for the expanded access.

First Name

62 characters allowed

Middle Initial

Last Name or Official Title *

If an official title is provided instead of a last name, leave the First Name, Middle Initial, and Degree fields blank.

62 characters allowed

Degree

30 characters allowed

Phone Number *

Enter a toll-free number using this format:

- U.S. or Canada: 800-555-5555
- Other countries: Country code + phone number

30 characters allowed

Extension

Enter the phone extension, if needed.

14 characters allowed

Email *

254 characters allowed

Central Contact Backup

Enter a person to contact if the central contact isn't available.

First Name

Middle Initial

62 characters allowed

Last Name or Official Title

If an official title is provided instead of a last name, leave the First Name, Middle Initial, and Degree fields blank.

62 characters allowed

Degree

30 characters allowed

Phone Number

Enter a toll-free number using this format:

- U.S. or Canada: 800-555-5555
- Other countries: Country code + phone number

30 characters allowed

Extension

Enter the phone extension, if needed.

14 characters allowed

Email

254 characters allowed

Overall Study Official

Identify the people who provide scientific leadership for the expanded access.

First Name

62 characters allowed

Middle Initial

Last Name or Official Title

If an official title is provided instead of a last name, leave the First Name, Middle Initial, and Degree fields blank

62 characters allowed

Degree

30 characters allowed

Organization Affiliation

Enter the full name of the official's organization. If there isn't one, enter "Unaffiliated".

255 characters allowed

Official's Role

- Select One -

+ Add Study Official

Remove

Save Changes

Clear Unsaved Changes

References

Definitions

You can use this module to:

- List citations for publications that provide background on this expanded access or report results of this expanded access
- Provide links to websites that give general information about the expanded access

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required

Citations

Enter a citation by entering the PubMed ID (PMID) or PubMed Central ID (PMCID) or by typing the full citation in the space provided.

How Will You Enter Your Citation?

(●) Enter the PubMed ID

Enter the ID to autofill the full PubMed citation. If you don't know the ID, you can search for it here.

Search

14 characters allowed

( ) Type in the Citation

Enter a **single** citation, using as much of the following information as possible: Authors, Article title, Journal name, Publication date, Volume number and pages.

Links

Enter links to websites that provide information that is directly related to the expanded access.

URL

3,999 characters allowed

Description

254 characters allowed

+ Add Link Remove

Save Changes