

ClinicalTrials.gov Registration Data Element Definitions for Expanded Access (**DRAFT**)

January 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 *

Defintion: 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), 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 ID).

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 identification number.

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 [ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies](#)).

- **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 FDA regulations. Select all that apply.

- 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](#)
- Not applicable: Expanded access is for a product (for example, device product) other than an investigational drug product covered by FDA expanded access regulations (21 CFR 312)

▼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 FDA.

▼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

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. FDA regulations in 21 CFR 312.3 or 21 CFR 812, respectively.

U.S. Food and Drug Administration IND or IDE Number *

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 is 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**Primary Disease or Condition [*]** (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.

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

Gender [*]

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: [*]

ZIP/Postal Code: [*]

Country [*]

Facility Contact

Definition: For each facility participating 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
- Affiliation: 160 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: PubMed Unique Identifier (PMID) for the citation in MEDLINE

Citation

Definition: A bibliographic reference in NLM's MEDLINE format

Results Reference?

Definition: Indicate if the reference provided reports on results from this expanded access.

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).

PRS TEST SYSTEM

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: 11/30/2018
[Burden Statement](#)

This is a test version of the Protocol Registration and Results System (PRS). Creating or modifying records in this system will have no effect on the production (operational) PRS or ClinicalTrials.gov.

The data on this system is occasionally replaced entirely with a copy of the latest data from the production system. [Data last copied from production PRS: Feb 4, 2016] If you had an account on the production PRS at that time, the same login information should work on this system.

WARNING: Do not use the PRS Test System to prepare data for the production PRS. This system sometimes runs a software release that is not fully compatible with that of the production system.

If you notice problems or have questions while using this test system, please contact us using the Contact ClinicalTrials.gov PRS link (in the upper right corner, after logging in).

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password:

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
[Send email to ClinicalTrials.gov PRS Administration](#)

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OMB NO: 0925-0586
EXPIRATION DATE: 11/30/2018
Burden Statement

Public reporting burden for this collection of information is estimated to average 7.0 hours per response for initial registration, 2.0 hours for each of 8 updates to the registration information during the course of the trial, 25.0 hours per response for initial results submission, 8.0 hours for two substantive updates to the results information. 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 Study Identification

[Help](#) [Definitions](#)

* Organization's Unique Protocol ID:	<input type="text"/>
* Brief Title:	<input type="text"/>
[*] Acronym: (if any)	<input type="text"/> <small>If specified, will be included at end of Brief Title in parentheses.</small>
[*] Official Title:	<input type="text"/>
[*] Secondary IDs: (if any)	<input type="button" value="+ Add Secondary ID"/>

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

Edit Study Status

[Help](#) [Definitions](#)

* Record Verification Date:	Month: <input type="text" value="--Select--"/> Year: <input type="text"/>
* Expanded Access Status:	<input type="text" value="--Select--"/> <small>Tip: Before selecting, see Expanded Access Status definition.</small>

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

Edit Sponsor/Collaborators

[Help](#) [Definitions](#)

* Responsible Party:	<input type="text" value="--Select--"/>
Select Sponsor unless the Investigator has been designated as Responsible Party per FDAAA.	
* Sponsor:	<input type="text"/>
Primary organization conducting study and associated data analysis (not necessarily a funding source).	
Collaborators:	<input type="text"/> <input type="button" value="x Delete"/>
<input type="button" value="+ 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 .	

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

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Edit Oversight

[Help](#) [Definitions](#)

* U.S. FDA IND/IDE Study: (Not public)	<input type="text" value="Yes"/>
Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?	
FDA Center:	<input type="text" value="--Select--"/>
Formerly IND/IDE Grantor	
IND/IDE Number:	<input type="text"/>

- * Required
- * § Required if Study Start 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.
NOTE: Detailed Description has not been entered.

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

Edit Conditions

[Help](#) [Definitions](#)

[*] Conditions or Focus of Study:

[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.

NOTE: "condition treated by drug" is not a recognized condition

of possible matches

Keywords:

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

Edit Interventions

[Help](#) [Definitions](#)

Interventions:

* Intervention Type:

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

[*] Other Names:
(if any)
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.

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

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Edit Eligibility

[Help](#) [Definitions](#)

[*] Sex:
Biological sex of eligible participants.

[*] Gender Based:
If applicable, indicate if participant eligibility is based on self-representation of gender identity.

[*] Age Limits: Minimum: Maximum:

[*] Eligibility Criteria:
[Special Characters](#)

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

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Edit Overall Contacts

[Help](#) [Definitions](#)

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

Central 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).

Overall Study Officials:

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

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Edit References

[Help](#) [Definitions](#)

Citations: PubMed ID:
Use the [PubMed Citation Matcher](#) to search for citations based on journal name, date, author(s), title and other criteria.

Citation:
Results Reference?

Links:

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

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